

**Faculty of Health Sciences
Curtin-Monash Accident Research Centre**

**Naturalistic Driving Behaviour and Self-Regulation Practices Among
Older Drivers with Bilateral Cataract: a Prospective Cohort Study**

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**This thesis is presented for the Degree of
Doctor of Philosophy
of
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Declaration

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgment has been made.

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university.

The research presented and reported in this thesis was conducted in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007), updated March 2014. The proposed research study received human research ethics approval from the Curtin University Human Research Ethics Committee (EC00262), Approval Number #HR29/2014.



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Keywords

Driving

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Cataract surgery

Visual acuity

Contrast sensitivity

Stereopsis

Abstract

INTRODUCTION

The prevalence of cataract in older populations, and longer life expectancy, means there will be an increasing number of older Australians with cataract on our roads. Conditions that diminish sight have a significant impact on the driving ability and safety of older drivers as they seek to maintain their quality of life and independence.

This prospective longitudinal cohort study examined older drivers before first eye, after first eye, and after second eye cataract surgery, which allowed for an in depth exploration of how objective visual measures (including visual acuity, contrast sensitivity, and stereopsis) and other factors affect driving habits, adverse events and driver self-regulation using objective and naturalistic methods. In this study, driving self-regulation practices were defined as the modification of habitual driving practices, patterns, exposure and/or habits. The majority of previous studies that have analysed the effects of cataract surgery on driving outcomes have combined participants who underwent only first, second or both eyes surgeries in their analyses and were therefore unable to determine the specific effects of first and second eye surgery separately. Furthermore, there is a lack of information about the specific effects of first and second eye cataract surgery on driver self-regulation practices, as measured by naturalistic driving technology.

The rich data from this project furthered our understanding of appropriate fitness to drive assessments for older drivers with bilateral cataract as they progressed through first and second eye surgery.

AIM

Overall, this study aimed to gain a better understanding of the impact of first and second eye cataract surgery on naturalistic measures of driver self-regulation practices and to determine which changes in objective measures of vision are associated with driver self-regulation practices throughout the cataract surgery process (before first eye, after first eye, and after second eye cataract surgery). Also, an examination of the

association between driving habits, adverse events, driver self-regulation and objective visual measures before first eye cataract surgery was undertaken.

OBJECTIVES

- 1) To undertake a comprehensive literature review on cataract/ataract surgery and driving.
- 2) To compare self-reported information obtained from a travel diary and naturalistic measured data using an in-vehicle driver monitoring device on driving exposure, habits, and practices in older drivers with bilateral cataract as they await first eye cataract surgery.
- 3) To measure the naturalistic driving exposure, habits and adverse events of older drivers with bilateral cataract who were awaiting first eye cataract surgery and to determine the factors associated with driving exposure.
- 4) To analyse the association between objective measures of vision (visual acuity, contrast sensitivity, and stereopsis), and driver self-regulation practices in bilateral cataract patients using a combination of naturalistic driving methods and self-reported data, as they wait for first eye cataract surgery.
- 5) To determine the separate impact of first and second eye cataract surgery on driver self-regulation status for bilateral cataract patients.
- 6) To determine which changes in objective measures of vision are associated with changes in driver self-regulation status throughout the cataract surgery process.

METHODS

Study design

A three year prospective longitudinal cohort study of older drivers with bilateral cataract was undertaken from December 2014 to February 2017. One hundred and eleven participants on the wait list for first eye cataract surgery were recruited from three public hospitals in Western Australia (Fremantle Hospital, Royal Perth Hospital and Sir Charles Gairdner Hospital) through two methods: direct invitation from ophthalmologists during their visit to the eye clinic or an invitation letter from the

researcher. The inclusion criteria were: a diagnosis of bilateral cataract; being on the wait list for first eye cataract surgery; aged 55+ years; a current Western Australian drivers licence; living in the Perth metropolitan area; and driving at least twice a week. Exclusion criteria for participants were: a diagnosis of any significant eye conditions such as macular degeneration, glaucoma or diabetic retinopathy; undergoing combined ocular surgery; having a cognitive impairment; a diagnosis of dementia, Alzheimer's disease, Parkinson's disease or physical impairment (e.g., wheelchair users); did not communicate in English or had previous cataract surgery.

Each participant was assessed at three time points: in the month before cataract surgery, at least one to three months after first eye cataract surgery and at least one month after second eye cataract surgery. Fifty-five participants completed the three assessments.

Data Collection

Participants received a Participant Information Sheet and provided written informed consent before any data were collected, following the tenets of the Declaration of Helsinki. Ethics approval was obtained from Curtin University and the three participating hospitals.

At each of the three assessments, identical researcher administered questionnaires collecting information about participants' sociodemographic and health information were administered. Participants' cognitive function was also assessed by the Mini-Mental-State Examination and the Useful Field of View to assess general cognitive function and higher order attentional skills.

Three objective visual tests were administered by the researcher at each of the assessments, which included visual acuity, contrast sensitivity, and stereopsis. The researcher received training by an ophthalmologist in order to administer the visual tests. A standardised protocol was followed to ensure that visual testing was administered under standard conditions at each assessment. Visual testing was administered under constant luminance and without mydriasis each time. A light meter was used to ensure that light was kept constant and tape measures were used to ensure that participants were reading the charts at the required distance. Participants' habitual correction was used for visual testing.

Participants' self-reported driving habits and self-regulation practices were assessed using the Driving Habits Questionnaire, which has been previously validated for use among a population of older drivers with bilateral cataract in Western Australia.

Participants were also provided with a travel diary they were required to fill in after each trip they drove as the driver, and an in-vehicle monitoring device that collected naturalistic driving data for a period of 7 days. Driving outcome measures that were collected included a variety of time-stamped second-by-second GPS data, such as date of travel, start and finish time of trips, number of trips, number of kilometres travelled, duration, average and maximum radius of driving exposure, speed, location, type of roads used (e.g., freeways, highways, heavy traffic roads), and time of day (e.g., day time, night time, sunset, sunrise, peak hour traffic, off peak hours).

Data obtained from the travel diary and the in-vehicle monitoring devices were compared to measure the agreement between both measures. Additionally, the data obtained by the Driving Habits Questionnaire and the in-vehicle monitoring devices were compared. Four driving situations obtained by the Driving Habits Questionnaire were selected, as they could be directly compared to the information obtained from the in-vehicle monitoring device. These four situations were used to classify participants as either self-regulating or non self-regulating their driving in each situation. These situations included "driving on highways/freeways", "on heavy traffic roads", "in peak hour traffic", and "night time driving". Each of the four driving situations were examined separately to determine if participants' self-regulated their driving in that situation. All four situations were then examined together and participants were classified as a "self-regulator" if they self-regulated their driving behaviour in at least one of the four driving situations. Otherwise, they were considered to be a "non self-regulator".

Statistical Analysis

Descriptive statistics were used to summarise the sociodemographic characteristics, as well as the health, visual, cognitive and driving characteristics of the cohort, at baseline and after both, first and second eye cataract surgery. Inferential statistics were used to assess changes among all variables of interest throughout the cataract surgery process.

Paired-samples *t*-tests were used to compare the differences obtained by the travel

diaries and in-vehicle monitoring devices, in terms of kilometres driven, number of trips, driving duration in minutes and number of trips driven on the weekends, during peak hour traffic, at night time and for overall driving.

Independent sample *t*-tests for continuous outcomes (age, driving experience, number of comorbidities, number of medications, Mini-Mental State Examination score, Useful Field of View score, number of trips, kilometres travelled, number of days driven, driving duration and maximum excursion radius from home) and chi-squared tests for categorical outcomes (gender, marital status, living arrangements and level of education) were used to compare the characteristics of the participants classified as self-regulators and non-self-regulators in terms of sociodemographic data, health status, driving characteristics, cognitive abilities, and objective visual measures.

Cohen's Kappa coefficient was used to measure the relative agreement between the information obtained from the self-reported Driving Habits Questionnaire and the in-vehicle monitoring devices. One-way repeated measures of analysis of variance (ANOVA) were used to measure the changes in the three objective measures of vision before first eye surgery, after first and after second eye cataract surgery. Cochran Q tests were used to analyse the changes in driver self-regulation status before first eye surgery, and after both first and second eye cataract surgery in the following driving situations: on heavy traffic roads, at night time, on the freeway and on heavy traffic roads.

A simple multiple linear regression was undertaken to determine whether there was an association between the three objective measures of vision (binocular visual acuity, binocular contrast sensitivity and stereopsis) and driving exposure before first eye cataract surgery. A multivariate logistic regression was also undertaken to analyse the association between driver self-regulation status and the three objective measures of vision before first eye cataract surgery.

Two separate Generalised Estimating Equation logistic models were undertaken to analyse the changes in self-regulation status before first eye cataract surgery, after first and second eye cataract surgery, and to determine which changes in the three objective measures of vision were associated with driving self-regulation status.

RESULTS

Six hundred and forty-five patients on the waitlist for first eye cataract surgery were reviewed for eligibility. Among those, 381 patients were immediately excluded, and 153 eligible participants declined participation. A total of 111 older drivers with bilateral cataract were recruited, of whom 55 completed all three assessments. The 55 participants had a mean age of 73.3 years ($SD = 7.8$) with 38.2% aged 65 to 74 years.

The results found that there were significant improvements in better eye, worse eye and binocular visual acuity after first and second eye cataract surgery ($p < 0.001$). Additionally, better eye, worse eye and binocular contrast sensitivity significantly improved after first and second eye cataract surgery ($p < 0.001$). However, stereopsis worsened after first eye cataract surgery, but improved after second eye cataract surgery ($p = 0.002$).

Significant differences were found between the travel diaries and objective data obtained from the in-vehicles monitoring devices. Older drivers significantly underestimated the number of overall trips ($p < 0.001$), weekend trips ($p = 0.002$) and trips during peak hours ($p = 0.004$). Participants also significantly overestimated overall ($p < 0.001$) and weekend driving duration ($p = 0.003$) in comparison to the data collected by the in-vehicles monitoring devices. However, there were no significant differences between the travel diaries and the naturalistic driving data in terms of kilometres travelled.

Ninety-two percent of participants drove during the 7 days period of data collection before first eye cataract surgery. At baseline, participants drove an average of 4.40 days and an overall distance of 115.8 kilometres, and made an average of 15.6 trips per week. Participants' maximum radius distance travelled from home was 14.1 kilometres. In addition, 41% of participants self-regulated their driving in at least one challenging situation before first eye cataract surgery, limiting significantly their mobility. The most commonly avoided situation was driving during night time (31%). Nearly 10 percent of those who did not meet the minimum visual standards for driving in Western Australia before first eye cataract surgery did not self-regulate their driving. Contrast sensitivity was the only objective measure of vision significantly associated with self-regulation practices, including driving exposure and avoiding driving in challenging situations before first eye cataract surgery. Older drivers who had poorer

binocular contrast sensitivity drove fewer kilometres per week prior to first eye cataract surgery and were more likely to avoiding driving in specific challenging situations than older drivers with better contrast sensitivity.

There was also a significant reduction in driver self-regulation practices after both first and second eye cataract surgery in comparison to the month before first eye cataract surgery. The odds of being a self-regulator in at least one driving situation significantly decreased by 70% after first eye cataract surgery (OR: 0.3, 95% CI: 0.1–0.7) and by 90% after second eye surgery (OR: 0.1, 95% CI: 0.1–0.4), compared to the odds before first eye surgery. Improvement in contrast sensitivity after cataract surgery was significantly associated with decreased odds of self-regulation (OR: 0.02, 95% CI: 0.01–0.4).

CONCLUSIONS

The results of this comprehensive study have provided a better understand of the association between objective visual measures, and real time driving behaviour throughout the cataract surgery process, using in-vehicle driver monitoring. It also validated the combined used of self-report Driving Habits Questionnaire with the in-vehicle monitoring devices, which will be more effective for monitoring patient-reported measures, now an important part of outcomes research. The majority of studies analysing the effects of cataract surgery on driving outcomes were based on self-reported questionnaires and combined participants who underwent first, second or both eye cataract surgery in their analyses. As a consequence, little is known about the self-regulation practices of older drivers with bilateral cataract while waiting for first and second eye cataract surgery. This is the first study to examine the specific effects of first and second eye cataract surgery on driving habits, adverse events and driver self-regulation using objective and naturalistic methods.

This study found that both first and second eye cataract surgery have a positive impact on driving outcomes and, therefore, on-road safety. As the population ages, there will be an increasing number of older drivers with cataract on the roads. Measures need to be taken to ensure that cataract can be funded in a timely manner to avoid costs associated with crashes and injuries. The findings suggest that clinicians could play a crucial role in ensuring their patients limit their driving by using self-regulation practices while waiting for first and second eye cataract surgery, to improve their

safety and the safety of other road users. The findings also suggest that road safety, policy makers and licensing authorities could benefit from using contrast sensitivity tests, in addition to visual acuity tests traditionally used, to improve road safety. However, further research should determine why some older drivers are not self-regulating their driving while waiting for cataract surgery and how older drivers with bilateral cataract could benefit from self-education programs promoting the use of self-regulation strategies.

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Publications and presentations

Peer reviewed publications

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Agramunt, S., Meuleners, L., Fraser, M. L., Chow, K. C., Ng, J. Q., Morlet, N., & Raja, V. (2017). Do older drivers with bilateral cataract self-regulate their driving while waiting for first eye cataract surgery? *Clinical Interventions in Aging*, 12, 1911-1920.

Agramunt, S., Meuleners, L., Fraser, M. L., Chow, K. C., Ng, J. Q., & Raja, V. (accepted for publication on 06/02/2018). First and second eye cataract surgery and driver self-regulation among older drivers with bilateral cataract: a prospective cohort study. *BMC Geriatrics*.

Agramunt, S., Meuleners, L. B., Fraser, M. L., Morlet, N., Chow, K. C., & Ng, J. Q. (2016). Bilateral cataract, crash risk, driving performance, and self-regulation practices among older drivers. *Journal of Cataract & Refractive Surgery*, 42(5), 788-794.

Conference presentations

Oral presentations

Agramunt, S., Meuleners, L., Chow, K. C., Ng, J. Q., Morlet, N., Raja, N., Keay, L., & Young, M. (2017, October 10). *Which objective visual measures are associated with driving exposure among older drivers with bilateral cataract?* Australasian Road Safety Conference (ARSC) 2017, Perth, Australia, October 10-12, 2017.

Agramunt, S., Meuleners, L., Chow, K. C., Ng, J. Q., Morlet, N., Raja, N., Keay, L., & Young, M. (2017, February 05). *The association between objective visual measures and naturalistic driving behaviours in older drivers with bilateral cataract*. ARVO Asia 2017, Brisbane, Australia, February 5-8, 2017.

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Poster Presentation

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List of Abbreviations

ADDAPT	Advanced Driving Decisions and Patterns of Travel
ANOVA	Analysis Of Variance
CI	Confidence Interval
CINAHIL	Cumulative Index to Nursing and Allied Health Literature
DCS-D	Driving Comfort Scale (Day)
DCS-N	Driving Comfort Scale (Night)
DEC	Driving as an Everyday Competence model
DHQ	Driving Habits Questionnaire
DPQ	Driving Patterns Questionnaire
ETDRS	Early Treatment Diabetic Retinopathy Study
GEE	Generalised Estimating Equations
GPS	Global Positioning System
log	Logarithm
logMAR	Logarithm of the Minimum Angle of Resolution
MMSE	Mini-Mental State Examination
MOTRS	Multilevel Older Persons Transportation and Road Safety model
n	Sample size
OBD II	On Board Diagnostic II
OR	Odds Ratio
PDA	Perceived Driving Ability
SD	Standard Deviation
SDA	Situation Driving Avoidance
SDF	Situation Driving Frequency
SEED	Singapore Epidemiology of Eye Disease
TRID	Transport Research International Documentation
UFOV	Useful Field of View
WHO	World Health Organisation

INTRODUCTION

Chapter 1 Introduction

1.1 Background

Older drivers represent the fastest-growing segment of the driving population (National Center for Statistics and Analysis, 2017). As the proportion of older individuals are living longer and healthier lives (Australian Institute of Health and Welfare, 2015), it is expected that the number of older drivers on the roads will increase further, which will have significant impacts on-road safety, policy makers and transport providers (Luiu, Tight, & Burrow, 2017).

Driving a car remains the main transport mode among the older population in developed countries such as Australia (Zeitler & Buys, 2015) and will continue to be among the future generations of older drivers (Currie & Delbosc, 2010). It contributes to older adults' mobility, flexibility and independence, and plays a significant role in maintaining their lifestyle (Gwyther & Holland, 2012) and quality of life (Zeitler & Buys, 2015). Access to a car has also been associated with overall transport satisfaction (Olsen, Macdonald, & Ellaway, 2017), and driving cessation has been associated with poorer health, cognitive social and physical function, as well as increased risk of depression, mortality, and admissions to long term care facilities (Chihuri et al., 2016).

As people age, medical conditions such as cataract are also becoming more common (Michael & Bron, 2011). Cataract is one of the leading causes of visual impairment globally, accounting for 33% of vision-related problems (Pascolini & Mariotti, 2012). Cataract can affect multiple aspects of vision such as visual acuity, contrast sensitivity (Helbostad et al., 2013; Shandiz et al., 2011) and stereopsis (Helbostad et al., 2013), and a growing body of evidence suggests that older drivers with cataract are less safe to drive (Owsley, Stalvey, Wells, & Sloane, 1999; Owsley, Stalvey, Wells, Sloane, & McGwin, 2001). However, unlike other conditions of ageing, cataract can be easily corrected by surgery, which has been shown to reduce crash risk by 12.7% in the year after first eye surgery (Meuleners, Hendrie, Lee, Ng, & Morlet, 2012a). In Australia however, public hospital patients often wait an average of 93 days before cataract surgery and 2.5% of patients have to wait long periods of more than 12 months (Australian Institute of Health and Welfare, 2016) generating concern among road

safety and licensing authorities about the impact of unoperated cataract on driving exposure and ability.

As a consequence of their impaired vision older drivers with cataract may self-regulate their driving and restrict it to specific self-identified situations which they consider as safe (Sullivan, Smith, Horswill, & Lurie-Beck, 2011). Driving self-regulation is a multidimensional (Molnar et al., 2014) and complex process (Molnar et al., 2013b; Wong, Smith, & Sullivan, 2016a), which has been described as a positive coping strategy to minimise driving risk (Gwyther & Holland, 2012). These practices might involve avoiding driving in challenging situations and/or reducing the number of kilometres and trips made (e.g., Baldock, Mathias, McLean, & Berndt, 2006; Ball et al., 1998; Fraser, Meuleners, Ng, & Morlet, 2013c; Molnar & Eby, 2008; Owsley et al., 1999). It has also been found that reduced contrast sensitivity (Keay et al., 2009), as well as poor visual acuity (Lotfipour et al., 2010) may be associated with driver self-regulation practices. However, previous research found that a high percentage of drivers with visual impairment do not self-regulate their driving (Okonkwo, Crowe, Wadley, & Ball, 2008).

Previous studies examining the effect of cataract and/or cataract surgery on driving outcomes have focused on self-reported driving difficulty (e.g., Bevin, Derrett, & Molteno, 2004; Castells et al., 1999; Elliott, Patla, Furniss, & Adkin, 2000; Mamidipudi, Vasavada, Merchant, Namboodiri, & Ravilla, 2003; McGwin, Scilley, Brown, & Owsley, 2003; Mönestam, Lundquist, & Wachtmeister, 2005; Mönestam & Lundqvist, 2006; Mönestam & Wachtmeister, 1997; Owsley et al., 1999) and self-regulation practices (Fraser, et al., 2013c; Owsley et al., 1999) which are limited by biases such as recall (Blanchard, Myers, & Porter, 2010) and social desirability (Af Wåhlberg, 2010). However, naturalistic studies using in-vehicle monitoring devices, which collect detailed Global Positioning System (GPS) information, allow an accurate and objective examination of driving outcomes as well as driver self-regulation. This rich source of information provides a means for assessing the safety impact of driving behaviours in an unobtrusive manner. To date, no published study has used naturalistic data to explore driving habits, adverse events and driver self-regulation for older drivers with bilateral cataract before first eye, after first eye, and after second eye cataract surgery, which represents a significant gap in the literature.

1.2 Rationale

The prevalence of cataract in older populations (Bourne et al., 2013; Khairallah et al., 2015; Klein & Klein, 2013; Koo et al., 2013; Pascolini & Mariotti, 2012) and increasing life expectancy (Australian Institute of Health and Welfare, 2015; United Nations, 2017) means there will be an increasing number of older Australians on our roads with cataract. Conditions that diminish sight will have a significant impact on the driving ability and safety of older drivers and, consequently, their crash risk as they seek to maintain their quality of life and independence.

This prospective cohort study will examine older drivers before first, after first, and after second eye cataract surgery, which will allow an in depth exploration of how objective visual measures (including visual acuity, contrast sensitivity, and stereopsis) and other factors affect driving habits, adverse events and driver self-regulation using objective and naturalistic methods. Furthermore, the majority of previous studies that have analysed the effects of cataract surgery on driving outcomes have combined participants who underwent only first, second or both eyes surgeries in their analyses and were therefore unable to determine the specific effects of first and second eye surgery separately.

The rich data from this project will also further our understanding of appropriate fitness to drive assessments for older drivers as they progress through first and second eye cataract surgery.

1.3 Aim and Study Objectives

The overall aim of this research study was to gain an understanding of the impact of first and second eye cataract surgery on naturalistic measures of driver self-regulation practices, and to determine which changes in objective measures of vision are associated with driver self-regulation practices throughout the cataract surgery process.

In addition, an examination of the association between driving habits, adverse events, driver self-regulation, and objective visual measures before first eye surgery was undertaken.

The specific study objectives were:

- 1) To undertake a comprehensive literature review on cataract/ataract surgery and driving (paper 1).
- 2) To compare self-reported information obtained from a travel diary and objectively measured data using an in-vehicle driver monitoring device on driving exposure, habits and practices in older drivers with bilateral cataract as they await first eye cataract surgery (paper 2).
- 3) To measure the naturalistic driving exposure, habits and adverse events of older drivers with bilateral cataract who were awaiting first eye cataract surgery and to determine the factors associated with driving exposure (paper 3)
- 4) To analyse the association between objective measures of vision (visual acuity, contrast sensitivity and stereopsis), and driver self-regulation practices in bilateral cataract patients using a combination of naturalistic driving methods and self-reported data, as they wait for first eye cataract surgery (paper 4).
- 5) To determine the separate impact of first and second eye cataract surgery on driver self-regulation status for bilateral cataract patients (paper 5).
- 6) To determine which changes in objective measures of vision are associated with changes in driver self-regulation status throughout the cataract surgery process (paper 5).

1.4 Significance of the Study

Despite the prevalence of cataract among the older population, there is a lack of evidence surrounding the impact of bilateral cataract surgery on driving outcomes and self-regulation practices for older drivers. Given the ageing population of Australia, issues related to the safety of this group as they continue to drive are paramount, particularly as older drivers are at higher risk of injury in the event of a crash.

This prospective cohort study will provide new insights into the complex association between objective visual measures (e.g., visual acuity, stereopsis and contrast sensitivity) and other factors affecting driving outcomes and self-regulation practices

among older drivers with bilateral cataract.

Gaining a better understanding of the driving situations that are the most challenging for older drivers with cataract may enable road safety authorities to implement educational interventions promoting the use of self-regulation practices. Findings from this prospective cohort study will also enable ophthalmologists to better inform their patients about the effects of their vision impairment on driving ability throughout the cataract surgery process, and how best to manage these to improve their safety and the safety of other road users. The study results will also provide a rationale for first and second eye cataract surgery in a timely manner to preserve older drivers' independence and mobility. Future long term benefits may include a reduction in the number of deaths and injuries for older drivers with cataract, consequently lessening the burden on the Australian health care system. Lastly, the results of this study may provide evidence to determine the most effective visual tests required to assess fitness to drive among cataract patients.

1.5 Outline of the Thesis

The organisation of the thesis is as follows:

Chapter 2 reviews the existing literature on older drivers, cataract, cataract surgery, objective visual measures, driving, driver self-regulation practices, and naturalistic driving.

Chapter 3 describes the methodology used in the study including the study design, sample and sample size, recruitment of sample, data collection, study instruments, ethics approval, and statistical analyses.

Chapter 4 presents a published review of the literature on cataract and cataract surgery and driving outcomes, and significant gaps in the literature that require further research.

Chapter 5 presents the findings of a published paper comparing the results of older drivers with bilateral cataract who completed self-reported travel diaries with naturalistic measured driving exposure, habits and adverse events while waiting for first eye cataract surgery.

Chapter 6 presents a manuscript submitted for publication examining the association between objective visual measures and naturalistic measured driving exposure, driving habits and adverse events in older drivers with bilateral cataract while waiting for first eye cataract surgery.

Chapter 7 presents the findings of a published paper examining the association between objective visual measures and naturalistic measured driver self-regulation practices among older drivers with bilateral cataract while waiting for first eye cataract surgery.

Chapter 8 presents the findings of a manuscript accepted for publication which examines the specific impacts of both first and second eye cataract surgery on naturalistic measured driver self-regulation practices and which measures of vision were associated with driver self-regulation status.

Chapter 9 presents the overall discussion which includes a synthesis of the findings, the strength and limitations of the study, recommendations for further research, and final conclusions.

LITERATURE REVIEW

Chapter 2 Literature Review

This chapter provides an overview of the current literature on cataract and cataract surgery and driving outcomes including driver self-regulation practices, and identifies gaps that require further research. Various databases of peer reviewed literature, government databases and research engines were searched including Cumulative Index to Nursing and Allied Health Literature (CINAHL), Google Scholar, Medline, Ovid, ProQuest, PsycInfo, PubMed, ScienceDirect, Scopus, Taylor & Francis, the Cochrane Library, Transport Research International Documentation (TRID), SpringerLink, and Web of Science. The following key words were used individually and in all possible combinations: cataract, bilateral cataract, cataract surgery, visual impairment, visual acuity, contrast sensitivity, stereopsis, vision, driving performance, driver self-regulation, crash risk, driving difficulty, driving cessation, driving restriction, motor vehicle crash, road crashes, accident, driver, safety, fitness to drive, older drivers, ageing population, aged drivers, senior drivers, travel diary, self-reported questionnaires, naturalistic driving studies, in-vehicle monitoring devices, Global Positioning System, GPS, and cataract surgery. Additional articles were selected from cited references included within the articles. All articles in this review originally appeared in scientific English language journals, books, theses or government reports, and the information was summarised in this chapter.

The literature review has been divided into five sections.

Section 2.1 provides some background information on the causes of the increase number of older drivers on the roads and the social role played by driving among this cohort.

Section 2.2 provides information on the effects of cataract and first and second eye cataract surgery on objective visual measures.

Section 2.3 provides information on the effects of cataract and first and second eye cataract surgery on driving including driving performance, driving difficulties, and crash risk. The association between these driving outcomes and objective measures of vision before and after first and second eye cataract surgery are reviewed also.

Section 2.4 reviews current literature about self-regulation practices, including the conceptual framework and factors associated with these practices, and discuss how older drivers self-regulate their driving before and after cataract surgery.

Section 2.5 provides information on naturalistic driving studies and discusses studies among older drivers that compared self-reported and objective measures of driving outcomes.

2.1 Older Drivers

Over the previous decades, a combination of three main factors have contributed to a significant increase in the number of older drivers on the roads: the ageing population (Austroads, 2016, United Nations, 2017), the increase in licensing rates (Austroads, 2016, Australian Department of Infrastructure and Regional Development, 2017) and the changes in travel demands (Austroads, 2016, Rosenbloom, 2012). For this reason, an extensive body of research has been devoted to older drivers in the road safety literature during this period of time (e.g. Austroads, 2016). Improvements in road safety have been implemented in Australia and considerable efforts have been made to achieve the Australian National Road Safety Strategy 2011-2020 target, which aims to reduce the number of road deaths and injuries by at least 30% by 2020 (Australian Department of Infrastructure and Regional Development, 2014; Australian Transport Council, 2011). Older drivers' demographic and economic changes are already impacting the number of road fatalities among older drivers (Australian Department of Infrastructure and Regional Development, 2014). It has been estimated that about 4,000 older drivers aged 65 years and over in Australia are hospitalised annually because of a road crash and that older drivers account for 250 fatality victims each year (Australian Department of Infrastructure and Regional Development, 2013). As older drivers are more fragile than younger driver cohorts, they are more likely to be injured or killed following a crash (Ichikawa, Nakahara, & Taniguchi, 2015; Mitchell, 2013). However, previous research suggests that not all older drivers have higher crash risk and that a "low mileage bias" accounts for the higher rate of crashes among older drivers who drive low mileages (e.g. Langford et al., 2013; Langford, Koppel, McCarthy, & Srinivasan, 2008; Langford, Methorst, & Hakamies-Blomqvist, 2006). As older drivers travel fewer kilometres than younger cohorts of drivers (Cicchino & McCart, 2014), they are more likely to drive in riskier situations (e.g., driving on local

roads with intersections and conflict points) than higher mileage drivers (Antin, et al., 2017; Langford et al., 2006). This may result in an overestimation of older drivers' crash rate per unit of distance driven (Antin, et al., 2017; Langford et al., 2006)

2.1.1 Growing proportion of older drivers

Older drivers represent the fastest-growing segment of the driving population (National Center for Statistics and Analysis, 2017). Globally, the proportion of people aged 60+ is growing faster than all younger age groups, at a rate of 3% per year (United Nations, 2017). It has been estimated that the proportion of older individuals aged 60+ will increase by more than two-fold by 2050 and by more than three-fold by 2100, increasing from 962 million in 2017, to 2.1 billion in 2050 and 3.1 billion in 2100 (United Nations, 2017). By 2050, individuals aged 60+ will account for approximately a quarter of the population in almost all regions of the world (United Nations, 2017).

2.1.2 Increase in licensing rates among older drivers

In Australia, there has been a considerable increase in the number of licenced drivers from 1922 to 2016 (Australian Department of Infrastructure and Regional Development, 2017), with an increase by 44% in the licence counts among the 65+ age group in the decade ending in 2013 (Australian Department of Infrastructure and Regional Development, 2013). A recent study found that the majority of older Australian adults (92.5%) aged about 70 are current drivers (Anstey, Li, Hosking, & Eramudugolla, 2017). As the proportion of older individuals is growing and older individuals are living longer and healthier lives (Australian Institute of Health and Welfare, 2015), the numbers of licenced drivers on Australian roads is expected to increase further by 25%, from 17.2 million in 2016 to 21.7 million by 2030 (Australian Department of Infrastructure and Regional Development, 2017).

2.1.3 Older drivers' changes in travel demand

The driving patterns of older drivers have changed throughout the years (Austroads, 2016) as a result of a combination of factors that include personal choice and greater needs to drive a vehicle to maintain mobility and independence (Rosenbloom, 2012). Older drivers are more likely to drive a car and less likely to use public transport than in the past (Rosenbloom, 2001, 2012). Driving a car is, for example, the prime mode

of transport among the 55+ age group in Australia (Zeitler & Buys, 2015). Reliance on private vehicles among older drivers aged 65+ has also increased in the United States (Rosenbloom, 2012).

Older people are driving longer and for longer distances, in comparison to previous cohorts of older drivers (OECD-Organisation for Economic Co-operation, 2001). By way of example, there has been significant increases in the number of trips, kilometres travelled, time spent driving and duration of trips in this age group, suggesting that older drivers have become more dependent on private cars (Rosenbloom, 2012). As older individuals are more active, healthier, fitter, and more likely to be working later in life than former generations, their travel needs might change again in the future (Musselwhite, Holland, & Walker, 2015). These changes will have significant impacts on road safety, policy makers and transport providers (Luiu et al., 2017). The increase in the number of older drivers who will be sharing the road network in the years to come in Australia (Austroads, 2016) means that a considerable effort is to be made to improve road safety and, at the same time, enhance people's mobility, in order to minimise traffic injuries and road deaths.

2.1.4 Older drivers and driving cessation

Driving plays an important role in an older adult's lifestyle, as it allows them to maintain their mobility, flexibility, and independence (Gwyther & Holland, 2012), and contributes to social participation (Pristavec, 2016). It also represents a way to maintain their connection to life and society (Donorfio, D'Ambrosio, Coughlin, & Mohyde, 2009). Driving cessation has also been associated with reduction in social activities and engagement (Curl, Stowe, Cooney, & Proulx, 2014; Liddle, Reaston, Pachana, Mitchell, & Gustafsson, 2014), life satisfaction (Liddle, Gustafsson, Bartlett, & Mckenna, 2012), loss of independence and self-determination (Nordbakke & Schwanen, 2014), and depressive symptomatology (Chihuri et al., 2016). It has also been associated with changes in self-perception and social identity (Jetten & Pachana, 2012), such as feeling older than the chronological age (Pachana, Jetten, Gustafsson, & Liddle, 2017), concerns about practical difficulties and life changes (Pachana et al., 2017), and impacting relationships with others (Pachana et al., 2017). Health, cognitive, social and physical function have also been negatively impacted by driving cessation (Chihuri et al., 2016). On average, driving cessation occurs after 70 years of

age (Hjorthol, 2013; Mitchell, 2013). However, a recent study found that over 92% of Australians aged in their seventies were still driving and were expected to drive for another 13 years (Anstey et al., 2017). The same study estimated that only approximately 1% of Australian older drivers in their early seventies stop driving each year (Anstey et al., 2017).

Males often cease driving after recommendations from other people, such as family members or health providers, although women often give up driving following health issues or a feeling of insecurity on the roads (Hjorthol, 2013). More specifically, one Norwegian nationwide study found that women ceased driving at an earlier age compared to men (average of 79.5 years) (Hjorthol, 2013). Another British study found that 25% of men and 38% of women who still held a drivers licence when they were 70 years old relinquished it by the age of 90 (Mitchell, 2013).

2.1.5 Ageing declines

As people age, declines in motor, sensory, cognitive (Anstey, Wood, Lord, & Walker, 2005) and visual function, such as cataract (Michael & Bron, 2011) become more common and have an impact on driving performance (e.g., Wood & Carberry, 2004, 2006), driving difficulty (Fraser, Meuleners, Lee, Ng, & Morlet, 2013b; Owsley et al., 1999) and crash risk (e.g., Owsley et al., 1999; Owsley et al., 2002). Increasing life expectancy (United Nations, 2017) has resulted in an increase in the prevalence of eye disease, including cataract, and is expected to further increase in the future (Laitinen et al., 2010), which suggests that the number of people with cataract on the roads will increase further.

2.2 Cataract, Cataract Surgery and Objective Visual Measures

2.2.1 Cataract

Cataract is defined as an opacification to various degrees of the crystalline lens of the eye which is usually transparent (Iroku-Malize & Kirsch, 2016; Spencer & Mamalis, 2010). Globally, cataract is the leading cause of blindness around the world (Bourne et al., 2013) and accounts for 33% of visual impairment (Pascolini & Mariotti, 2012). In 2010, 10.8 million individuals were blind and 35.1 million people were visually impaired due to cataract (Khairallah et al., 2015).

Cataract results from a disruptive interaction of inter and intra crystalline proteins in the lens causing an exposition of hydrophobic surfaces, which will aggregate and form cataract (Zhao et al., 2015). Cataract can be clinically classified in different ways depending on their position, appearance, aetiology, and age of appearance (Spencer & Mamalis, 2010). Age causes three main types of cataract: nuclear, cortical and posterior subcapsular, with nuclear cataract being the most frequent type of age-related cataract (Spencer & Mamalis, 2010). People often develop multiple types of cataract simultaneously (Glynn, Rosner, & Christen, 2009).

As the changes caused by cataract are painless and gradual, individuals might not notice for several years that their vision has been deteriorating (Craig, 2015). For example, the Singapore Epidemiology of Eye Disease (SEED) Study found that approximately 68.8% of people with significant cataract did not realise they were affected by this condition (Chua et al., 2017). These gradual changes in vision can have a significant impact on a patient's quality of life (Fraser, Meuleners, Lee, Ng, & Morlet, 2013a) and functional impairment in a patient's everyday life (Chaudhary et al., 2016). The World Health Organisation (WHO) implemented an action plan in 2013 to reduce the prevalence of avoidable visual impairment such as cataract by 25% by 2019, as it can be corrected by cataract surgery (WHO, 2013).

2.2.2 Cataract surgery

Cataract extraction is the most common elective surgery procedure in Australian public hospitals (Australian Institute of Health and Welfare, 2016, 2017). Cataract surgery performed in Australia has increased by 5.3% since 2015-2016, with approximately 71,000 admissions for this surgery between 2016 and 2017 (Australian Institute of Health and Welfare, 2017). It is currently the only treatment available for cataract removal (Selin, Orsini, Ejdervik Lindblad, & Wolk, 2015) and is a highly effective and safe procedure to restore vision in the operated eye (Chaudhary et al., 2016; Clark, Morlet, Ng, Preen, & Semmens, 2011; Roberts et al., 2013; WHO, 2013).

2.2.3 Impact of cataract on objective measures of vision before and after cataract surgery

Cataract affects different aspects of vision including visual acuity, contrast sensitivity, (Helbostad et al., 2013; Shandiz et al., 2011) and stereopsis (Helbostad et al., 2013).

However, an extensive body of research suggests that all these aspects of vision can be improved by cataract surgery (e.g., Fraser, et al., 2013a,b; To, et al., 2014b,c)

2.2.3.1 Visual acuity

2.2.3.1.1 Impact of cataract on visual acuity

Visual acuity, which is the “ability to resolve fine spatial details” is the most frequent visual outcome assessed in road safety research (Wood & Black, 2016). It is a measure of “the recognition of small (high spatial frequency), high contrast letters” and therefore accounts sensitively for the changes in refractive error (Woods & Wood, 1995). Previous research has found that cataract can have a negative impact on visual acuity (Huisinigh, McGwin, Wood, & Owsley, 2014; Shandiz et al., 2011). For example, it has been found that visual acuity decreases as the severity of cataract increases (Shandiz et al., 2011). Visual acuity is also the conventional measure to assess visual function among people with cataract (Shandiz et al., 2011). It is often used as a measure to prioritise patients on the waitlist for cataract surgery (Chaudhary et al., 2016). However, it has been suggested that the emphasis should be on a comprehensive measure of functional vision rather than on an objective measure of visual acuity, as visual acuity testing does not account for patients’ problems in their day to day life (Chaudhary et al., 2016).

2.2.3.1.2 Impact of first and second eye cataract surgery on visual acuity

A growing body of research has found that cataract surgery improves visual acuity in the operated eye (e.g., Castells et al., 1999, 2006, Elliott et al., 1997, 2000; Finger et al., 2012; Foss et al., 2006; Fraser et al., 2013a,b; Gothwal et al., 2011; Lee et al., 2013; Lundström et al., 2011; Meuleners et al., 2012b; Palagyi et al., 2017; Shekhawat et al., 2017; To, et al., 2014a,b). More specifically, previous research suggests that visual acuity is improved after both first and second eye cataract surgery (Castells et al., 2006; Lee et al., 2013; Palagyi et al., 2016; To, et al., 2014a,b). A randomised controlled trial found that first eye cataract surgery results in major improvements in visual acuity (88%), but second eye surgery only improves visual acuity by 12% (Castells et al., 2006). However, undergoing only first eye cataract surgery can increase the discrepancy in visual acuity between both eyes, but this can be reduced by second eye surgery (Castells et al., 2006).

2.2.3.2 Contrast sensitivity

2.2.3.2.1 Impact of cataract on contrast sensitivity

Contrast sensitivity, which is “the ability to distinguish between dark and light contrasts”, has been found to be negatively impacted by cataract (Bal, Coeckelbergh, Van Looveren, Rozema, & Tassignon, 2011; Fraser, et al., 2013a,b; McGwin et al., 2003; Owsley et al., 2001; Shandiz et al., 2011; Wood & Carberry, 2006; Wood & Owens, 2005; Wood & Troutbeck, 1995). As cataract severity increase, contrast sensitivity impairment increases, which indicates that contrast sensitivity tests may provide supplementary information over the conventional visual acuity tests (Shandiz et al., 2011). Previous research suggests that some patients with cataract might have poor contrast sensitivity, despite having good visual acuity (Bal et al., 2011) and that contrast sensitivity might be a better measure to assess functional visual impairment among cataract patients (Elliott & Situ, 1998). Similarly, another study among cataract patients found that contrast sensitivity might be a more important measure to use than visual acuity (Adamsons, Vitale, Stark, & Rubin, 1996) as the environment is surrounded by more low contrast clues (Datta et al., 2008).

2.2.3.2.2 Impact of first and second eye cataract surgery on contrast sensitivity

Evidence suggests that cataract surgery significantly improves contrast sensitivity in the operated eye (Castells et al., 2006; Comas, Castells, Acosta, & Tuñí, 2007; Elliott et al., 2000; Foss et al., 2006; Fraser et al., 2013a,b; Laidlaw & Harrad, 1993; Laidlaw et al., 1998; Lee et al., 2013; McGwin, Gewant, Modjarrad, Hall, & Owsley, 2006; Owsley et al., 2007; Palagyi et al., 2017; To et al., 2014a,b). Similar to visual acuity, previous research found that contrast sensitivity improved after both first and second eye cataract surgery (Lee et al., 2013; To et al., 2014a,b). However, it has been found that the major improvements were the result of first eye cataract surgery (96%), as only 4% of the improvement in contrast sensitivity was related to second eye cataract surgery (Castells et al., 2006). As with visual acuity, undergoing first eye cataract surgery only can increase the discrepancy in contrast sensitivity between both eyes, but this can be reduced by second eye surgery (Castells et al., 2006).

2.2.3.3 Stereopsis

2.2.3.3.1 Impact of cataract on stereopsis

Stereopsis is a measure of depth perception which is defined as “the perception of the three dimensions of an object under binocular vision and occurs through fusion of signals from disparate retinal elements” (Suliman & Ali, 2017). Cataract has also been associated with decreased stereopsis (Helbostad et al., 2013). As stereopsis is a binocular function to see the world in three dimensions, it requires adequate visual acuity (Comas et al., 2007; Kwapiszeski, Gallagher, & Holmes, 1996) and contrast sensitivity in both eyes (Comas et al., 2007). Previous research has, for example, found that patients with unilateral cataract had reduced stereopsis, which was correlated with their visual acuity in the same eye (Kwapiszeski et al., 1996).

2.2.3.3.2 Impact of first and second eye cataract surgery on stereopsis

Previous research suggests that cataract surgery provides significant improvements in stereopsis (Castells et al., 2006; Elliott et al., 2000; Foss et al., 2006; Laidlaw & Harrad, 1993; Talbot & Perkins, 1998; To, et al., 2014a,b). Improvements in stereopsis have been found after both first and second eye cataract surgery (Castells et al., 2006; Laidlaw et al., 1998; To et al., 2014a,b). Second eye cataract surgery brings greater benefits to stereopsis than first eye cataract surgery (Castells et al., 2006). More specifically, previous research suggests that first eye cataract surgery accounts for 46% of improvements in stereopsis and second eye surgery for 54% (Castells et al., 2006). The improvements in stereopsis could be explained by the fact that second eye cataract surgery reduces the difference in visual acuity and contrast sensitivity between both eyes (Castells et al., 2006; Elliott et al., 2000), as stereopsis is a binocular measure (Comas et al., 2007; Laidlaw et al., 1998). When cataract surgery is only performed in one eye among bilateral cataract patients, it increases the differences in these measures of vision in both eyes, which has a negative impact on stereopsis (Castells et al., 2006). Differences in both eyes can lead to binocular inhibition causing the binocular visual acuity or contrast sensitivity values to be worse than the values of the better eye (Azen et al., 2002).

2.3 Cataract, Cataract Surgery and Driving

Driving depends heavily on visual functioning (Desapriya et al., 2011; Johnson & Wilkinson, 2010; Owsley & McGwin, 2010) and it has been suggested that vision accounts for approximately 90% of sensory input required for driving (Messinger-Rapport, 2003). As a consequence, an extensive body of research has shown that cataract may have a negative impact on driving performance as measured by self-reported questionnaires, driving simulators, and on-road assessments. A recent research study conducted among older drivers on the waitlist for cataract surgery found that 53% of current drivers with cataract self-reported that cataract had a negative impact on their driving (Keay et al., 2016). The driving outcomes impacted by cataract included driving performance (e.g., Wood et al., 2012; Wood, Chaparro, Carberry, & Chu, 2010; Wood & Carberry, 2004, 2006), crash risk (e.g., Owsley et al., 1999; Owsley et al., 2002), driving difficulty (e.g., Bevin et al., 2004; Fraser et al., 2013b; McGwin et al., 2003; Owsley et al., 1999) and self-regulation practices (e.g., Fraser et al., 2013c; Owsley et al., 1999). The impact of cataract on driver self-regulation practices will be presented in a chapter dedicated to self-regulation practices itself, as it is part of the main topic of this thesis.

2.3.1 Impact of cataract on driving

2.3.1.1 Impact of cataract on driving performance

An extensive body of evidence has found that cataract has a negative impact on driving performance (e.g., Marrington, Horswill, & Wood, 2008; Wood et al., 2010, 2012; Wood, Chaparro, Carberry, & Hickson, 2006; Wood, Chaparro, & Hickson, 2009; Wood & Carberry, 2004, 2006, Wood & Troutbeck, 1994, 1995). For example, two closed-road circuit studies found that young adults (Wood & Troutbeck, 1994) and older drivers (Wood & Troutbeck, 1995) who met visual standards for driving and who wore goggles to simulate the effects of cataract had higher impairment to overall driving performance than when subjected to other simulated impairments (monocular vision and visual field restriction). More specifically, simulated cataract induced changes in road position (Wood & Troutbeck, 1995), reduced speed (Wood & Troutbeck, 1994), increased time when reversing (Wood & Troutbeck, 1994), increased time to complete the circuit when manoeuvring around cones, and reduced

peripheral awareness (Wood & Troutbeck, 1994, 1995) in comparison to participants' driving performance at baseline without the goggles.

Two other closed-road circuit studies found that older drivers with bilateral cataract had poorer driving performance than the aged-matched control group with normal vision (Wood & Carberry, 2004, 2006). More specifically, bilateral cataract participants had poorer overall driving scores, were worse at recognising road signs and road hazards, were worst at steering to avoid road hazards (Wood & Carberry, 2004, 2006) and at keeping within the lane than the aged-matched control group, (Wood & Carberry, 2004). The authors concluded that these impairments might affect older drivers' ability to follow road rules, use road sign clues, and avoid pedestrians, large debris on the roads and speed bumps while driving (Wood & Carberry, 2004). The severity of cataract also seems to affect driving performance. It has been found, for example, that drivers who wore moderate level simulated cataract goggles took more time to detect and anticipate traffic hazards than a control group, and mild level of cataract only slowed the ability to detect the presence of hazards (Marrington et al., 2008).

Night time driving performance has also been found to be impaired by cataract (Wood et al., 2010). Participants with simulated cataract took more time to drive, drove more slowly, hit more traffic hazards on the roads, and were worse at recognising traffic signs at night time than drivers with normal or blurred simulated vision (Wood et al., 2010). In addition, when pedestrians were wearing black clothes, participants with simulated cataract were not able to see them (Wood et al., 2010). However, when pedestrians were wearing biomotion clothes, participants with simulated cataract were able to detect them 80% of the time (Wood et al., 2010). Another study found that participants with simulated visual impairment (cataract or blurred vision) had more trouble recognising pedestrians at night than people with normal vision (Wood et al., 2012). This effect was stronger for people with simulated cataract than with simulated blurred vision (Wood et al., 2012). Participants with normal vision could detect the pedestrians at a 5.5 fold longer distance than cataract patients (Wood et al., 2012). The authors explained their findings by the fact that cataract impacted contrast sensitivity more than blurring did (Wood et al., 2012, 2010).

Another closed-road circuit study analysing the effects of multitasking on visual

impairment and age found that driving performance was impaired by multitasking, and the effects were worst for participants with simulated cataract in comparison to participants with blurred and normal vision (Wood et al., 2006). Similarly, another closed-road circuit study analysing the effects of visual impairment on age and distractors, found that driving performance was significantly reduced with simulated cataract and was worsened with visual distractors (Wood et al., 2009). In both studies, the impairments in driving performance were also greater for older drivers with simulated cataract than younger drivers (Wood et al., 2006, 2009). However, all these studies relied on small sample sizes, which may affect the generalisability of the results.

2.3.1.2 Impact of cataract on driving difficulty

Previous research has found that cataract has a significant impact on driving difficulties (e.g., Bevin et al., 2004; Fraser et al., 2013b; McGwin et al., 2003; Mönestam & Wachtmeister, 1997; Owsley et al., 1999). For example, a prospective cohort study found that 82% of cataract patients with a drivers licence self-reported having visual functional problems while driving (Mönestam & Wachtmeister, 1997). In another study, the findings from self-reported questionnaires were that participants with cataract were four times more likely to report having difficulties driving in challenging situations than participants without cataract (Owsley et al., 1999).

More specifically, a prospective cohort study found that 6% drivers on the waitlist for cataract surgery reported having “great difficulties”, 31% “moderate difficulties”, 16% a “little difficulty” and 31% “no difficulties” driving during day time (Bevin et al., 2004). More than half of the sample (57%) reported having “great difficulties”, 15% having “moderate difficulties”, 14% “a little difficulty” and 10% “no difficulties” while driving during night time (Bevin et al., 2004). A prospective cohort study also found that participants self-reported having difficulties driving during day time (34%) and at night time (44%) before undergoing cataract surgery (Mönestam et al., 2005). Night time driving seems therefore to be a particular challenging situation for cataract patients (Bevin et al., 2004; Fraser et al., 2013c; Mönestam et al., 2005; Mönestam & Wachtmeister, 1997; Owsley et al., 1999, 2001). In two self-reported studies for example, night time driving was the most self-reported challenging situation for cataract patients, with between 71% and 77% of participants self-reporting this

difficulty (Mönestam & Wachtmeister, 1997; Owsley et al., 2002). Another prospective cohort study, which compared a group of participants who decided to undergo cataract surgery with a group of participants who declined surgery, found that participants who decided to undergo surgery had greater difficulties in day and night time driving than participants who decided not to undergo surgery (McGwin et al., 2003). However, the majority of these studies only used two questions to assess day and night time driving which may affect the generalisability of the results.

Besides night time driving, other driving situations are challenging for cataract patients include driving in the rain (67%), in rush hour (45%), in high traffic (36%), on highways or freeways (26%), alone (24%), and making turns across oncoming traffic (21%) (Owsley et al., 1999). In addition, another study found that 37% of participants self-reported having difficulties with distance estimation, 11% with glare from oncoming vehicles and 7% with fatigued eyes while driving (Mönestam & Wachtmeister, 1997).

2.3.1.3 Impact of cataract on crash risk

An increasing body of evidence has found that older drivers with cataract have an elevated risk of being involved in a motor vehicle collision. A recent study conducted among older drivers on the waiting list for cataract surgery found that 9% of current drivers with cataract had a crash in the last 12 months (Keay et al., 2016). Two other studies found that older drivers with cataract were 2.5 times more likely to be involved in an at-fault crash in the past 5 years, in comparison to people without cataract (Owsley et al., 1999, 2001).

2.3.2 Association between driving and objective measures of vision

2.3.2.1 Visual acuity

Visual acuity is the objective measure of vision most frequently used by licensing authorities to assess fitness to drive around the world (Owsley & McGwin, 2010; Owsley, Wood, & McGwin, 2015). Currently most licensing authorities rely on an assessment of visual acuity when a person obtains or renews a driver's licence (Ortiz, Castro, Alarcón, Soler, & Anera, 2013). In Australia, for example, drivers are required to have at least a vision of 6/12 in one or both eyes to meet the minimum Australian

visual acuity standard for driving (Austroads, 2017).

In terms of driving outcomes, there is evidence that visual acuity impairment is associated with self-perceived driving difficulty (Van Rijn et al., 2002), the ability to recognise road signs and hazards (Higgins & Wood, 2005; Wood, 1999, 2002) and difficulties reading road signs at safe distances on highways (Schieber, 2004), as well as driving on high traffic roads and during night time (McGwin, Chapman, & Owsley, 2000). However, there is increasing evidence that relying on visual acuity to assess drivers' fitness to drive is insufficient (Babizhayev, 2003; Bal et al., 2011; Wood & Owens, 2005), because licensing authorities use high contrast charts under high luminance conditions to measure visual acuity (Owsley & McGwin, 2010; Wood & Owens, 2005), but such charts are not associated with drivers' ability to recognise road objects (e.g., road signs, hazards, pedestrians) (Wood & Owens, 2005). Additionally, high contrast charts do not account for other visual factors impaired among cataract patients, such as contrast sensitivity (Woods & Wood, 1995).

As visual acuity tests were originally designed for clinical assessments, they do not account for all visual functions involved in real life driving situations (Owsley & McGwin, 2010). For example, a study found that 78% of drivers would be considered as unfit to drive, if stray light ("unwanted light in an optical system" [Fest, 2013]) was taken into consideration, even though they meet current European visual acuity requirements for driving (Bal et al., 2011). In the same way, 31% of participants meeting the European visual acuity requirements for driving would be considered as unfit to drive if contrast sensitivity was also taken into consideration (Bal et al., 2011).

In terms of cataract patients more specifically, there are some conflicting results in the literature about the impact of visual acuity on driving outcomes among this group, which might be related to the study design and characteristics of the sample. Although some studies fail to find an association between visual acuity and driving, including crash risk (Owsley et al., 2001) and driving difficulty (Fraser et al., 2013b), other studies found that the association was significant (McGwin et al., 2000; Walker, Anstey, Hennessy, Lord, & Von Sanden, 2006a). Specifically, a self-reported study found that people with poor visual acuity were more likely to have driving difficulties, with visual acuity predicting driving ability, even though contrast sensitivity was the strongest visual predictor of driving (Walker, Anstey, & Lord, 2006b). A cross-

sectional study among older drivers with visual impairment of which 3 out of 4 had cataract, found that drivers with poor visual acuity reported having more driving difficulties (McGwin et al., 2000). These driving difficulties included driving at night and on heavy traffic roads (McGwin et al., 2000).

2.3.2.2 Contrast sensitivity

A growing body of evidence has found that contrast sensitivity has been associated with a variety of driving outcomes, including crash risk (Guo, Fang, & Antin, 2015; Huisingh et al., 2017), driving performance (Wood, 2002), and driving difficulty (McGwin et al., 2000; Van Rijn et al., 2002). Contrast sensitivity has also been associated with decreased driving performance during the day and at night time (Ball et al., 1998; Brabyn, Schneck, Lott, & Haegerström-Portnoy, 2005; Wood, 2002; Wood et al., 2009), decreased driving exposure (Freeman, Muñoz, Turano, & West, 2005; Keay et al., 2009; Sandlin et al., 2014) and driving cessation (Freeman et al., 2005; Keay et al., 2009).

In terms of cataract patients more specifically, similar results were found with an association between contrast sensitivity and increased crash risk (Owsley et al., 2002, 2001), driving difficulty (Fraser et al., 2013b), impaired driving performance (Wood & Carberry, 2004, 2006), and difficulties turning across oncoming traffic (McGwin et al., 2000). For example, a cross-sectional study found that contrast sensitivity equal to or smaller than 1.25 log units was the only measure of vision significantly associated with crash risk, before adjusting for potential confounding factors. Visual acuity and disability glare were not associated with crash risk when parameters were unadjusted (Owsley et al., 2001). Older drivers who were involved in a past crash were 8 times more likely to have a severe contrast sensitivity impairment in the worse eye and 6 times more likely to have a contrast sensitivity impairment in both eyes, than older drivers who were not involved in a past crash in the last five years (Owsley et al., 2001).

2.3.2.3 Stereopsis

There are some discrepancies in the literature about the effects of stereopsis on driving outcomes, and only a few studies have analysed its effects on cataract patients. Although some studies failed to find an association between driving outcomes and

impaired stereopsis (Bauer, Dietz, Kolling, Hart, & Schiefer, 2001; Fleck & Kolling, 1996; Johnson & Wilkinson, 2010; McKnight, Shinar, & Hilburn, 1991; Tijtgat, Mazyn, De Laey, & Lenoir, 2008), other studies have found that stereopsis was associated with driving outcomes such as higher risks of failing driving a car through a slalom course (two parallel lines of traffic cones) (Bauer et al., 2001; Bauer, Kolling, Dietz, Zrenner, & Schiefer, 2000), misestimation (Owens, Wood, & Carberry, 2010), and increased crash risk (Gresset & Meyer, 1994; Owsley et al., 1998).

In terms of cataract patients, few studies have analysed the effects of stereopsis on driving outcomes. Among those, Fraser et al. (2013b) failed to find an association between stereopsis and driving difficulty.

2.3.3 Impact of cataract surgery on driving

2.3.3.1 Impact of cataract surgery on driving performance

An on-road study which looked at the effects of first and second eye cataract surgery on driving performance found that participants who underwent both eye surgeries improved their overall driving performance, their ability to recognise road signs and road hazards, as well as the ability to avoid road hazards after first and second eye cataract surgery, to the levels of controls with normal vision (Wood & Carberry, 2004). However, this study had a small sample size of 28 participants with bilateral cataract and 18 age-matched controls, which may affect the generalisability of the results. Similarly, another on-road study found that bilateral cataract surgery improved overall driving performance, road sign and road hazards recognition, as well as roads hazards avoidance, to the level of the control group (Wood & Carberry, 2006). However, contrary to the previous study, the participants were assessed only before first eye cataract surgery and after second eye cataract surgery and therefore no information was provided about the specific contribution of first eye and second eye cataract surgery separately.

2.3.3.2 Impact of cataract surgery on crash risk

A prospective cohort study aiming to compare crash risk among older drivers who decided to undergo cataract surgery with older drivers who decided not to undergo cataract surgery found that cataract surgery in general reduced by half the crash risk

over the 4 to 6 year follow-up periods, resulting in a reduction rate of 4.74 crashes per million miles (1,609,344 kilometres) travelled (Owsley et al., 2002). However, first and both eye cataract procedures were combined in the analyses. A population based study using Western Australian linked data between 1997 and 2006 found that there was a reduction of 12.7% in crashes one year after first eye cataract surgery, resulting in \$4.3 million cost savings (Meuleners, et al., 2012a). A more recent population based study using Western Australian linked data from 2004 to 2014 found that motor vehicle crashes were reduced respectively by 47% and 45% after first and second eye cataract surgery, resulting in \$22.1 million cost savings for the community in the year after second eye cataract surgery (Meuleners, Brameld, Fraser, Chow, & Agramunt, submitted). This suggests that second eye cataract surgery provides significant additional benefits to road safety (Meuleners et al., submitted).

2.3.3.3 Impact of cataract surgery on driving difficulty

The majority of studies that analysed the impact of cataract surgery on driving difficulties relied on self-reported questionnaires, which might be subject to social desirability (Af Wählberg, 2010) and recall biases (Blanchard et al., 2010). A meta-analysis aiming to analyse the effects of cataract surgery on driving outcomes found that driving difficulties decreased by 88% following cataract surgery (Subzwari et al., 2008). This meta-analysis was based on four prospective cohort studies (Mamidipudi et al., 2003; Mönestam et al., 2005; Mönestam & Lundqvist, 2006; Mönestam & Wachtmeister, 1997) and one retrospective cohort study (Chang-Godinich, Ou, & Koch, 1999), but no information was provided about the specific effects of first and second eye cataract surgery separately.

However, Mönestam & Wachtmeister (1997) found a significant reduction in self-reported driving difficulties after cataract surgery, with a reduction by 31.1 percentage points in having difficulties with distance estimations, decreasing from 37% to 5.9% (Mönestam & Wachtmeister, 1997). In addition, 25% of participants who held a drivers licence but did not drive before cataract surgery, started to drive after surgery (Mönestam & Wachtmeister, 1997). This is similar to another study that found an increase of 11 percentage points in participants who drove 4 months after undergoing cataract surgery, from 83% to 94% (Mönestam & Lundqvist, 2006). Another study found that there was a significant reduction in the composite scores for driving

difficulty on the Driving Habits Questionnaire (DHQ) following cataract surgery (Owsley et al., 2002). However, participants who had only first eye surgery (44%) were combined with participants who had both eye surgeries (56%) in the analyses (Owsley et al., 2002). Although these studies suggest that driving difficulties decrease following cataract surgery, previous research suggest that the type of lenses inserted during cataract surgery might be associated with patients' changes in driving habits 2 to 3 years after having been operated (Beiko, 2015).

Various studies have analysed the effects of cataract surgery on day and night time driving difficulties and there is a general consensus that day and night time driving improve significantly after cataract surgery (Bevin et al., 2004; Mamidipudi et al., 2003; McGwin et al., 2003; Mönestam et al., 2005). However, the majority of these studies used only two questions to assess day and night time driving. A prospective cohort study found that day time driving difficulties were reduced by 45 percentage points (from 72% to 27%) following cataract surgery, and night time driving difficulties were reduced by 37 percentage points, from 90% to 53% after surgery (Bevin et al., 2004). Similarly, another study found that difficulties driving during day time and night time decreased from 50% to 6% and from 69% to 24% respectively after cataract surgery (Mönestam et al., 2005). Five years after cataract surgery, 95% of the sample self-reported having no difficulties during daytime, and 56% reported having no difficulties driving at night (Mönestam et al., 2005). Another study, based on the same population study as Mönestam et al. (2005) found that among participants who had surgery in only one eye, 48% still reported having difficulties while driving at night, and 41% of participants who had both eyes done still reported having difficulties at night time (Mönestam & Lundqvist, 2006). Similarly, day time driving improved by 15.1 points and night time driving by 18.9 points before and after cataract surgery in another study (McGwin et al., 2003). However, the authors did not specify whether participants underwent first eye, second eye surgery or whether both eyes were combined in the analyses in each of these studies.

Few studies have analysed the specific effects of first and second eye cataract surgery on driving difficulty separately, and the results were all derived from self-reported questionnaires. Among those, a study found that first eye surgery improved both day and night time driving, but second eye cataract surgery improved only night time

driving scores (Elliott et al., 2000). However, a prospective study found that both day and night time driving improved after second eye cataract surgery (Castells et al., 1999). More specifically, there was a 89% improvement in day time driving for participants who underwent first eye surgery only, yet there was 100% improvement in day time driving scores for those who underwent second eye cataract surgery (Castells et al., 1999). In the same way, 79% of participants who underwent first eye surgery improved night time driving, but there was 100% improvement in night time driving for those who underwent second eye cataract surgery (Castells et al., 1999).

2.3.4 Impact of cataract surgery on driving and its association with visual outcomes

While some studies found an association between contrast sensitivity and driving difficulty after first eye cataract surgery (Fraser, et al., 2013b) as well as contrast sensitivity and driving outcomes after second eye cataract surgery (Wood & Carberry, 2006), other studies failed to do so. In Wood & Carberry (2006), contrast sensitivity changes after bilateral cataract surgery were the best predictors of improved driving performance. However, visual acuity was not associated with changes in driving performance (Wood & Carberry, 2006). Similarly, Fraser et al. (2013b) found that contrast sensitivity in the operated eye after first eye cataract surgery rather than visual acuity and stereopsis were significantly associated with improvements in self-reported driving difficulties. By contrast, another study found that the proportion of drivers meeting the United Kingdom standards for driving rose from 52% after first eye surgery to 85% after second eye surgery, based on their visual acuity measure (Talbot & Perkins, 1998). Yet another study found that changes in both contrast sensitivity and visual acuity after first eye surgery were associated with difficulty driving at night time (McGwin et al., 2003). In this study, changes in vision scores after cataract surgery accounted for 60% of the variances in changes in night time driving (McGwin et al., 2003). It is possible that the discrepancies between studies is a result of different sample, sample size, and study design. Despite the fact that various studies have shown an association between cataract and driving outcomes, this literature review did not find any studies that examined the association between objective measures of vision and driver self-regulation practices among older drivers with bilateral cataract throughout the cataract surgery process, using objective naturalistic driving data.

2.3.5 Cataract, cataract surgery and driving: identifying gaps in the evidence

While a growing body of research has found that cataract surgery has a positive impact on driving, little is known about the specific impact of first and second eye cataract surgery separately. Indeed, the majority of previous studies have combined participants who underwent only first, second or both eyes surgeries in their analyses. Even though cataract is usually bilateral (Asbell et al., 2005), cataract surgery is often performed one eye after the other, to avoid complications that could occur bilaterally such as endophthalmitis (Lundström, Barry, Henry, Rosen, & Stenevi, 2012). Patients undergoing cataract surgery in public hospitals in Australia often have to wait a median of 93 days before surgery and some patients (2.5%) might even be waitlisted for more than 365 days (Australian Institute of Health and Welfare, 2016), which suggests that they might be driving on the roads with poor and declining vision while waiting for first and second eye cataract surgery. It is of particular importance for road safety, as little is known how older drivers behave while driving with an operated and unoperated eye. In addition, the majority of studies relied on self-reported questionnaires or on closed-road circuits with small sample size, which might not account for the naturalistic driving behaviour of participants who may experience a wider range of driving situations on the roads. Identifying the impact of first and second eye cataract surgery on driving outcomes may provide a rationale for performing first and second eye cataract surgery in a timely manner to preserve older drivers' independence, mobility, and safety.

Furthermore, it has been suggested that traditional visual acuity tests do not account for all visual function involved in driving (Owsley & McGwin, 2010), even though they are usually used by most licensing authorities to determine fitness to drive (Austroads, 2017; Ortiz et al., 2013). Analysing which objective measures of vision are associated with driving outcomes after first and second eye cataract surgery would provide valuable information to licensing authorities and policy makers.

2.4 Driver Self-Regulation Practices

2.4.1 Definition of self-regulation

Driving self-regulation is a multidimensional (Molnar et al., 2014) and complex

process (Molnar, et al., 2013b; Wong, Smith, & Sullivan, 2016a), which has been described as a positive coping strategy to minimise driving risk (Gwyther & Holland, 2012). Self-regulation suggests that older drivers may modify their driving behaviours and avoid driving in situations perceived as challenging for themselves. These behavioural changes might be used to compensate for age-related declines (Sullivan et al., 2011), such as in cognitive and physical functions, or health including vision (Anstey et al., 2005; Baldock et al., 2006; Lyman, McGwin, & Sims, 2001), and other reasons unrelated to declining abilities, such as older drivers' lifestyle (Charlton et al., 2006; Molnar et al., 2013b) and individual preferences (Molnar et al., 2013b). Driver self-regulation practices can be considered on a continuum from complete driving independence to driving cessation (Lyman et al., 2001) and is a process that happens progressively over time (Donorfio et al., 2009). Self-regulation practices have also been categorised across a driving continuum of three classes ranging from drivers with 'no modifications' to 'self-regulators' and 'former drivers' (O'Connor, Edwards, Small, & Andel, 2011; Unsworth, Wells, Browning, Thomas, & Kendig, 2008). A recent study found that the continuum could be refined into five classes including drivers with 'no modifications', 'low self-regulators', 'medium self-regulators', 'high self-regulators' and 'former drivers' (Bergen et al., 2017). Self-regulation practices might involve avoiding driving in challenging situations (Fraser, et al., 2013c; Owsley et al., 1999), reduction in driving exposure (Owsley, Stalvey, & Phillips, 2003) and driving cessation (Lyman et al., 2001). Therefore, self-regulation practices are likely to involve a variety of factors (Charlton et al., 2006).

2.4.2 Conceptual framework

Various studies have developed models to explain the multidimensionality of older driver self-regulation practices (e.g., Anstey et al., 2005; Choi, Adams, & Mezuk, 2012; Donorfio et al., 2009; Lindstrom-Forneri, Tuokko, Garrett, & Molnar, 2010; Lindstrom-Forneri, Tuokko, & Rhodes, 2007; Wong, Smith, & Sullivan, 2017; Wong, et al., 2016a), but only a limited number of them have taken into account age-related declines, such as visual impairment. These models are described below.

2.4.2.1 The Multifactorial Model of Older Driver Safety

Anstey et al. (2005) developed a model, the Multifactorial Model of Older Driver

Safety, which considers age-related decline in vision, cognition, and physical function. In this model, the capacity to drive safely is determined by an older driver's vision, cognition and physical function, while the self-monitoring beliefs about one's capacity to drive are determined by cognition (Anstey et al., 2005). Both the self-monitoring beliefs about the capacity to drive safely, and the capacity to drive safely itself, contribute to driving behaviour and therefore to self-regulation practices, such as avoiding driving in certain conditions because of impaired vision (Anstey et al., 2005). A study aiming to test some constructs of the Multifactorial Model of Older Driver Safety, including vision and cognitive function, found that the capacity to drive safely deteriorates with age (Anstey, Horswill, Wood, & Hatherly, 2012). The researchers also found, however, that visual and cognitive factors, which were not dependent on age, were also associated with driving safety (Anstey et al., 2012).

2.4.2.2 A Multidimensional Model of Self-regulation

Psychological processes also play an important role in the Multidimensional Model of Self-regulation (Donorfio et al., 2009). In this model, four dimensions have a strong impact on self-regulation practices: "driving skill and ability", "life and society", "self-worth", "automobile". In the driving skill and ability factor, older drivers become self-aware that they are experiencing age-related declines, which have an impact on their driving ability and their self-confidence (Donorfio et al., 2009). Therefore, their driving ability becomes limited and changes in their driving behaviour become apparent such as driving more slowly. In this model, self-regulation is also affected by the fact that older drivers want to remain connected to society and life and modify their behaviour in order to do so, such as planning trips ahead or carpooling (life and society) (Donorfio et al., 2009). Self-regulation is also affected by the fact that driving enhances older drivers' self-worth and therefore their reluctance to lose their independence when losing their ability to drive (self-worth) (Donorfio et al., 2009). Self-regulation practices are also affected by the availability of alternative transport, such as public transport (automobile) (Donorfio et al., 2009). However, this model depends on a qualitative survey and does not, therefore, consider the quantitative contribution and interaction of each dimension; consequently it is unable to quantify the extent to which these four dimensions contribute significantly or not to driver self-regulation practices.

2.4.2.3 The Driving as an Everyday Competence model (DEC)

The DEC (Lindstrom-Forneri et al., 2010), considers the role played by age-related declines such as visual impairment in determining driving performance by analysing the interaction of individual, personal, and environmental factors, which are moderated by psychosocial factors (e.g., self-awareness and beliefs about driving), to determine older drivers' level of competence and driving behaviour. However, this model does not quantify the extent to which all these factors interact and contribute to driving behaviour and, therefore, to self-regulation practices.

2.4.2.4 A stress-coping conceptual model of self-regulation

Choi and colleagues (2012) developed a conceptual model of self-regulation (driving cessation), based on the existing stress-coping model developed by Lazarus and Folkman (e.g. Lazarus, 1966, Lazarus & Folkman, 1984). In this model, primary stressors (visual, cognitive and functional impairments) produce secondary internal (e.g., discomfort about driving) or external stressors (social pressure to stop driving) that might have an impact on an older driver's decision to stop driving, which in turn impacts quality of life (Choi et al., 2012). Older drivers can adopt two different types of coping strategies (emotion-focused coping and problem-focused coping) to cope with the stressors (Choi et al., 2012). By adopting effective emotion-focused coping strategies, older drivers can, for example, accept the fact that they are at risk for driving and stop driving (Choi et al., 2012). However, adopting ineffective emotion-focused coping might lead to denial of their impairment and continuing to drive while at risk (Choi et al., 2012). Older drivers can also adopt problem-focused coping strategies and directly act to cope with their stressors, such as adopting self-regulation strategies (Choi et al., 2012). Other variables, such as sociodemographic characteristics, spatial (e.g., urban environment) and temporal (e.g., availability of public transport) contexts also have an impact on the model (Choi et al., 2012). Even though it is one of the first models to take into account the well-known stress-coping framework (Lazarus & Folkman, 1984) to describe driver self-regulation practices, the model did not quantify the extent to which all these factors interacted.

2.4.2.5 The Multilevel Older Persons Transportation and Road Safety (MOTRS) model

In the MOTRS model (Wong, Smith, Sullivan, & Allan, 2016b), self-regulation results from an inhibitory or excitatory trigger received in parallel from two factors: sociodemographic variables and driving-specific-variables, which have a combined influence on psychosocial factors. Sociodemographic variables refer to the factors that have an influence on individuals at a personal level (e.g., age, gender), age-related declines such as visual impairment, and on the environmental level (e.g., attitudes towards driving in society). Driving-specific-variables refer to the variables related to drivers' mobility at an individual level (e.g., driving experience, mobility) and the environmental level (public transport, conditions of the roads). Psychosocial factors include variables such as driving confidence and perceived control. A recent study aiming to validate some of the construct of the MOTRS model confirmed previous findings (Wong et al., 2016b) that self-regulation practices were influenced by psychosocial factors which, in turn, were influenced by sociodemographic and driving-related factors. In their modified model, which only selected some of the constructs of the MOTRS model, they found that attitudes towards driving was the strongest predictor of self-regulating practices (Wong et al., 2017).

2.4.3 Factors associated with driver self-regulation practices

Driver self-regulation practices have been associated with a variety of factors, including attitudes towards driving (Wong et al., 2017), having less driving experience (Carmel, Rechavi, & Ben-Moshe, 2014), poor confidence in driving (e.g., Baldock et al., 2006; Carmel et al., 2014; Charlton et al., 2006; Molnar & Eby, 2008), and self-awareness of personal abilities (Blanchard & Myers, 2010; Charlton et al., 2006; MacDonald, Myers, & Blanchard, 2008; Molnar & Eby, 2008). Previous studies also suggest that females self-regulate their driving more than males (e.g., Bergen et al., 2017; Charlton et al., 2006; Conlon, Rahaley, & Davis, 2017). For example, a study analysing the self-regulation practices of drivers aged 75 or older found that women drove fewer kilometres (6,449 km) than men (9,274 km) per year. In addition, 29.3% of women reported driving every day, 58.0% quite a few times weekly, and 12.7% once a week or less. In comparison, men reported driving more frequently, with 41.3% reporting driving daily, 52.1% a few times a week, and 6.5% once a week or less

(Siren & Meng, 2013).

Self-regulation strategies have also been associated with not being the principal driver in the household (Charlton et al., 2006), having been involved in a crash in the past two years (Charlton et al., 2006), visual problems (Bergen et al., 2017; Carmel et al., 2014; Charlton et al., 2006), and poorer health (Bergen et al., 2017; Carmel et al., 2014; Conlon et al., 2017). While previous research suggests that health outcomes and driver self-efficacy are directly associated with driver self-regulation practices, it has been found that driving experience and visual problems were mediated by driver self-efficacy (Carmel et al., 2014). More specifically, contrast sensitivity (Fraser, et al., 2013b; Freeman, Muñoz, Turano, & West, 2006; Keay et al., 2009; Rubin, 1994), visual acuity (Freeman et al., 2006; Keeffe, et al., 2002; Lotfipour et al., 2010), and stereopsis (Rubin, 1994) have been significantly associated with driver self-regulation practices among cohorts of older drivers. However, it has been suggested that a certain number of high-risk drivers, including those with visual impairments, did not practise self-regulation (Okonkwo et al., 2008).

Increasing age has also been associated with higher odds of self-regulation (Carmel et al., 2014; Charlton et al., 2006), but it is apparent that the effect of age on self-regulation is mainly because of the interaction between age and health declines (Donorfio, D'Ambrosio, Coughlin, & Mohyde, 2008). However, recent research has found that self-regulation practices were also common among younger drivers (Naumann, Dellinger, & Kresnow, 2011).

These findings suggest that self-regulation might be related to a range of factors to be considered in addition to self-regulation as a compensatory strategy in response to functional declines because of ageing (Molnar, et al., 2013b). For example, such changes might also illustrate preventive strategies used to reduce crash risk and increase safety, or even illustrate older drivers' lifestyle, such as changes in employment status or moving houses (Charlton et al., 2006; Molnar et al., 2013b) or even individual preferences (Molnar et al., 2013b). Molnar et al. (2013b) found that driving behavioural changes were mostly associated with personal preferences and lifestyle rather than self-regulation practices. Previous research also found that self-regulation involved not only behavioural changes but also psychological processes (Donorfio et al., 2009; Lindstrom-Forneri et al., 2007; Wong et al., 2016a,b), such as

attitude towards driving (Wong et al., 2017).

2.4.4 Older drivers and self-regulation practices

While previous research also found that a significant number of high-risk drivers did not self-regulate their driving (Okonkwo et al., 2008) or that a low number avoided driving in challenging situations (Charlton et al., 2006; Gwyther & Holland, 2012; Horswill, Anstey, Hatherly, Wood, & Pachana, 2011; Molnar & Eby, 2008; Sullivan et al., 2011; Wong, Smith, & Sullivan, 2015), other studies found that a high number of older drivers did self-regulate their driving (Ball et al., 1998; Ruechel & Mann, 2005). The extent to which older drivers self-regulate their driving varies widely among studies. This could be attributed in part to the definition of self-regulation, the sample size and its characteristics, the variety of questionnaires used, the specific situations measured, and the factors chosen to measure driver self-regulation practices. For example, two studies conducted among older drivers found that only approximately 25% of participants self-regulated their driving (Charlton et al., 2006; Molnar & Eby, 2008), and in another study, self-regulators accounted for 15% (Molnar, et al., 2013b) of the sample.

2.4.5 Self-regulation practices

2.4.5.1 Avoiding driving in challenging situations

Older drivers seem to avoid specific driving situations that they find challenging for themselves. For example, a study aiming to compare self-reported driving performances with objective on-road measures of driving found that participants self-reported having trouble when driving into the sun, at night or dusk, in wet conditions and in unfamiliar situations (Wood, Lacherez, & Anstey, 2013b). Another study found that the three most common situations drivers aged 75 and older reported avoiding were driving when not feeling well, when tired and when the road was slippery (Siren & Meng, 2013). In another study, the three most common situations avoided were driving in the rain or fog, at high speed, and at night or in the dark (Carmel et al., 2014). Similarly, previous research found that the most common situations avoided by older drivers were driving during night time (19.1%), driving when weather conditions were bad (8.8%), using expressways (8.8%) and driving outside of local areas (13.2%)

(Molnar & Eby, 2008). Those results were supported in a study by Molnar et al., (2013b) who found driving during peak hour traffic (46%), at night time in bad weather (44%), in bad weather (35%) and at night time (22%) were the situations most commonly avoided by older drivers. Yet again, another study conducted among 860 drivers found that situations mostly avoided by older drivers aged 70 and over were driving in the rain or fog, at high speed, at night or in the dark, long trips, passing other vehicles and in unfamiliar places (Carmel et al., 2014). Driving situations that drivers reported avoiding were mostly linked to inner states or adverse conditions rather than conditions related to infrastructure (Siren & Meng, 2013). On the other hand, the situations reported being the least-avoided were roundabouts, left turns and junctions without traffic lights (Siren & Meng, 2013), driving in the neighbourhood or in the city (Carmel et al., 2014) and driving alone (Molnar et al., 2013b).

2.4.5.2 Changes in driving exposure

Despite the discrepancies among studies about the specific challenging situations most avoided by older drivers, a growing body of evidence has found that older drivers also self-regulate their driving by reducing their driving exposure (Owsley et al., 2003). Reduced driving exposure has been associated with visual impairment (e.g., Fraser et al., 2013b; Freeman et al. 2005; Owsley et al., 1999; Ross et al., 2009; Sandlin et al., 2014), loss of confidence (Blanchard & Myers, 2010), impaired physical function (Vance et al., 2006) and cognitive function (Ross et al., 2009; Stutts, 1998; Vance et al., 2006).

In Charlton et al. (2006), 41% of drivers reported that they had reduced the distances driven when compared to distances they drove five years previously, while 45% of drivers did not make any changes in the number of kilometres driven. Similarly, a longitudinal study over four years found that participants reduced the weekly distance driven compared to four years previous, reduced from an average of 94 miles (151.278 kilometres) per week in the first year to an average of 78 miles (125.529 kilometres) per week during the last year (Braitman & Williams, 2011). In that study, lifestyle and social changes were associated with the changes in driving exposure throughout the years (Braitman & Williams, 2011). More specifically, there was a reduction of 35 miles (56 kilometres) driven per week if participants had lost their job or had retired, and 61 miles (98 kilometres) if they had moved from a retirement home to a private

home or assisted living (Braitman & Williams, 2011). However, there was an increase of 25 miles (40 kilometres) per week if they became divorced or widowed (Braitman & Williams, 2011). The Braitman and Williams (2011) study highlights again the importance of taking into account lifestyles changes (Charlton et al., 2006; Molnar et al., 2013b) when analysing driver self-regulation practices.

2.4.6 Self-regulation practices and driving difficulty among older drivers with cataract

Despite an increase in the number of studies examining older driver self-regulation practices in the last two decades, only a few studies have analysed the specific effects of cataract or cataract surgery on driving self-regulation practices. In terms of driving exposure, previous research found that older drivers with cataract reduced the number of days, trips and miles travelled per week in comparison to older drivers without cataract (Owsley et al., 1999). Similarly, a recent study found that 41% of older drivers waiting for first eye cataract surgery self-reported that they had reduced the number of hours and distance driven (Keay et al., 2016). First eye cataract surgery enabled to increase the average number of kilometres travelled per week by 22.3 kilometres per week (Fraser et al., 2013b). Another study found that 40% of participants who had cataract surgery started to increase their driving frequency after cataract surgery (Mönestam & Wachtmeister, 1997). However, Mönestam & Wachtmeister (1997) did not specify whether participants underwent first, second eye surgery or both eyes combined.

Older drivers with cataract reported higher overall avoidance of driving in specific situations than drivers without cataract (Ball et al., 1998). More specifically, 47.5% of older drivers with bilateral cataract self-reported they did not drive in at least one difficult situation while waiting for first eye surgery (Fraser et al., 2013c). Likewise, a recent study conducted among older drivers on the waitlist for cataract surgery found that 53% of current drivers with cataract self-reported that cataract had impacted their driving (Keay et al., 2016). Driving at night was the most commonly avoided situation (40.4%), followed by driving on the freeway (12.1%), when it was raining (9.1%), and when parallel parking (8.1%) (Fraser et al., 2013c). In Keay et al. (2016), 26% reported they reduced their speed, and self-reported avoiding driving at night (85%), in the rain (36%), in unfamiliar places (28%), in peak hour traffic (15%) and over 20% long

distances. Older drivers with cataract also preferred to be driven by others and to drive closer to their home, and reported driving slower than the general traffic (Owsley et al., 1999). However, these studies relied on self-reported questionnaires only, which might be subject to recall (Blanchard et al., 2010) and social desirability bias (Af Wåhlberg, 2010).

2.4.7 Cataract, cataract surgery and driver self-regulation practices: identifying gaps in the evidence

Although these findings suggest that cataract patients might self-regulate their driving while waiting for first eye cataract surgery, the majority of studies relied on self-reported questionnaires, which might be subject to recall (Blanchard et al., 2010) and social desirability bias (Af Wåhlberg, 2010). These studies lacked objective and real-world data. To date no research has used naturalistic driving data such as in-vehicle monitoring devices to measure self-regulation practices among a cohort of cataract patients.

In addition, little is known about the self-regulation practices of older drivers throughout the cataract surgery process. Indeed, the majority of studies analysed the effects of cataract surgery in general, combining participants who underwent only first, second or both eyes surgeries in their analyses. Accurate determination of the extent to which cataract patients self-regulated their driving after first and second eye cataract surgery is difficult to determine from self-reported questionnaires only.

Furthermore, little is known about the objective measures of vision that are specifically associated with driver self-regulation practices throughout the first and second eye cataract surgery process. While previous studies suggest that contrast sensitivity is an important measure to consider (e.g., Fraser et al., 2013b), those studies did not analyse the specific effects of contrast sensitivity on both eye surgeries separately.

Gaining a better understanding of the separate impact of first and second eye cataract surgery on driver self-regulation status for bilateral cataract patients may enable ophthalmologists to better inform their patients about the effects of their vision impairment on driving ability throughout the cataract surgery process, and how best to manage these to improve their safety and the safety of other road users. Determining which objective measures of vision are associated with driver self-regulation practices

after first and second eye cataract surgery would also provide valuable information to licensing authorities and policy makers.

2.5 Naturalistic Driving Studies

An increasing number of road safety studies have used naturalistic driving studies in recent years to observe and analyse the driving behaviour of individuals in their “natural environment” using driver in-vehicle monitoring devices. These devices, which are connected to a participant’s car, measure a variety of driving behaviours including driving patterns, exposure, habits, and adverse events. They collect GPS time-stamped second by second data for speed, location, date of travel, kilometres travelled, type of roads used, conditions of travelling and start/end times of trips in real time (Grengs, Wang, & Kostyniuk, 2008).

2.5.1 Naturalistic driving studies over self-reported measures

Even though a large number of studies have relied on self-reported questionnaires or travel diaries to measure driving patterns and self-regulation practices in the past, research has found that self-reported measures of driving behaviour might be inaccurate and unreliable (Blanchard et al., 2010; Crizzle, Myers, & Almeida, 2013; Grengs et al., 2008; Huebner, Porter, & Marshall, 2006; Molnar et al., 2013a; Porter et al., 2015). Driver in-vehicle monitoring devices have various benefits over self-reported measures such as questionnaires or travel diaries, as they provide valid and accurate measures of driving outcomes (Huebner et al., 2006) by overcoming the limitations of self-reported measures such as recall bias (Blanchard et al., 2010), social desirability (Af Wählberg, 2010) and participants’ rough estimates (Grengs et al., 2008). They also provide more comprehensive measures of driving outcomes than self-reported measures (Marshall et al., 2007). Monitoring devices record participants’ driving behaviour in real time as drivers are in motion, and they can collect a wide range of measures not collected by self-reported measures such as speed, hard acceleration, hard braking, and turns (Grengs et al., 2008; Marshall et al., 2007). As naturalistic data can provide information time-stamped second by second, they can also be associated with weather and light conditions, to determine the context in which the participants’ trips were made (Marshall et al., 2007).

Naturalistic driving data are also considered by participants to be more practical and

convenient to use than self-reported measures (Blanchard et al., 2010; Marshall et al., 2007) and enable the collection of driving data over a longer period of time (Grengs et al., 2008). If participants become fatigued when completing travel diaries over a long period (Marshall et al., 2007), high rates of non-completion might occur (Wolf, Guensler, & William, 2001). In-vehicle monitoring devices also minimise missing data or last-minute completion of travel diaries (Marshall et al., 2007). Previous studies have also used naturalistic driving data to measure driver self-regulation practices (Blanchard & Myers, 2010), which might be difficult to measure when self-reported.

2.5.2 Disadvantages of naturalistic driving data

Despite these advantages, using in-vehicle monitoring devices to capture participants' objective driving patterns, exposure and habits has drawbacks. Naturalistic driving devices collect a large amount of data (Grengs et al., 2008) and, consequently, have been used over short periods of time (e.g., 7 days) in previous studies (Blanchard & Myers, 2010; Blanchard et al., 2010; Thompson, Baldock, Mathias, & Wundersitz, 2016) to reduce the amount of data and the time needed for analysis (Thompson et al., 2016).

In addition, in-vehicle monitoring devices are often not equipped with hardware devices, such as key fobs (Porter et al., 2015) or cameras, which enable researchers to identify the driver of the vehicle. As a consequence, trips made might be attributed to the wrong drivers, such as participants' family members or friends, which could affect the study results.

Further, the collection of naturalistic driving data raises some ethical concerns for protecting the privacy and confidentiality of participants while conducting the research study (Blanchard et al., 2010; Grengs et al., 2008). As all participants' driving patterns can be measured, including the exact location of places travelled, the speed and the occurrence of adverse events such as crashes, extra caution needs to be taken to protect participants' privacy. Further, older drivers are often concerned that they might be reported to licensing authorities (Blanchard et al., 2010); these matters need to be taken into consideration when conducting naturalistic studies with a cohort of older drivers.

The main disadvantage of using in-vehicle monitoring device over self-reported measures is that the purpose of a participant's trips is not captured (Grengs et al.,

2008). Therefore, previous studies suggest that naturalistic driving data should be used in conjunction with self-reported measures, as they provide complementary sources of information, such as the context of driving (Blanchard et al., 2010; Molnar et al., 2018; Myers, Trang, & Crizzle, 2011).

2.5.3 Naturalistic driving studies among older drivers

Only a few studies have compared self-reported and naturalistic driving data among cohorts of older drivers (e.g. Blanchard & Myers, 2010; Blanchard et al., 2010; Huebner et al., 2006; Marshall et al., 2007; Molnar et al., 2018; Thompson et al., 2016). Table 1 summarises the studies that compared self-reported and naturalistic driving data among cohorts of older drivers. The major findings of these studies will be summarised in the following pages.

Table 1. Studies comparing self-reported questionnaires and naturalistic driving among older drivers

Study	Sample Size	Age	Self-reported measure	Naturalistic driving measure	Results
Babulal et al. (2016)	N = 20	≥ 65 years	-DHQ	-GPS device	Distance driven: -Strong correlation ($r = 0.83$; $p \leq 0.05$) between the DHQ and the GPS device
Blanchard et al. (2010)	$n = 61$	Mean age = 80.4 ($SD = 5.5$) (range = 67-92)	-Adapted DHQ - Situation Driving Frequency (SDF) - Situation Driving Avoidance (SDA) -Trip logs -Travel diary -Interview	-CarChip E/X® (device without GPS) -Otto Driving Mate® (GPS receiver)	Distance driven: -Inaccurate estimation of distance driven: 25% of participants under/overestimated the distance driven by over 100 kilometres, while 55% by over 50 kilometres. Driving duration: -No significant differences in duration of trips between self-reported and naturalistic driving data: -When comparing the results obtained by the DHQ and the data logger without GPS, 34% of participants had similar results. 57% of the sample overestimated their driving duration, while 9% underestimated it. Number of days driven, trips and stops made: -Underestimation of trips and stops made when comparing the travel diaries with the CarChip E/X®. - Similarity in the number of days driven between self-reported and naturalistic data with a perfect match for 52% of the sample. Self-regulation practices: -Participants self-regulate less than what they report. -No significant differences between the self-reported driving questionnaire and the naturalistic driving data at night time, at night time in bad weather, and on the freeways -Discrepancy between self-reported and naturalistic driving data while making turns across oncoming traffic, driving at dawn/dusk, in

Study	Sample Size	Age	Self-reported measure	Naturalistic driving measure	Results
					bad weather, in heavy rain, fog, making trips over 2 hours, in unfamiliar routes, in peak hour on highways and in town, turning across oncoming traffic with and without signs, on highways, in rural areas and with a passenger.
Hanson & Hildebrand, (2011)	$n = 60$	Age range = 54-92	-Travel diary survey	-GPS receiver	<p>Self-regulation practices:</p> <ul style="list-style-type: none"> -More self-regulation practices than what is self-reported -More than half of the sample avoiding night time driving, while only 10% of the participants self-reported doing it. -40% of participants travelled less than 1% of the total number of kilometres travelled on highways, but only about 20% of the sample reported doing so.
Huebner et al. (2006)	$n = 20$	Men mean age = 73.2 ($SD = 9.1$) (range: 60-89) Women mean age = 70.5 ($SD = 7.7$) (range:62-81)	-DHQ	-CarChip E/X® (device without GPS) -GeoExplorer II Trimble GPS receiver	<p>Distance driven:</p> <ul style="list-style-type: none"> -Underestimation and overestimation of the distance driven with a coefficient of variation of 33.6%.
Marshall et al. (2007)	$n = 20$	Mean age = 78 (range:70-85)	-Travel diary	-CarChip® (device without GPS) -FleetPulse™ (GPS receiver)	<p>Distance driven:</p> <ul style="list-style-type: none"> -Very strong correlation between the travel diary and CarChip® ($r = 0.9$; $p < 0.01$) -Moderate correlation between the travel diary and FleetPulse™ ($r = 0.56$; $p = 0.02$)
Molnar, et al. (2013a)	$n = 156$	Mean age = 79.2 ($SD = 3.2$) (range = 75-88)	-Various self-reported questionnaires, functional assessments used in the Candrive II/Ozcandrive study (Marshall et al. 2013) -Advanced Driving Decisions and Patterns of Travel (ADDAPT)	-Otto View-CD Autonomous Data Logging device (GPS receiver)	<p>Distance driven:</p> <ul style="list-style-type: none"> -Correlation between self-reported and naturalistic driving data -Older drivers underestimating the total number of kilometres travelled per week by a factor of 0.44 <p>Number of days driven:</p> <ul style="list-style-type: none"> Underestimation of the number of days driven per week when compared to naturalistic driving data by a factor of 0.49 <p>Self-regulation practices:</p>

Study	Sample Size	Age	Self-reported measure	Naturalistic driving measure	Results
Molnar et al., (2018)	$n = 2131$	Mean age = 71.2 (range = 65–79)	-Comprehensive questionnaire used and developed by Molnar et al. (2009) -Clinical assessment	-GPS/datalogger	<p>-Correspondence with a certain number of self-reported measure of driving avoidance and naturalistic data (driving on high speed roads, at night time and in unfamiliar places), - No correspondence for other situations (turning across oncoming traffic, driving in peak hour traffic)</p> <p>Driving exposure (days driven and number of kilometres travelled): -Correspondence between self-reported and objective measures, but differences in gender:</p> <ul style="list-style-type: none"> • Better match for women than men when looking at the number of days driven • Better match for men when looking at the total number of kilometres travelled <p>Self-regulation practices: -Correspondence with all self-reported measure of driving avoidance and naturalistic data (driving at night, during rush hour, unfamiliar places and on high speed roads).</p> <ul style="list-style-type: none"> • Different effects of gender on predictions when driving in unfamiliar areas, rush hour (marginal effect), and high speed roads. • Effect of age on predictions when driving during rush hour traffic <p>-No correspondence when making left turn across oncoming traffic -Largest influence of driving comfort on the discrepancy between self-reported and objective measures, when adjusting for potential confounding factors.</p>
Myers et al. (2011)	$n = 47$	Mean age = 77.2 ($SD = 6.6$) (range = 65-91)	-SDF -SDA - Driving Comfort Scale (Day) (DCS-D)	-CarChip® (device without GPS) -Otto Driving Companion® (GPS)	<p>Self-regulation practices: -Participants self-regulate less than what they report. - Actual driving scores on the frequency index were higher than on the SDF, with only two participants scoring the same</p>

Study	Sample Size	Age	Self-reported measure	Naturalistic driving measure	Results
			- Driving Comfort Scale (Night) (DCS-N) - Perceived Driving Ability (PDA) -General driving questionnaire -Interview	receiver)	-40 older drivers travelled at least once a week at night time, but only 27.5% of those self-reported avoiding night time driving on the SDA scale
Porter et al. (2015)	<i>n</i> = 159	Mean age = 77 (<i>SD</i> = 5) (range = 70-92)	-Various self-reported questionnaires, functional assessments used in the Candrive II/Ozcandrive study (Marshal et al.2013) ¹	-Otto View -CD Autonomous Data Logging device (GPS receiver)	Distance driven: -Moderate agreement between self-reported and naturalistic data with a weighted kappa statistic of 0.57, even though no overall significant difference between both measures -45.3% estimated inaccurately the distance driven -34% of participants who misestimated their distance driven were within one adjacent category while 7.6% were within 2 categories
Thompson et al. (2016)	<i>n</i> = 55	Mean age = 79.9 (<i>SD</i> = 3.8) (rural participants) Mean age = 80.7 (<i>SD</i> = 3.5) (urban participants) (range = 75-90)	- Driving Patterns Questionnaire (DPQ)	-747ProS GPS Trip recorder	Distance driven: -No significant difference between the DPQ and the GPS device Driving duration: - Correspondence in driving duration between both measures Self-regulation practices: -More self-regulation practices than what is self-reported in the DPQ in four measured driving situations: making turns across oncoming traffic, driving at night time, in peak hour traffic and on freeway/highway.

¹ The question used for the present study was: “Please estimate the number of kilometres you have driven in the past year” with 8 categorical answers provided to the participants

2.5.4 Naturalistic studies and driver self-regulation

Among the few older drivers studies that compared self-reported and naturalistic driving data, some studies found there was a correspondence between self-reported and naturalistic driving data (e.g., Babulal et al., 2016), while other studies found there was a partial correspondence for some measures of self-reported and naturalistic data, but a discrepancy for others (e.g., Blanchard et al., 2010; Molnar et al., 2013a).

2.5.4.1 Driving exposure

2.5.4.1.1 Distance driven

Inconsistent findings have been found in the literature when comparing self-reported measures of distance driven with naturalistic data. Previous research suggests that both measures are concordant. For example, a study comparing two different types of in-vehicle monitoring devices (data logger with GPS and data logger without GPS) with travel diaries among a cohort of older drivers from the general population, found a very strong correlation between self-reported measures of total distance travelled and the devices without the GPS ($r = 0.9$; $p < 0.01$) (Marshall et al., 2007). However, the correlation between the total distance travelled as measured by the travel diaries and the devices with GPS was moderate ($r = 0.56$; $p = 0.02$) (Marshall et al., 2007). Similarly, a pilot study aiming to compare self-reported and naturalistic driving data among older adults with and without preclinical Alzheimer's disease, found a strong correlation ($r = 0.83$; $p \leq 0.05$) between the DHQ and naturalistic driving data (Babulal et al., 2016). Another study found no significant difference in the number of kilometres travelled during the week between self-reported and naturalistic driving data (Thompson et al., 2016).

However, four other studies found that self-reported measures of driving exposure were poor (Blanchard et al., 2010; Huebner et al., 2006), moderate (Porter et al., 2015) and of "greater concern" (Molnar et al., 2013a). In Blanchard et al. (2010), overall, participants overestimated or underestimated the distance driven. More specifically, 25% of the sample, underestimated or overestimated the distance driven by over 100 kilometres, while 55% by over 50 kilometres (Blanchard et al., 2010). Similarly, Huebner et al. (2006) found that participants underestimated and overestimated the distance driven in comparison to naturalistic driving data, with a coefficient of

variation of 33.6%. However, these studies only assessed driving behaviour for a short period of time.

Another study that compared driving exposure, assessed by a self-reported questionnaire and an in-vehicle monitoring device over one year, found moderate agreement between both measures, with a weighted kappa statistic of 0.57 (Porter et al., 2015). Slightly fewer than half of the participants (45.3%) estimated inaccurately the distance driven, and 34% of participants who misestimated their distance driven were within one adjacent category (Porter et al., 2015). In all these previous studies, the misestimation was towards both directions (underestimation or overestimation) (Blanchard et al., 2010; Crizzle et al., 2013; Huebner et al., 2006; Porter et al., 2015). More specifically, in Porter et al. (2015), participants who self-reported driving fewer than or equal to 5,000 kilometres per year, constantly underestimated the numbers of kilometres travelled, while those who reported driving greater than or equal to 20 kilometres per year constantly overestimated it compared to the data obtained by the in-vehicle monitoring devices. The authors concluded that licensing authorities or clinicians should not use self-reported measures for individual assessments of fitness to drive (Porter et al., 2015). However, in another study, the misestimation tended to be unidirectional, with older drivers underestimating the total number of kilometres travelled per week by a factor of 0.44 (Molnar et al., 2013a).

2.5.4.1.2 Driving duration

Previous research suggests that there is no significant difference between self-reported and naturalistic driving data, in terms of driving duration. In Blanchard et al. (2010), there was no significant differences in duration of trips when comparing the travel diaries to the data obtained by the data loggers without GPS. When comparing the results obtained by the self-reported questionnaire (the DHQ), with the data logger without GPS, 34% of participants had similar results. However, 57% of the sample overestimated their driving duration, while 9% underestimated it (Blanchard et al., 2010). Similarly, another study found that self-reported measures of driving duration corresponded to naturalistic driving data (Thompson et al., 2016).

2.5.4.1.3 Number of days driven, trips and stops

Contrasting results have been found in the literature when analysing the number of

days driven. A study found that there was a similarity in the number of days driven by older drivers as obtained by the self-reported and naturalistic driving data (Blanchard et al., 2010). More than half of the sample (52%) was able to exactly report the number of days driven (Blanchard et al., 2010) during the week. In addition, in Blanchard et al. (2010), participants underestimated the number of trips and stops made when comparing the travel diaries with the data logger without GPS. Another study found that older drivers tended to under-report the number of days driven per week when compared to naturalistic driving data, by a factor of 0.49 (Molnar et al., 2013a).

2.5.4.2 Avoiding driving in challenging situations

In the same way, studies that have compared self-reported and naturalistic driver self-regulation practices have found contrasting results. In Blanchard et al., (2010), participants did not self-regulate as much as they reported. There was no significant differences between the self-reported driving questionnaire and the naturalistic driving data at night time, at night time in bad weather, and on the freeways (Blanchard et al., 2010). However, there was a discrepancy between self-reported and naturalistic driving data while driving in all other situations, including making turns across oncoming traffic, driving at dawn or dusk, in bad weather, in heavy rain and fog (Blanchard et al., 2010). Similar results were found in another study: older drivers drove more frequently in challenging situations than what they self-reported (Myers et al., 2011). Another study found that there was a correspondence between a certain number of self-reported measure of driving avoidance and naturalistic data (driving on high speed roads, at night time and in unfamiliar places), but not for others (turning across oncoming traffic, driving in peak hour traffic) (Molnar et al., 2013a).

In contrast, two other studies found that older drivers self-regulated more of their driving than what they self-reported (Hanson & Hildebrand, 2011; Thompson et al., 2016). In Thompson et al., (2016), older drivers' driving avoidance was measured in four driving situations (making turns across oncoming traffic, driving at night time, in peak hour traffic and on freeways/highways) and compared to the results obtained from the Driving Patterns Questionnaire. In each of the four situations there was no association with the naturalistic driving data (Thompson et al., 2016), because the majority of participants under-reported driving avoidance in these situations. Only 16% of participants reported that they "sometimes", "often" or "always" avoided

making right hand turns across oncoming traffic, and 24% of participants had a greater ratio of left to right turns (Thompson et al., 2016). As well, while none of the participants reported “always” avoiding driving on freeway/highway, approximately 36% of participants did not drive on these types of roads, even though those participants came from rural areas where there was a higher number of highways/freeways (Thompson et al., 2016). Also, night time driving did not occur for 46% of participants, even though only 44% of participants reported avoiding it (Thompson et al., 2016). In the same way, 85% of the sample travelled 10% or fewer of their trips at night time, while 67% of older drivers self-reported that they “rarely” or “never” avoided driving in this situation (Thompson et al., 2016). Approximately 50% of participants travelled 10% or fewer of their trips during peak hour traffic, while 70% of the sample self-reported that they “rarely” or “never” avoided driving in this situation (Thompson et al., 2016). Similar patterns were found by Hanson & Hildebrand (2011): more than half of the sample avoided night time driving, while only 10% of the participants self-reported such avoidance. As well, 40% of participants travelled less than 1% of the total number of kilometres travelled on highways, but only about 20% of the sample reported doing so (Hanson & Hildebrand, 2011).

The contrasting results between these studies could be attributed to different factors interacting together, including the different types and configurations of in-vehicle monitoring devices and self-reported questionnaires used, the definition of self-regulation, the size and characteristics of the sample (e.g., proportion of males and females), the number of days of monitoring, as well as the statistical method chosen to measure the level of agreement. The inconsistency in results suggests that self-reported data alone might not be a reliable method to capture older drivers’ driving exposure and self-regulation practices.

2.5.5 Naturalistic driving studies: identifying gaps in the evidence

Although these studies suggest that self-reported data may not be accurate on their own, there is a lack of studies that relied on naturalistic driving data to analyse cataract patients’ driving behaviour. Self-regulation studies among cataract patients lack objectivity and accuracy, because data did not measure participants’ natural driving behaviour. Relying on self-reported data to measure self-regulation practices among cataract patients may therefore provide biased information on the complex association

between objective visual measures (e.g., visual acuity, contrast sensitivity and stereopsis) and other factors affecting driving outcomes and self-regulation practices throughout the cataract surgery process. Accurate and objective instruments are therefore required to analyse the specific effects of first and second eye cataract surgery on self-regulation practices to provide evidence-based guidelines to clinicians, licensing authorities, and policy makers.

2.6 Summary and conclusion

There will be a significant impact on-road safety as the proportion of older drivers with cataract increases, particularly between the waiting period between first and second eye cataract surgery. As driving depends heavily on visual function, cataract may have an impact on driving. As a consequence, older drivers with cataract may self-regulate their driving by avoiding challenging situations and/or reducing the number of kilometres and trips made. Previous research examining the effect of cataract and/or cataract surgery on driving outcomes focused on self-reported driving difficulty and self-regulation practices, which are subject to social desirability and recall biases. However, naturalistic studies using in-vehicle monitoring devices, which collect detailed GPS information, allow an accurate and objective examination of driving outcomes as well as driver self-regulation. To date, no published study has used naturalistic data to explore driving habits, adverse events, and driver self-regulation for older drivers with bilateral cataract before first eye, after first eye, and after second eye cataract surgery, which represents a significant gap in the literature. Furthermore, little is known about the objective measures of vision that are specifically associated with driver self-regulation practices throughout the first and second eye cataract surgery process. Although previous studies suggest that contrast sensitivity is an important measure to consider when assessing fitness to drive, those studies did not analyse the specific effect of contrast sensitivity on both eye surgeries separately. Gaining a better understanding of the separate impact of first and second eye cataract surgery on driver self-regulation status, and determining which objective measures of vision are associated with these practices, may provide valuable information to ophthalmologists, licensing authorities and road safety policy makers.

RESEARCH DESIGN

Chapter 3 Research Design

3.1 Study Design

A three year prospective cohort study of older drivers with bilateral cataract was undertaken from December 2014 to February 2017. Each participant was assessed at three time points: in the month before cataract surgery, at least one to three months after first eye cataract surgery and at least one month after second eye cataract surgery.

3.2 Study Sample

In Western Australia, all eligible patients with clinically significant cataract are undergoing surgery through the public hospital system at no financial cost. Eligible participants on the wait list for first eye cataract surgery were recruited from three public hospitals in Western Australia: Fremantle Hospital, Royal Perth Hospital and Sir Charles Gairdner Hospital. These three sites account for the majority of cataract surgery undertaken in Perth.

Eligible criteria stipulated that participants were drivers aged 55+ years who had been diagnosed with bilateral cataract and who had never had cataract surgery previously. In order to increase the number of participants recruited over a short period of time, it was decided to include participants aged 55+. Participants were required to be on the wait list for first eye cataract surgery, possess a current WA drivers licence, drive at least twice a week, live in the Perth metropolitan area, and be able to communicate in English. Participants who had any other major eye conditions that would impact on visual outcomes after surgery, such as macular degeneration, glaucoma and retinopathy were excluded, as well as participants who underwent combined ocular surgery, such as cataract and vitrectomy. Participants with a cognitive impairment (a score less than 24 on the Mini-Mental State Examination), a diagnosis of dementia, Alzheimer's disease, Parkinson's disease or physical impairment (e.g., wheelchair users) were also excluded from participation.

3.3 Sample Size Calculations

The demographics of the participants of this study resemble those of Fraser et al.

(2013b), who recruited 99 participants from the same Perth setting. Fraser et al. (2013b) observed a mean driving exposure of 104.46 kilometres per week and a standard deviation of 88.41 kilometres per week from their participants before the first eye cataract surgery. With their $n = 99$ sample, Fraser et al. (2013b) detected a difference of 23.20 kilometres per week after the first surgery ($p < 0.001$). Therefore it was considered appropriate to base the sample size and power calculations of this new study to the study of Fraser et al. (2013b).

This present study aimed to recruit a sample of at least $n = 110$ participants and anticipated that the majority would go through all three phases of assessments and follow-ups. It was expected that the present study would find a mean driving exposure of 104.46 kilometres per week from $n = 110$ participants before their first cataract surgery, similar to Fraser et al. (2013b) study. The standard deviation was rounded up from 88.41 and estimated to be 90 kilometres per week to be conservative. An effect size of 0.29, equating to a difference in mean driving exposure of $0.29 \times 90 = 26.1$ kilometres per week after the first or second eye cataract surgery, would achieve 90% power at the 5% significance level.

A sample of $n = 111$ participants was initially recruited to meet objectives 2, 3, 4, 5 and 6 as outlined in this thesis. The attrition rate of participants after the initial phase of assessment was higher than expected: 83 participants returned for their follow-up assessment after the first eye cataract surgery, then 55 participants returned after their second eye cataract surgery. With $n = 55$ available towards meeting objectives 5 and 6, an effect size of 0.40, equating to a difference in mean driving exposure of $0.40 \times 90 = 36.0$ kilometres per week after the first or second eye cataract surgery, would still achieve 90% power at the 5% significance level.

3.4 Recruitment of Sample

Participants were recruited into the study using two different methods. The first was by direct contact by the ophthalmologists at Sir Charles Gairdner Hospital. The second was by an invitation letter followed by a phone call from the researcher at Fremantle Hospital and Royal Perth Hospital. These recruitment methods have been successfully used in previous studies among older participants with bilateral cataract (Fraser et al. 2013a,b,c; Palagyi et al., 2017) .

At Sir Charles Gairdner Hospital, the researcher attended a cataract pre-admission clinic, which was held once a week. After being invited to take part in the study by the ophthalmologists, eligible participants were required to sign a form (Appendix A) permitting the researcher to contact the participants. The researcher then approached the participants to explain the study and to establish participant eligibility. As well, a participant information pamphlet was also provided to the participants (Appendix B) explaining the nature and purpose of the study. It was also specified to them that it was not compulsory to take part in the study and it would not impact on their treatment if they refused.

At Fremantle Hospital and Royal Perth Hospital, the researcher received a list of all patients who were on a wait list for bilateral cataract surgery once a month. Participants were then sent an invitation letter (Appendix C) and a participant information pamphlet (Appendix B). This was followed up with a telephone call by the researcher one week later inviting the participants to take part in the research study and to also screen for eligibility.

If the participants agreed to take part in the study, an appointment was made for the month prior to first eye cataract surgery. All participants were offered a taxi voucher to travel to and from the assessment, which was at Curtin University. A map with the researcher's contact details and the date of appointment was provided or posted to each participant if the contact was made over the phone. Participants were reminded of their appointment by a phone call from the researcher prior to each of the three assessments.

Six hundred and forty-five patients on the waitlist for first eye cataract surgery were reviewed for eligibility (Figure 1). Among those, 381 patients were ineligible. Reasons for exclusion included: patients not driving at least twice a week ($n = 91$), undergoing second eye cataract surgery ($n = 85$), having severe health issues impairing their ability to come to Curtin University for the assessments ($n = 73$), having comorbid eye conditions ($n = 34$), inability to speak English ($n = 25$), living outside the Perth metropolitan area ($n = 23$), undergoing combined eye surgery ($n = 19$), being younger than 55 years old ($n = 11$), having unilateral cataract ($n = 10$), using a wheelchair ($n = 5$), having a cognitive impairment ($n = 3$), and having Parkinson's disease ($n = 2$). One hundred and fifty-three eligible participants declined participation.

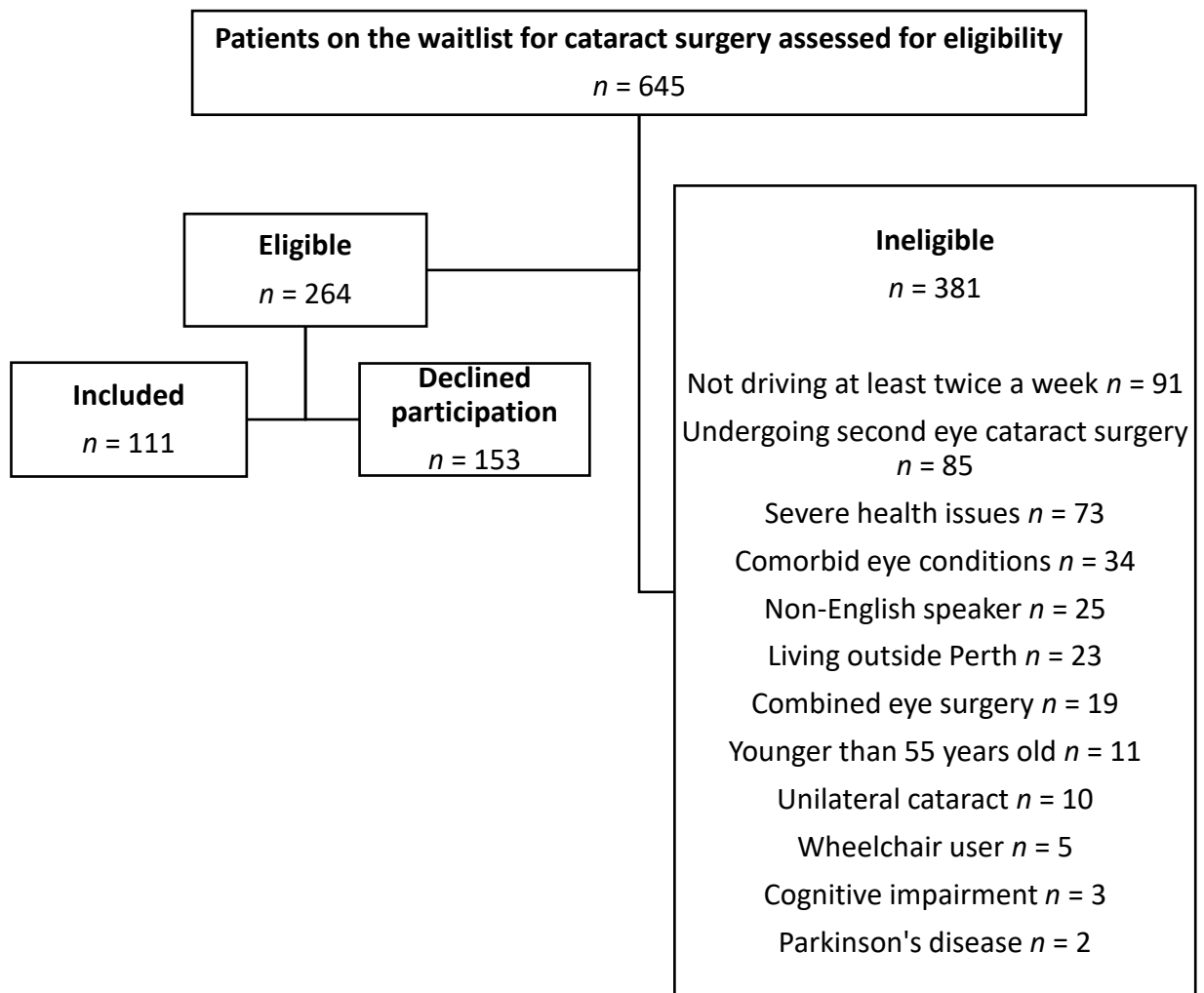


Figure 1. Flow chart of study sample

The final sample consisted of 111 participants who were recruited from the three public hospitals (Table 2). The breakdown by hospital was as follows: 21% ($n = 23$) were recruited from Fremantle Hospital, 23% ($n = 26$) were recruited from Royal Perth Hospital and 56% ($n = 62$) from Sir Charles Gairdner Hospital.

Table 2. Distribution of participants recruited at each site

Site	<i>n</i>	Frequencies %
Fremantle Hospital	23	21
Royal Perth Hospital	26	23
Sir Charles Gairdner Hospital	62	56
Total	111	100

3.5 Data Collection before First, after First and Second Eye Cataract Surgery

Information was collected at three time points: in the month prior to first eye cataract surgery, at least one to three months after first eye surgery and at least one month after second eye cataract surgery (Figure 2). This time-frame was based on recommendations from the ophthalmologists, as the interval allows optimal vision to be reached. Identical assessments were undertaken each time point which took approximately ninety minutes to complete. Participants were offered a \$10.00 gift voucher after the baseline assessment, a \$15.00 voucher after the first follow-up assessment and a \$20.00 voucher after the second follow-up assessment as a thank you for their participation in the study. All assessments were conducted by the same researcher.

The mean duration between the baseline assessment and first eye cataract surgery was 47.78 days ($SD = 43.08$). The first follow-up assessment was conducted between one to three months after first eye cataract surgery. The mean duration between first eye cataract surgery and the first follow-up assessment was 59.75 days ($SD = 41.25$). The second follow-up assessment was conducted at least one month after second eye cataract surgery. The mean duration between second eye cataract surgery and the second follow-up assessment was 111.44 days ($SD = 40.24$).

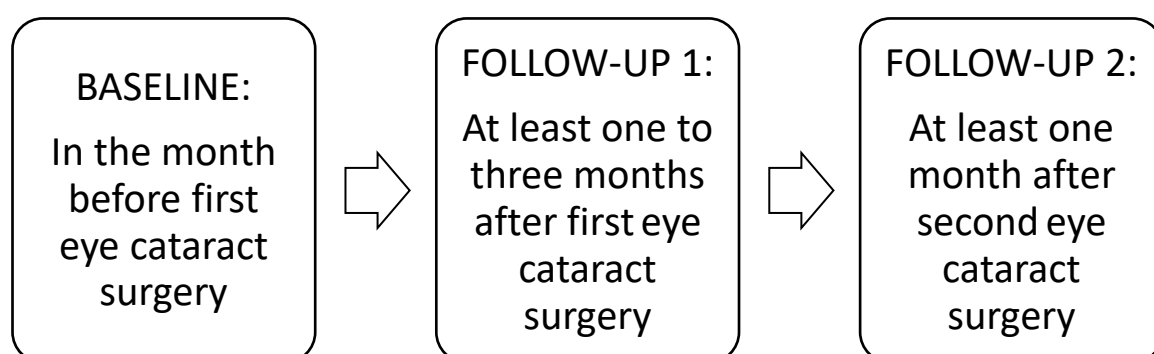


Figure 2. Sequence and timeframe of data collection

3.6 Study Instruments

A questionnaire collecting information about participants' sociodemographic and health information was administered by the researcher (Appendix D). Participants' cognitive function was also assessed via the MMSE (Folstein, Folstein, & McHugh, 1975) and the Useful Field of View (UFOV) (Visual Awareness, Inc.). Use of the UFOV was approved by the authors. Participants also undertook three visual tests, which included visual acuity, contrast sensitivity and stereopsis. Participants' self-reported driving habits and self-regulation practices were assessed using the DHQ (Owsley et al., 1999) (Appendix D). Participants were also provided with a travel diary they were required to fill in after each trip (Appendix E) and an in-vehicle monitoring device to collect naturalistic driving data. Table 3 summarises the instruments used for data collection at each of the three assessments.

Table 3. Study Instruments

Variable	Instruments
Objective measures of vision	
Visual acuity	Early Treatment Diabetic Retinopathy Study (ETDRS) chart (Ferris, Kassoff, Brensick, & Bailey, 1982)
Contrast sensitivity	Mars Letter Contrast Sensitivity Test (Mars Perceptrix ©)
Stereopsis	Titmus Fly Stereotest (Stereo Optical Co., Inc.)
Self-reported questionnaires	
Socio-demographic data	Researcher administered questionnaire (Appendix D)
Health information	Researcher administered questionnaire (Appendix D)
Driving exposure, habits, patterns and self-regulation practices	Driving Habits Questionnaire (DHQ)(Owsley et al., 1999) (Appendix D)
Driving exposure, habits, patterns and self-regulation practices	Travel diary (Appendix E)
Naturalistic driving data	
Driving exposure, habits, patterns and self-regulation practices	In-vehicle monitoring devices (GO6 Geotab©)
Cognition	
General cognitive function	Mini-Mental State Examination (MMSE) (Folstein et al., 1975)
Processing speed	Useful Field of View (UFOV) test software (Visual Awareness, Inc.)

3.6.1 Objective measures of vision

Three objective visual tests were administered by the researcher at each of the assessments. The researcher received training by an ophthalmologist in order to administer the visual tests. A standardised protocol was followed to ensure that visual testing was administered under standard conditions at each assessment. Visual testing was administered under constant luminance and without mydriasis each time. A light meter was used to ensure that light was kept constant and tape measures were used to ensure that participants were reading the charts at the required distance. Participants wore their habitual correction for visual testing, such as long distance glasses for the visual acuity test and reading glasses for the contrast sensitivity and the stereopsis tests if needed.

3.6.1.1 Visual acuity

Visual acuity is a measure of sharpness of vision which has been defined as “the spatial resolving capacity of the eye or the size of an object that can be resolved with an eye” (Kaiser, 2009). The Early Treatment Diabetic Retinopathy Study (ETDRS) chart is considered as “the gold standard” measure for the majority of primary outcomes of clinical trials or interventions (Hazel & Elliott, 2002; Kaiser, 2009). In Australia, drivers are required to have a minimum score of 6/12 in at least one eye or in both eyes to meet the visual acuity standards for driving (Austroads, 2017).

Distance monocular and binocular visual acuity, were measured using an ETDRS chart (Ferris et al., 1982) (Figure 3). The chart consists of 70 letters, arranged in 14 rows of five letters each. The size of the letters progress from line to line, with bigger letters at the top and smaller letters at the bottom of the chart. Each line is of equal difficulty and each letter has a value of 0.02 logMAR. Lower scores on the chart represent better vision. The ETDRS chart was set up at a distance of 3 metres away from the participants by using a tape measure. The minimum external illumination of the room was set up at 480 lux to ensure 100% contrast. Better eye, worse eye and both eyes were measured.

Scoring of the ETDRS chart was performed using the “staircase method”: Participants were asked to read the top-left letter on the chart and then read down the first letter of each row. When the test became challenging, participants were asked to read all the letters on the row. If any mistakes were made on that row, participants had to move to the row above and read again. According to standard protocol, participants were encouraged to make a guess if they were unsure. Participants were then asked to continue reading the chart until at least three mistakes were made in the same row, despite being pushed to guess. A letter by letter scoring method was used and scores were expressed as the logarithm of the minimum angle of resolution (logMAR) (Ferris et al., 1982) with possible scores ranging from -0.3 to 1 logMAR.

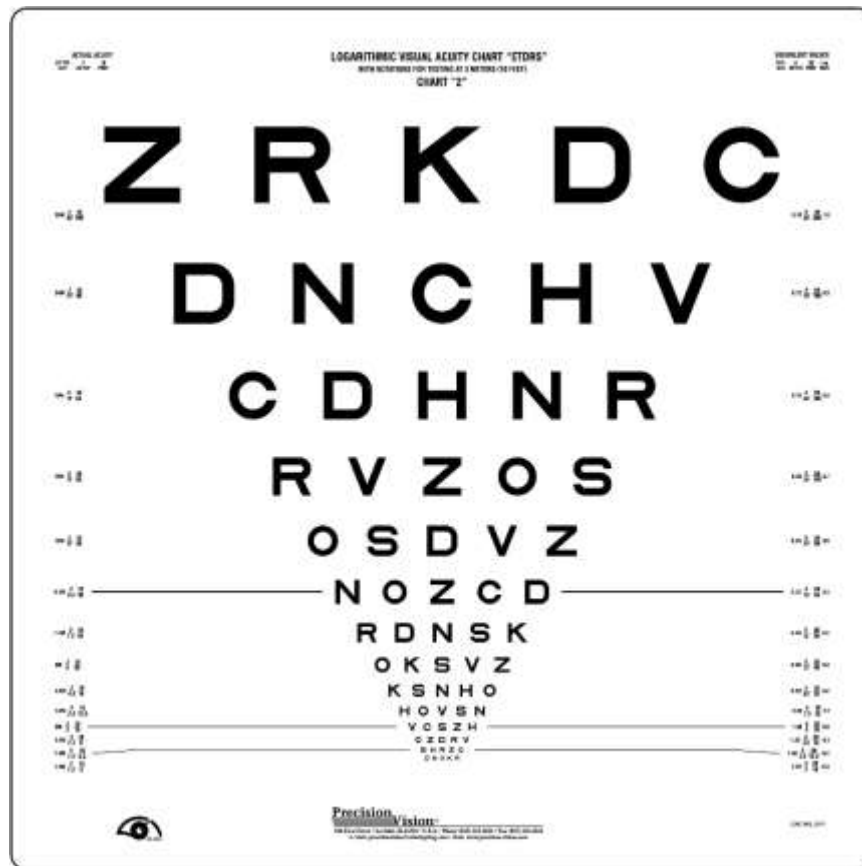


Figure 3. Early Treatment Diabetic Retinopathy Study (ETDRS) chart, used to measure visual acuity (Picture: Precision Vision)

3.6.1.2 Contrast sensitivity

Contrast sensitivity measures “the reciprocal of the minimum contrast required to detect objects, as objects with have small contrast with their background are difficult to detect” (Barten, 1999). Monocular and binocular contrast sensitivity were measured using the Mars Letter Contrast Sensitivity Test (Mars Perceptrix ©) (Figure 4). This test contains a set of three charts, which assess low retinal spatial frequencies for the left eye, right eye and both eyes (Mars Perceptrix©). Each chart consists of 48 letters, arranged in eight rows of 6 letters each and the value of each letter decreases by 0.04 log units from left to right (Mars Perceptrix©). All three charts were set up at a distance of 50 centimetres from the participants by using a tape measure. The illumination of the room was set up at a minimal of 189 lux and a maximum of 377 lux and the chart was illuminated uniformly, according to standard protocol (Mars Perceptrix©). Better eye, worse eye and both eyes were measured and participants were required to wear their habitual correction for near vision. Participants were asked to read the chart from

left to right across each line, from top to bottom and were encouraged to guess the letters if they were unsure, until making two consecutive mistakes (Mars Perceptrix©). According to standard protocol, the number of errors prior to the final correct letter was subtracted from the last letter log contrast sensitivity value to obtain a score in log units (Mars Perceptrix©). The possible scores range from 0.00 to 1.92 log units. Higher scores on the test represent better contrast sensitivity.



Figure 4. Mars Letter Contrast Sensitivity Test, used to measure contrast sensitivity (Picture Mars Perceptrix©)

3.6.1.3 Stereopsis

Stereopsis, a measure of depth perception, refers to our ability to “judge the relative distance of objects from the observer by means of binocular vision only” (Rabbetts, 2007), because of the lateral displacement of the eyes, which have a different projection onto the retinas of both eyes. Stereopsis was assessed using the Fly Stereo Acuity Test (Good-Lite Co., Inc.) (Figure 5). This test assesses gross and fine stereopsis using the Wirt Fly and circles tests, from 4,800 to 20 seconds of arc. Lower scores on the test present better vision. It makes uses of vectographs that can be viewed through polarised 3D glasses.



Figure 5. Fly Stereo Acuity Test used to measure stereopsis (Picture: Good-Lite Co., Inc)

In section A of the test, participants are required to pinch the wing of a fly to assess gross stereopsis (ranging from 4,800 to 3,000 seconds of arc). In section B, which tests fine stereopsis, participants are required to identify which graded circle is popping out in three-dimension among 10 different squares, ranging from 400 seconds to 20 seconds of arc. The measures were converted into log units and participants who could only identify the right wing of the fly were assigned a score of 4,800 seconds of arc.

3.6.2 Cognition

3.6.2.1 The Mini-Mental State Examination (MMSE)

The MMSE was used to assess participants' general cognitive function (Folstein et al., 1975). A short test which takes approximately 10 minutes to administer (Molloy & Standish, 1997), it was initially developed to quantify the severity of cognitive impairment and cognitive changes over time (Folstein et al., 1975) and as a screening tool for clinicians (Molloy & Standish, 1997). Nowadays, it is the most widely used screening test of cognitive functioning (Tombaugh & McIntyre, 1992) and cognitive impairment (Burns, Brayne, & Folstein, 1998) and is frequently used in epidemiological studies and community surveys (Tombaugh & McIntyre, 1992) to assess participants' cognitive eligibility for study inclusion (Molloy & Standish, 1997). The test includes a variety of questions assessing orientation to time (maximum score = 5) and place (maximum score = 5), registration of three words (maximum score

= 3), attention and calculation (maximum score = 5), recall of three words (maximum score = 3), language (maximum score = 8), and visuoconstruction (maximum = 1) (Tombaugh & McIntyre, 1992). An overall score is calculated from the total number of correct responses (Folstein et al., 1975). Scores range from 0 to 30 with higher scores indicating better cognitive function (Folstein et al., 1975). A score of at least 24 points is a common cut-off to indicate normal cognitive function and was part of our eligibility criteria (Folstein et al., 1975). None of the participants recruited in the present study had a score lower than 24. The MMSE is a valid (Burns et al., 1998) and reliable instrument (Folstein et al., 1975), possessing satisfactory psychometric properties (Tombaugh & McIntyre, 1992) with high levels of sensitivity for moderate to severe cognitive impairment, while it only possesses lower levels of sensitivity for mild cognitive impairment (Tombaugh & McIntyre, 1992). The MMSE internal consistency varies between 0.68 and 0.96 (Tombaugh & McIntyre, 1992) and has a test–retest ability of between 0.38 and 0.99, according to different studies (Tombaugh & McIntyre, 1992).

3.6.2.2 The Useful Field of View (UFOV)

The UFOV (Visual Awareness, Inc., Chicago, IL) is a widely used computer test which assesses higher order attentional skills and visual sensory information (Ball & Owsley, 1993). It is divided into three subtests assessing visual processing speed, divided attention and selective attention (Figure 6).



Figure 6. The Useful Field of View (UFOV) assessing processing speed (left), divided attention (middle) and selective attention (right)

The UFOV has been commonly used in road safety research as a valid and reliable measure of crash risk (Clay et al., 2005). In the first subtest assessing processing speed,

participants are required to identify a stimulus (either a car or a truck), which is briefly presented in the centre of the screen. In the second subtest assessing divided attention, participants have to pay attention to two different targets presented simultaneously, and are first requested to indicate which target was presented in the centre of the screen (a car or a truck). Following this, they are required to identify which one of the eight cardinal directions the other target was presented, without having to determine the type of target (a car or a truck). The third subtest assessing selective attention is identical to the second subtest. However, the eight cardinal directions are surrounded by 47 distractors represented by small triangles on the screen. While the UFOV can be used on a computer touchscreen, the version used in the current study used a PC-mouse format where participants had to select the stimuli with a mouse. A raw score between 17 and 500 milliseconds was calculated for each test, based on the duration a participant took to identify correctly the objects presented at an accuracy level of 75%. As per the user's manual, participants were assessed in a dark quiet room at a viewing distance between 46 and 71 centimetres from the monitor and were required to wear their short distance glasses if needed. A squared monitor of 17 inches was used and researchers ensured that glare on the screen was minimal, as required by the user's manual.

3.6.3 Sociodemographic and health status

A structured researcher administered questionnaire was administered to collect information on participants' sociodemographic and health characteristics (Appendix D). It included information on age, gender, marital status, country of birth, level of education, employment status, living arrangements, medications, health conditions, driver's licence, years of driving experience, current prescription glasses or lenses worn. The health questionnaires included a list of pre-defined conditions to determine if participants had suffered from any musculoskeletal, circulatory, respiratory and endocrine conditions (Appendix D).

3.6.4 Self-reported driving

3.6.4.1 The Driving Habits Questionnaire

The Driving Habits Questionnaire (DHQ) (Owsley et al., 1999) (Appendix D) was

used to collect information on six driving domains: “current driving status and miscellaneous issues”, “driving exposure”, “dependence on other drivers”, “driving difficulties”, “driving space”, and “self-reported crashes and citations”. The driving difficulty section of the DHQ (Owsley et al., 1999) was used to examine participants’ self-reported self-regulation practices. As the six domains of the DHQ are scored separately, using only the driving difficulty section to assess self-regulation practices was appropriate and did not have an impact on its interpretation. This section of the questionnaire collected information on eight specific driving situations: driving in the rain, driving alone, parallel parking, turning across oncoming traffic, driving on highways/freeways, driving on heavy traffic roads, driving in peak hour traffic, and driving at night time. Driving in the rain, driving alone, parallel parking, and turning across oncoming traffic were not included in the analysis because these conditions could not be recorded by the in-vehicle monitoring devices. Participants were required to indicate if they had stopped driving in each of these four situations: driving on highways/freeways, on heavy traffic roads, in peak hour traffic, and at night time. Participants were considered to self-regulate their driving if they indicated that they stopped driving in a situation, regardless of the reason. Self-regulation practices for each of the four specific domains were considered as binary variables; if participants indicated that they stopped driving in that situation, a score of 1 was assigned; if they indicated that they did not stop driving in that situation, a score of 0 was assigned. In accordance with previous Australian studies that have used the DQH (Fraser et al., 2013b,c), some adjustments were made to the original questions (Owsley et al., 1999) to account for the Australian driving context. For example, while on the original DHQ participants were asked whether they made “left turns in traffic”, in Australian studies (Fraser et al., 2013b,c) participants are asked whether they make “right hand turns across oncoming traffic” to account for the fact that people drive on the left side of the road. The DHQ has been previously used to assess driving behaviour of older drivers with cataract (Fraser, et al., 2013b,c; Owsley et al., 1999) and specifically in Western Australia (Fraser et al., 2013b,c). The DHQ is reliable and has good to high internal consistency with Cronbach’s alpha coefficients ranging from 0.572 to 0.961 for the different sections (Song, Chun, & Chung, 2015). The driving difficulty section of the questionnaire has been shown to have a high Cronbach alpha coefficient of 0.871 (Song et al., 2015) and a test–retest reliability of 0.60 ranging from 0.44 to 0.74 (Owsley et al., 1999).

3.6.4.2 Travel diary

A travel diary was provided to each participant at the end of each of the three assessments (Appendix E). Participants were required to complete it each time they drove a motor vehicle (motorbikes or scooters were excluded) for a period of 7 days. They were instructed to fill out the diary as soon as possible after the completion of the trip to avoid any recall bias. Information collected included: date, start and finish time of a trip; kilometres travelled; the age and position in the car of passengers (front seat vs. back seat); make, model and year of the car; and purpose of the trip. Participants were required to treat trip chains as different trips and to indicate if someone else drove their car while the device was recording; thus, the data from these trips were not included in any of the analyses. The travel diaries were returned to the researcher in a pre-paid envelope at the end of the 7-day period. Travel diaries have been used in previous studies among older drivers, in addition to in-vehicle monitoring devices (Blanchard et al., 2010; Marshall et al., 2007).

3.6.4.3 Driver in-vehicle monitoring device

Participants were also provided with an in-vehicle monitoring device with GPS log receiver (Geotab G06TM, Oakville, Canada) (Figure 7) at each of the three assessments. Participants were required to use the in-vehicle monitoring device for a period of 7 days after each assessment.



Figure 7. In-vehicle monitoring device used to measure naturalistic driving behaviour

The device data logger transmits GPS information in a real time manner via wireless transmission utilising the Telstra Telecommunication network. The small device (8.5x11x3.2cm) was manually connected to the cigarette lighter for vehicles manufactured before 2006 or onto the On Board Diagnostic II (OBD II) port of the vehicle for vehicles manufactured after January 2006 (Figure 8).



Figure 8. In-vehicle monitoring device connected onto OBD II port (left) and the cigarette lighter (right)

Participants were instructed to use the device for 7 days to record their naturalistic

driving patterns and to drive their car as they normally would in their daily routine. Participants were instructed how to connect and disconnect the device, and were required to connect it into their car only if they were the drivers of the vehicle. They were also instructed to move the device from one vehicle to another when driving another vehicle. They were shown by the researcher how to connect the device into their car and were provided with an information sheet (Appendix F). As the devices were automatically switched on when the ignition was turned on and shut down when the ignition was off, participants were not required to manipulate the devices and could drive without paying attention to them. Participants were required to return the in-vehicle monitoring device in the same pre-paid envelope as the travel diaries. A follow-up interview was made by the researcher to ensure there was no issue while using the in-vehicle monitoring device and to confirm that no one else drove the vehicle while the device was connected. A check was made during the follow-up interview to ensure that participants recorded in their travel diaries whether they were the driver of the vehicle or not. Any trips reported as being made by another driver were removed during data cleaning.

The data collected by the vehicles was read by a fleet management software (MyGeotab, Oakville, Canada) provided by Geotab©. Driving outcome measures that were collected included a variety of time-stamped second-by-second GPS data, such as date of travel, start and finish time of trips, number of trips, number of kilometres travelled, duration, average and maximum radius of driving exposure, speed, location, type of roads used (e.g., freeways, highways, heavy traffic roads), and time of day (e.g., day time, night time, sunset, sunrise, peak hour traffic, off peak hours). The in-vehicle monitoring devices contained sensors which measured speed and acceleration directly. The device provided a time-stamp (date and time), the GPS positioning of the vehicle (latitude and longitude), the travel speed of the vehicle, the direction the vehicle was heading, and the G-force of the vehicle. The coordinates were then used separately to estimate the distance travelled and the relative distance between locations, in order to measure, for example, the trip radius. In order to determine night time and day time driving, the data obtained by the in-vehicle monitoring devices were linked to the Australian Government's Bureau of Meteorology website (Australian Government, 2017). Day time driving was defined as the period between sunrise and

sunset, while night time driving was defined as the period between sunset and sunrise. Peak hour driving was defined as the period from 6:00 a.m. to 9:00 a.m. and 4:00 p.m. to 7:00 p.m. during weekdays, from Monday to Friday. Heavy traffic roads were defined as roads with more than 4,000 vehicles per day per lane (Main Roads, 2015). To determine if participants drove on highways or freeways, the researcher examined an interactive map accessible on the fleet management software (MyGeotab, Oakville, Canada) (Figure 9). When trips took place in multiple conditions (e.g., trips that started during day time and ended during night time and trips that started on secondary roads and ended on freeways), the largest portion of the trips was classified as the dominant driving condition.

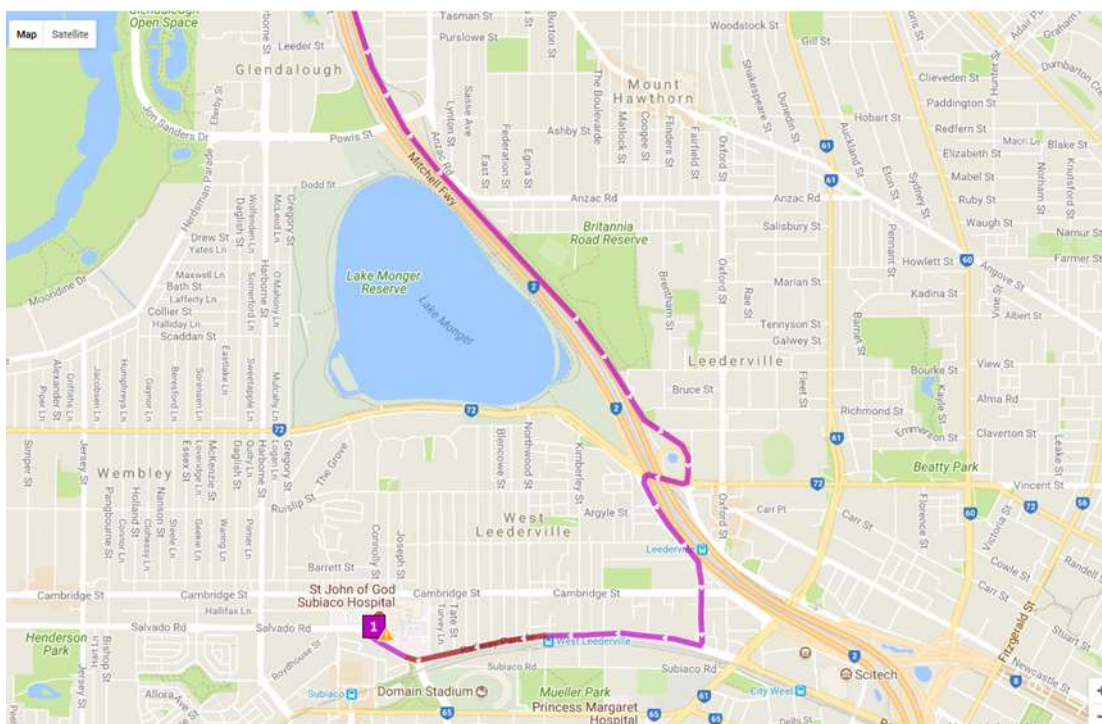


Figure 9. Example of a trip provided by Geotab© illustrating a participant driving on the freeway

The data collected was made available as three separate files downloaded from the fleet management software (MyGeotab, Oakville, Canada), for each device deployed:

- 1) A first file called “speeding report” containing the instance-by-instance recording of driving data, of each time instance collected. Attributes include the time stamp of the instance (date + time), the GPS positioning of the vehicle at that instance

as latitude and longitude, the travel speed of the vehicle at the instance, and the direction the vehicle was heading at the instance.

2) A second file called “trips detail report” containing trip details as determined by Geotab© using their in-house algorithm. The algorithm identified any prolonged stoppage of the monitored vehicle (trips that lasted less than 10 seconds or less than 20 metres) and identified the associated time period of each as a “non-trip”. Therefore, any driving performed between the “non-trips” would be classified as a trip, and the start and end times of each trip, as well as details such as locations, were summarised by Geotab© into the second file.

3) A third file called “exceptions report” containing the time and location of any “event” having been recorded. “Harsh braking” events were observed by the in-vehicle monitoring device; to avoid spurious instances of high acceleration/braking, the less sensitive option provided by MyGeotab was chosen and was defined as an acceleration forward or braking smaller than -0.61G (Geotab©) (Branch, 2017). As a consequence, only acceleration forward or braking smaller than -0.61G were included in the analyses. The time stamp and location of all events were summarised by Geotab© into the third file.

The data files were checked and verified to ensure the absence of any anomalies which were identified by a pilot study. Following the pilot study, it was discovered that additional trips were systematically recorded by the devices.

These additional trips were due to two different reasons:

- a) Trips that were meant to be a unique trip were counted as separate trips: Geotab© determined the start and end of a trip by measuring when the engine was on and off. For example, when a car was idling at a red traffic light and then began moving when the light turned green, two trips were reported even though the driver was making one unique trip. Additional trips were also counted when the engine was on for a short period of time, such as when cars were moved a few metres in the driveway.
- b) Some trips were false trips: in certain car models, the vehicles monitoring devices plugged into the OBD II port tended to reboot themselves at midnight and send a false signal, which the device interpreted as a moving car, even though the car was stationary.

A basic software program was developed to check for these abnormalities, to determine whether trips should be combined, counted as separate trips, or discarded.

Trips that lasted less than 10 seconds or less than 20 metres were excluded by the software as they were considered as “false trips”. Trips were then manually checked by the researcher to determine if the calculations made by the software were meaningful, and then corrected if the wrong decision was made. Spot checks on a 3D Google map by the researcher compared the longitudes and latitudes provided by the devices. The spot checks helped to determine, for example, whether a car was idling at a traffic light and was therefore part of the same trip or a chain of trips. The data was also further cleaned by the researcher to remove trips made by people other than the participant, as well as trips made from and to Curtin University as they were not part of participants’ usual driving behaviour. All files were then uploaded onto a secure server at Curtin University.

The three cleaned files were then merged into a single Excel summary file for each individual device using a customised algorithm. The trip starts and trip ends from the second file (trips detail report), as well as events from the third file (exceptions report), were matched to the correct instances from the first file (speeding report). The summary file summarised the driving per trip (every single trip), as well as the purpose per trip-type (such as going to the shops and returning home). A unique identification number was created for all trips, with each instance of driving then linked to one of these identification numbers, so that only instances associated with a particular trip would be collected and aggregated for that trip. For example, attributes such as average speed, average distance and number of events were calculated and summarised for all trips. Using time and destination data, each trip was further associated with multiple trip types. Additional variables defining different trip types, such as day of week (weekday or weekend), daylight (day or night), time of day (peak or non-peak hours), purpose of trip (work, leisure, etc.,) were created and matched for each instance recorded. For example, the average speed, average distance, and number of events, etc., of “weekday peak hour” trips would only be collected and aggregated from those instances with “weekday” as the day of week variable, as well as “peak” as the time of day variable.

Additionally, because the date, time, and GPS position of the vehicle was known, the calculation of the solar position relative to the vehicle was possible for each instance recorded using standard formulations. Therefore, the availability of sunlight was known for each instance of driving in a reliable manner. This was desirable as a simpler

definition of day time as hours between 6:00 a.m. and 6:00 p.m. would be too crude, given that sunset and sunrise times would change throughout the year.

The summary files for individual devices extracted from Excel were then merged into a single SPSS (SPSS Inc., Chicago, IL, USA) database for analysis, with information from the individual summaries rearranged and sorted into a single row of information, one row for each participant, in this SPSS (SPSS Inc., Chicago, IL, USA) database. The Geotab G06™ devices have been previously used in a research study among older drivers (Payyanadan et al., 2017).

3.7 Ethics Approval

Ethics approval was obtained from Curtin University and the three participating hospitals (Appendix G). Following the tenets of the Declaration of Helsinki, written informed consent was obtained from each participant before data collection and a copy of the participant information sheet and consent form was provided to them (Appendix H). Participants were given the opportunity to ask any questions before enrolling into the study. This research study followed the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (National Health and Medical Research Council, 2015).

Before any data collection, participants were informed that participation in the study was voluntary and that they could withdraw at any time without affecting their surgery or their relationship with their ophthalmologists at the hospital. A revocation of consent form was also provided to them in case they wanted to withdraw their consent (Appendix I). Participants were also informed that any identifiable information that was collected would remain confidential. They were also informed that data collected by the in-vehicle monitoring devices could be used in a court of law following a traffic accident, but not passed onto their health practitioners, the hospitals or the Department of Transport. All information collected was stored on the university server, password protected and anonymised. Only the researcher had access to the participants' names and whereabouts, for the purpose of organising the participants' follow-up appointments. However, separate files were kept for data collected and contact details of individuals. Identification information and contact details were destroyed after data collection. All information collected was stored on the university server and was password protected, with access limited to the researcher and the research team.

Participants' consent forms were kept in a secure, locked filing cabinet at the Curtin-Monash Accident Research Centre. The information collected will be held for at least 7 years after the publication of the thesis.

All tests were non-invasive and posed no risk to the participants. However, participants were provided with a free contact number (*Lifeline: 13 11 14*) to call if they felt distressed by any of the questions asked during the assessments. Participants were also advised that they did not need to answer any questions if the questions caused them to feel uncomfortable. If the visual tests showed that a participant did not meet the minimal visual standard for driving in at least one eye or both eyes (visual acuity 6/9 or worse than 0.30 logMAR) (Austroads, 2017), the participant received a letter from the research supervisor advising them not to drive and to consult their general practitioner or ophthalmologist (Appendix J). A follow-up call was made by the researcher within 7 days to see if the participant had sought medical advice.

3.8 Statistical Analysis

3.8.1 Descriptive and inferential statistics

Descriptive statistics were used to summarise the sociodemographic characteristics, as well as the health, visual, cognitive and driving characteristics of the cohort, at baseline and after both, first and second eye cataract surgery. Inferential statistics were used to assess changes among all variables of interest throughout the cataract surgery process.

Paired-samples *t*-tests were used to compare the differences obtained by the travel diaries and in-vehicle monitoring devices, in terms of kilometres driven, number of trips, driving duration in minutes and number of trips driven on the weekends, during peak hour traffic, at night time and for overall driving.

Independent sample *t*-tests for continuous outcomes (age, driving experience, number of comorbidities, number of medications, MMSE score, UFOV score, number of trips, kilometres travelled, number of days driven, driving duration and maximum excursion radius from home) and chi-squared tests for categorical outcomes (gender, marital status, living arrangements and level of education) were used to compare the characteristics of the participants classified as self-regulators and non-self-regulators in terms of sociodemographic data, health status, driving characteristics, cognitive

abilities, and objective visual measures.

Cohen's Kappa coefficient was used to measure the relative agreement between the information obtained from the self-reported DHQ and the in-vehicle monitoring devices. Cohen's Kappa coefficient is suitable for categorical data (Pallant, 2007). One-way repeated measures of analysis of variance (ANOVA) were used to measure the changes in the three objective measures of vision before surgery, between surgeries and after second eye cataract surgery. One-way repeated measures of ANOVA are suitable when comparing the mean scores of the same subjects on the same continuous scale on more than two occasions (Pallant, 2007). Cochran Q tests were used to analyse the changes in driver self-regulation status before first eye surgery, and after both first and second eye cataract surgery in the following driving situations: on heavy traffic roads, at night time, on the freeway, and on heavy traffic roads. Cochran Q tests are suitable when analysing changes in frequencies across time with non-parametric categorical data (Bayaga & Lekena, 2010).

3.8.2 Multiple linear regression

To determine whether there was an association between the three objective measures of vision (binocular visual acuity, binocular contrast sensitivity and stereopsis) and driving exposure, a simple multiple linear regression was undertaken. Multiple linear regressions are used to explore the association between one continuous dependent variable and at least two or more predictors or independent variables (Tabachnick & Fidell, 2013). Standard multiple linear regressions are adapted for this type of analysis, taking into account that the sample size is big enough, variables are not multicollinear, outliers are excluded, and residuals are independent (Tabachnick & Fidell, 2013). Driving exposure, a continuous variable, was entered as the main outcome and the three objective measures of vision as explanatory variables. As we were interested in how much variance in driving exposure could be explained by the measures of vision, the independent variables were entered as a group using a standard multiple regression, after controlling for potential confounding factors such as age, gender, retirement status, living arrangements, the number of comorbidities, and cognitive status (Tabachnick & Fidell, 2013).

A multivariate logistic regression was also undertaken to analyse the association between driver self-regulation status and the three objective measures of vision.

Multiple linear regressions are not suitable with categorical dependent variables (Tabachnick & Fidell, 2013), such as self-regulation status. However, multivariate logistic regressions are suitable to explore the association between categorical outcomes with either continuous or categorical variables (Tabachnick & Fidell, 2013). Self-regulation status was therefore entered as the outcome variable. The three objective measures of vision were entered as explanatory variables, after controlling for potential confounding factors such as age, gender, marital status, comorbidities, cognitive function and divided attention. Gender and marital status were entered as categorical variables, while the remaining variables were entered as continuous variables. As we were interested in how much variance in self-regulation status could be explained by the measures of vision, the independent variables were entered as a group using a Forced Entry Method, to assess their predictive ability (Pallant, 2007). The Forced Entry Method is preferred over the Stepwise method, as the latter can be heavily impacted by random variation in the dataset (Pallant, 2007; Tabachnick & Fidell, 2013).

3.8.3 Generalised Linear Estimating Equations (GEE)

Two separate GEE logistic models were undertaken. The first model analysed the changes in self-regulation status before first eye, after first eye, and after second eye cataract surgery. Self-regulation status was entered as the outcome variable. The time of surgery, as well as the three objective measures of vision, were entered as explanatory variables after controlling for potential confounding factors such as age, gender, marital status, retirement status, number of comorbidities, and cognitive function. The time of surgery, gender, age, marital and retirement status were entered as categorical variables, while the remaining variables were entered as continuous variables. GEE methods provide a robust regression method accounting for correlated variables (Mancl & Derouen, 2001). They are used with repeated measures or longitudinal data where there is no independence of the observations within each subject (Zeger & Liang, 1986) and account for within-subject correlations (Ballinger, 2004) by estimating the covariance matrix of the coefficients of regression (Zeger & Liang, 1986). Each of the main outcomes of the model were analysed as continuous variables.

A second GEE logistic model was undertaken to specifically analyse which changes

in the three measures of vision were associated with driving self-regulation status. Self-regulation status was entered as the outcome variable. The three objective measures of vision were entered as explanatory variables, after controlling for potential confounding factors such as age, gender, marital status, retirement status, number of comorbidities, and cognitive function. Gender, age, marital and retirement status were entered as categorical variables, while the remaining variables were entered as continuous variables.

All statistical analyses were performed using SPSS version 22.0 (SPSS Inc., Chicago, IL, USA) and Stata 15 (Stata Corp, 2017). The level of significance was defined as $p < 0.05$.

PUBLICATIONS

Chapter 4 Publication 1

Bilateral cataract, crash risk, driving performance, and self-regulation practices among older drivers

Chapter 4 is a peer reviewed paper, which has been published in the Journal of Cataract and Refractive Surgery: Agramunt, S., Meuleners, L. B., Fraser, M. L., Morlet, N., Chow, K. C., & Ng, J. Q. (2016). Bilateral cataract, crash risk, driving performance, and self-regulation practices among older drivers. *Journal of Cataract & Refractive Surgery*, 42(5), 788-794.

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Bilateral cataract, crash risk, driving performance, and self-regulation practices among older drivers

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This comprehensive literature review summarizes published studies examining cataract and cataract surgery and driving outcomes to identify gaps in the literature that require further research. Six electronic databases were searched for articles published up to and including March 2015. Articles were reviewed if they included older drivers with cataract or drivers who had cataract surgery and at least 1 of the following driving outcomes: crash risk, driving self-regulation practices, and driving performance. There was consistent evidence that cataract negatively affects driving and that cataract surgery is beneficial to driving outcomes. Future research should examine the separate effects of first- and second-eye cataract surgery on crash risk, driving self-regulation, and driving performance. It should also determine how visual measures relate to driving performance among cataract patients so those most at risk for driving difficulties can be identified, advised, and possibly prioritized for surgery.

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Cataract is a leading cause of visual impairment globally, accounting for 33% of impairment.¹ It is also a leading cause of blindness, with approximately 20 million people blind due to cataract.² Cataract surgery

is one of the most common eye surgeries,³ and it is widely accepted that it leads to significant improvements in vision.⁴

By 2030, one-quarter of individuals who are driving are estimated to be 65 years or older.⁵ Older drivers are more likely to drive a vehicle and less inclined to use public transport than they were a decade ago.⁶ Driving often represents an important social role for older adults, and previous research has linked driving with independence, self-worth, and the ability to stay engaged with society and life.⁷ It has been found that older drivers, more than younger drivers, feel that driving is important for maintaining their independence, mobility, and flexibility.⁸ Driving cessation has been linked to depression in this age group.⁹

Driving is a complex task, requiring many aspects of visual functioning.¹⁰ It has been suggested that vision is responsible for 90% to 95% of the sensory input required for driving,¹¹ and cataract can negatively affect different aspects of vision such as contrast sensitivity and visual acuity, potentially having serious consequences for driving ability.¹² Despite the increasing number of

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studies reporting the impact of cataract on driving outcomes, significant gaps in the evidence exist. Due to the aging population, the effect of cataract surgery on driving outcomes is of particular relevance and concern. This comprehensive review summarizes the literature examining cataract, cataract surgery, and driving outcomes including crash risk, driving self-regulation, and driving performance. Studies examining visual measures associated with these outcomes are also reviewed. This should enable researchers to identify gaps in the literature that require future research.

MATERIALS AND METHODS

A review of Medline, Ovid, CINAHL, ScienceDirect, Taylor & Francis, and SpringerLink was undertaken between February and March 2015. The following terms were used individually and in all possible combinations: *cataract, bilateral cataract, visual impairment, vision, driving performance, driver self-regulation, crash risk, motor vehicle crash, road crashes, accident, driver safety, fitness to drive, older drivers, aging population, aged drivers, senior drivers, and cataract surgery*. Additional articles were selected from cited references included within the articles. All articles in this review originally appeared in scientific English language journals, books, or reports published between 1997 and 2015 and were available online. Articles were reviewed if they included older drivers with cataract or drivers who had cataract surgery and at least 1 of the following driving outcomes: crash risk, driving self-regulation practices, and driving performance. All study designs were included. The researchers excluded articles from this literature review if they were not in English, were unpublished, or were theses.

Literature Review

The review included the following studies: 3 examining cataract and cataract surgery and crash risk, 2 examining driving self-regulation, and 15 studies and 1 metaanalysis examining driving performance outcomes.

Cataract and Crash Risk Three studies examined cataract, cataract surgery, and crash risk or visual measures associated with crash risk. Results were published in 7 articles.

A recent population-based linked database study¹³ analyzed the impact of first-eye cataract surgery on motor vehicle crash risk in Western Australia and found a 12.7% reduction in crash risk in the year following first-eye cataract surgery, accounting for community cost savings of A\$4.3 million. However, when examined by sex, there was no significant reduction in crash risk in women after first-eye cataract surgery.¹⁴

The prospective Impact of Cataract on Mobility (ICOM) Project conducted in the United States found that older drivers with cataract were almost 2.5 times as likely to have had an at-fault crash in the previous 5 years than those without cataract (relative risk [RR], 2.46; 95% confidence interval [CI], 1.00-6.16).¹⁵ A subsequent follow-up study over a 4- to 6-year period reported that cataract patients who had surgery experienced only half the crash risk of cataract patients who did not have surgery (RR, 0.47; 95% CI, 0.23-0.94).¹⁶ This study is limited by the small sample size of 174 drivers who had surgery and 103 controls and the subsequent low number of at-fault crashes recorded. The study also combined those who had first-eye cataract surgery

(44%) and those who had surgery in both eyes (56%) during the study period in the analysis.¹⁶ Since most cataract cases are bilateral, it remains unclear whether first-eye surgery alone reduces crash risk and whether second-eye surgery provides additional reduction in crash risk.

Recently, a model was developed based on data from the ICOM Project to simulate the motor vehicle crash experience of the older U.S. population.¹⁷ The study reported that performing cataract surgery at an earlier stage than the current practice would decrease the mean number of motor vehicle crashes, deaths, and costs associated with crashes by approximately 21%. To date, the ICOM project is the only study to examine the association between visual measures and crash risk in cataract patients. Owsley et al.¹⁷ reported that reduced contrast sensitivity was the only independent predictor of crash involvement in the previous 5 years and the relationship was stronger for worse-eye contrast sensitivity than better eye Visual acuity and disability glare measures were not associated with crash risk.¹²

Cataract and Driving Self-Regulation Practices Self-regulation is a complex¹⁸ and multidimensional process.¹⁹ Experts consider it a positive coping strategy that enables individuals to reduce driving risk.⁸ The concept of driving self-regulation assumes that as certain driving situations become more difficult due to functional decline, older people will restrict their driving practices to situations in which they feel safe.²⁰ Some studies reported that visual impairment, including impairment in visual acuity, contrast sensitivity, stereopsis, and visual field, were associated with driver self-regulation.^{21,22} However, other studies reported that a significant proportion of high-risk drivers, including those with visual impairments, did not practice self-regulation.²³ Although drivers with cataract may adjust or self-regulate their driving practices as a result of their impairment, there has been minimal research in this area.

Only 2 studies that specifically examined cataract and or cataract surgery and driver self-regulation were found; the results were published in 3 articles. Owsley et al.¹⁵ used the Driving Habits Questionnaire to examine the driving habits of 279 older drivers with cataract and 105 with no cataract. They reported that those with cataract had significantly fewer days of driving and destinations than those without cataract, but cataract was not related to driving fewer kilometers per week.¹⁵ The authors concluded that older adults with cataract were significantly more likely to restrict their driving habits than those without cataract.¹⁵

An Australian study²⁴ also used the Driving Habits Questionnaire to examine the driving self-regulation practices of 99 drivers aged 55 years and older with bilateral cataract. It found that 48% reported self-regulating their driving to avoid at least 1 challenging situation and the situations most commonly avoided were driving at night (40%), driving on the freeway (12%), driving in the rain (9%), and parallel parking (8%).²⁴ It also found that contrast sensitivity in the worse eye was significantly associated with driver self-regulation before cataract surgery.²⁴ The same authors reported that after first-eye cataract surgery, the mean driving exposure for participants increased by 22 km per week.²⁵

Cataract and Driving Performance Outcomes Despite evidence for decreased crash risk with cataract surgery, the impact of cataract and/or cataract surgery on driving performance is not well understood. To date, studies have examined the impact of cataract and or cataract surgery

on self-reported driving difficulty and closed-road driving performance.

Self-Reported Driving Difficulty Eleven studies and 1 meta-analysis examined cataract and/or cataract surgery and self-reported driving difficulty or visual measures associated with driving difficulty; results were published in 15 articles.

The majority of studies evaluating the impact of cataract and cataract surgery on driving performance outcomes have examined self-reported driving difficulty using instruments such as the Activities of Daily Vision Scale,²⁵ Visual Function Index,²⁷ the National Eye Institute Visual Function Questionnaire,²⁸ and the Driving Habits Questionnaire.²⁹ Many studies have reported increased self-reported driving difficulty with cataract. A recent study²⁹ reported that drivers with cataract had more difficulties with parallel parking, driving in heavy traffic, driving at night, and driving in rush hour than drivers without cataract. Owsley et al.¹⁵ reported earlier that drivers with cataract also had difficulty driving in the rain, alone, and on interstates.

One metaanalysis³⁰ (including data from 5 studies) and 6 additional studies examined the impact of cataract surgery on self-reported driving difficulty. These studies are detailed in Table 1.^{16,25,31-39} The metaanalysis reported a 88% decrease in self-reported driving difficulties after cataract surgery.³⁰ It included data from 5 studies conducted in the U. S., India, and Sweden. One of the studies was retrospective,³¹ and 4 were prospective.³²⁻³⁶ Six additional studies that examined the impact of cataract surgery on self-reported driving difficulty also reported overall improvements following surgery.^{15, 25,36-39}

However, several of these studies measured driving difficulty with general questionnaires that contained only 2 driving-related items addressing day and night driving. In addition, most of the studies did not define whether participants had surgery in the first, second, or both eyes or they analyzed all participants together. Therefore, the separate effects of first- and second-eye cataract surgery on driving difficulty remain inconclusive.

Two of the above studies analyzed driving difficulty following first-eye surgery specifically and found that driving difficulty worsened for a significant proportion of bilateral cataract patients.^{25,37} A recent Australian study found that while self-reported driving difficulty improved overall among bilateral cataract patients after first-eye cataract surgery, 16% did not improve and driving difficulty worsened in 11%.³⁸ Similarly, a prospective study reported that 11% and 7% of cataract patients reported more difficulty with day driving and night driving, respectively, after first-eye surgery and 14% reported no improvement in night driving.³⁷

Four studies examined visual measures associated with self-reported driving difficulty among cataract patients and reported conflicting results. Two reported that contrast sensitivity was the measure most strongly associated with driving difficulty,^{25,40} 1 reported visual acuity was the only measure associated,⁴¹ and 1 reported that both contrast sensitivity and visual acuity predicted change in driving difficulty after surgery.³⁹ Stereopsis and disability glare were not found to be associated with self-reported driving difficulty.^{25,39,41}

Closed-Road Driving Performance Four studies⁴²⁻⁴⁵ examined the impact of cataract on closed-road driving performance. One⁴² also examined the impact of cataract surgery and visual measures on driving performance. Three

studies⁴²⁻⁴⁴ used goggles to simulate the effects of cataract and examined driving performance on a closed-road circuit. A study of 20 younger and 20 older drivers free of ocular pathology reported poorer overall driving scores and difficulties recognizing traffic hazards on a closed-road circuit during the day when wearing the cataract-simulating goggles.⁴² Another study of 20 younger drivers on a closed-road circuit at nighttime reported that the cataract goggles significantly increased the time taken to complete the circuit and reduced recognition of road signs and avoidance of road hazards.⁴³ The most recent study of 28 younger drivers found that under night conditions, simulated cataract impairment significantly reduced the frequency of recognition of pedestrians and the distance at which they were seen.⁴⁴

An earlier study by Wood and Cargery⁴⁵ compared the closed-road driving performance of 29 older drivers with bilateral cataract and 18 controls with normal vision. Those with cataract had significantly poorer overall driving performance, road sign recognition, hazard recognition, and hazard avoidance.⁴⁵ This was the only study that examined the impact of cataract surgery on closed-road driving performance. The authors found that overall driving performance improved after bilateral cataract surgery and that participants were better at avoiding and recognizing hazards as well as recognizing road signs. The study reported that the improvement in contrast sensitivity in the second operated eye predicted the positive changes in driving performance.⁴⁵

DISCUSSION

This review of the impact of cataract and cataract surgery on driving outcomes including crashes, driving self-regulation, and driving performance provides consistent evidence that cataract negatively impacts driving and that cataract surgery is beneficial for driving outcomes.

In terms of the quality of the studies reviewed, all were observational study designs, which exposes them to bias, including selection bias. However, since it is difficult and may be unethical to randomize cataract patients to surgery or no-surgery groups, observational study designs represent the best method for studying the impact of cataract and cataract surgery on driving outcomes. The majority of studies examining the impact of cataract surgery used prospective designs, reducing the risk for bias and confounding. However, several prospective studies had sample sizes of less than 100.^{25,35,36,38} One of the studies examining cataract surgery and crash risk used a retrospective population-based design.¹³ Although this study was unable to capture detail such as visual measures, it had the advantage of a large sample size. Several studies also did not have comparison groups, exposing them to confounding.^{13,25,31-36} Overall, the studies examining the impact of cataract surgery on crash risk, driving self-restriction, and closed-road driving performance used appropriate or validated measures of these outcomes. However, the 11 studies examining self-reported driving difficulty used 5 different questionnaires to

Table 1. Studies examining the impact of cataract surgery on self-reported driving difficulty.

Study ^a	Country	Study Design	Participants (Drivers)	Instrument	First- or Second-Eye Surgery	Findings
Owsley ^{16,7}	USA	Prospective cohort	174 surgery; 103 no surgery	DHQ	First or both eyes combined	No significant difference between groups in driving difficulty at first annual follow-up; significantly less driving difficulty in surgery group at second annual follow-up
Fraser ²³	Australia	Prospective cohort	99 first-eye surgery; no controls	DHQ	First-eye surgery	Significant improvement in driving difficulty score after first-eye surgery
Chang-Godinich ²²	USA	Retrospective	101 surgery; no controls	ACDCF	First and second eyes combined	Significant improvement in driving problems after surgery
Mamidipudi ²⁷	India	Prospective cohort	116 surgery; no controls	NEI VFQ-25 (modified)	Not specified	Significant improvement in day and night driving after surgery
Mönestam ²⁰ ; Mönestam ²⁶	Sweden	Prospective cohort	189 surgery; no controls	VF-14, additional items	First, second, or both eyes combined	Significant decrease in proportion experiencing difficulty with day and night driving 5 years after surgery; no significant difference in driving difficulty between those who had first- and both-eye surgeries
Mönestam ²¹	Sweden	Prospective cohort	19 surgery; no controls	Not specified	First, second, or both eyes combined	Significant decrease in proportion experiencing visual problems while driving after surgery
Bevin ²⁴	New Zealand	Prospective cohort	29 surgery; no controls	VF-14	Not specified	Significant decrease in proportion experiencing difficulty with day- and night-driving after surgery
Castells ²⁵	Spain	Cohort analysis of RCT	249 first-eye surgery; 66 second-eye surgery	VF-14	First and second eyes analyzed separately	Majority of first-eye group and all of second-eye group improved in day- and night-driving scores after surgery
Elliott ²⁸	Canada	Prospective cohort	17 first-eye surgery; 25 second-eye surgery; 25 no cataract	ADVS	First and second eyes analyzed separately	Significant improvement in day- and night-driving scores after first-eye surgery; significant improvement in night-driving score only after second-eye surgery
McGwin ²⁹	USA	Prospective cohort	156 surgery; 89 no surgery	ADVS	First or both eyes combined	Significant improvement in day- and night-driving scores in surgery group; no significant change in scores in nonsurgery group

ACDCF = The American Society of Cataract and Refractive Surgery (ASCRS) Cataract Data Collection Form; ADVS = Activities of Daily Vision Scale; DHQ = Driving Habits Questionnaire; NEI VFQ-25 = 25-item National Eye Institute Visual Function Questionnaire; RCT = randomized controlled trial; VF-14 = Visual Function Index

^aFirst author

⁷Results from same study using different measurement instruments

assess this outcome (Table 1), some of which used only 2 driving questions addressing day and night driving and had not been validated as measures of driving difficulty.

Despite positive findings overall, significant gaps in the evidence exist. Many of the observational studies reviewed did not define whether participants had surgery in the first or second eye or analyzed both eyes together. Therefore, the separate effects of first- and second-eye surgery on crash risk, self-regulation, and driving performance remain inconclusive. Although first-eye surgery has been shown to bring about significant improvements in vision, patients frequently report problems while waiting for second-eye surgery, most likely due to differences in the vision in operated and unoperated eyes. In some public health systems, bilateral cataract patients who opt to have surgery in both eyes may wait 6 months to a year or more between surgeries. This suggests that they drive for substantial periods of time while waiting for second-eye surgery,⁴⁶ which highlights the importance of fully understanding the specific aspects of driving performance affected by cataract and by first- and second-eye cataract surgery. There is a particular lack of information on the impact of second-eye cataract surgery on driving outcomes and self-regulation practices. It is also important to determine whether second-eye surgery provides specific additional benefits for driving performance or crash risk and for which groups of patients it is effective.

Further research using a detailed and validated driving difficulty questionnaire would provide valuable information on the specific driving difficulties bilateral cataract patients experience before and after first- and second-eye surgery and how surgery influences these. The closed-road studies provide useful preliminary information on the impact of cataract and cataract surgery on specific aspects of driving performance.⁴²⁻⁴⁵ However, these studies are limited by small sample sizes. Driving simulators also offer a safe and effective method for examining the impact of eye disorders on driving performance, but to date they have not been used specifically for older people with cataract. Driving simulation represents an approach that is repeatable and easily adaptable, including the ability to quickly alter driving scenarios and expose drivers to hazardous situations in a systematic way.^{47,48} In addition, driving simulators can be configured specifically to test particular components of the driving task thought to be problematic for people with cataract.^{49,50} A large simulator study would provide useful information on changes in driving performance throughout the cataract surgery process.

Evidence from 2 studies suggests that older drivers with cataract may self-regulate their driving before surgery,^{15,28} possibly reducing their risk for a crash.

However, there is currently no information on how older drivers with cataract self-regulate their driving throughout the cataract surgery process and whether their self-regulation practices are associated with actual driving performance. In recent years, a growing number of studies have used in-vehicle monitoring devices to assess naturalistic driving patterns and self-regulation practices rather than using self-reported information, which may be subject to bias.^{19,51-53} To date, no research has used in-vehicle driver monitoring devices to measure self-regulation practices among cataract patients.

A small number of studies examined visual measures associated with crashes, self-regulation, and driving performance.^{12,24,25,39-41,45} Results were somewhat inconsistent, which may be due to small sample sizes and varying use of better-eye and worse-eye values for visual measures. Despite this, contrast sensitivity is emerging as a potentially important measure that may be predictive of crash risk, driver self-regulation, and driving performance. Contrast sensitivity, however, is not currently used in visual testing for licensing, prioritizing patients for cataract surgery, or assessing the success of surgery. Therefore, it is essential that future research investigate in depth how visual measures (including contrast sensitivity) relate to driving outcomes before, between, and after cataract surgeries.

Finally, cataract surgery often necessitates a change in spectacle prescription, which may affect driving performance. Recent research by Fraser et al.⁵⁴ found that only 22% of 99 bilateral cataract patients had purchased new glasses after their first-eye surgery. Most bilateral patients requiring new glasses held off purchasing them until after their second-eye surgery due to the expense, resulting in their driving with less than optimum vision. There is minimal research examining the impact of refractive management on driving performance before, between, and after cataract surgery.

In conclusion, although research to date agrees that cataract surgery provides benefits for driving outcomes, important gaps in the evidence remain. Future research should examine the separate effects of first-eye and second-eye cataract surgery on crash risk, driving self-regulation, and driving performance. It should also aim to determine how visual measures relate to driving performance among cataract patients so those most at risk for driving difficulties can be identified, advised, and possibly prioritized for surgery.

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Chapter 5 Publication 2

A validation study comparing self-reported travel diaries and objective data obtained from in-vehicle monitoring devices in older drivers with bilateral cataract

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A validation study comparing self-reported travel diaries and objective data obtained from in-vehicle monitoring devices in older drivers with bilateral cataract



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ABSTRACT

Background: Advances in technology have made it possible to examine real-world driving using naturalistic data obtained from in-vehicle monitoring devices. These devices overcome the weaknesses of self-report methods and can provide comprehensive insights into driving exposure, habits and practices of older drivers.

Aim: The aim of this study is to compare self-reported and objectively measured driving exposure, habits and practices using a travel diary and an in-vehicle driver monitoring device in older drivers with bilateral cataract.

Methods: A cross-sectional study was undertaken. Forty seven participants aged 58–89 years old (mean = 74.1; S.D. = 7.73) were recruited from three eye clinics over a one year period. Data collection consisted of a cognitive test, a researcher-administered questionnaire, a travel diary and an in-vehicle monitoring device. Participants' driving exposure and patterns were recorded for one week using in-vehicle monitoring devices. They also completed a travel diary each time they drove a motor vehicle as the driver. Paired t-tests were used to examine differences/agreement between the two instruments under different driving circumstances.

Results: The data from the older drivers' travel diaries significantly underestimated the number of overall trips ($p < 0.001$), weekend trips ($p = 0.002$) and trips during peak hour ($p = 0.004$). The travel diaries also significantly overestimated overall driving duration ($p < 0.001$) and weekend driving duration ($p = 0.003$), compared to the data obtained from the in-vehicle monitoring devices. No significant differences were found between instruments for kilometres travelled under any of the driving circumstances.

Conclusions: The results of this study found that relying solely on self-reported travel diaries to assess driving outcomes may not be accurate, particularly for estimates of the number of trips made and duration of trips. The clear advantages of using in-vehicle monitoring devices over travel diaries to monitor driving habits and exposure among an older population are evident.

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1. Introduction

The population of the world is ageing and this trend is expected to continue for several decades (United Nations, 2015). It has been estimated that at least a quarter of the population globally, will be aged 60 years or over by 2050 (United Nations, 2015). In

Australia, for example, older adults are living longer, healthier lives (Australian Institute of Health and Welfare, 2015). This has led to an increase in the number of older drivers on the road with driving licence counts increasing by 44% for the 65+ age group in the decade ending in 2013 (Bureau of Infrastructure, Transport and Regional Economics (BITRE), 2014).

In Australia, driving is the most common form of transport for people aged over 65 years (Australian Bureau of Statistics, 2004). Driving enables an ageing population to maintain their independence, mobility and flexibility (Gwyther and Holland, 2012) and is strongly associated with older adults' social participation

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(Pristavec, 2016). In contrast, driving cessation has been linked to poorer health, social, cognitive and physical function and an increased risk of depressive symptomatology (Chihuri et al., 2016). However, as people age, sensory, motor and cognitive declines as well as medical conditions common in older adults such as cataract, can affect the ability to safely operate a motor vehicle.

Cataract is an opacification of the crystalline lens of the eye (Iroku-Malize and Kirsch, 2016) which causes a gradual decline in visual function and is one of the leading causes of vision impairment globally (Pascolini and Mariotti, 2011). By age 70, almost everyone will have developed some degree of cataract (Taylor et al., 2005). There is evidence to suggest that cataract patients may modify their driving exposure, habits and practices while waiting for surgery (Fraser et al., 2013; Owsley et al., 1999). An early study from the USA found that cataract patients reported reductions in the number of days and destinations driven, driving slower than the general traffic flow and preferring someone else to drive as a result of their visual impairment (Owsley et al., 1999). More recently, Australian cataract patients reported avoiding driving at night, on freeways, in the rain and parallel parking due to their visual impairment (Fraser et al., 2013). However, it should be noted that these studies only used self-report questionnaires to measure the driving exposure, habits and practices of drivers with cataract. These sources however, may be limited in the depth and accuracy of information they can provide about driver behaviour and may be affected by recall and social desirability bias.

Recent research has found that self-reported measures of driving exposure (driving distance) among older adults may be inaccurate (Blanchard et al., 2010; Porter et al., 2015). This raises questions concerning the validity of other self-reported driving practices. In addition, recent naturalistic driving studies found that older drivers in general may not restrict their driving as much as they report on questionnaires (Blanchard and Myers, 2010; Myers et al., 2011). For example, older drivers with Parkinson's Disease were found to accurately report their number of days driving in morning/afternoon driving and residential/city area driving when compared to data collected from an in-vehicle driver monitoring device (Crizzle et al., 2013). However, they drove more at night, in bad weather, in peak hour traffic and on highways than they self-reported (Crizzle et al., 2013). Similarly, an Australian study of 156 older drivers found that participants tended to underreport their average number of days per week and kilometres per week driven. However, participants accurately reported avoidance of driving at night, in unfamiliar areas and on high speed roads (Molnar et al., 2013). It has also been reported that participants prefer to use in-vehicle monitoring devices over self-reported travel diaries or questionnaires (Blanchard et al., 2010). Indeed, travel diaries may lead to high dropout rates among participants and are seen as an encumbrance when required to be filled in daily (Marshall et al., 2013). However naturalistic driving research overcomes the weaknesses of self-report methods, providing objective measures of real-world driving and allowing comprehensive insights into the driving exposure, habits and practices of older adults. In-vehicle driving monitoring devices are small electronic devices that can be attached to a participant's own car and record electronic, time-tagged GPS data on location and speed which allows naturalistic examination of real life driving patterns.

Older adults with cataract are a unique group of older drivers. Since cataract, unlike other conditions of ageing, can be quite easily corrected by surgery, it is important to determine whether these patients temporarily modify their driving exposure, habits and patterns while waiting for surgery, potentially reducing their crash risk. To date however, the limited investigations of driving patterns among cataract patients have used self-report measures only (Fraser et al., 2013; Owsley et al., 1999). Before further research is undertaken among cataract patients, it is essential to determine

the accuracy of self-reported measures (including travel diaries) of driving exposure, habits and patterns, as compared to data obtained from more costly in-vehicle monitoring devices. Current evidence suggests that self-report methods are often inaccurate among general older drivers, however findings are inconsistent on which driving measures older adults are able to accurately report or record, for example, night driving exposure (Crizzle et al., 2013; Molnar et al., 2013). In addition, the majority of these studies sampled from the general older population. Since those awaiting cataract surgery are more likely to be actively and temporarily modifying their driving exposure, habits and patterns than general older drivers, it is essential to determine whether this group are able to accurately report these driving outcomes using a travel diary, as compared to data obtained from in-vehicle monitoring devices.

Therefore, the aim of this study is to compare self-reported information obtained from a travel diary and objectively measured data using an in-vehicle driver monitoring device on driving exposure, habits and practices in older drivers with bilateral cataract as they await first eye cataract surgery.

2. Methods

2.1. Research design and participants

A cross-sectional study was undertaken. Participants with bilateral cataract who were scheduled for first eye cataract surgery within one month were recruited from three eye clinics in Perth, Western Australia (WA). Inclusion criteria stipulated that participants were aged 55 years or older, possessed a current WA driver's licence, drove at least twice a week, had access to a motor vehicle, and lived in the Perth metropolitan area. Participants were excluded from the study if they had a diagnosis of dementia, Alzheimer's disease, Parkinson's disease, were wheelchair bound, colour-blind, did not speak English or had any other ocular conditions that would limit visual outcome. Patients with diagnoses of refractive error or dry eye were acceptable for inclusion in the study.

2.2. Data collection

Participants were recruited and data collected over a one year period in 2015. They were provided with a Participant Information Sheet and informed consent was obtained before any information was collected by a trained researcher. Data collection consisted of three visual tests (under the guidance of an ophthalmologist), a cognitive test, a researcher-administered questionnaire, travel diary and use of an in-vehicle monitoring device. It took approximately 50 min to complete the questionnaire, cognitive and visual tests for each participant. The travel diary and in-vehicle driver monitoring device were provided to each participant at the assessment. The results of the visual tests are not presented as part of this paper. Medical records were also accessed to validate information on co-morbid medical conditions, and current and previous treatments and medication(s). Ethics approval was obtained from Curtin University as well as the three public hospital eye clinics.

2.2.1. Questionnaires/instruments

Socio-demographic data, such as age, gender, level of education, marital and employment status, country of birth, living situation, medications, co-morbid conditions and years of driving experience was collected using a researcher administered questionnaire. Each participant was also asked about their driving experience and confidence when driving. All participants were also assessed to determine their cognitive status using the Mini-Mental Status Examination (MMSE) (Folstein et al., 1975).



Fig. 1. In-vehicle driver monitoring device.

2.2.2. In-vehicle monitoring device

The in-vehicle driving monitoring device provides information on real-time driving exposure, patterns and speed. The device also includes GPS tracking which allows for recording of the routes that the vehicle has taken. The system transmits time stamped second-by-second data on speed and location for all trips. It is small ($8.5 \times 11 \times 3.2$ cm), operates from the cigarette lighter for cars manufactured before 2006 and the On Board Diagnostic II (OBD II) port for more recent vehicles (Fig. 1). The data collected, regardless of the year of the motor vehicle, was exactly the same. Data were transmitted to a secure service provider which was then uploaded by the researcher to a secure server at the University for each participant.

Participants were instructed on the use of the in-vehicle monitoring device at the assessment and also provided with an information sheet on how to use the device. The device can be easily inserted and removed from the vehicle within seconds and this was demonstrated and participants given the opportunity to practice in the presence of the researcher. Participants were instructed to use the in-vehicle device for seven days and drive as they normally would with the equipment installed in their vehicle. They were told they should disconnect the device if someone else drove the vehicle. If they were unable to or forgot to disconnect the device when someone else drove the vehicle, they were asked to note this in their travel diary. Participants were also instructed to move the device from one vehicle to another if they drove multiple vehicles during the seven day period and record this in their travel diary. Participants were asked to return the in-vehicle monitoring device and travel diary by post in a pre-paid envelope at the end of the seven day period. After receiving the device, the researcher interviewed each participant to clarify any data issues that may have arisen during the seven day period, check their use of multiple vehicles and confirm whether there had been any other drivers of the vehicle while the device was connected.

2.2.3. Travel diary

Each participant was also required to complete a travel diary each time they drove as the driver of a motor vehicle (not including motorbike or scooter) during the seven day collection period. They were instructed to fill out the diary as soon as possible after the completion of the trip so that their recall was accurate. Information collected included the type of vehicle driven (make, model and year), the number, age and position of passengers driven, purpose of the trip, date, start and finish time of the trip, start and finish kilometres recorded on the odometer, duration of trip and distance travelled. The diary also allowed participants to note if anyone else drove the vehicle while the device was connected.

2.3. Statistical analysis

Descriptive statistics were used to describe the demographic characteristics of the cohort. The data from the in-vehicle monitoring devices and the travel diaries were cleaned and entered into a SPSS database. Each trip in the participant's travel diary was manually checked by the researcher against the data recorded from the in-vehicle monitoring device by date and time of day. Any trips that were reported in the travel diary as being made by another driver were removed. No participants reported driving more than one vehicle during the seven day period, either in the travel diary or interview. Self-reported driving outcomes from the travel diary were compared to data from the in-vehicle monitoring devices over the seven day monitoring period. Pairwise deletion was used in the analysis to deal with missing data. Outcomes of interest from the in-vehicle monitoring device included driving exposure (kilometres driven), number of trips, duration of travel, weekend driving, night-time driving and driving in peak hour traffic. Peak hour driving was defined as driving between the hours of 6 and 9 a.m. or from 4 to 7 p.m. Day time was defined as the period between sunrise and sunset and night time was defined as the period from sunset to sunrise, with the sunset and sunrise times of the study period obtained from the Australian Government's Bureau of Meteorology website (www.bom.gov.au). Paired *t*-tests were used to examine differences between the two instruments.

3. Results

3.1. Demographic characteristics

The demographic characteristics of the 47 participants (57.4% male and 42.6% female) are summarised in Table 1. The participants

Table 1
Descriptive characteristics.

Variable	N = 47	%
Gender		
Male	27	57.4
Female	20	42.6
Age Group		
55–64	6	12.8
65–74	20	42.6
75–84	15	31.9
> 85	6	12.8
Marital Status		
Single/separated/divorced/widowed	22	46.8
De facto/married	25	53.2
Highest level of education completed		
Primary or secondary school	21	44.7
Tertiary education/training	26	55.3
Country of birth		
Australia	22	57.4
Other countries	20	42.6
Employment status		
Retired on pension	33	70.2
Retired self-funded	9	19.1
Employed	3	6.4
Self-employed	2	4.3
Living arrangements		
Live alone	20	42.6
Lives with spouse/family members/others	27	57.4
Prescription medication		
No	4	8.5
Yes	43	91.5
Presence of comorbidities		
No	1	2.1
Yes	46	97.9

Table 2
Results of paired *t*-tests for driving outcomes from the in-vehicle monitoring devices and the self-reported travel diaries during a one week observation period.

Driving Outcome	Self-report travel diaries		In-vehicle monitoring devices		95% CI for Mean Difference	<i>t</i>	<i>df</i>	<i>p</i> -value	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>n</i>					
Overall									
Kilometres driven	166.17	125.61	143.49	111.47	17 ^a	-0.72, 46.1	2.05	16	0.057
Number of trips	12.6	7.85	19.38	10.49	47	-9.16, -4.41	-5.75	46	< 0.001
Driving duration per week (minutes)	347.96	254.16	181.96	136.38	24 ^b	84.16, 247.84	4.2	23	< 0.001
Number of days driving	4.74	1.66	4.85	1.59	47	-0.41, 0.2	-0.7	46	0.49
Weekend driving									
Kilometres driven during weekend	51.97	56.98	45.46	54.48	17 ^c	-2.03, 15.04	1.62	16	0.126
Number of trips during weekend	3.34	2.68	4.91	4.1	47	-2.53, -0.62	-3.33	46	0.002
Driving duration during weekend (minutes)	109.83	103.49	56.54	57.48	24 ^b	20.22, 206.36	3.33	23	0.003
Number of days with driving during weekend	1.36	0.74	1.34	0.7	47	-0.11, 0.15	0.33	46	0.743
Peak hour driving									
Kilometres driven during peak hours	41.27	37.35	36.52	35.51	15 ^c	-4.01, 13.51	1.16	14	0.264
Number of trips during peak hours	3.29	3.26	4.75	4.21	24 ^b	-2.4, -0.52	-3.21	23	0.004
Driving duration during peak hours (minutes)	152	262.84	49.75	48.24	24 ^b	-2.12, 206.62	2.03	23	0.054
Number of days with driving during peak hours	1.92	1.44	2.38	1.47	24 ^b	-0.74, -0.18	-3.41	23	0.002
Night time driving									
Kilometres driven during night time	17.05	27.44	13.91	19.68	15 ^c	-5.11, 11.37	0.82	14	0.428
Number of trips during night time	1.46	2.92	1.58	2.41	24 ^b	-0.73, 0.48	-0.43	23	0.671
Driving duration during night time (minutes)	26.71	44.07	16.58	26.01	24 ^b	-1.55, 21.8	1.8	23	0.086
Number of days with night time driving	0.71	0.91	0.83	1.05	24 ^b	-0.31, 0.06	-1.37	23	0.185

^a 30 of the 47 participants had missing information in the odometer entries of their travel diaries.

^b 23 of the 47 participants had missing information in the time entries of their travel diaries.

^c 32 of the 47 participants had missing information in both the time and odometer entries of their travel diaries.

were aged 58 to 89 years with a mean age of 74.1 (SD = 7.73) years. More than half of the participants (57.4%) were born in Australia. For the majority (55.3%), an apprenticeship or University degree was the highest level of education. More than half of the sample (53.2%) were married/de facto and the majority of participants lived with another person (57.4%). Retired participants accounted for 89.3% of the sample, whereas 10.7% were still employed. The majority of participants (97.9%) had at least one co-morbid health condition in addition to cataract and were taking prescribed medications (91.5%). The mean Mini-Mental Status Examination (MMSE) score for participants was 27.78 (SD = 1.90) which is consistent with normal cognitive functioning.

The mean number of years of driving for the cohort was 52 (S.D. = 10.92) years. Despite participants having bilateral cataract, the majority of participants (85.1%) reported having no difficulty when driving during the daytime in familiar places. All drivers owned their own car and always wore a seatbelt when driving. The majority of participants considered themselves to be either good drivers (44.7%) or excellent drivers (31.9%). However 10.6% of the drivers reported that in the past year it was suggested to them by family, friends or other people that they should stop or limit their driving.

3.2. In-vehicle monitoring devices and self-reported travel diaries

3.2.1. Overall driving

The results of paired *t*-tests for driving exposure are summarised in Table 2.

Compared to the self-reported travel diaries, the in-vehicle monitoring devices recorded less (not significant) kilometres driven ($p = 0.057$), significantly more trips undertaken ($p < 0.001$) and less driving time per week ($p < 0.001$). According to the

in-vehicle monitoring devices, an average of 143.49 kilometres (S.D. = 111.47) were driven during the study period, whereas participants self-reported that they drove 166.17 (S.D. = 125.61) kilometres.

An average of 19.38 (S.D. = 10.49) trips were captured by the in-vehicle monitoring devices, while the participants' self reported that they undertook an average of 12.60 (S.D. = 7.85) trips. Participants also significantly overestimated the duration of their driving, with the information from the travel diaries reporting that participants drove an average of 348 min per week (S.D. = 254 min), compared to 182 min (S.D. = 136 min) recorded by the in-vehicle monitoring devices ($p < 0.001$). However, in terms of the mean number of days driven during the seven day period, the results from the in-vehicle monitoring device and travel diaries were very similar with no significant difference observed ($p = 0.490$).

3.2.2. Weekend driving

Similar patterns were also observed in regards to weekend driving. Compared to the self-reported travel diaries, the in-vehicle monitoring devices recorded less (not significant) kilometres driven on the weekend than the self-reported travel diaries ($p = 0.126$). According to the in-vehicle monitoring devices, an average of 45.46 kilometres (S.D. = 54.48) were driven on the weekend, whereas participants self-reported that they drove an average of 51.97 kilometres (S.D. = 56.98) on the weekend.

A significant difference ($p = 0.002$) was observed in terms of the number of trips taken during the weekend with an average of 4.91 (S.D. = 4.1) trips recorded using the in-vehicle monitoring devices compared to 3.34 (S.D. = 2.68) trips recorded in the self-reported travel diaries. Again, participants significantly overestimated the duration of their driving during the weekend, with 110 min (S.D. = 103 min) recorded on the travel diaries, while a

shorter duration (57 min; S.D. = 57 min) was actually recorded by the devices ($p = 0.003$). There was no significant difference ($p = 0.743$) between the data obtained by the in-vehicle monitoring devices and the travel diaries in regard to the number of days driven during the weekend (1.34 and 1.36 days respectively).

3.2.3. Peak hour driving

The information obtained from the in-vehicle monitoring devices reported less kilometers driven, though not significant ($p = 0.264$), significantly more trips taken ($p = 0.004$), less time driving though not significant ($p = 0.054$) and significantly greater number of days driving ($p = 0.002$) during peak hours, compared to the self-reported travel diaries.

Participants drove 36.52 kilometres (S.D. = 35.51) during peak hours according to the in-vehicle monitoring device, compared to 41.27 kilometres (S.D. = 37.35) recorded in the travel diaries. The self-reported driving duration during peak hours was again over-estimated in the travel diaries (though not significant) with an average of 152 min (S.D. = 263 min) reported compared to 50 min (S.D. = 48 min) by the in-vehicle monitoring devices. There was a greater number of trips made during peak hours per week according to the in-vehicle monitoring devices, compared to the travel diaries, with 4.75 trips (S.D. = 4.21) and 3.29 trips (S.D. = 3.26) made respectively. In addition, a significantly higher average number of days driving during peak hour were recorded by the in-vehicle monitoring devices (2.38 days; S.D. = 1.47), compared to the self-reported diaries (1.92 days; S.D. = 1.44).

3.2.4. Night time driving

No significant differences were found for night driving between the information provided by the in-vehicle monitoring devices and the travel diaries. Information obtained by the travel diaries reported an average of 17.05 kilometres of night time driving amongst the participants (S.D. = 27.44), while the in-vehicle monitoring devices reported an average of 13.91 kilometres per week (S.D. = 19.68). This difference was not significant ($p = 0.428$).

In regards to the number of night time trips, there was also no significant difference ($p = 0.671$) between the travel diaries which reported an average of 1.46 (S.D. = 2.92) trips during the night, compared to the in-vehicle monitoring devices which reported an average of 1.58 trips (S.D. = 2.41). No significant difference ($p = 0.086$) was evident in relation to driving duration at night with the travel diaries recording an average of 27 min (S.D. = 44 min), and the in-vehicle monitoring devices recording an average of 17 min (S.D. = 26 min). The average number of days participants drove during the night was also not significantly different ($p = 0.185$) between the travel diaries and the in-vehicle monitoring devices with an average of 0.71 (S.D. = 0.91) days and 0.83 (S.D. = 1.05) days recorded respectively.

4. Discussion

This is the first study to compare the driving exposure and practices of bilateral cataract patients awaiting surgery as obtained by self-reported travel diaries and in-vehicle monitoring devices. The study found that there were significant differences between self-reported driving outcomes and those obtained from the in-vehicle monitoring devices. Overall, the data from the older drivers' travel diaries significantly underestimated the number of trips made in certain conditions and frequently overestimated their driving duration, as compared to the objective data obtained from the in-vehicle monitoring devices.

It should be noted that a high proportion of participants had missing information in their travel diaries, in terms of either the odometer entries (64% of the participants), time entries (49% of the

participants), or both time and odometer entries (68% of the participants). This indicates that a high proportion of older drivers were unable to accurately or completely fill in the travel diary for a period of a week. In general, those participants who were able to complete the travel diary quite accurately recorded their kilometres travelled and days driven, but did not accurately record their number of trips or driving duration. Together, these findings demonstrate that travel diaries might not be an optimal tool for collecting driving patterns of older drivers. More reliable sources of driving data such as in-vehicle monitoring devices should be encouraged when collecting information about naturalistic driving behaviours.

A growing body of evidence has assessed driving behaviours using naturalistic in-vehicle monitoring devices (Blanchard and Myers, 2010; Blanchard et al., 2010; Huebner et al., 2006; Molnar et al., 2014; Porter et al., 2015). It has been shown that in-vehicle monitoring devices connected through the OBD-II port, as well as GPS devices provide accurate and valid measures of driving outcomes (Huebner et al., 2006). Travel data obtained by GPS devices have been found to equal or surpass the quality of data obtained by travel diaries (Wolf et al., 2001). Research has also found that these devices are preferred by study participants over travel diaries, particularly among older drivers (Blanchard et al., 2010; Marshall et al., 2007).

In the current study, the participants' travel diaries significantly under-reported the number of trips taken overall, on the weekend and in peak hours and significantly over-estimated the duration spent driving in the overall study period and on the weekend. These results are consistent with other studies which showed that drivers tend to underestimate the number of trips recorded in their travel diaries compared to the trips recorded by electronic devices (Blanchard et al., 2010). Similarly, another study showed that drivers overestimated the travel duration of their trips (Stopher et al., 2007). There are several possible reasons for these observed discrepancies between the self-reported travel diaries and the in-vehicle monitoring devices. Although participants were requested by the researcher to fill out the travel diary immediately after completion of their trip, it is possible that some participants may not have done this and completed the diary at a later date. There is also the possibility of a lack of accuracy due to memory impairment or fatigue after a long trip (Marshall et al., 2007). It is also possible that some participants may have included the duration of their whole trip even when they were not driving, thus overestimating the duration of their trips.

Interestingly, no significant differences were found between the travel diaries and in-vehicle monitoring devices in terms of kilometres driven overall, on the weekend, during peak hour or a night. However, a higher average number of kilometres were consistently reported in the travel diaries, compared to the in-vehicle monitoring devices. It is possible that the lack of significant results for kilometres driven could be due to the small sample size available for this outcome and this should be investigated in further research.

The travel diaries also accurately reported the number of days of the week driven overall, on the weekend and at night compared to the in-vehicle monitoring devices, but significantly under-reported the number of days driving in peak hour. This is similar to previous research which found significant variation between self-reported and actual driving during challenging situations such as peak hour traffic (Crizzle et al., 2013).

Interestingly, the results for night time driving exposure differed from the other driving situations examined in the study. There was no significant differences in the number of kilometres travelled, night time trips taken, the duration of night time driving or number of days with night time driving between the travel diaries and in-vehicle monitoring devices. The more accurate recording of night driving outcomes may be due to the fact that drivers with cataract in this study drove less at night than they did in the other driv-

ing situations examined. Previous research has found that older drivers with cataract report difficulty with and self-restrict their night driving (Fraser et al., 2013; Owsley et al., 1999). Therefore, the infrequency of night driving and difficulty experienced may have made the details of night driving exposure easier for participants to recall and record accurately. These findings are similar to those from a large Australian study that older drivers accurately report avoidance of night driving (Molnar et al., 2013).

The results of this study in relation to actual driving exposure are consistent with previous research using objective measures. In particular, the results of the in-vehicle monitoring device reported that participants drove an average of 143 km per week compared to 164 km reported by Blanchard et al. (2010) and 186 by Marshall et al. (2007). The lower mileage travelled may be due to the fact that the cohort was waiting for their first eye cataract surgery and may not have been driving as they would under normal circumstances.

There were several strengths of the study. The in-vehicle monitoring devices used in this study were able to be easily installed in all cars. Some devices that have been examined previously were restricted to use in cars manufactured from 1996 onwards due to the vehicle interface. The data from the in-vehicle monitoring devices were also linked to the Australian Government's Bureau of Meteorology website to determine light conditions which provided an accurate representation of day and night time driving patterns for participants. Furthermore, participants recruited did not have any other major eye conditions besides cataract, such as glaucoma or macular degeneration, as those conditions could have had an impact on their driving behaviour.

However, the study has limitations. The use of a convenience sample, small sample size and the large amount of missing data may affect the generalisability of the results. Recall bias may also be present. Additionally, driving was monitored for one week only and it is possible, given the age-group of participants, that illness may have curtailed driving exposure during the week of the assessment. Generally driving fluctuates from week to week and a longer monitoring time is optimal to identify driving outcomes. Furthermore one week may limit the type of environmental conditions participants may experience such as avoiding driving in the rain. While no participants reported driving multiple vehicles during the seven day period, either in their travel diary or interview, it is possible that they did so without reporting it, affecting the accuracy of the data. It is also possible that a person other than the participant drove the vehicle while the in-vehicle monitoring device was connected. However, the ease of removal and installation of the device, short collection period of seven days and the opportunity for participants to record other drivers in the travel diary or report them in the interview would have reduced the likelihood of this occurring.

In conclusion, the results of this study found that relying solely on self-reported travel diaries to assess driving outcomes for cataract patients awaiting surgery may not be accurate, particularly for estimates of number and duration of trips. The accuracy of estimates of kilometres driven requires further research. Also the potential for attrition of participants using a travel diary is high due to subject fatigue and continuously updating the travel diary. The clear advantages of the in-vehicle monitoring devices over the travel diaries are evident, particularly for an older driving population.

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Chapter 6 Publication 3

An examination of driving exposure, habits and adverse events in older drivers with bilateral cataract using naturalistic driving data

Chapter 6 is a manuscript, which has been submitted for publication and is currently under review: Agramunt, S., Meuleners, L., Fraser, M.L., Chow, K. C., Ng, J. Q., Raja, V., & Morlet, N. (submitted). An examination of driving exposure, habits and adverse events in older drivers with bilateral cataract using naturalistic driving data.

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An examination of driving exposure, habits and adverse events in older drivers with bilateral cataract using naturalistic driving data

Short title: Naturalistic driving exposure and adverse events in older drivers with bilateral cataract

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Abstract

Purpose: To examine driving exposure, habits and adverse events in older drivers with bilateral cataract using naturalistic driving data.

Methods: Ninety six older drivers aged 55+ years were assessed in the month prior to first eye cataract surgery. Data collection consisted of a researcher administered questionnaire, a cognitive test and visual measures including visual acuity, contrast sensitivity and stereopsis. Participants' driving exposure, driving habits and adverse events were measured using an objective in-vehicle driver monitoring device. A multiple linear regression model was undertaken to examine predictors of driving exposure in older drivers with bilateral cataract.

Results: After controlling for potential confounding factors, only binocular contrast sensitivity ($p < 0.05$) and gender ($p < 0.05$) were significantly associated with kilometres travelled in a seven day period. One log unit increase in contrast sensitivity score was associated with an increase of 163 kilometres driven during the study period. Males drove an average of 50 kilometres more per week than women. Only eleven participants experienced an adverse event (harsh braking) during the driving monitoring period.

Conclusion: The study provides a better understanding of the driving exposure, habits and adverse events of bilateral cataract patients while waiting for first eye cataract surgery. Contrast sensitivity is an important measure to consider when determining the impact of cataract on driving. Further longitudinal research is required to examine changes in visual measures, driving exposure, habits and adverse events after first eye surgery and whether second eye surgery provides additional benefits for driving.

Introduction

Cataract is one of the leading causes of visual impairment worldwide. It is the main cause of blindness (51%) and accounts for 33 percent of visual impairment globally [1]. Approximately 50% of older people will develop cataract by their seventies and this increases to around 90% by their eighties [2]. The incidence of cataract worldwide has increased rapidly over the past 20 years and this is expected to continue as the population ages [3].

Cataract can affect multiple aspects of vision and a growing body of evidence suggests that older drivers with cataract are less safe to drive [4,5]. However, unlike other conditions of ageing, cataract can be easily corrected by surgery, which has been shown to reduce crash risk by thirteen percent one year after first eye surgery [6]. In Australia however, public hospital patients often wait long periods of up to 12 months before cataract surgery [6], generating concern among road safety and licensing authorities about the impact of unoperated cataract on driving exposure and ability.

Previous research examining the effect of cataract surgery on driving outcomes has focused only on self-reported driving difficulty. A meta-analysis of five studies found that the risk of driving difficulty reduced by 88% after cataract surgery (OR 0.12, 95% CI 0.10 to 0.16) [7]. There has also been limited research investigating driving exposure and habits among cataract patients, and the research to date has used self-report measures only [4,8]. These studies found that older drivers with cataract reported reduced driving exposure in terms of number of days, trips and distance travelled per week prior to surgery [4,8]. However, driving exposure was assessed using a self-reported questionnaire which has inherent biases and limitations. Previous research has found that self-reported measures of driving outcomes may be less reliable than naturalistic data collection methods [9,10].

Naturalistic studies which collect detailed GPS information allow an accurate and objective examination of driving outcomes such as driving exposure as well as adverse events including harsh braking. This rich source of information provides a means for assessing the safety impact of driving behaviours in an unobtrusive manner. Several studies to date have used in-vehicle devices to measure rapid deceleration events and have used them as a surrogate measure for near crashes [11,12] with positive correlations found between incidents, near crashes and actual crashes [13]. The deceleration and acceleration behaviour of drivers specifically has also been shown predict at-fault crash involvement [11].

To date, no published study has used naturalistic data to explore driving exposure, habits and adverse events for older drivers with bilateral cataract. This information is of relevance to licensing authorities and clinicians in terms of understanding cataract patients' driving habits in the waiting period for cataract surgery and the frequency of adverse events experienced. This would allow older drivers with cataract to be appropriately advised on driving risks they could face while awaiting first eye surgery and assist them in making an informed decision on whether they continue to drive or not during this wait time. Furthermore, the identification of participants whose driving performance would most benefit from cataract surgery would be useful in the prioritisation for surgery. Therefore the aim of this study was to describe the naturalistic driving exposure, habits and adverse events of older drivers with bilateral cataract who were awaiting surgery and to determine factors associated with driving exposure (kilometres travelled).

Materials and methods

Participants

Participants awaiting first eye cataract surgery were recruited from three public hospital eye clinics in Western Australia either by an invitation letter or a direct approach made by clinicians at the hospitals. Inclusion criteria stipulated that participants were aged 55+ years, drove at least twice a week, had bilateral cataract and had no other significant eye conditions, such as glaucoma, macular degeneration

or diabetic retinopathy. Participants were excluded from the study if they were wheelchair-bound, diagnosed with dementia, Alzheimer's disease, Parkinson's disease, were non-English speaking or had cataract surgery previously.

Data collection

Participants were recruited between December 2014 and February 2017. Data collection consisted of a researcher administered questionnaire, a cognitive test, the Mini-Mental State Examination (MMSE) [14] and three objective visual assessments, which were administered at Curtin University. Participants were also provided with an in-vehicle monitoring device at the end of the assessment. Informed written consent was obtained from each participant before any information was collected, following the tenets of the Declaration of Helsinki. Ethics approval was obtained from the three participating hospitals (Fremantle Hospital, Royal Perth Hospital and Sir Charles Gairdner Hospital) and the Curtin University Human Research Ethics Committee.

Questionnaires

Sociodemographic data

Information on age, gender, marital status, country of birth, level of education, employment status, living arrangements, medications, comorbidities, driver's licence and years of driving experience were collected via a researcher administered questionnaire.

Driving Habits Questionnaire (DHQ)

All participants completed the Driving Habit Questionnaire (DHQ) [4]. It includes questions about actual driving, driving exposure, dependence, avoidance, crashes and driving space. This questionnaire has been previously validated for use with a Western Australian population of older drivers with bilateral cataract [8].

Mini-Mental State Examination (MMSE)

The Mini-Mental State Examination (MMSE) [14] was administered to all participants. It assesses general cognitive function and is used as a screening tool for

cognitive impairment. Scores range from 0 to 30 with a higher score indicating better cognitive functioning. The inclusion criterion was a score ≥ 24 on the MMSE which indicates normal cognitive function.

Measures of vision

Three objective visual measures were administered under the guidance of an ophthalmologist under standard conditions, constant luminance and without mydriasis. Participants wore their habitual correction for visual testing.

Visual acuity: Monocular and binocular visual acuity were assessed using an Early Treatment Diabetic Retinopathy Study acuity chart (ETDRS), calibrated for a 3 metre distance [15]. A letter by letter scoring method was used and scores were expressed as a logarithm of the minimum angle of resolution (logMAR).

Contrast sensitivity: Monocular and binocular contrast sensitivity were measured using the Mars Letter Contrast Sensitivity Test, at a distance of 50 centimetres (Mars Perceptrix©) and expressed as log units.

Stereopsis: Stereopsis was assessed using the Titmus Fly Stereotest (Good-Lite Co., Inc.) and scores were expressed as log seconds of arc.

In-vehicle monitoring device

All participants were provided with an in-vehicle monitoring device and instructed to use it for a period of seven days. Participants were instructed to only use it when they were driving their motor vehicle. They were also provided with a travel diary that they were asked to complete each time they drove their motor vehicle. The diary recorded the model, make and year of their vehicle, number, age and position of passengers, time, date, start and end time of the trip and distance travelled. At the conclusion of the monitoring period, a researcher interviewed participants to identify any issues with the devices and to confirm no one else drove the vehicle while the device was connected. Instructions were provided to all participants regarding the use of the device in the participant information sheet. They had to plug the device into their car's

On Board Diagnostic II (OBD II) port for vehicles manufactured after January 2006 or the cigarette lighter prior to 2006 (Fig 1). The in-vehicle monitoring GPS system transmitted time-stamped second-by-second data on speed and location for all trips and collected information on real time driving exposure, time, date of travel and adverse events, such as harsh braking. The GPS data was cleaned to exclude “false trips” of less than 200 metres or which lasted less than 10 seconds. Trips made from the University after the assessments were excluded, as they were not representative on the participants’ habitual driving behaviour.



Fig 1. In-vehicle driver monitoring device.

Operational Definitions

Adverse events were defined as a harsh braking episode. Harsh braking episodes were defined as G-force exertion more harsh than $-0.61G$ (Geotab©).

Day time driving was defined as the period from sunrise to sunset and night time driving as the period from sunset to sunrise, for each day. Specific times of sunrise and sunset for each day of the year were obtained from the Australian Government's Bureau of Meteorology website (www.bom.gov.au).

Driving between the hours of 6 and 9 a.m. or from 4 to 7 p.m. on weekdays was defined as peak hour driving.

The mean excursion radius for a driver was calculated as the mean distance (km) of the vehicle from the home of the driver [16], scaled to the amount of time the vehicle was present at each location away from home while the vehicle was in motion (i.e. speed > 0), with the moments in time the vehicle was stationary (i.e. speed = 0) excluded from the calculations.

Statistical analysis

Descriptive statistics were used to summarise the sociodemographic and visual characteristics of the cohort. Driving exposure, habits and adverse events were also described in detail. Since the number of participants experiencing adverse events was low, only descriptive statistics were calculated. The primary outcome of interest was driving exposure as measured by total number of kilometres travelled in a seven day period prior to first eye cataract surgery. A multiple linear regression model was undertaken to determine the association between three objective visual measures (binocular visual acuity, binocular contrast sensitivity and stereopsis) and driving exposure in a seven day period. Binocular visual measures were chosen since these take into account how better and worse eye vision interact when undertaking tasks in the real world. The three objective measures of vision were entered as explanatory variables in the models and potential confounding factors such as age, gender, the

number of comorbidities, cognitive status, retirement status and whether the participant lived alone were controlled for. All statistical analyses were performed using SPSS statistical software, version 22 (SPSS Inc., Chicago, IL, USA).

Results

One hundred and eleven participants with bilateral cataract who were waiting for first eye cataract surgery were recruited into the study. Fifteen participants were excluded from the analysis due to poor data integrity from the in-vehicle monitoring device which was caused by faulty cigarette lighters and/or the loss of the monitoring devices. The final sample consisted of 96 participants.

The ninety six participants ranged in age from 55 to 91 years old, with a mean age of 73.4 years (SD=8.6). The mean number of years driving was 51.4 years (SD=10.6). As illustrated in Table 1, 18.8% of the sample were aged between 55 and 64 years, 35.4% between 65 and 74, 36.5% between 75 and 84 and 9.4% were 85 or older. The majority of participants were male (52.1%), married or in a de facto relationship (57.3%), were retired (72.9%) and did not live alone (58.3%). Forty-five percent (44.8%) were born in Australia, 60.4% had completed a higher degree and 43.8% wore bifocal or multifocal glasses. Ninety-eight percent (97.9%) of the participants reported at least one comorbid medical condition in addition to cataract, with a mean of 5.4 comorbid medical conditions per participant (SD=2.8). These conditions included musculoskeletal, circulatory, respiratory and endocrine conditions. Eighty-nine percent of participants were also taking prescribed medications, with a mean of 3.4 (SD=3.0) medications taken per participant. All participants had normal cognitive function according to the MMSE, with an overall mean for the sample of 27.7 (SD=2.1).

Table 1. Demographic characteristics of older drivers with bilateral cataract aged 55+ (n=96).

	Number	Percent
Gender		
Male	50	52.08
Female	46	47.92
Marital status		
De facto/ married	55	57.29
Single/Separated Divorced/ Widowed	41	42.71
Age group		
55-64	18	18.75
65-74	34	35.42
75-84	35	36.46
>=85	9	9.38
Highest educational level		
Primary or Secondary School	38	39.58
Higher Education (University/TAFE)	58	60.42
Country of birth		
Australia	43	44.79
Other	53	55.51
Employment status		
Retired	70	72.92
Employed/self-employed	18	18.75
Unemployed	6	6.25
Medical disability pension	2	2.08
Living arrangements		
Lives alone	40	41.67
Lives with other people	56	58.33
Habitual correction		
No correction	41	42.71
Single vision spectacles	12	12.50
Bifocals or multifocals	42	43.75
Contact lenses	1	1.04
Presence of comorbidities		
No	2	2.08
Yes	94	97.92
Prescription medication		
No	11	11.46
Yes	85	88.54

Responses to the self-reported DHQ questionnaire found that approximately half of the sample (51.1%) reported that cataract did not affect their driving. However, 10.6% of participants (n=10) reported that someone suggested that they stop or limit their driving in the past year. Among the participants who were told that they should stop or limit their driving, four participants did not drive at all during the seven day period.

Eighty-one percent of participants (80.9%) preferred to drive themselves rather than being driven by someone else and the majority of participants considered themselves to be good (46.8%), excellent (24.5%) or average drivers (25.5%). Only few participants considered themselves to be a fair (2.1%) or poor drivers (1.1%). Ninety-seven percent of the sample (96.8%) owned their own car, and 98.9% used a seatbelt while driving.

The results of the visual measurements prior to first eye cataract surgery are shown in Table 2. Mean binocular visual acuity, as measured by the ETDRS chart, was 0.14 logMAR (SD=0.16). Mean binocular contrast sensitivity, as measured by the MARS contrast sensitivity chart was 1.65 log units (SD=0.15) and mean stereopsis as measured by the Titmus Fly test was 2.32 log seconds of arc (SD=0.72).

Table 2. Visual characteristics of older drivers with bilateral cataract aged 55+ (n=96).

Visual tests	Mean	SD
Visual acuity (logMAR)		
Better eye	0.19	0.15
Worse eye	0.43	0.29
Both eyes	0.14	0.16
Log contrast sensitivity		
Better eye	1.57	0.15
Worse eye	1.37	0.34
Both eyes	1.65	0.15
Stereopsis (log seconds of arc)		
Both eyes	2.32	0.72

In-vehicle monitoring devices

The final sample used for the analysis of the in-vehicle monitoring device was 96 participants. No significant difference was found between those who undertook the in-vehicle monitoring and those who did not in terms of gender (p=0.77), age (p=0.45), visual acuity (p=0.65), contrast sensitivity (p=0.74), and stereopsis (p=0.62). A total of eight participants (8.3%) did not drive at all during the study period. Reasons for

this included “difficulties driving at night”, “in the rain”, or participants were told by someone else that “they should stop or limit their driving”.

Overall driving exposure and naturalistic driving patterns

Ninety-two percent of participants (n=88) drove during the 7 day period. As illustrated in Table 3, participants, overall, undertook an average of 15.6 trips (SD=10.5), drove an average distance of 115.8 kilometres per week (SD=99.0), and drove an average of 4.40 days (SD=2.1) in a seven day period. The maximum distance that participants travelled from home was 14.1 (SD=11.9) kilometres.

Table 3. Naturalistic driving patterns of older drivers with bilateral cataract aged 55+ over a seven day period (n=96).

	Mean	SD
Overall driving (n=88)		
Kilometres travelled	115.77	98.97
Number of trips	15.56	10.51
Driving duration per week (minutes)	186.51	149.03
Number of days driving	4.40	2.06
Maximum excursion radius from home (km)	14.08	11.87
Day time driving (n=88)		
Kilometres travelled	101.27	87.45
Number of trips	14.04	9.15
Driving duration during day time (minutes)	165.00	127.82
Number of days driving	4.32	2.02
Night time driving (n=43)		
Kilometres travelled	14.50	29.47
Number of trips	1.52	3.49
Driving duration during night time (minutes)	21.51	47.37
Number of days driving	0.93	1.41
Weekday driving (n=88)		
Kilometres travelled	86.10	72.56
Number of trips	12.00	8.38
Driving duration per weekday (minutes)	142.48	113.13
Number of days driving	3.23	1.50
Weekend driving (n=72)		
Kilometres travelled	29.67	42.67
Number of trips	3.56	3.64
Driving duration per weekend (minutes)	44.03	55.85
Number of days driving	1.17	0.80
Peak hour driving (n=75)		
Kilometres travelled	33.97	38.48
Number of trips	4.56	4.39
Driving duration during peak hours (minutes)	57.84	61.38
Number of days driving	2.19	1.59

Daytime driving

Ninety-two percent of participants (n=88) drove during the daytime. Participants undertook an average of 14.0 trips (SD=9.2), drove an average distance of 101.3 kilometres per week (SD=87.5), and drove an average of 4.3 days (SD=2.0) during daytime in a seven day period.

Night time driving

Slightly less than half of the sample (45%) drove at night time (n=43). Participants undertook an average of 1.52 trips (SD=3.49), drove an average distance of 14.50 kilometres (SD=29.47), and drove an average of 0.93 days (SD=1.41) during the night in a seven day period.

Weekday driving

Ninety-two percent of participants (n=88) drove during the week (Monday to Friday). Participants undertook an average of 12.0 trips (SD=8.4), drove an average distance of 86.1 kilometres (SD=72.6), and drove an average of 3.2 days (SD=1.5) during the work week.

Weekend driving

Seventy-five percent of participants (n=72) drove during the weekend. Participants undertook an average of 3.6 trips (SD=3.6), drove an average distance of 29.7 kilometres (SD=42.7), and drove an average of 1.2 days (SD=0.8) during the weekend.

Peak hour driving

Seventy-eight percent of participants (n=75) drove during peak hour traffic. Participants undertook an average of 4.6 trips (SD=4.4), drove an average distance of 34.0 kilometres (SD= 38.5), and drove an average of 2.2 days (SD=1.6) during peak hour traffic.

Harsh braking events

Eleven percent of participants (n=11) recorded at least one episode of harsh braking during the seven day period with the majority of these participants (90.9%, n=10) experiencing one episode of harsh braking, and one participant experiencing two episodes of harsh braking. Eighty-three percent (n=10) of harsh braking events occurred during the day, 16.7% (n=2) occurred during night time driving, while 41.7% (n=5) occurred while driving during peak hour traffic (Table 4). Eighty-three percent of harsh braking events (n=10) occurred while the participants were travelling on local

roads and 16.7% (n=2) of events occurred while they were driving on a freeway or highway. There was no significant differences between the participants who did and did not record any adverse events in terms of age (p=0.15), gender (p=0.68), binocular contrast sensitivity (p=0.73), binocular visual acuity (p=0.80) and stereopsis (p=0.79).

Table 4. Frequency of harsh braking events.

	n=12	%
Harsh braking events		
Time of the day:		
Day time	10	83.3
Night time	2	16.7
Traffic:		
Peak hour	5	41.7
Non-peak hour	7	58.3
Type of roads:		
Highway/freeway	2	16.7
Local roads	10	83.3

Multivariate Analysis

The results of the multiple linear regression model examining the association between visual measures and the total kilometres travelled in a seven day period are presented in Table 5. Binocular contrast sensitivity (p<0.05) and gender (p<0.05) were the only variables significantly associated with driving exposure (total kilometres travelled) after controlling for potential confounding factors. Neither binocular visual acuity (p=0.89) nor stereopsis (p=0.30) were significantly associated with driving exposure. Participants with better contrast sensitivity scores drove more kilometres than those who had poorer contrast sensitivity scores. More specifically, one log unit increase in contrast sensitivity score was associated with an increase of 163 kilometres per week driven during the seven day study period. Males drove an average of 50 kilometres more per week than females.

Table 5. Factors associated with total kilometres travelled for bilateral cataract patients waiting for first eye surgery (n=96).

Predictor	B	Standard Error	95% CI	<i>p</i> value
Total km travelled				
Age	-2.60	1.65	-5.88 0.68	0.12
Gender: (male)	50.49	21.85	7.05 93.94	0.02*
Number of comorbidities	1.93	3.55	-5.13 9.00	0.59
Living situation: (not alone)	13.43	21.27	-28.86 55.72	0.53
Employment status: (retired)	-18.32	29.91	-77.78 41.14	0.54
Binocular visual acuity	10.15	72.17	-133.32 153.62	0.89
Binocular contrast sensitivity	163.41	74.83	14.66 312.16	0.03*
Stereopsis	-14.52	13.92	-42.19 13.15	0.30
Cognition (MMSE score)	1.52	4.91	-8.23 11.28	0.76

MMSE: Mini-Mental State Examination

**p*<0.05

Discussion

This is one of the first studies to specifically examine the driving exposure, habits and adverse events of older drivers with bilateral cataract, using objective naturalistic driving data as they wait for first eye cataract surgery. Driving is a complex task and cataract can negatively affect aspects of vision such as visual acuity, contrast sensitivity and stereopsis which can have a serious impact on driving ability [8,17]. The results of the study found that older drivers with poorer binocular contrast sensitivity drove significantly fewer kilometres per week prior to first eye cataract surgery, than those with better contrast sensitivity. This is consistent with findings

from the general older driver population [18]; however that research used self-reported driving exposure, which is subject to bias. Visual acuity was not significantly associated with driving exposure in this study and inconsistent findings have been reported on this relationship in the literature [19]. However, this study confirms previous findings that contrast sensitivity may be a more important measure related to a range of driving outcomes than visual acuity among cataract patients [5,8,20].

Gender was significantly associated with driving exposure with males driving more kilometres per week than females. Previous research also found that females report poorer driving confidence, greater driving difficulty and more negative attitudes to driving than males [21,22]. Females are also less likely than males to be the principal driver [22] which may explain the results of our study as 57% of participants were married.

Previous research has consistently found that as drivers age, they report driving fewer kilometres per week [18,23]. This may be due to a variety of reasons which include older drivers having poorer health, mobility issues and being more frail [24]. However, the cohort in our study travelled fewer kilometres in a typical week than reported in previous older driver studies [10,25]. They also appeared to restrict their driving to their local neighbourhood with the mean distance travelled from home being fourteen kilometres. This restriction of driving to the local neighbourhood is consistent with other research among older drivers [26]. Eight participants did not drive at all during the seven day monitoring period while waiting for cataract surgery, due to driving difficulties or suggestions from others to stop or limit their driving. Overall, these findings may be indicative of participants acknowledging their driving limitations due to cataract and reducing their driving exposure. This reduction in travel by cataract participants as they wait for first eye surgery can be viewed as a positive safety response as it reduces their exposure on the road and the possible risk of crash involvement. It is also acknowledged however, that older drivers may participate in fewer activities that require driving due to changes in lifestyle or retirement [27]. Therefore, it should be noted that approximately 80% of participants in this study were retired or unemployed, which may have limited the need for travel by this group and contributed to the results.

Despite the overall low driving exposure observed, 81% of participants in this study still preferred to drive themselves rather than being driven by someone else, almost half of the cohort (n=43) drove at night time and 75 participants drove during peak hour which have been found to be challenging driving situations for older drivers with cataract [4]. This raises concerns about fitness to drive while waiting for cataract surgery. Previous research has found that older drivers with cataracts, despite limiting their driving exposure, have an increased risk for at-fault crashes compared to age-matched controls without cataract [4]. This has also been confirmed in previous research which examined the impact of simulated cataract on driving performance [28,29]. Therefore, ophthalmologists could play an important role in ensuring that cataract patients are provided with adequate information about driving difficulties and risks they may experience due to cataract and how to limit their exposure to these while waiting for cataract surgery. They could then make an informed decision on whether they continue to drive during this period.

Previous research has found that drivers who brake rapidly may be at a greater risk for a crash or a near miss [12]. In particular, a sudden stop has been shown to be associated with rear end crashes [30]. However, only eleven participants in this study recorded at least one episode of harsh braking. This is much lower than previous older driver research which found that 64% of participants were involved in at least one episode over a 12 month period [12]. Further research using a larger sample size over a longer period of time is required to explore this issue further, as the lower number of harsh braking events recorded might be due to monitoring the participants for one week only.

A major strength of this study is that naturalistic driving behaviour was measured using objective in-vehicle monitoring devices in the participants own vehicle. However there are several limitations to this study. The strict inclusion criteria may have impacted on the generalisability of the results. Furthermore, participants' naturalistic driving behaviour was only measured over a period of seven days, which may have limited driving exposure and the number of adverse events that were recorded. However, the choice of a seven day timeframe is consistent with previous naturalistic studies which has found this time frame to be representative of older drivers patterns and habits [9,25,31]. In addition, participants may have modified their driving behaviour while using the devices, due to the fact that their driving behaviour was monitored. A further

limitation is that 14% of participants were excluded from the study, due to missing information related to the devices. It should be noted however there was no significant difference between the two groups in terms of gender and age and visual impairment. Other visual measures such as visual field were also not collected in this study. We also did not collect video footage of driving which would provide more in depth information regarding driving events. Further monitoring of driving exposure over a longer period of time before first eye cataract surgery and a larger sample is warranted. Despite these limitations, this study controlled for a wide range of potential confounding factors when examining the driving patterns, adverse events and exposure of older drivers while waiting for first eye cataract surgery.

Conclusion

The results of this study provide a better understanding of driving exposure, habits and adverse events of bilateral cataract patients while waiting for first eye cataract surgery. It also substantiates previous research that contrast sensitivity is an important visual measure to consider when determining the impact of cataract on driving. Further longitudinal research is required to determine the impact of first and second eye cataract surgery on the objective driving exposure, habits and adverse events of bilateral cataract patients, particularly as information on the impact of second eye cataract surgery on driving outcomes is lacking.

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Chapter 7 Publication 4

Do older drivers with bilateral cataract self-regulate their driving while waiting for first eye cataract surgery?

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Do older drivers with bilateral cataract self-regulate their driving while waiting for first eye cataract surgery?

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Objectives: To analyze the association between visual impairment and driver self-regulation among a cohort of older drivers waiting for first eye cataract surgery.

Methods: Ninety-six drivers with bilateral cataract aged 55+ years were assessed before first eye cataract surgery. Data collection consisted of a researcher-administered questionnaire, objective visual measures (visual acuity, contrast sensitivity and stereopsis), a visual attention test (the useful field of view test) and a cognitive test (the Mini-Mental State Examination). Driver self-regulation practices were collected using the Driving Habits Questionnaire and were also measured with an in-vehicle monitoring device. Characteristics of self-regulators and non-self-regulators were compared and a logistic regression model was used to examine the association between 3 objective visual measures and driver self-regulation status.

Results: After controlling for potential confounding factors, only binocular contrast sensitivity ($p=0.01$), age ($p=0.03$) and gender ($p=0.03$) were significantly associated with driver self-regulation status. The odds of participants with better contrast sensitivity scores (better vision) self-regulating their driving in at least 1 driving situation decreased (odds ratio [OR]: 0.01, 95% CI: 0.00–0.28) while those of increasing age reported an increased odds of self-regulating their driving (OR: 1.08, 95% CI: 1.01–1.15). The odds of males self-regulating their driving was decreased compared with females (OR: 0.28, 95% CI: 0.09–0.86).

Conclusions: Worse binocular contrast sensitivity scores, increasing age and being female were significantly associated with driver self-regulation. The study highlighted that while self-regulation was common among cataract patients, a proportion of those with poor vision did not self-regulate. Further research should determine how cataract patients could benefit from self-regulation strategies while waiting for cataract surgery.

Keywords: driver self-regulation, older drivers, naturalistic data, cataract, contrast sensitivity, driving, visual impairment


Introduction

The aging population¹ has seen an increase in the number of older drivers on Australian roads, with a 44% rise in the number of licensed drivers aged 65+ between 2005 and 2013.² Recent research from the UK also showed that 11% of older drivers aged 65+ purchased a new vehicle and 14% purchased a second-hand vehicle in the last 2 years.³ As private transportation is the preferred mode of travel among the 65+ age group, it is predicted that >95% of people who will be aged 65+ in the next decade, will be active drivers.⁴ Driving contributes to older drivers' quality of life, sense of independence⁵ and social participation,⁶ and driving cessation has been linked to depressive symptoms, mortality and admission to extended care institutions.⁷

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Driver self-regulation refers to the situation in which older drivers modify their driving behaviours and avoid driving in situations that they usually find challenging, to compensate for age-related decline.³ This strategy allows older drivers to remain mobile while reducing their crash risk through lower exposure to difficult driving situations.⁸ Driver self-regulation has also been shown to be associated with gender (females), increasing age, poorer health, cognitive impairment, previous crashes, driving confidence and ability, as well as visual impairment.⁴⁻¹³

Driving is a complex activity that involves many aspects of visual function.¹⁴ Age-related cataract can affect these visual functions, therefore impacting on driving performance and crash risk.¹⁵ Despite an increase in the number of studies examining the self-regulation practices of older drivers in the last decade, only a few studies have analyzed the specific effects of cataract on driver self-regulation practices. One study using self-reported information found that older drivers with cataract were more likely to modify their driving exposure, in terms of the number of days and destinations traveled per week, compared with older drivers without cataract.¹⁶ However, there were no significant differences between groups in terms of kilometers traveled per week.¹⁶ Another study using self-reported information found that 48% of older drivers with bilateral cataract avoided driving in at least 1 challenging situation while waiting for cataract surgery.¹⁷ The most commonly avoided situation was driving at night time (40%), followed by driving on the freeway (12%), in the rain (9%) and parallel parking (8%).¹⁷ This study also examined the association between objective measures of visual impairment and driver self-regulation practices among cataract patients. It found that older drivers who self-regulated had poorer contrast sensitivity (the ability to distinguish between light versus dark contrast) in the worse eye and that visual acuity and stereopsis were not associated with self-regulation.¹⁷ Similarly, other studies examining the general older population also found that contrast sensitivity impairment was associated with driver self-regulation practices,¹⁸⁻²⁰ driving exposure^{18,21} and crash involvement.^{22,23}

It is now possible, due to technological advances, to objectively measure the naturalistic driving behavior of drivers. In-vehicle driver monitoring devices are small electronic devices that can be easily connected to a participant's car in order to collect time-tagged global positioning system (GPS) data that provides a variety of driving information, including speed, location, distance, date of travel and start/stop times of trips. They can also be used to assess driver self-regulation practices.²⁴ These devices have advantages

over self-reported questionnaires or travel diaries as they provide objective measures of driving outcomes²⁵ and participants consider them to be more convenient and practical to use than self-reported travel diaries or questionnaires.²⁶⁻²⁷ In-vehicle monitoring also overcomes the limitations of self-reported information/diaries such as recall bias.²⁸

A growing body of evidence has found a lack of consistency between self-reported questionnaires and naturalistic driving data. For example, while some studies found that older drivers actually self-regulated their driving more than they reported,^{24,29} other studies found they self-regulated less than they reported.³⁰ These findings suggest that using self-reported data from questionnaires alone is not a reliable method.

It is important to better understand whether older adults with cataract self-regulate their driving while waiting for first eye cataract surgery and how this relates to their visual impairment. Therefore, the aim of this study is to examine the association between objective visual measures and self-regulation practices in bilateral cataract patients using a combination of naturalistic driving methods and self-reported data, as they wait for first eye cataract surgery.

Methods

Participants

One hundred and eleven older drivers with bilateral cataract were recruited through 3 public ophthalmology clinics in Western Australia. Participants were recruited through direct contact by the ophthalmologists at the clinic or by an invitation letter. Eligible participants were drivers aged 55+ years, (53% males/47% females) diagnosed with bilateral cataract, who had never had cataract surgery previously and who did not have any other eye comorbidities (eg, macular degeneration, glaucoma, and retinopathy). They were also required to speak and understand English, to drive at least twice-weekly and have no cognitive or physical impairment (eg, dementia, Alzheimer's disease, Parkinson's disease, wheelchair user). Recruitment occurred from December 2014 to February 2017 and the assessments were undertaken in the month prior to first eye cataract surgery. The human research ethics committees of Curtin University and the participating hospitals granted ethics approval, and following the tenets of the Declaration of Helsinki, written informed consent was obtained from each participant before collecting any data.

Data collection

This study is part of a larger study titled "The Cataract Extraction and Driving Ability Research Study – The CEDAR study".²⁰ Participants completed a researcher-administered

questionnaire (the Driving Habits Questionnaire [DHQ]¹⁶) and naturalistic driving data were collected by an in-vehicle monitoring device that was provided to each participant at the assessment. Three objective visual assessments were also administered to all participants. The assessment took place at Curtin University.

Measures

Objective visual measures

Three different objective visual tests were administered to the participants under standard conditions, constant luminance and without mydriasis. Participants wore their habitual correction for visual testing.

Visual acuity (monocular and binocular) was measured using an Early Treatment Diabetic Retinopathy Study¹⁷ acuity chart. The chart was standardized for a 3 m distance, used a letter by letter scoring method and scores were expressed on a logarithm of the minimum angle of resolution (logMAR) scale.

Contrast sensitivity (monocular and binocular) was measured using the Mars Letter Contrast Sensitivity Test,¹² calibrated for a distance of 50 centimeters and scores were expressed in log units.

Stereopsis was assessed with the Titmus Fly Stereotest,¹³ which measures stereopsis from 4,800 to 20 seconds of arc. Scores were expressed as log seconds of arc.

Cognitive assessments

The useful field of view (UFOV) test¹⁴

Visual attention was measured using the UFOV test.¹⁴ This computer-based test is divided into 3 subtests assessing visual processing speed, divided attention and selective attention (Figure 1). It is a valid and reliable predictor of crash risk.¹⁵ In the first subtest (processing speed), participants had to identify a stimuli (either a car or a truck), which was briefly presented in the center of the screen. In the second subtest (divided attention), participants were required to look at 2 different targets at the same time and were requested to determine which target was presented in the center of the

screen (a car or a truck) and then identify on which 1 of the 8 cardinal directions the other target was presented. The third subtest (selective attention) was similar to the second subtest. However, the 8 cardinal directions were surrounded by 47 small triangles, which were distractors. Participants had to use a mouse to select the stimuli. A raw score was calculated for each test based on the duration a participant took to identify correctly the objects presented at an accuracy level of 75%.

Mini-mental state examination (MMSE)

The MMSE¹⁸ was used to assess general cognitive function. It is a screening tool for cognitive impairment and scores range from 0 to 30 with higher scores indicating better cognitive function. The inclusion criterion was a score ≥ 24 on the MMSE, which indicates normal cognitive function.

Driving patterns and self-regulation

Self-reported driving measures

A researcher-administered questionnaire collected general information about participants' socio-demographic characteristics and self-reported measures of driving patterns and self-regulation were collected using the DHQ.¹⁶ This questionnaire has been previously validated among a population of older drivers with bilateral cataract in Western Australia.¹⁷ Information collected included participants' driving exposure, driving difficulty and avoidance, driving dependence and previous crashes. The driving difficulty and avoidance part of the questionnaire was used to collect information about participants' self-regulation practices in 8 specific situations: "driving in the rain", "driving alone", "parallel parking", "turning across oncoming traffic", "driving on highways/freeways", "on heavy traffic roads", "in peak hour traffic" and "at night time".

Only 4 of these driving situations obtained from the self-reported DHQ could be directly compared with the information obtained from the in-vehicle monitoring device. These 4 situations were used to classify participants as either



Figure 1 The useful field of view test, which includes assessing processing speed (A); divided attention (B) and selective attention (C).



Figure 2 In-vehicle driver monitoring device.

self-regulating or non-self-regulating their driving in each of the driving situations. These situations included “driving on highways/freeways”, “on heavy traffic roads”, “in peak hour traffic” and “at night time”.

Naturalistic driving measures

All participants were provided with an in-vehicle monitoring device (Geotab GO6™, Oakville, Canada). (Figure 2).

Participants were asked to use it for a period of 7 days and to drive as they normally would. They were also instructed to only use it when they were the driver of the vehicle and were asked to move the device from one vehicle to another when using multiple vehicles or remove it if they were not the driver of the vehicle for that specific trip. The devices were manually connected to the On Board Diagnostic II port for

vehicles manufactured from 2006 or the cigarette lighter for vehicles manufactured prior to 2006 (Figure 3). Participants were also provided with a travel diary that they were asked to complete after each trip. The following information was collected: date, start and finish time of a trip, kilometers traveled, age and position of the passengers (whether they sat in the front seat or the back passenger seat), make, model and year of the vehicle driven, and purpose of the trip. The diary was also used to validate that they had been the driver of the motor vehicle.

Participants were instructed to return the travel diary and the in-vehicle monitoring device at the end of the 7-day period in a pre-paid envelope. Participants were then interviewed to verify that there were no issues while using the device and that they were the only driver of the vehicle while using the device. The data from the devices was then read by Fleet management Software (MyGeotab, Oakville, Canada) and uploaded by the researchers to a secure server at the University. The data was cleaned in order to exclude trips made from the University, as they were not part of the participants’ typical driving behavior. Trips that lasted fewer than 10 seconds or 200 meters were also excluded in order to avoid “false trips”. The devices collected a variety of time stamped second-by-second GPS data, such as date of travel, location, type of roads used, start/stop times of trips, and distance traveled. Night time was defined as the period between sunset and sunrise. Peak hour was defined as driving between 6 and 9 am or between 4 and 7 pm, Monday to Friday. Each of the routes driven by participants were represented on an interactive map provided by Geotab, which identified whether participants drove on highways/freeways and/or heavy traffic roads. Heavy traffic roads were defined as roads where there were >4,000 vehicles per day per lane³⁸ (Figure 4).



Figure 3 In-vehicle driver monitoring device inserted either into the On Board Diagnostic II (OBD II) port of the vehicle (A) or the cigarette lighter (B).

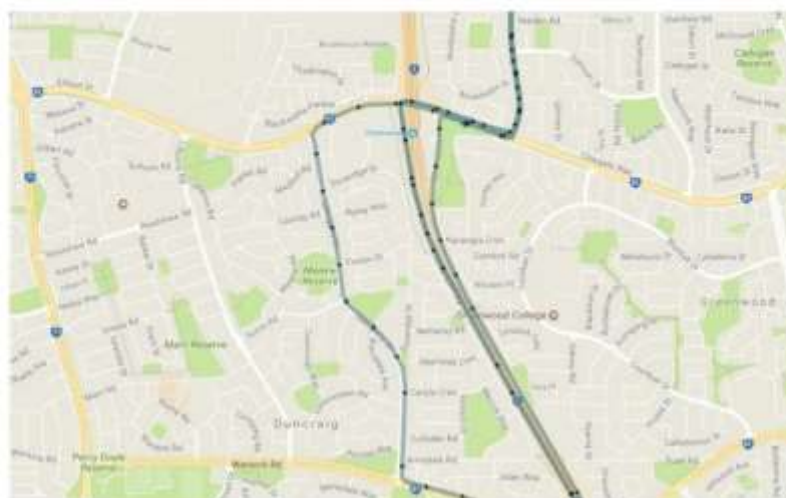


Figure 4 A 59-year-old female participant who drove on the freeway and did not self-regulate her driving.
 Note: Map downloaded from MyGeotab, Geotab, Calverville, Canada <https://securatrak.geotab.com>

Classification criteria for driver self-regulation

Each of the 4 challenging driving situations obtained from the DHQ and the in-vehicle monitoring devices were examined separately. For example: if a participant responded that they had not driven during peak hour traffic in the DHQ and this was confirmed by the data obtained from the in-vehicle monitoring device, then the participant was classified as a self-regulator for peak hour driving. Otherwise, they were considered to be a non-self-regulator for peak hour driving. This same procedure was undertaken for all 4 challenging driving situations. Finally, all 4 driving situations were examined for each participant. Participants were classified as a self-regulator if they had self-regulated their driving on at least 1 of the challenging driving situations.

Statistical analysis

Descriptive statistics were used to summarize the socio-demographic, visual characteristics and driving patterns of the cohort. Independent sample *t*-tests and chi-squared tests were initially used to compare the 2 groups. Cohen's kappa coefficient was used to measure the relative agreement between the information obtained from the self-reported DHQ and the in-vehicle monitoring devices. A multivariate logistic regression model was then undertaken to analyze the association between driver self-regulation status and the 3 objective measures of vision (binocular visual acuity,

binocular contrast sensitivity and stereopsis). The main outcome of interest was driver self-regulation status (did not drive in 1 or more driving situations due to vision: yes or no). The 3 objective measures of vision (binocular visual acuity, binocular contrast sensitivity and stereopsis) were entered as explanatory variables in the model, as well as age, gender, marital status, comorbidities, and the scores obtained from the MMSE. These variables were chosen as they have shown to be associated with driver self-regulation in the literature.¹⁰⁻¹⁷ Only the divided attention subtest was entered in the model as an explanatory variable due to multicollinearity among the 3 subtests of the UFOV.¹⁸ This subtest was selected as it was the strongest predictor of crash involvement among all subtests of the UFOV in previous research.¹⁹ The 3 measures of vision, the MMSE scores and the divided attention subtest were entered as continuous variables. Gender and marital status (single/de-facto or married) were entered as categorical variables in the model. All statistical analyses were performed with IBM SPSS Statistics 22.0 (SPSS Inc., Chicago, IL, USA).

Results

The final sample consisted of 96 participants. Fifteen of the 111 participants were excluded from the analysis due to poor data integrity from the in-vehicle monitoring device caused by faulty cigarette lighters and the loss of the monitoring devices. There was no significant difference between those

who undertook the in-vehicle monitoring and those who did not in terms of age ($p=0.45$), gender ($p=0.77$), contrast sensitivity ($p=0.74$), visual acuity ($p=0.65$) and stereopsis ($p=0.62$).

Table 1 compares the characteristics of the drivers classified as self-regulators ($n=39$, 40.6%) and non-self-regulators ($n=57$, 59.4%). Self-regulators were older than non-self-regulators with an average age of 75.7 years (SD =8.9) and 71.9 years (SD =8.2), respectively ($p<0.05$). There were no significant differences between the 2 groups for any other socio-demographic characteristics. Fifty-six percent of self-regulators and 42.1% of non-self-regulators were female. For self-regulators, 46.2% were married/de-facto and

48.7% did not live alone and for non-self-regulators, 64.9% were married/de-facto and did not live alone. In addition, the majority of self-regulators (51.3%) and non-self-regulators (66.7%) had completed higher education. Self-regulators were also very similar to non-self-regulators in terms of years of driving experience (51.7 years [SD =13.4] and 51.1 years [SD =8.3], respectively), MMSE scores (27.9 [SD =2.0] and 27.6 [SD =2.2], respectively), number of co-morbidities (5.1 [SD =3.0] and 5.6 [SD =2.8], respectively), and number of medications taken (3.7 [SD =3.2] and 3.2 [SD =2.8], respectively). Co-morbidities included respiratory, musculoskeletal, endocrine and circulatory conditions. While self-regulators scored worse than non-self-regulators on the divided attention subtest of the UFOV (123.4 [SD =151.3] and 76.6 [SD =98.2], respectively), this difference was not significant.

According to the information obtained from the in-vehicle monitoring devices, participants who were classified as self-regulators drove fewer days, less kilometers and made fewer trips per week than non-self-regulators ($p<0.001$). The duration of trips and the maximum excursion radius from home for the non-self-regulators were also longer than for the self-regulators ($p<0.001$) (Table 1).

Drivers who were classified as self-regulators had worse binocular contrast sensitivity scores, seeing approximately 2 letters less than drivers who were classified as non-self-regulators ($p<0.05$). There were no significant differences between the 2 groups in any of the other visual measures that included visual acuity and stereopsis (Table 2).

Overall, 11.5% of participants ($n=11$) did not meet Australian visual acuity standards for driving.⁴⁴ These 11 participants had a visual acuity poorer than 6/12 (0.30 logMAR) when

Table 1 Characteristics of older drivers with bilateral cataract by self-regulation status ($n=96$)

Characteristics	Self-regulators (n=39)	Non-self-regulators (n=57)	p-value
Age, mean (SD) ^a	75.67 (8.89)	71.87 (8.16)	0.03 ^b
Gender, n (%)			
Female	22 (56.41)	24 (42.11)	0.24
Male	17 (43.59)	33 (57.89)	
Marital status, n (%)			
Single/separated/divorced/widowed	21 (53.85)	20 (35.09)	0.11
De facto/married	18 (46.15)	37 (64.91)	
Living arrangements, n (%)			
Alone	20 (51.28)	20 (35.09)	0.17
Not alone	19 (48.72)	37 (64.91)	
Level of education, n (%)			
Primary or secondary school	19 (48.72)	19 (33.33)	0.19
Higher education	20 (51.28)	38 (66.67)	
Driving experience (years), mean (SD)	51.67 (13.41)	51.14 (8.25)	0.82
Number of comorbidities, mean (SD)	5.13 (2.98)	5.61 (2.75)	0.41
Number of medications taken, mean (SD)	3.71 (3.22)	3.24 (2.80)	0.46
Cognitive function (MMSE), mean (SD)	27.92 (1.95)	27.61 (2.16)	0.48
UFOV, mean (SD)			
Processing speed (ms)	30.51 (39.62)	29.39 (48.29)	0.91
Divided attention (ms)	123.44 (151.25)	76.64 (98.16)	0.09
Selective attention (ms)	194.81 (127.98)	174.40 (100.44)	0.39
Overall driving per week, mean (SD)			
Number of trips	9.77 (9.78)	19.53 (9.12)	<0.001 ^a
Kilometers traveled	50.55 (59.00)	160.39 (96.26)	<0.001 ^a
Number of days driven	3.15 (2.15)	5.25 (1.50)	<0.001 ^a
Driving duration (minutes)	90.72 (107.48)	252.05 (138.11)	<0.001 ^a
Maximum excursion radius from home (km)	7.35 (7.34)	18.65 (12.22)	<0.001 ^a

Note: ^aSignificant at $p<0.05$.

Abbreviations: MMSE, mini-mental state examination; UFOV, useful field of view.

Table 2 Visual characteristics of older drivers with bilateral cataract by self-regulation status ($n=96$)

Visual tests	Self-regulators (n=39)		Non-self-regulators (n=57)		p-values
	Mean	SD	Mean	SD	
Visual acuity (logMAR)					
Better eye	0.18	0.17	0.19	0.14	0.92
Worst eye	0.45	0.31	0.42	0.27	0.62
Binocular	0.15	0.18	0.14	0.14	0.76
Log contrast sensitivity					
Better eye	1.54	0.15	1.59	0.16	0.12
Worst eye	1.30	0.39	1.41	0.30	0.13
Binocular	1.61	0.16	1.68	1.40	0.03 ^a
Stereopsis (log seconds of arc)					
Binocular	2.47	0.78	2.22	0.67	0.10

Note: ^aSignificant at $p<0.05$.

Abbreviations: log, logarithm; logMAR, logarithm of the minimum angle of resolution.

measured with each eye alone and with both eyes together (with the aid of spectacles or lenses if needed). More specifically, among the 39 participants classified as self-regulators, 15.4% of participants did not meet Australian visual acuity standards for driving ($n=6$). However, among the 57 older drivers classified as non-self-regulators, 8.8% of participants ($n=5$) did not meet Australian visual acuity standards for driving.

Forty-one percent of the cohort ($n=39$) were classified as self-regulators since they self-regulated their driving on at least one of the four challenging driving situations as confirmed by the DHQ and driver monitoring device. For each of the four situations specifically, 31.3% ($n=30$) of participants self-regulated their driving at night, 10.4% ($n=10$) did not drive in peak hour traffic, 9.4% ($n=9$) did not drive on heavy traffic roads, and 8.3% ($n=8$) avoided freeway/highway driving. Overall, 25.0% ($n=24$) of participants self-regulated their driving on 1 challenging driving situation only, 12.5% ($n=12$) on 2 driving situations, 1.0% ($n=1$) on 3 driving situations, and 2.0% ($n=2$) self-regulated on all 4 driving situations.

When comparing the agreement between the DHQ self-reported information and the in-vehicle monitoring device data for each of the challenging driving situations there was minimal agreement for peak hour driving (Kappa 0.17, $p=0.09$), driving on the freeway/highway (Kappa 0.07, $p=0.30$), and driving on heavy traffic roads (Kappa 0.13, $p=0.16$). However, for night time driving, there was agreement between the self-reported DHQ and the in-vehicle monitoring device (Kappa 0.30, $p<0.001$).

Multivariate analysis

Table 3 presents the results of the multivariate logistic regression model analyzing the association between visual measures and self-regulation status. The model explained 30.90% of the variance (R^2). After controlling for potential confounding factors, only binocular contrast sensitivity ($p=0.01$), age ($p=0.03$) and gender ($p=0.03$) were significantly associated with driver self-regulation status. The odds of participants with better contrast sensitivity scores (better vision) self-regulating their driving in at least 1 driving situation decreased (odds ratio [OR]: 0.01, 95% CI: 0.00–0.28) while those of increasing age reported an increased odds of self-regulating their driving (OR: 1.08, 95% CI: 1.01–1.15). The odds of males self-regulating their driving was decreased compared with females (OR: 0.28, 95% CI: 0.09–0.86). Neither binocular visual acuity ($p=0.270$), nor stereopsis ($p=0.135$) were significantly associated with self-regulation status.

Table 3 Results of multivariate logistic regression model for driver self-regulation status ($n=96$)

Variable	Adjusted odds ratio	Standard error	95% CI	p-value
Age (years)	1.08	0.03	1.01 1.15	0.03*
Gender, male	0.28	0.58	0.09 0.86	0.03*
Marital status, de facto/married	0.48	0.54	0.17 1.36	0.17
Number of comorbidities	0.87	0.09	0.73 1.04	0.12
Binocular visual acuity (logMAR)	0.15	1.74	0.01 4.45	0.27
Binocular contrast sensitivity (log units)	0.01	1.98	0.00 0.28	0.01*
Stereopsis (log seconds of arc)	1.69	0.35	0.85 3.35	0.14
Cognitive function (MMSE score)	1.14	0.14	0.87 1.50	0.33
UFOV, divided attention score (ms)	1.00	0.00	1.00 1.01	0.50

Note: *Significant at $p<0.05$.

Abbreviations: log, logarithm; logMAR, logarithm of the minimum angle resolution; MMSE, mini-mental state examination; UFOV, useful field of view.

Discussion

This is one of the first studies to specifically examine whether older drivers with cataract self-regulate their driving while waiting for first eye surgery using a combination of naturalistic driving data and self-reported information from the DHQ. The study found that 40.60% of participants were classified as self-regulating their driving prior to first eye cataract surgery in at least 1 challenging driving situation. This is consistent with Fraser et al¹⁷ who found that 47.5% of older drivers with bilateral cataract waiting for cataract surgery in Western Australia were also classified as self-regulators. While that study also used the DHQ and a comparable definition of self-regulation, it relied on self-reported information only to assess self-regulation practices, which may be subject to recall and social desirability bias.

Our study also found that older drivers aged 55+ years with worse binocular contrast sensitivity scores were more likely to self-regulate their driving than those who had better contrast sensitivity scores. This finding is consistent with previous research among cataract patients, which found that there was a significant difference in worse eye contrast sensitivity scores between self-regulators and non-self-regulators.¹⁷ Similarly, other studies among the general population of older drivers, also found an association between contrast sensitivity impairment and self-regulation practices.^{18,19} Contrast sensitivity is important for driving as many objects on the road are represented in low contrast²¹ and contrast sensitivity is frequently impaired among people

with cataract.¹⁴ No significant association between visual acuity and driver self-regulation was found, which is consistent with previous research.¹⁷ This is of importance for road safety policy makers and licensing authorities who mainly rely on visual acuity for assessing fitness to drive, despite the significance of contrast sensitivity being highlighted in a large body of research.^{17,20,21,22,42} As the population is aging,¹ there will be an increased number of older drivers on the roads. It is therefore a priority to investigate how licensing authorities could benefit from using additional measures of vision, such as contrast sensitivity tests to improve road safety.

In this study, the likelihood of self-regulating was associated with increasing age. This is consistent with previous research using self-report methods, which showed that older age was associated with driving less kilometers.¹¹ This may be due to lower mobility, frailty, poor health⁴³ and lower levels of function⁴⁴ associated with aging.

Females were also more likely to self-regulate their driving than males, which is consistent with previous research.^{3,11,45,46} This may be explained by the fact that men report more confidence in their driving abilities, find driving more enjoyable and important to them⁴⁷ and have less driving difficulties than women.¹¹

A strength of the study was the large sample size ($n=96$) compared with similar studies^{3,4,25} as well as the use of a combination of naturalistic and self-reported data in order to gain an accurate picture of driver self-regulation due to cataract. Naturalistic driving data provide valid information on driving outcomes,²⁵ which can be of higher quality and accuracy than self-reported data.⁴⁷ For example, 9 participants did not drive at all in any of the challenging driving situations according to the naturalistic data, but the self-reported data revealed that only 3 people reported that they were deliberately self-regulating in all driving situations. It was also not possible to determine, using naturalistic data alone, whether participants deliberately self-regulated their driving in a particular situation or they simply have no need or desire to drive. While naturalistic information may be superior to self-report in terms of objective measurement of variables such as driving exposure, it does not provide contextual information about the driving situation itself. This study demonstrated that to better understand the context of driver self-regulation, there may be a role for self-report information, particularly when used in conjunction with objective naturalistic data.

There were limitations to this study. Participants consisted of a convenience sample who volunteered for the study. In addition, it is possible that some participants with poorer vision did not wish to take part in the study, fearing

that their drivers license might be suspended. The definition of "self-regulator" in this study was based on only 4 challenging driving situations in the DHQ as it was not possible to determine whether participants avoided situations such as driving alone or in the rain from the naturalistic data. Therefore, the results of the study may have underestimated the true number of people who self-regulate their driving while waiting for first eye cataract surgery. Future research should include a wider range of challenging situations that are known to be problematic for older drivers such as intersections⁴⁵ and long-distance driving,⁵ which can be obtained from in-vehicle monitoring devices. Furthermore, participants' driving exposure was measured over a period of 7 days, which might not be representative of their usual driving patterns, due to specific circumstances such as health issues or environmental conditions such as the weather.⁴⁸ However, other naturalistic studies have used a 7-day time period, which is the same as our study.^{24,26,28}

Overall, this study highlighted that 40.6% of bilateral cataract patients awaiting cataract surgery self-regulated their driving in at least 1 challenging driving situation and that this self-regulation was associated with poorer vision (contrast sensitivity). While this is promising, nearly 10% of those who did not meet the minimum visual standards for driving in Western Australia, did not self-regulate their driving. This suggests that while self-regulation is common among cataract patients, a proportion with poor vision do not self-regulate. Therefore, promoting the use of self-regulation strategies could be a way to enhance road safety among older drivers while they are waiting for cataract surgery.

Conclusion

This study found that worse binocular contrast sensitivity scores, increasing age and being female were significantly associated with driver self-regulation among bilateral cataract patients awaiting first eye surgery. It also highlighted that while driver self-regulation was common, a proportion of those with poor vision did not self-regulate. Further research should determine how cataract patients could benefit from educational intervention programs promoting the use of self-regulation strategies while waiting for cataract surgery.

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Disclosure

The authors report no conflicts of interest in this work.

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Chapter 8 Publication 5

First and second eye cataract surgery and driver self-regulation among older drivers with bilateral cataract: a prospective cohort study

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First and second eye cataract surgery and driver self-regulation among older drivers with bilateral cataract: a prospective cohort study

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ABSTRACT

Background: Driving a car is the most common form of transport among the older population. Common medical conditions such as cataract, increase with age and impact on the ability to drive. To compensate for visual decline, some cataract patients may self-regulate their driving while waiting for cataract surgery. However, little is known about the self-regulation practices of older drivers throughout the cataract surgery process. The aim of this study is to assess the impact of first and second eye cataract surgery on driver self-regulation practices, and to determine which objective measures of vision are associated with driver self-regulation.

Methods: Fifty-five older drivers with bilateral cataract aged 55+ years were assessed using the self-reported Driving Habits Questionnaire, the Mini-Mental State Examination and three objective visual measures in the month before cataract surgery, at least one to three months after first eye cataract surgery and at least one month after second eye cataract surgery. Participants' natural driving behaviour in four driving situations was also examined for one week using an in-vehicle monitoring device. Two separate Generalised Estimating Equation logistic models were undertaken to assess the impact of first and second eye cataract surgery on driver-self-regulation status and which changes in visual measures were associated with driver self-regulation status.

Results: The odds of being a self-regulator in at least one driving situation significantly decreased by 70% after first eye cataract surgery (OR: 0.3, 95% CI: 0.1 - 0.7) and by 90% after second eye surgery (OR: 0.1, 95% CI: 0.1 - 0.4), compared to before first eye surgery. Improvement in contrast sensitivity after cataract surgery was significantly associated with decreased odds of self-regulation (OR: 0.02, 95% CI: 0.01 - 0.4).

Conclusions: The findings provide a strong rationale for providing timely first and second eye cataract surgery for older drivers with bilateral cataract, in order to improve their mobility and independence.

Key words: older drivers, bilateral cataract, cataract surgery, self-regulation, contrast sensitivity

BACKGROUND

Globally, driving a car is the most common form of transport among the older population in developed countries [1,2] and plays an important role in their lifestyle [3]. Driving cessation has been associated with poorer physical, social and cognitive function as well as depression [4]. As adults are living longer and healthier lives [5] the number of older drivers on the roads will increase, which will have a significant impact on-road safety [6].

Cataract is a common medical condition which increases with age and impacts on the ability to drive, increasing crash risk as well as driving difficulties [7,8,9]. To compensate for visual decline, previous research has found that some patients with cataract may self-regulate their driving while waiting for cataract surgery [10,11]. Self-regulation refers to an older driver adjusting their driving in response to a perceived deterioration in their health, cognitive or functional abilities [12] which may result in a reduction in their driving or avoidance of specific driving situations [12,13].

Surgery is a highly effective treatment for cataract. However bilateral cataract surgery is usually performed one eye at a time to avoid complications, such as endophthalmitis [14]. This means patients may be driving during the period between first and second eye surgery. To date, there is limited information about the impact of cataract surgery on driver self-regulation practices, specifically the separate effects of first and second eye surgery for bilateral cataract patients. While it is likely that first eye cataract surgery reduces the need for driver self-regulation it is unknown whether second eye surgery provides any additional benefits. As well, previous research has suggested that poor contrast sensitivity is strongly associated with driver self-regulation among the general older population [15,16,17,18,19]. It would therefore be useful to determine whether improvement in contrast sensitivity or other visual measures after first and second eye cataract surgery is associated with a reduction in driver self-regulation.

Naturalistic driving studies using in-vehicle monitoring devices can provide objective and accurate measures of driver self-regulation practices [20] and are able to capture participants' real life driving behaviour. A growing body of evidence comparing self-reported driving behaviour and naturalistic driving data has found that older drivers often misjudge their kilometres travelled, days driven per week as well as frequency

of driving in challenging situations such as at night, in bad weather, in peak hour traffic and on highways [20,21]. Therefore it is recommended that these devices be used to monitor driving outcomes rather than self-reported questionnaires alone [22]. To date, no study has used naturalistic driving data to examine changes in driver self-regulation behaviour throughout the cataract surgery process.

Therefore, the aim of this study is to assess the separate impact of first and second eye cataract surgery on driver self-regulation status, for bilateral cataract patients. A secondary aim of the study is to determine which changes in objective measures of vision are associated with changes in driver self-regulation status throughout the cataract surgery process.

METHODS

Study Design

A longitudinal prospective cohort study of older drivers with bilateral cataract was undertaken as part of the larger Cataract Extraction Driving Ability Research Study (CEDAR Study) [23]. A convenience sample of eligible participants were recruited consecutively from three public hospitals in Western Australia through two methods: direct invitation from ophthalmologists during their visit to the eye clinic or invitation letter from the researcher. From 290 eligible patients invited to take part in the study, 111 participated (38%) and 55 of these completed all three assessments.

Eligibility criteria

The inclusion criteria were: a diagnosis of bilateral cataract; aged 55+ years; a current Western Australian driver's licence; and driving at least twice a week. Exclusion criteria for participants were: a diagnosis of any significant eye conditions such as macular degeneration, glaucoma or diabetic retinopathy; a diagnosis of dementia, Alzheimer's or Parkinson's disease; wheelchair-bound; did not speak English or had previous cataract surgery.

Data collection

Eligible participants were recruited between December 2014 and February 2017. Information was collected at three time points for the participants: in the month before first eye surgery, at least one to three months after first eye surgery and at least one month after second eye surgery. Participants received a Participant Information Sheet and provided written informed consent before any data were collected, following the tenets of the Declaration of Helsinki. Ethics approval was obtained from the Curtin University Human Research Ethics Committee (Curtin University HR 29/2014), the Royal Perth Hospital Human Research Ethics Committee (Royal Perth #14-033), the South Metropolitan Health Service Human Research Ethics Committee (Fremantle Hospital #14-033), and the Sir Charles Gairdner Group Human Research Ethics Committee (Sir Charles Gairdner Hospital #2014-113).

Questionnaires

Participants' demographic characteristics were collected. As well, the Driving Habits Questionnaire (DHQ) [10] collected information on participants' self-reported driving patterns, exposure and self-regulation practices in eight driving situations at the three assessments. The DHQ has been previously validated for use among a population of older drivers with bilateral cataract in Western Australia [24].

Mini-Mental State Examination (MMSE)

General cognitive function was assessed using the Mini-Mental State Examination (MMSE) at the three assessments [25]. The inclusion criterion stipulated a score of at least 24 indicating normal cognitive function.

Objective visual measures

Visual acuity, contrast sensitivity and stereopsis were assessed at the three time points by the researcher under the guidance of an ophthalmologist. A standardised protocol was followed under constant conditions and luminance. Participants wore their habitual corrective lenses or glasses used for driving for visual testing. Monocular and binocular visual acuity were measured at a distance of three metres using an Early Treatment Diabetic Retinopathy Study (ETDRS) acuity chart [26]. Letter by letter scoring was used and scores were converted to the logarithm of the minimum angle resolution (logMAR). Monocular and binocular contrast sensitivity were measured at

50 centimetres using the Mars Letter Contrast Sensitivity Test [27]. Scores were expressed as log units and participants were encouraged to guess the letters if hesitating, as directed by the protocol. Stereopsis was measured using the Titmus Fly Stereotest (Good-Lite Co., Inc.), measuring disparity from 4800 to 20 seconds of arc.

In-vehicle monitoring device

A Geotab G06™ in-vehicle monitoring device with GPS log receiver was provided to the participants at the three assessments to record their naturalistic driving patterns for a period of seven days. The devices were connected either to the cigarette lighter for vehicles manufactured before 2006 or the On Board Diagnostic II (OBD II) port for vehicles manufactured after January 2006. The device can be easily inserted and removed and this was demonstrated to the participants. They were asked to disconnect the device if someone else drove the vehicle and move the device to any other vehicle they drove during the study period. Participants were also provided with a travel diary which was used to validate whether the participant was the driver of the vehicle for each trip. They were instructed to fill in the diary as soon as possible after the completion of each trip so their recall was accurate. Information collected included the type of vehicle driven, the number, age and position of passengers, purpose of the trip, date, start and finish time, odometer readings, trip duration and distance travelled. If they were unable to or forgot to disconnect the device when another person drove the vehicle, they were also asked to record this in the travel diary. After returning the device, each participant was interviewed to clarify any data issues, check their use of multiple vehicles and confirm whether there had been any other drivers of the vehicle while the device was connected.

The objective data obtained from the in-vehicle monitoring device included driving exposure, time and date of travel, speed, type of road and location. Night time driving was defined as the period between sunset and sunrise as obtained from the Australian Government Bureau of Meteorology website [28]; peak hour driving was from six to nine am and/or four to seven pm from Monday to Friday. Roads where there were more than 4000 vehicles per day per lane were defined as “heavy traffic roads” [29]. This information was obtained from Main Roads WA which is the State Government agency responsible for the road network in WA. To determine whether participants

drove on highways/freeways, the researcher examined an interactive map provided by Geotab© which detailed each trip made by the participant.

Classification criteria for driver self-regulation practices

Four driving situations were obtained from the self-reported DHQ which could be directly compared to the information obtained from the in-vehicle monitoring device. These four situations were used to classify participants as either self-regulating or non-self-regulating their driving in each situation. These situations included “*driving on highways/freeways*”, “*on heavy traffic roads*”, “*in peak hour traffic*”, and “*night time driving*”. Initially, each of the four driving situations were examined separately to determine if participants’ self-regulated their driving in that situation. For example, participants were considered to have self-regulated their driving if they responded that they had not driven at night time based on information from the DHQ and the data from the in-vehicle monitoring device confirmed the same behaviour. Then all four driving situations were examined together and participants were classified as a “self-regulator” if they self-regulated their driving behaviour in at least one of the four driving situations. Otherwise, they were considered to be a “non self-regulator”.

Statistical analysis

Descriptive statistics were used to describe the characteristics of the cohort. Repeated measures of analysis of variance (ANOVA) were used to assess the changes in the objective measures of vision. Cochran’s Q Tests were used to analyse the changes in driver self-regulation status in the four driving situations.

The outcome of interest was driver self-regulation status (self-regulator/ non self-regulator). Two separate Generalised Estimating Equation (GEE) logistic models were undertaken. The GEE method is suitable for longitudinal or repeated measures study designs where observations within each participant are not independent [30]. GEEs permit specification of a certain working correlation matrix that accounts for this within-subject correlation, thus providing more robust regression coefficients. The first GEE logistic model analysed whether there was a significant change in self-regulation status after first and second eye cataract surgery, while controlling for potential confounding factors. The visual measures were not included in this model because vision changed as a result of the surgery.

The second model was undertaken to examine which changes in the three visual measures were associated with changes in driver self-regulation status. Potential confounding factors such as cognitive status (MMSE score), age group (55-64/ 65-74/ 75+ years), gender (female/male), marital status (single/ married or de facto), retirement status (not retired/ retired), and the number of comorbidities were entered in both models. All statistical analyses were performed using STATA 15®.

RESULTS

Fifty-five participants completed all three assessments resulting in 165 observations. Table 1 presents the baseline demographic characteristics of the cohort before first eye cataract surgery. Participants' mean age was 73.3 years (SD =7.8) with 43.6% aged 75 years or older. The majority of participants were female (54.5%), married or in a de facto relationship (61.8%), had completed a higher education degree (58.2%), lived with another person (54.5%) and were retired (76.4%). The mean score of 27.6 (SD=2.2) on the MMSE indicated normal cognitive function. Participants also reported an average of 5.3 medical conditions (SD=2.5) and an average of 50.9 years (SD=9.5) driving experience at baseline.

Table 1. Baseline demographic characteristics of older drivers with bilateral cataract (n=55)

Variable	n (%)
Age: mean (SD)	73.3 (7.8)
Age group (years)	
55-64	10 (18.2%)
65-74	21 (38.2%)
75+	24 (43.6%)
Country of birth	
Australia	21 (38.2%)
Not Australia	34 (61.8%)
Gender	
Female	30 (54.5%)
Male	25 (45.5%)
Marital status	
Single/separated/divorced/widowed	21 (38.2%)
De facto/married	34 (61.8%)
Retirement status	
Not retired	13 (23.6%)
Retired	42 (76.4%)
Living arrangements	
Alone	25 (45.5%)
Not alone	30 (54.5%)
Level of education:	
Primary or Secondary School	23 (41.8%)
Higher Education	32 (58.2%)
Driving experience (years): mean (SD)	50.9 (9.5)
Number of comorbidities: mean (SD)	5.3 (2.5)
MMSE score: mean (SD)	27.6 (2.2)

MMSE: Mini-Mental State Examination; SD= standard deviation

Participants' visual characteristics are presented in Table 2.

Table 2. Mean visual characteristics of older drivers before, after first and second eye cataract surgery (n=55)

Variable	Before surgery Mean (SD)	After first eye surgery Mean (SD)	After second eye surgery Mean (SD)	P value
Visual acuity (logMAR)^a				
Better eye	0.18 (0.15)	0.10 (0.22)	-0.00 (0.19)	<0.001
Worse eye	0.39 (0.24)	0.36 (0.26)	0.11 (0.19)	<0.001
Binocular	0.15 (0.15)	0.08 (0.21)	-0.02 (0.19)	<0.001
Log contrast sensitivity (log units)^b				
Better eye	1.57 (0.14)	1.62 (0.28)	1.68 (0.11)	<0.001
Worse eye	1.41 (0.29)	1.47 (0.27)	1.61 (0.13)	<0.001
Binocular	1.64 (0.14)	1.67 (0.25)	1.75 (0.08)	<0.001
Stereopsis (log seconds of arc)^a				
Binocular	2.14 (0.64)	2.31 (0.72)	1.96 (0.60)	0.002

^a Lower scores represent better vision ^b Higher scores represent better vision log= logarithm; logMAR= logarithm of the Minimal Angle of Resolution; SD= standard deviation

Mean binocular visual acuity significantly improved from 0.15 logMAR (SD=0.15) at baseline, to 0.08 logMAR (SD=0.21) after first eye surgery and -0.02 logMAR (SD=0.19) after second eye surgery (p<0.001).

Binocular contrast sensitivity significantly improved (p<0.001) from 1.64 log units (SD=0.14) before first eye cataract surgery, to 1.67 log units (SD=0.25) after first eye cataract surgery and 1.75 log units (SD=0.08) after second eye cataract surgery.

A significant change (p=0.002) in stereopsis was found with stereopsis measuring 2.14 log seconds of arc (SD=0.64) at baseline; worsening to 2.31 log seconds of arc (SD=0.72) after first eye cataract surgery and improving to 1.96 log seconds of arc (SD=0.60) after second eye surgery.

Situations in which drivers self-regulated

Before first eye surgery, 47.3% of participants were classified as self-regulators in at least one driving situation. This reduced to 29.1% after first eye surgery and 18.2%

after second eye surgery. In terms of the specific driving situations avoided, before first eye surgery, 12.5% of participants did not drive on heavy traffic roads, while only 8.3% and 2.1% did not drive in this situation after first and second eye cataract surgery respectively, representing a significant change ($p=0.020$). Before first eye surgery, 37.0% of participants did not drive at night which decreased to 21.7% after first and 10.9% after second eye cataract surgery, which was significant ($p=0.002$). There was no significant change in driver self-regulation status for driving during peak hour traffic ($p=0.100$) and freeway/ highway driving ($p=0.900$).

Multivariate analysis

The results of the logistic Generalised Estimating Equation (GEE) model examining changes in self-regulation status after first and second eye cataract surgery are presented in Table 3. The odds of being a self-regulator in at least one driving situation significantly decreased by 70% after first eye cataract surgery (OR: 0.3, 95% CI: 0.1 - 0.7) and by 90% after second eye surgery (OR: 0.1, 95% CI: 0.1 - 0.4), compared to before first eye cataract surgery, after adjusting for potential confounders. The odds of males self-regulating significantly decreased by 60% compared to females (OR: 0.4, 95% CI: 0.1 – 1.3). In addition, retired participants had 5.6 times the odds of self-regulating, compared to those who were employed (OR: 5.6, 95% CI: 1.1 - 27.7).

Table 3. GEE Logistic Model of the impact of first and second eye cataract surgery on self-regulation status

Variable	Odds Ratio	95% CI	P value
Cataract surgery			
Before first eye surgery	1.0		
After first eye surgery	0.3	0.1-0.7	0.004
After second eye surgery	0.1	0.1-0.4	<0.001
Gender			
Female	1.0		
Male	0.4	0.1-1.3	0.122
Age group (years)			
55-64	1.0		
65-74	0.1	0.1-1.2	0.072
75+	0.7	0.6-8.0	0.737
Marital status			
Single	1.0		
Married/de facto	0.3	0.1-1.2	0.096
Retirement status			
Not retired	1.0		
Retired	5.6	1.1-27.7	0.036
Number of comorbidities	1.1	0.9-1.4	0.257
MMSE score	1.0	0.9-1.2	0.803

CI= confidence interval; GEE= Generalised Estimating Equation; log= logarithm; logMAR= logarithm of the Minimal Angle of Resolution; MMSE=Mini-Mental State Examination; SD= standard deviation

The results of the logistic Generalised Estimating Equation (GEE) model examining changes in the three objective measures of vision and driver self-regulation status are presented in Table 4. Improvement in contrast sensitivity after cataract surgery was significantly associated with decreased odds of self-regulating (OR: 0.02, 95% CI: 0.01 - 0.4). Again, males had significantly lower odds of being self-regulators (OR: 0.2; 95% CI: 0.04 - 1.0) and retired participants had significantly higher odds of being self-regulators (OR: 10.1, 95% CI: 1.8 - 54.8).

Table 4. GEE Logistic Model of change in visual measures and self-regulation status among older drivers with bilateral cataract

Variable	Odds Ratio	95% CI	P value
Gender			
Female	1.0		
Male	0.2	0.04-1.0	0.045
Age group (years)			
55-64	1.0		
65-74	0.1	0.1-1.4	0.091
75+	0.6	0.1-6.7	0.125
Marital status			
Single	1.0		
Married/de facto	0.6	0.2-2.6	0.523
Retirement status			
Not retired	1.0		
Retired	10.1	1.8-54.8	0.008
Number of comorbidities			
	1.2	0.9-1.5	0.174
MMSE score			
	1.0	0.8-1.3	0.882
Binocular visual acuity (logMAR)			
	2.5	0.2-26.9	0.455
Binocular contrast sensitivity (log units)			
	0.02	0.01-0.4	0.019
Stereopsis (log seconds of arc)			
	1.3	0.5-3.5	0.648

CI= confidence interval; GEE= Generalised Estimating Equation; log= logarithm; logMAR= logarithm of the Minimal Angle of Resolution; MMSE=Mini-Mental State Examination; SD= standard deviation

DISCUSSION

This is one of the first studies to use naturalistic driving information to assess the impact of first and second eye cataract surgery on driver self-regulation practices among a cohort of older drivers with bilateral cataract. We found a significant reduction in driver self-regulation in at least one situation after both first and second eye cataract surgery, compared to the month before first eye cataract surgery. The study also found that changes in contrast sensitivity were associated with the reduction in driver self-regulation after cataract surgery.

The results of our study are consistent with some of the limited existing research on the impact of cataract surgery on driver self-regulation. A population based study from Sweden found that 40% of all drivers increased their driving frequency after first eye

or bilateral cataract surgery [31]. In addition, this study and a more recent prospective study from Sweden reported that between 25% and 37% of all patients who ceased driving before first eye cataract surgery started to drive after first eye or bilateral surgery [31,32]. However, an earlier study from the USA, which followed cataract patients over a period of 4 to 6 years, found that driving exposure (mileage) decreased over time in a similar fashion for those who had cataract surgery and those who did not [33]. It is therefore possible that decreased self-regulation observed in our study was perhaps a “rebound” effect with increased driving and less self-regulation occurring in the period immediately following surgery. Our study was unable to address the longer term impact of cataract surgery on driver self-regulation and this warrants further research.

Since previous studies combined participants who underwent only first, or both eye surgeries in the analyses, they were unable to measure the specific effects of first and second eye cataract surgery separately. Our study demonstrated that while first eye surgery had a large impact on reducing the need for driver self-regulation among bilateral cataract patients, second eye surgery also had a significant impact, reducing the odds of driver self-regulation by a further 20% compared to baseline. This suggests the importance of timely second eye cataract surgery for bilateral cataract patients.

Previous research also supports our findings on the association between contrast sensitivity and driving outcomes. Contrast sensitivity has been associated with changes in driving difficulty after first eye [24] and after second eye cataract surgery [34]. Among the general population, contrast sensitivity has also been associated with driver self-regulation and cessation [15,16,18,19] as well as crash risk [35]. It should be noted that our cohort had better baseline vision, including contrast sensitivity than in previous studies examining the impact of cataract or cataract surgery on driving difficulty and self-regulation [10,11,36,37]. Despite this, 47.3% of participants still felt the need to self-regulate their driving due to their vision while waiting for first eye surgery, representing a significant limitation for their mobility. In addition, the relatively small improvement in binocular contrast sensitivity from baseline to after second eye surgery was still associated with a significant reduction in driver self-regulation. Although driver self-regulation is necessary and positive for road safety, it nevertheless limits an older person’s mobility and independence in the community. It

is well known that driving cessation can have a negative impact on their lifestyle [3], but evidence suggests that self-regulation without cessation may also increase depressive symptoms among the general older population [38] and cataract patients specifically [11]. Therefore, our findings suggest that first and second eye cataract surgery can have a significant positive impact on restoring the mobility of drivers with bilateral cataract, even if their visual impairment is relatively mild.

The study also found that both first and second eye cataract surgery significantly reduced driver self-regulation in two specific situations; driving at night and on heavy traffic roads. A previous study also found that night time driving was the most common situation avoided by older drivers awaiting first eye cataract surgery [11]. Previous research also reported that 36% of older drivers with cataract had difficulty driving on heavy traffic roads [10]. However, neither of these studies examined how self-regulation status changed throughout the cataract surgery process and relied on the DHQ questionnaire alone to assess driving difficulty, which might be subject to recall and social desirability bias.

Lastly, this study found that male cataract patients were less likely to self-regulate their driving than females and is consistent with previous research [39,40]. Retired drivers were also more likely to self-regulate their driving possibly due to the fact they have more flexibility to choose when and where they drive than those who are employed [41].

The major strength of this study was the use of naturalistic objective driving data to examine self-regulation practices and associated changes in objective visual measures throughout the cataract surgery process. Naturalistic data provide valid information and are more accurate than self-reported questionnaires, which are prone to social desirability and recall biases [20]. However, there were several limitations. Participants' naturalistic driving behaviour was only measured for a period of one week meaning this may not be representative of their overall driving patterns, although this time frame is consistent with some previous research [21,42]. As well, the study was only able to measure four difficult driving situations and further research should include an extended range of driving situations which have been shown to be

challenging among cataract patients such as driving in the rain and parallel parking [11].

CONCLUSION

It is well known that driving provides older adults with mobility, independence and enhances quality of life [3]. The current study found that even among a cohort of cataract patients with better vision at baseline, a significant proportion self-regulated or restricted their driving while awaiting surgery. First eye cataract surgery significantly reduced driver self-regulation, with second eye surgery providing further reductions. This study provides a strong rationale for providing timely first and second eye cataract surgery for older drivers with bilateral cataract in order to improve their mobility and independence.

ABBREVIATIONS

ANOVA= analysis of variance

CI= confidence interval

DHQ=Driving Habits Questionnaire

ETDRS= Early Treatment Diabetic Retinopathy Study

GEE= Generalised Estimating Equation

log= logarithm

logMAR= logarithm of the Minimal Angle of Resolution

MMSE=Mini-Mental State Examination

OBD II= On Board Diagnostic II

OR=Odds ratio

SD= Standard deviation

DECLARATIONS

Ethics approval and consent to participate: Ethics approval was obtained from the Curtin University Human Research Ethics Committee (Curtin University HR 29/2014), the Royal Perth Hospital Human Research Ethics Committee (Royal Perth #14-033), the South Metropolitan Health Service Human Research Ethics Committee (Fremantle Hospital #14-033), and the Sir Charles Gairdner Group Human Research Ethics Committee (Sir Charles Gairdner Hospital #2014-113). Participants provided

written informed consent before any data were collected, following the tenets of the Declaration of Helsinki.

Consent for publication: Not applicable

Availability of data and material: The material used during the current study is available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests

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Authors' contributions: SA collected the data, conducted the data analysis, interpretation of data, and drafted the manuscript. LM led the design of the study, conducted the data analysis, interpretation of data, and drafted the manuscript. MF, KC, JN and VR contributed to the analysis and interpretation of data. All authors read, revised and approved the final manuscript.

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DISCUSSION

Chapter 9 Discussion

9.1 Overview

The overall aim of this study was to gain a better understanding of the impact of first eye and second eye cataract surgery on naturalistic measured driver self-regulation practices, and how changes in this outcome were associated with changes in objective visual measures before and after first and second eye cataract surgery. Significant improvements were found in vision and reduction in self-regulation practices after both first and second eye cataract surgery. In addition, changes in self-regulation practices after first and second eye cataract surgery were associated with changes in contrast sensitivity but not visual acuity or stereopsis.

The study also examined the associations between naturalistic measures of driving exposure, habits and adverse events and objective visual measures before first eye cataract surgery, with contrast sensitivity being the only objective measure of vision significantly associated with the number of kilometres travelled.

Finally, the study also examined the agreement between self-reported travel diaries and in-vehicle monitoring devices and found significant differences between both measures in terms of number of trips, days driven, and trips duration, while no significant differences were found in terms of kilometres travelled.

9.2 Comparison Between Self-Reported Travel Diaries and Naturalistic Data Obtained from In-Vehicle Monitoring Devices

The results of this study found there were significant differences between self-reported and naturalistic driving data. Data collected by the travel diaries significantly underestimated the number of overall trips and weekend trips, number of days driven, and trips made during peak hours. This is consistent with previous research, which found that data collected by travel diaries underestimated the number of trips made in comparison to in-vehicle monitoring devices (Blanchard et al., 2010), with 7.4% of trips found to be under-reported by participants (Stopher, FitzGerald, & Xu, 2007).

The results also demonstrated that the duration of overall trips and weekend driving were significantly overestimated in comparison to the data obtained by the in-vehicle monitoring devices. This is similar to previous research which found that participants overestimated the travel duration of their trips (Stopher et al., 2007). Even though our participants were requested to fill in their travel diary after each trip, it is possible that some participants might have completed it at a later date. They might also have included the duration of their whole trip, even though they might not have been driving. Participants may also have lacked the necessary judgement that would enable them to provide accurate estimations. Lack of accuracy may also be the result of fatigue after a long trip, memory impairment or recall bias (Marshall et al., 2007).

However, no significant differences were found between the two instruments in terms of the numbers of kilometres travelled. This is consistent with previous research conducted among older drivers from the general population, which found a very strong correlation between travel diaries and in-vehicle monitoring devices without GPS logger in terms of total distance travelled (Marshall et al., 2007). Similarly, other studies that relied on self-reported questionnaires found strong correlations (Babulal et al., 2016) or no overall significant differences between both measures (Porter et al., 2015; Thompson et al., 2016). As our participants were required to report the odometer reading of their vehicles in their travel diaries immediately, and not to give an estimated of the total number of kilometres travelled, such results could have been expected. However, previous studies that relied on self-reported questionnaires, and therefore self-estimations, found that participants systematically underestimated the total numbers of kilometres travelled (Molnar, et al., 2013a), while other studies found that participants over-reported or under-reported the total number of kilometres travelled on average (Blanchard et al., 2010; Huebner et al., 2006). Further research should compare the differences in measurements obtained from both travel diaries and self-reported questionnaires, and relate them to the data obtained by the in-vehicle monitoring devices.

Additionally, approximately half of our participants (49%) had missing information in their time entries. More than half of the missing entries were for kilometres travelled (64%), and 68% for both time and kilometres travelled. Previous research found that participants become fatigued when completing their travel diaries (Marshall et al.,

2007), as participants consider self-reported measures to be less practical and convenient to use than naturalistic data (Blanchard et al., 2010; Marshall et al., 2007). This could have accounted for high rates of non-completion (Wolf et al., 2001).

The findings suggest that relying only on self-reported travel diaries to measure driving outcomes may not be accurate, because they may be affected by recall, social desirability bias and missing data. Naturalistic driving data is a more reliable source of information than self-reported measures on their own, and may be less subject to missing data caused by non-completion or fatigue. The results of this study are consistent with previous research that found naturalistic driving data can surpass the quality of self-reported measures (Wolf et al., 2001), and that self-reported measures of driving outcomes may be unreliable or inaccurate (Blanchard et al., 2010; Crizzle et al., 2013; Grengs et al., 2008; Huebner et al., 2006; Molnar et al., 2013a; Porter et al., 2015). Using both self-reported and naturalistic driving data may enable researchers to better understand the context of driving, such as the purpose of the trips (Grengs et al., 2008); as such, the use of in-vehicle monitoring devices should be encouraged, which is consistent with previous research (Blanchard et al., 2010; Myers et al., 2011).

9.3 Driving Habits and Adverse Events in Older Drivers Before First Eye Cataract Surgery Using Self-Reported and Naturalistic Driving Data

The study found that 51% of participants self-reported that cataract did not affect their driving. In addition, 81% preferred to drive themselves rather than being driven by someone else, even though 11% of participants reported that they had been advised to limit or stop their driving in the past year. In addition, a large proportion of our participants (45%) drove during night time and peak hour traffic (78%), even though these situations have been previously found to be challenging for cataract patients (Owsley et al., 1999). These results suggest that some participants may not be aware that cataract is affecting their driving, because almost half of the sample considered themselves as “*good drivers*” and almost one quarter of participants rated themselves as “*excellent drivers*”. Clinicians could therefore play an important prevention role in ensuring that patients are provided with sufficient information about visual and driving difficulties they may encounter while driving with cataract.

With regard to adverse events, 11% of participants experienced at least one episode of harsh braking during the seven days of data collection, before first eye cataract surgery, as measured by the in-vehicle monitoring devices. Among this group, 91% of participants recorded one harsh braking episode, while 9% experienced two episodes of harsh braking. Previous research found that drivers who brake suddenly have higher odds of being involved in a crash or near miss (Chevalier et al., 2017), such as rear end crashes (Harb, Radwan, Yan, & Abdel-Aty, 2007). As previous studies found that older drivers with cataract are 2.5 times more likely to be involved in an at-fault crash risk than older drivers without cataract (Owsley et al., 1999, 2001), further research is required to explore harsh braking events among older drivers with cataract over extended periods of time.

9.4 The Impact of First and Second Eye Cataract Surgery on Objective Visual Measures and Driver Self-Regulation Practices Using Naturalistic Driving Data

9.4.1 The impact of first and second eye cataract surgery on objective visual measures

The study found that there were significant improvements in better eye, worse eye and binocular visual acuity after first and second eye cataract surgery. Mean binocular visual acuity significantly improved from 0.15 logMAR (SD = 0.15) at baseline, to 0.08 logMAR (SD = 0.21) after first eye surgery and -0.02 logMAR (SD = 0.19) after second eye surgery ($p < 0.001$). However, first eye cataract surgery did not bring changes in vision that were clinically meaningful in comparison to before surgery, as it is commonly accepted that a change of one line in logMAR visual acuity (0.1 logMAR units) is considered as clinically significant (Elliott & Sheridan, 1988). However, after second eye surgery these changes became clinically significant in comparison to participants' visual acuity before surgery. The number of participants who did not meet the Australian visual acuity standard for driving dropped from 9% at baseline, to 5% after first eye cataract surgery and to 4% after second eye cataract surgery. This is consistent with previous research which found that after first eye cataract surgery (Fraser et al., 2013b) and first, second or both eyes cataract surgery (Mönestam & Wachtmeister, 1997), 4% of participants still did not meet visual acuity standard for driving. However, in Mönestam & Wachtmeister (1997), no distinction

was made between patients who underwent first, second or both eyes surgeries.

The study also found that better eye, worse eye and binocular contrast sensitivity significantly improved after first and second eye cataract surgery. Binocular contrast sensitivity significantly improved ($p < 0.001$) from 1.64 log units ($SD = 0.14$) before first eye cataract surgery, to 1.67 log units ($SD = 0.25$) after first eye cataract surgery and 1.75 log units ($SD = 0.08$) after second eye cataract surgery. However, none of these changes were considered to be clinically meaningful, as it is commonly accepted that a change of one line (0.3 log units) in log units in contrast sensitivity for cataract patients is clinically significant (Elliott, Sanderson, & Conkey, 1990). Our results are consistent with previous research which found improvements in binocular visual acuity and contrast sensitivity after first and second eye cataract surgery (To et al., 2014a, b).

In this study, stereopsis worsened after first eye cataract surgery, but improved after second eye cataract surgery. More specifically, a significant change ($p = 0.002$) in stereopsis was found with stereopsis measuring 2.14 log seconds of arc ($SD = 0.64$) at baseline; worsening to 2.31 log seconds of arc ($SD = 0.72$) after first eye cataract surgery and improving to 1.96 log seconds of arc ($SD = 0.60$) after second eye surgery. The changes between first eye and second eye cataract surgery were clinically meaningful as it is commonly accepted that a change in stereopsis of 0.30 log seconds of arc is clinically significant (Rubin et al., 2001). This is consistent with previous research conducted in Western Australia which found that 24% of participants had declines in stereopsis after first eye surgery and that there were no changes in stereopsis before and after first eye cataract surgery for 21% of participants (Fraser, 2011). Another study also found no significant improvement before first eye and after cataract surgery in stereopsis (Elliott et al., 2000). As stereopsis measures depth perception, first eye cataract surgery may cause an impairment in stereopsis due to an imbalance between both eyes, which could explain why stereopsis worsened after first eye cataract surgery (Comas et al., 2007). However, similar to this present study, it has been found that stereopsis can be improved by second eye cataract surgery (Comas et al., 2007).

Even though the participants in this present study had better vision at baseline than previous studies among cataract patients (Comas et al., 2007; Fraser, et al., 2013a,b,c;

Owsley et al., 1999; To, et al., 2014a,b), it was found that second eye cataract surgery provides further improvement in all measures of vision, which is consistent with previous research (Comas et al., 2007).

9.4.2 Driver self-regulation practices before first eye cataract surgery

The study found that 92% of participants drove during the seven days of data collection before first eye cataract surgery. Participants drove an average of 4.40 days and an overall distance of 115.8 kilometres, with an average of 15.6 trips per week. The results are similar to Fraser et al. (2013b), who found that participants self-reported driving an average of 104.5 kilometres per week before first eye cataract surgery. Additionally, pre-surgical participants classified as self-regulators (that is, participants who self-regulated in at least one driving situation which included driving on highways/freeways, on heavy traffic roads, in peak hour traffic, and during night time) drove fewer kilometres and made fewer trips per week than participants classified as non self-regulators. For example, self-regulators and non self-regulators' maximum excursion radius from home was 7 and 19 kilometres respectively, while the overall maximum excursion radius travelled from home was 14.1 kilometres. This is consistent with previous research, which found that cataract patients limited their driving to places closer to their home, and reduced their driving exposure by driving fewer days per week to fewer destinations with fewer kilometres per trip, in comparison to older drivers without cataract (Owsley et al., 1999).

This study also found that 41% of participants self-regulated their driving in at least one challenging situation before first eye cataract surgery, limiting significantly their mobility. More specifically, 31% of participants self-regulated their driving at night time, 10% in peak hour traffic, 9.4% on heavy traffic roads and 8% on highways/freeways. A quarter of the sample self-regulated their driving on one challenging situation only, 13% on two situations, 1% on three situations and 2% on four driving situations. These results are consistent with a study among older drivers with cataract that found 48% of cataract patients self-regulated their driving in at least one challenging situation, the most commonly being driving at night (Fraser et al., 2013c).

9.4.3 Association between objective measures of vision and driver self-regulation practices before first eye cataract surgery

The study found that contrast sensitivity was the only objective measure of vision significantly associated with self-regulation practices, such as driving exposure and avoiding driving in challenging situations, before first eye cataract surgery. Older drivers who had poorer binocular contrast sensitivity drove fewer kilometres per week prior to first eye cataract surgery than participants with better contrast sensitivity after controlling for potential confounding factors. More specifically, one log unit increase in binocular contrast sensitivity score was associated with an increase of 163 kilometres driven per week. These results are consistent with previous research among the general population of older drivers, which found significant association between reduced driving exposure and contrast sensitivity (Freeman et al., 2006; Sandlin et al., 2014).

In the same way, older drivers with worse contrast sensitivity scores were more likely to avoid driving in specific challenging situations than older drivers with better contrast sensitivity before first eye cataract surgery. The odds of participants with better contrast sensitivity scores (better vision) self-regulating their driving in at least one challenging situation decreased. These results are consistent with previous findings among bilateral cataract patients, which found that there was a significant difference in worse eye contrast sensitivity between self-regulators and non self-regulators (Fraser et al., 2013c). Previous studies among the general population of older drivers also found significant association between avoidance of driving in challenging situations and contrast sensitivity (Freeman et al., 2006; Molnar et al., 2014).

These results suggest that older drivers may acknowledge cataract as the cause of their visual impairment and self-regulate their driving by reducing their driving exposure and avoiding driving in challenging situations. Even though these results are positive for road safety by demonstrating that older drivers with cataract self-regulate their driving to places they feel confident and safe to drive, the findings also suggest that a proportion of older drivers with bilateral cataract do not self-regulate their driving while waiting for cataract surgery. In our study, approximately 10% of participants who did not meet the minimum visual acuity standards for driving in Western Australia

did not self-regulate their driving. While a large portion of the study participants did practise self-regulation, a proportion with poor vision did not self-regulate and this is concerning from a safety perspective. Further research should therefore determine why some older drivers are not self-regulating their driving. Clinicians could play a crucial role in ensuring that their patients limit their driving while waiting for first and second eye cataract surgery to improve their safety and the safety of other road users.

9.4.4 Driver self-regulation practices after first and second eye cataract surgery

This study found a significant reduction in driver self-regulation practices after both first and second eye cataract surgery in comparison to the month before first eye cataract surgery. The odds of being a self-regulator significantly decreased by 70% after first eye cataract surgery and by 90% after second eye cataract surgery. The further reduction of 20 percentage points in driver self-regulation suggests that second eye cataract surgery needs to be performed in a timely manner to improve older drivers' mobility and independence, and to enhance their quality of life. The results of this study are consistent with previous research (Mönestam et al., 2005; Mönestam & Wachtmeister, 1997). Cataract surgery has been associated with improved driving performance after the extraction of both cataracts (Wood & Carberry, 2006) and changes in driver self-regulation practices, such as return to driving after surgery (Mönestam et al., 2005; Mönestam & Wachtmeister, 1997); however, as those studies combined participants who underwent only first or bilateral cataract surgery in the analyses, they were unable to account for the specific effects of first and second eye cataract surgery separately.

In addition, this study also found a reduction in driver self-regulation practices when driving at night time and on heavy traffic roads after both first eye and second eye cataract surgery. Previous research also found night time driving was the most common situation avoided by older drivers before first eye cataract surgery (Fraser et al., 2013c), and driving on heavy traffic roads was reported to be a difficulty among 36% of participants (Owsley et al., 1999). However, both studies relied on the Driving Habits Questionnaire to measure driving difficulty, which may be subject to bias, and the studies did not examine how self-regulation status changed after first and second eye cataract surgery. These findings suggest that self-regulation should be considered

as a dynamic continuum to be constantly modulated over time, moving from driving independence to driving cessation and from driving cessation to driving independence due to modifiable risk factors, such as cataract surgery, for example (Lyman et al., 2001).

9.4.5 Association between objective measures of vision and driver self-regulation practices after first and second eye cataract surgery

Our study also found that improvements in contrast sensitivity after first and second eye cataract surgery were significantly associated with decreased odds of self-regulation. Participants with better contrast sensitivity drove in more challenging driving situations than before surgery. This is consistent with previous research, which found that contrast sensitivity was associated with changes in driving difficulty after first eye (Fraser et al., 2013b) and second eye cataract surgery (Wood & Carberry, 2006). In addition, in this present study, neither visual acuity nor stereopsis were significantly associated with avoiding driving in challenging situations, which is consistent with previous research among older drivers with bilateral cataract (Fraser et al., 2013b). This is also consistent with the study of Keay et al. (2009), which found that reduced contrast sensitivity—not visual acuity—was significantly associated with driving restriction or cessation among older drivers from the general population.

The results of this present study, together with studies conducted by other researchers, suggest that contrast sensitivity may be a very important measure to consider when analysing driving outcomes and fitness to drive among older drivers with cataract (Fraser et al., 2013b; Owsley et al., 2001; Wood & Carberry, 2006), for the reason that many objects on the roads are presented in low contrast (Van Rijn et al., 2011). This is important for licensing authorities and road safety policy makers, who mainly rely on visual acuity tests to determine fitness to drive, even though a large body of evidence has shown the key role played by contrast sensitivity in driving and crash risk (e.g. Fraser, et al., 2013b; Freeman et al., 2006; Huisinigh et al., 2017; Keay et al., 2009; Molnar et al., 2014; Sandlin et al., 2014; Van Rijn et al., 2011; Walker et al., 2006b; Wood, Horswill, Lacherez, & Anstey, 2013a)

The present results suggest that road safety policy makers and licensing authorities could benefit from using contrast sensitivity tests, in addition to the traditionally used

visual acuity tests to improve road safety. The contrast sensitivity tests used in the present study (Mars Perceptrix©) could be easily administered during a routine vision test to determine fitness to drive; it was well received by the participants, is easy and relatively quick to administer. Further research is required to determine to what extent administering the contrast sensitivity test in addition to the traditional visual acuity test could bring additional cost savings to the community by reducing crash risk. Future research should also evaluate how the combination of the tests could improve the safety of older drivers and other road users and enable licensing authorities and clinicians to define cut-off score among the contrast sensitivity test for safe driving.

9.5 Study Strengths

This is one of the first prospective cohort studies to have analysed the specific effects of first and second eye cataract surgery on driver self-regulation practices, as previous studies did not specify whether participants underwent first eye cataract surgery, second eye cataract surgery or combined both eyes in their analyses. As a proportion of cataract patients can wait more than one year to undergo first then second eye cataract surgery in public hospitals (Australian Institute of Health and Welfare, 2016, 2017), the results provided by this study are of great interest for clinicians, road safety and licensing authorities to enhance patients' safety while driving with impaired vision.

In addition, this is one of the first studies to have used a combination of self-reported measures and naturalistic data to assess driving patterns, habits, and self-regulation practices among a cohort of older drivers with bilateral cataract. Four self-reported driving situations (driving at night time, during peak hour traffic, on highways/freeways and on heavy traffic) were specifically matched to the data obtained by the in-vehicles monitoring devices, providing an accurate measure of driver self-regulation practices. As self-reported measures of driving outcomes may be unreliable or inaccurate (Blanchard et al., 2010; Crizzle et al., 2013; Grengs et al., 2008; Huebner et al., 2006; Molnar et al., 2013a; Porter et al., 2015), it was necessary to investigate the naturalistic driving behaviour of older drivers with cataract using valid measures without being subject to the flaw of self-reported measures, such as recall (Blanchard et al., 2010) and social desirability bias (Af Wählberg, 2010).

A further strength of this study was the use of in-vehicle monitoring devices, which could be installed not only in participants' own cars, but also in all types of cars. Some studies using in-vehicle monitoring devices to obtain naturalistic driving data were restricted to cars manufactured in or after 1996 because of the technology in those vehicles and not in earlier car models (Blanchard et al., 2010).

Another strength of the study was that the collected naturalistic driving data were linked to the Australian Government's Bureau of Meteorology website to specifically determine day and night time driving, as has been done in previous research using naturalistic driving data (Blanchard et al., 2010) to take into account changes in sunset and sunrise hours throughout the year.

The inclusion of two other objective measures of vision (contrast sensitivity and stereopsis) in addition to the visual acuity tests traditionally used by licensing authorities was an additional strength of this study. Even though previous research found that stereopsis might have a negative impact on driving outcomes (Comas et al., 2007), the majority of studies among cataract patients did not measure its impact (Owsley et al., 1999, 2001; Wood et al., 2006). While this study did not find an association between stereopsis and self-regulation practices, it provided additional information on the importance of using contrast sensitivity tests when determining fitness to drive among cataract patients.

The recruited participants did also not have any other major eye conditions, besides cataract, allowing the specific effects of this condition on driving outcomes to be determined. Previous research about self-regulation conducted among older drivers with cataract included 14% of participants with comorbid eye conditions, including glaucoma, macular degeneration, and diabetic retinopathy, which may have affected the generalisability of the results (Fraser, et al., 2013c).

Another strength of the study is that binocular measures of vision were used in our analysis to take into account the phenomena of binocular inhibition (in which the binocular visual acuity or contrast sensitivity values are worse than the values of the better eye) or summation (in which the binocular visual acuity or contrast sensitivity values are better than the values of the better eye) (Azen et al., 2002), which might have had an impact on the participants' driving behaviour (Comas et al., 2007). As people usually use both eyes while driving, it was important to account for this

phenomena by measuring binocular values, because some studies with cataract patients only used better eye (McGwin et al., 2000), or separated better eye and worse eye values in their analyses (Fraser et al., 2013c; Owsley et al., 2001).

9.6 Study Limitations

Even though 111 participants were recruited at baseline, only 55 participants underwent first and second eye cataract surgery by the end of the data collection period. The small sample size in the study may have affected the generalisability of our results. However, a closed-road study analysing the effects of first and second eye cataract surgery on driving performance used a smaller sample size of cataract patients ($n = 28$) and aged-matched control participants ($n = 18$) to account for the changes in driving performance (Wood & Carberry, 2006).

As older drivers who decided to take part in the research study were all volunteers, it is possible that participants with poorer vision did not wish to participate, fearing they may be reported to licensing authorities and that their licence may be suspended. This could explain why these participants did have better vision than participants recruited in previous studies among older drivers with bilateral cataract (Comas et al., 2007; Fraser et al., 2013a,b,c; Owsley et al., 1999; To et al., 2014a,b), which could have affected the findings of the analyses into the driving behaviour of the participants in this present study.

As well, no other objective measures of vision were included in the analysis, such as refractive error (Palagyi et al., 2017), visual field (Owsley et al., 1999; Wright, Singh, Henriksen, McFadden, & Olson, 2017), and stray light as a measure of disability glare (Bal et al., 2011; Van Den Berg, 2017), even though these have been found to be affected in cataract patients (e.g., Bal et al., 2011; Owsley et al., 1999; Palagyi et al., 2017; Van Den Berg, 2017; Wright et al., 2017). The type of lenses inserted during cataract surgery was also not recorded, even though it has been found to be associated with patients' changes in driving habits (Beiko, 2015).

Naturalistic driving patterns were monitored for only a short period of 7 days. Given the age of the participants, it is therefore possible that health issues might have affected the driving behaviour of the participants during this short period, therefore monitoring older participants over longer periods of time would be preferred. In addition, as

driving fluctuates from week to week, it was not possible to determine whether participants' driving behaviour was reflecting a typical week. Furthermore, it was not possible to specifically determine whether participants' driving exposure was mainly because of their cataract or their lifestyle (Charlton et al., 2006; Molnar et al., 2013b) or even individual preferences (Molnar et al., 2013b). Even though participants' driving patterns were only assessed for a period of 7 days, previous naturalistic studies have used the same number of days to monitor driving behaviour among older participants (Blanchard & Myers, 2010; Blanchard et al., 2010; Thompson et al., 2016). Previous research also found that older drivers with cataract who underwent cataract surgery and older drivers who decided not to undergo cataract surgery had similar reduction in self-reported annual mileage over the two years of follow-up (Owsley et al., 2002). It is therefore possible that decreased self-regulation observed in the study was perhaps a "rebound" effect with increased driving and less self-regulation occurring in the period immediately following surgery. This study was unable to address the longer term impact of cataract surgery on driver self-regulation and warrants further research.

Ethical considerations prevented the recruitment of a control group of older drivers with bilateral cataract who did not undergo cataract surgery or whose cataract surgery was delayed (McGwin et al., 2003). In addition, limited resources prevented the recruitment of a group of older drivers with non-impaired vision (Owsley et al., 1999; Wood & Carberry, 2004). If a control group had been included, it is possible that an increase in self-regulation practices for that group would have been found due to the ageing process (Owsley et al., 2002). As this study found a decrease in self-regulation among cataract patients, any comparison with a control group would probably have further affirmed the study's findings. However, a previous study among older drivers with bilateral cataract used a similar study design without a comparison group to analyse the effects of cataract and first eye cataract surgery on driver self-regulation practices and driving difficulties (Fraser et al., 2013b,c).

In addition, study participants were classified as self-regulators after assessing only four challenging situations, which were: driving at night time, during peak hour traffic, on highways/freeways and on heavy traffic roads. It was therefore not possible to determine whether participants drove on their own or in the rain for example, as no

video footage was recorded. Consequently, the study might have underestimated the percentage of people who self-regulated their driving. In addition, no weighting of the specific driving situations to control for under-reported or over-reported situations was undertaken when developing the self-regulation composite variable. Further research is required to analyse a wider range of challenging driving situations that are known to be problematic for older drivers with cataract, such as driving in the rain and parallel parking (Fraser et al., 2013c), which could be measured by in-vehicle monitoring devices with video footage.

Even though participants were required to disconnect the devices when they were not driving their vehicle, and to note in their travel diaries whether they were the driver of the vehicles, no hardware device enabling driver identification, such as a key fob, was provided. It may be possible, then, that people other than the participants might have driven the cars. It is also possible that some participants may have driven multiple vehicles without recording their trips. In an attempt to minimise such possibilities, a follow-up interview was conducted with the participants after each assessment to confirm that no else was driving their cars and to ensure that all trips made were recorded. Key fobs have been previously used in naturalistic studies among older drivers to identify the driver of the vehicle (Porter et al., 2015).

Further, participants' driving behaviour might have been modified during data collection, because they were aware that their driving behaviour was being monitored by a device. Such a response, the Hawthorne effect (McCambridge, Witton, & Elbourne, 2014) could explain any impact on participants' self-regulation practices.

The strict inclusion criteria might also have affected the generalisability of the results. Study participants were required to drive at least twice a week, which could have excluded participants who drove less frequently and who were already self-regulating their driving because of their cataract, or who had poorer vision and were therefore unable to drive. However, previous research among older drivers also included participants who were required to drive twice a week in their analysis (Payyanadan et al., 2017).

Despite these limitations, the study controlled for a wide range of potential confounding factors which could have affected the interpretation of the results, and

therefore the study contributes to a better understanding of the effects of cataract, and first and second eye cataract surgery on driving patterns, habits and self-regulation practices.

9.7 Recommendations

Nonetheless, further research is required to gain a better understanding of how older drivers are impacted by cataract, by overcoming the limitations highlighted above. The findings from the study suggest the following research and clinical recommendations.

9.7.1 Research recommendations

- Further research is needed to assess whether cataract patients could benefit from educational intervention programs promoting the use of self-regulation strategies while waiting for cataract surgery.
- Further research should determine how licensing authorities could benefit from using contrast sensitivity tests in addition to the traditional visual acuity tests to determine fitness to drive.
- Further longitudinal research with a larger sample size is required to replicate the results of this study.
- Participants using an in-vehicle monitoring device should be monitored for longer than 7 days and the long term effects of first and second eye cataract surgery on driving self-regulation practices should be analysed.
- Measures of refractive management, visual fields, and disability glare should be included in future research among cataract patients.
- Assessing driving using on-road driving assessments tests, driving simulators or in-vehicle video technology would enable researchers to account for additional measures of driving performance, including lane boundary crossings, sign identification, speed, traffic, weather and light conditions, interactions with other road users, gap selections, and reaction time to adverse events.
- Further studies should also use eye trackers to assess the driving behaviour of older

drivers with bilateral cataract throughout the cataract surgery process. It might be hypothesised that eye movement patterns made during scanning behaviour while driving might change throughout the cataract surgery process, as a result of the improvements in vision.

- The literature would greatly benefit from studies that determine to what extent older drivers with bilateral cataract could benefit from driving autonomous vehicles in the future.
- Further research is needed to identify additional factors associated with the self-regulation practices—or lack of—among drivers with visual impairment. Questionnaires about coping strategies, decision-making, engagement and motivation, driving confidence and comfort, impulsivity and personality traits could, for example, be administered to identify whether these variables mediate the association between visual impairment and self-regulation practices.

9.7.2 Clinical recommendations

- Clinicians need to advise patients of possible driving limitations and difficulties they may encounter when driving, while waiting for first and second cataract surgery.
- Cataract surgery should be provided in a timely manner as it can lead to improvements in mobility and independence, as well as road safety benefits.

9.8 Conclusion

The prevalence of cataract in older populations (WHO, 2013), and increasing life expectancy (United Nations, 2017), means there will be an increasing number of older Australians with cataract on our roads. Conditions that diminish sight have a significant impact on the driving ability and safety of older drivers as they seek to maintain their quality of life and independence. The onset of cataract is insidious and there are no established criteria for eligibility for cataract surgery. Clinicians should be encouraged to discuss driving behaviour with their patients to determine how it is affected by their visual impairment, in order to prioritise patients for cataract surgery. In this study, approximately 10% of older drivers waiting for cataract surgery did not meet current visual standards for driving.

The results of this comprehensive study have provided a better understanding of the association between visual measures, cataract requiring surgery, and real time driving behaviour using in-vehicle monitoring devices. It also validated the combined use of the self-report driving questionnaire (DHQ) with the in-vehicle monitoring devices, which will be more effective for monitoring patient-reported measures, an important part of outcomes research. Further research should identify which additional factors are associated with self-regulation practices among drivers with visual impairment. Analysing the motivation and reasons behind engagement in avoidance behaviours could, for example, determine if those avoidance behaviours are due to other reasons than visual declines, such as intentions. A further strength of this longitudinal study was that it followed a cohort of cataract patients throughout the cataract surgery process using the technologies of in-vehicle driver monitoring devices to objectively measure natural driving patterns and self-regulation practices, which provided a comprehensive examination of driving outcomes before first, after first, and after second eye cataract surgery.

In conclusion, it is anticipated that the results of this study may provide significant overall cost savings to the community by providing the evidence to fund cataract surgery in a timely manner (both for first and second eye), thus avoiding costs associated with crashes and injury. It may also better inform those who provide funding for road safety awareness campaigns of the issue of cataract and driving performance. Cataract diminished vision is another impairment, albeit more subtle than the effect of tiredness and alcohol. Although people will continue to drive as dictated by need, an awareness campaign will prompt earlier presentation for assessment for cataract surgery and a greater willingness to proceed to cataract surgery, rather than wait until visual acuity is markedly reduced. The results of the study may also highlight the need for better visual testing by licensing authorities, who rely largely on the visual acuity measure when setting standards of visual competence for fitness to drive for visually impaired drivers such as cataract patients.

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“Every reasonable effort has been made to acknowledge the owners of copyright material. I would be pleased to hear from any copyright owner who has been omitted or incorrectly acknowledged.”

APPENDICES

Appendix A Contact information release form

A.1 Contact information release form



Cataract Extraction and Driving Ability Research Study

Contact information release form

You have spoken to one of our doctors and expressed an interest in participating in a Curtin University research project that is looking at how cataract surgery affects a person's driving performance.

This study aims to explore the impact of cataract surgery on driving performance and self-regulation practices. The results of this study may provide significant overall cost savings to the community by providing the evidence to fund cataract surgery in a timely manner (both for first and second eye) to avoid the costs associated with crashes and injury.

The study is being conducted by Professor Lynn Meuleners, Curtin-Monash Accident Research Centre at Curtin University. The study is funded by the Australian Research Council.

By signing this form, you agree to Sir Charles Gairdner Hospital providing Curtin University with your address and phone number, so they can contact you in order to give you more information about this study. The researchers will not disclose your personal information to any other person.

You can also contact the Curtin University researchers directly:

- Professor Lynn Meuleners on (08) 9266 4636
- Seraina Agramunt (PhD student) on (08) 9266 9591

Signature:.....Date:

First Name:	
Last Name:	
Address:	
Home Phone:	
Mobile:	

Appendix B Pamphlet

B.1 Pamphlet: Fremantle Hospital

The CEDAR Study: Cataract Extraction and Driving Ability Research

PARTICIPANT INFORMATION

What if I don't want to take part in the study or want to withdraw later?

Participation in this study is **entirely voluntary**: it is completely up to you whether or not you participate. If you decide not to participate, or choose to withdraw from the study later, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

Will anyone else know the results?

Any identifiable information that is collected about you in connection with this study will remain strictly confidential and only the researchers will have access to your identifiable details.

A report of the study may be submitted for publication, but individual names will not be included. We will also share some information about the tests and questionnaires used in this study to work out how useful they are in determining effective management strategies for people with cataract.

Will the study benefit me?

While we intend that this research study furthers our knowledge and may improve services for people with cataract in the future, it may not be of direct benefit to you.

What if I require further information?


If you would like to know more about this study at any stage, please feel free to contact Seraina Agramunt at The Curtin-Monash Accident Research Centre, Western Australia.

CONTACT US
Seraina Agramunt (PhD student)
Curtin-Monash Accident Research Centre
7 Parker Place, Technology Park
Bentley WA 6102
Email: seraina.agramunt@curtin.edu.au
Telephone: 08 9256 9591

The Cataract Surgery and Driving study is coordinated by The Curtin-Monash Accident Research Centre, Western Australia and is also being conducted through the George Institute in Sydney. This research is supported by a grant from the Australian Research Council.

Fremantle Hospital & Health Service
Curin University
Sir Charles Gairdner Hospital
Royal Perth Hospital
THE GEORGE INSTITUTE
for Global Health

This research has been approved by the Curtin University Human Research Ethics Committee. Approval number: HR 29/2014.
Any person with concerns or complaints about the conduct of this study should contact the Ethics Committee Secretary on (08) 9266 9223 or ethic@curtin.edu.au



Curin University
C-MARC
CURTIN-MONASH ACCIDENT RESEARCH CENTRE

FRH Version 3 20/05/14

INFORMATION FOR PARTICIPANTS

Impact of first and second eye cataract surgery on driving outcomes

What is the study about?

You are invited to take part in a research study looking at how cataract surgery affects a person's driving. This includes when and where you drive and your driving performance.

This study aims to explore the impact of cataract surgery on driving performance and self regulation practices.

The results of this study may provide significant overall cost savings to the community by providing the evidence to fund cataract surgery in a timely manner (both for first and second eye) to avoid the costs associated with crashes and injury.

Why am I invited to participate?

You have been invited to take part in this study because you are aged 55 years or older, have a current drivers licence, drive at least twice a week, live in the Perth metropolitan area, are able to attend three assessment visits, have not had cataract surgery before and are now recommended for cataract surgery in both eyes.

Who is carrying out the study?

The study is being conducted at Fremantle Hospital by Dr Dimitri Yellachich, Department of Ophthalmology. The study has been funded by a grant from the Australian Research Council and is coordinated by the Curtin-Monash Accident Research Centre at Curtin University in WA.

What does the study involve?

If you choose to take part in this study, you will be invited to attend three face-to-face visits with our research team at Curtin University. In addition to this you will be provided with an in-vehicle driving device that will record data for one week on three separate occasions.

The First Visit

You will be asked to attend Curtin University one month before your first eye surgery to complete a set of questionnaires about your access to eye care and referral for surgery, attitudes to cataract surgery, difficulty with vision, your driving habits, self-regulation and driving difficulties and health and medical information

We will test your vision. This includes reading charts, measuring visual fields (side vision) and measuring how the two eyes work together. We will also measure your glasses.

We will also perform three simple cognitive tests that involve answering questions and looking at pictures.

You will drive a specific route in our driving simulator.

You will be provided with driving recording device to be placed in your vehicle for one week.

The Second and Final Visits

We will need to see you at Curtin University on two other occasions:

- 3 months after your first eye cataract surgery, and
- 3 months after your second eye cataract surgery.

At these visits we will again measure your vision and glasses, perform cognitive tests and a questionnaire and provide you with the driving recording device to place in your car for one week. You will also again drive in the simulator at these visits.

How much time will the study take?

The three visits required of you as a participant will each take 1.5-2 hours.

Your total time in the study will be up to 3 years or 6 months after your second eye cataract surgery, whichever is soonest. You will be paid \$10 after the first assessment, \$15 after the second assessment, and \$20 after the final assessment

Do I need to prepare anything for my involvement?

If you wear glasses, you will need you to bring these along to each of the three study visits.

Remember to bring the glasses that you wear most often and to bring any new glasses that you might get before the second and final study visits.

Participants must also have their own vehicle.

B.2 Pamphlet: Royal Perth Hospital

What if I don't want to take part in the study or want to withdraw later?

Participation in this study is **entirely voluntary**: it is completely up to you whether or not you participate. If you decide not to participate, or choose to withdraw from the study later, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

Will anyone else know the results?

Any identifiable information that is collected about you in connection with this study will remain strictly confidential and only the researchers will have access to your identifiable details.

A report of the study may be submitted for publication, but individual names will not be included. We will also share some information about the tests and questionnaires used in this study to work out how useful they are in determining effective management strategies for people with cataract.

Will the study benefit me?

While we intend that this research study furthers our knowledge and may improve services for people with cataract in the future, it may not be of direct benefit to you.

What if I require further information?

If you would like to know more about this study at any stage, please feel free to contact Seraina Agramunt at The Curtin-Monash Accident Research Centre, Western Australia.


CONTACT US

Seraina Agramunt (PhD student)
Curtin-Monash Accident Research Centre
7 Parker Place, Technology Park
Bentley WA 6102

Email: seraina.agramunt@curtin.edu.au
Telephone: 08 9266 9591

The CEDAR Study: Cataract Extraction and Driving Ability Research


PARTICIPANT INFORMATION



The Cataract Surgery and Driving study is coordinated by The Curtin-Monash Accident Research Centre, Western Australia and is also being conducted through the George Institute in Sydney. This research is supported by a grant from the Australian Research Council.



This research has been approved by the Curtin University Human Research Ethics Committee (approval number: HR 292014). Any person with concerns or questions about the conduct of this study should contact the Ethics Committee Secretary on (08) 9 266 9223 or email hres@curtin.edu.au



Curtin University

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INFORMATION FOR PARTICIPANTS

Impact of first and second eye cataract surgery on driving outcomes

What is the study about?

You are invited to take part in a research study looking at how cataract surgery affects a person's driving. This includes when and where you drive and your driving performance.

This study aims to explore the impact of cataract surgery on driving performance and self regulation practices.

The results of this study may provide significant overall cost savings to the community by providing the evidence to fund cataract surgery in a timely manner (both for first and second eye) to avoid the costs associated with crashes and injury.

Why am I invited to participate?

You have been invited to take part in this study because you are aged 55 years or older, have a current drivers licence, drive at least twice a week, live in the Perth metropolitan area, are able to attend three assessment visits, have not had cataract surgery before and are now recommended for cataract surgery in both eyes.

Who is carrying out the study?

The study is being conducted at Royal Perth Hospital by A/Prof Nigel Morlet, Department of Ophthalmology. The study has been funded by a grant from the Australian Research Council and is coordinated by the Curtin-Monash Accident Research Centre at Curtin University in WA.

What does the study involve?

If you choose to take part in this study, you will be invited to attend three face-to-face visits with our research team at Curtin University. In addition to this you will be provided with an in-vehicle driving device that will record data for one week on three separate occasions.

The First Visit

You will be asked to attend Curtin University one month before your first eye surgery to complete a set of questionnaires about your access to eye care and referral for surgery, attitudes to cataract surgery, physical activity, risk of falls, difficulty with vision, your driving habits, self-regulation and driving difficulties and health and medical information.

We will test your vision. This includes reading charts, measuring visual fields (side vision) and measuring how the two eyes work together. We will also measure your glasses.

We will also perform three simple cognitive tests that involve answering questions and looking at pictures.

You will drive a specific route in our driving simulator.

You will be provided with driving recording device to be placed in your vehicle for one week.

The Second and Final Visits

We will need to see you at Curtin University on two other occasions:

- 3 months after your first eye cataract surgery, and
- 3 months after your second eye cataract surgery.

At these visits we will again measure your vision and glasses, perform cognitive tests and a questionnaire and provide you with the driving recording device to place in your car for one week. You will also again drive in the simulator at these visits. You will be paid \$10 for the first assessment, \$15 for the second assessment, and \$20 for the final assessment.

How much time will the study take?

The three visits required of you as a participant will each take 1.5-2 hours.

Your total time in the study will be up to 3 years or 6 months after your second eye cataract surgery, whichever is soonest.

Do I need to prepare anything for my involvement?

If you wear glasses, you will need you to bring these along to each of the three study visits.

Remember to bring the glasses that you wear most often and to bring any new glasses that you might get before the second and final study visits.

Participants must also have their own vehicle.

B.3 Pamphlet: Sir Charles Gairdner Hospital

What if I don't want to take part in the study or want to withdraw later?

Participation in this study is **entirely voluntary**: it is completely up to you whether or not you participate. If you decide not to participate, or choose to withdraw from the study later, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

Will anyone else know the results?

Any identifiable information that is collected about you in connection with this study will remain strictly confidential and only the researchers will have access to your identifiable details.

A report of the study may be submitted for publication, but individual names will not be included. We will also share some information about the tests and questionnaires used in this study to work out how useful they are in determining effective management strategies for people with cataract.

Will the study benefit me?

While we intend that this research study furthers our knowledge and may improve services for people with cataract in the future, it may not be of direct benefit to you.

What if I require further information?

If you would like to know more about this study at any stage, please feel free to contact Seraina Agramunt at The Curtin-Monash Accident Research Centre, Western Australia.

CONTACT US

Seraina Agramunt (PhD student)
Curtin-Monash Accident Research Centre
7 Parker Place, Technology Park
Bentley WA 6102

Email: seraina.agramunt@curtin.edu.au
Telephone: 08 9256 9591

The Cataract Surgery and Driving study is coordinated by The Curtin-Monash Accident Research Centre, Western Australia and is also being conducted through the George Institute in Sydney. This research is supported by a grant from the Australian Research Council.

Curtin University
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Royal Perth Hospital

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for Global Health

This research has been approved by the Curtin University Human Research Ethics Committee (approval number: HR 29/2014). Any person with concerns or complaints about the conduct of this study should contact the Ethics Committee Secretary on (08) 9266 9223 or email hres@curtin.edu.au

The CEDAR Study: Cataract Extraction and Driving Ability Research

PARTICIPANT INFORMATION



Curtin University

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CURTIN-MONASH ACCIDENT RESEARCH CENTRE

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INFORMATION FOR PARTICIPANTS

Impact of first and second eye cataract surgery on driving outcomes

What is the study about?

You are invited to take part in a research study looking at how cataract surgery affects a person's driving. This includes when and where you drive and your driving performance.

This study aims to explore the impact of cataract surgery on driving performance and self regulation practices.

The results of this study may provide significant overall cost savings to the community by providing the evidence to fund cataract surgery in a timely manner (both for first and second eye) to avoid the costs associated with crashes and injury.

Why am I invited to participate?

You have been invited to take part in this study because you are aged 55 years or older, have a current drivers licence, drive at least twice a week, live in the Perth metropolitan area, are able to attend three assessment visits, have not had cataract surgery before and are now recommended for cataract surgery in both eyes.

Who is carrying out the study?

The study is being conducted at Sir Charles Gairdner Hospital by Dr Vignesh Raja, Department of Ophthalmology. The study has been funded by a grant from the Australian Research Council and is coordinated by the Curtin-Monash Accident Research Centre at Curtin University in WA.

What does the study involve?

If you choose to take part in this study, you will be invited to attend three face-to-face visits with our research team at Curtin University. In addition to this you will be provided with an in-vehicle driving device that will record data for one week on three separate occasions.

The First Visit

You will be asked to attend Curtin University one month before your first eye surgery to complete a set of questionnaires about your access to eye care and referral for surgery, attitudes to cataract surgery, difficulty with vision, your driving habits, self-regulation and driving difficulties and health and medical information

We will test your vision. This includes reading charts, measuring visual fields (side vision) and measuring how the two eyes work together. We will also measure your glasses.

We will also perform three simple cognitive tests that involve answering questions and looking at pictures.

You will drive a specific route in our driving simulator.

You will be provided with driving recording device to be placed in your vehicle for one week.

The Second and Final Visits

We will need to see you at Curtin University on two other occasions:

- 3 months after your first eye cataract surgery, and
- 3 months after your second eye cataract surgery.

At these visits we will again measure your vision and glasses, perform cognitive tests and a questionnaire and provide you with the driving recording device to place in your car for one week. You will also again drive in the simulator at these visits.

You will be paid \$10 after the first assessment, \$15 after the second assessment, and \$20 after the final assessment.

How much time will the study take?

The three visits required of you as a participant will each take 1.5-2 hours.

Your total time in the study will be up to 3 years or 3 months after your second eye cataract surgery, whichever is soonest.

Do I need to prepare anything for my involvement?

If you wear glasses, you will need you to bring these along to each of the three study visits.

Remember to bring the glasses that you wear most often and to bring any new glasses that you might get before the second and final study visits. Participants must also have their own vehicle.

Appendix C Invitation letter

C.1 Invitation letter: Fremantle Hospital



Dear Mr/Mrs,

Re. The CEDAR Study: Cataract Extraction and Driving Ability Research

We are writing to you from the Ophthalmology Department of Fremantle Hospital to tell you about a research study being conducted by colleagues at Curtin University, that you might be interested in participating in.

The researchers are interested in the health and needs of older people with cataracts and the study will investigate how cataract and cataract surgery affect driving.

We are contacting you on behalf of the Curtin University researchers because you are due to visit our eye clinic, were born before 1960, have cataract in both eyes and have not previously had cataract surgery.

We have enclosed a detailed information sheet about the study. Please note that participation in this research project is *entirely voluntary*. You do not have to participate. If you decide not to participate this will in no way affect the care you receive at Fremantle Hospital.

If you are interested in participating in the study, or would like more information, please contact the Curtin University researchers directly:

- Professor Lynn Meuleners on (08) 9266 4636 or
- Seraina Agramunt (PhD student) on (08) 9266 9591

A Fremantle Hospital staff member will give you a follow-up call early next week to confirm you have received this letter and answer any questions you might have.

Yours sincerely,

Dr Dimitri Yellachich

Fremantle Hospital

C.2 Invitation letter: Royal Perth Hospital



Dear Mr/Mrs,

Re. The CEDAR Study: Cataract Extraction and Driving Ability Research

We are writing to you from the Ophthalmology Department of Royal Perth Hospital to tell you about a research study being conducted by colleagues at Curtin University, that you might be interested in participating in.

The researchers are interested in the health and needs of older people with cataracts and the study will investigate how cataract and cataract surgery affect driving.

We are contacting you on behalf of the Curtin University researchers because you are due to visit our eye clinic, were born before 1960, have cataract in both eyes and have not previously had cataract surgery.

We have enclosed a detailed information sheet about the study. Please note that participation in this research project is *entirely voluntary*. You do not have to participate. If you decide not to participate this will in no way affect the care you receive at Royal Perth Hospital.

If you are interested in participating in the study, or would like more information, please contact the Curtin University researchers directly:

- Professor Lynn Meuleners on (08) 9266 4636 or
- Seraina Agramunt (PhD student) on (08) 9266 9591

A Royal Perth Hospital staff member will give you a follow-up call early next week to confirm you have received this letter and answer any questions you might have.

Yours sincerely,

A/Prof Nigel Morlet
Royal Perth Hospital

Appendix D Researcher administered questionnaires

D.1 Researcher administered questionnaires

Date:		Interviewer:		ID:		
1. DEMOGRAPHIC DETAILS				Baseline	FU1	FU2
				<i>(please select)</i>		
1.1 Gender	<input type="checkbox"/> [0]Female <input type="checkbox"/> [1]Male		1.9 Does anybody else live in the home with you? <input type="checkbox"/> [1]Live alone <input type="checkbox"/> [2]Spouse only <input type="checkbox"/> [3]Spouse & children <input type="checkbox"/> [4]Child/children <input type="checkbox"/> [5]Relatives/friends <input type="checkbox"/> [6]Other (please specify): <hr/> Comments:			
1.2 Marital Status	<input type="checkbox"/> Single <input type="checkbox"/> De facto <input type="checkbox"/> Married <input type="checkbox"/> Separated <input type="checkbox"/> Divorced <input type="checkbox"/> Widowed					
1.3 Highest Educational Level	<input type="checkbox"/> Did not go to school <input type="checkbox"/> Year 6 or below <input type="checkbox"/> Year 7 or below <input type="checkbox"/> Year 8 or below <input type="checkbox"/> Year 9 or below <input type="checkbox"/> Year 10 or below <input type="checkbox"/> Year 11 or below <input type="checkbox"/> Year 11 or below <input type="checkbox"/> TAFE/Apprenticeship <input type="checkbox"/> University					
1.4 DOB						
1.5 Country of birth	<input type="checkbox"/> [1]Australian <input type="checkbox"/> [2]New Zealand <input type="checkbox"/> [3]United Kingdom <input type="checkbox"/> [4]Europe <input type="checkbox"/> [5]Vietnam <input type="checkbox"/> [6]China & Hong Kong <input type="checkbox"/> [7]Middle East <input type="checkbox"/> [8]Other (please specify): <input type="checkbox"/> [9]Don't know					
1.6 Language spoken at home	<input type="checkbox"/> [1]English <input type="checkbox"/> [2]Other (please specify):					
1.7 Employment status	<input type="checkbox"/> [1]Retired on pension <input type="checkbox"/> <input type="checkbox"/> [4]Self-employed <input type="checkbox"/> <input type="checkbox"/> [2]Retired self-funded <input type="checkbox"/> <input type="checkbox"/> [5]Unemployed <input type="checkbox"/> [3]Employed <input type="checkbox"/> <input type="checkbox"/> [6]Medical disability pension					
1.8 Residence type	<input type="checkbox"/> [1]Home <input type="checkbox"/> <input type="checkbox"/> [4]Independent living unit <input type="checkbox"/> [2]Granny flat <input type="checkbox"/> <input type="checkbox"/> [5]Serviced apartment <input type="checkbox"/> [3]Unit <input type="checkbox"/> [6] Other (please specify):					
2. VISION STATUS						

2.1 Habitual correction <i>Refractive correction worn the majority of the time including when walking</i>	<input type="checkbox"/> [1]No correction <input type="checkbox"/> [3]Bifocals or multifocals <input type="checkbox"/> [2]Single vision spectacles <input type="checkbox"/> [4]Contact lenses	2.1.2 Frame material	<input type="checkbox"/> [1]Metal <input type="checkbox"/> [2]Plastic									
2.1.1 Date last updated	_____ / _____ (MM/YYYY)	2.1.3 Frame colour										
2.2 Habitual correction worn during: <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td data-bbox="304 555 635 712"> 2.2.1 Walking within the home <input type="checkbox"/> [1]Yes <input type="checkbox"/> [0]No – If no, indicate correction worn below: </td> <td data-bbox="635 555 1002 712"> 2.2.2 Walking outdoors <input type="checkbox"/> [1]Yes <input type="checkbox"/> [0]No – If no, indicate correction worn below: </td> <td data-bbox="1002 555 1402 712"> 2.2.3 Walking out of home but inside <input type="checkbox"/> [1]Yes <input type="checkbox"/> [0]No – If no, indicate correction worn below: </td> </tr> <tr> <td data-bbox="304 712 635 875"> <input type="checkbox"/> [1]No correction <input type="checkbox"/> [2]Single vision spectacles <input type="checkbox"/> [3]Bifocals or multifocal spectacles <input type="checkbox"/> [4]Contact lenses </td> <td data-bbox="635 712 1002 875"> <input type="checkbox"/> [1]No correction <input type="checkbox"/> [2]Single vision spectacles <input type="checkbox"/> [3]Bifocals or multifocal spectacles <input type="checkbox"/> [4]Contact lenses </td> <td data-bbox="1002 712 1402 875"> <input type="checkbox"/> [1]No correction <input type="checkbox"/> [2]Single vision spectacles <input type="checkbox"/> [3]Bifocals or multifocal spectacles <input type="checkbox"/> [4]Contact lenses </td> </tr> </table>				2.2.1 Walking within the home <input type="checkbox"/> [1]Yes <input type="checkbox"/> [0]No – If no, indicate correction worn below:	2.2.2 Walking outdoors <input type="checkbox"/> [1]Yes <input type="checkbox"/> [0]No – If no, indicate correction worn below:	2.2.3 Walking out of home but inside <input type="checkbox"/> [1]Yes <input type="checkbox"/> [0]No – If no, indicate correction worn below:	<input type="checkbox"/> [1]No correction <input type="checkbox"/> [2]Single vision spectacles <input type="checkbox"/> [3]Bifocals or multifocal spectacles <input type="checkbox"/> [4]Contact lenses	<input type="checkbox"/> [1]No correction <input type="checkbox"/> [2]Single vision spectacles <input type="checkbox"/> [3]Bifocals or multifocal spectacles <input type="checkbox"/> [4]Contact lenses	<input type="checkbox"/> [1]No correction <input type="checkbox"/> [2]Single vision spectacles <input type="checkbox"/> [3]Bifocals or multifocal spectacles <input type="checkbox"/> [4]Contact lenses			
2.2.1 Walking within the home <input type="checkbox"/> [1]Yes <input type="checkbox"/> [0]No – If no, indicate correction worn below:	2.2.2 Walking outdoors <input type="checkbox"/> [1]Yes <input type="checkbox"/> [0]No – If no, indicate correction worn below:	2.2.3 Walking out of home but inside <input type="checkbox"/> [1]Yes <input type="checkbox"/> [0]No – If no, indicate correction worn below:										
<input type="checkbox"/> [1]No correction <input type="checkbox"/> [2]Single vision spectacles <input type="checkbox"/> [3]Bifocals or multifocal spectacles <input type="checkbox"/> [4]Contact lenses	<input type="checkbox"/> [1]No correction <input type="checkbox"/> [2]Single vision spectacles <input type="checkbox"/> [3]Bifocals or multifocal spectacles <input type="checkbox"/> [4]Contact lenses	<input type="checkbox"/> [1]No correction <input type="checkbox"/> [2]Single vision spectacles <input type="checkbox"/> [3]Bifocals or multifocal spectacles <input type="checkbox"/> [4]Contact lenses										
2.4 Distance vision with habitual correction <i>High contrast Early Treatment Diabetic Retinopathy Study (ETDRS) acuity chart, 3m testing</i>	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width: 20px;">2.5.1</td> <td style="width: 50px;">RE:</td> <td style="width: 100px;">(Score 1–70)</td> </tr> <tr> <td>2.5.2</td> <td>LE:</td> <td>(Score 1–70)</td> </tr> <tr> <td>2.5.3</td> <td>OU:</td> <td>(Score 1–70)</td> </tr> </table>	2.5.1	RE:	(Score 1–70)	2.5.2	LE:	(Score 1–70)	2.5.3	OU:	(Score 1–70)	Comments:	
2.5.1	RE:	(Score 1–70)										
2.5.2	LE:	(Score 1–70)										
2.5.3	OU:	(Score 1–70)										
2.5 Contrast sensitivity <i>MARS chart, 50cm testing distance, near correction</i>	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width: 20px;">2.6.1</td> <td style="width: 50px;">RE:</td> <td style="width: 100px;">log CS errors</td> </tr> <tr> <td>2.6.2</td> <td>LE:</td> <td>log CS errors</td> </tr> <tr> <td>2.6.3</td> <td>OU:</td> <td>log CS errors</td> </tr> </table>	2.6.1	RE:	log CS errors	2.6.2	LE:	log CS errors	2.6.3	OU:	log CS errors	2.6 Stereopsis <i>Titmus Fly Stereotest + circles</i> (Score 1–10; 0 if fly only)	Cannot see fly <input type="checkbox"/>
2.6.1	RE:	log CS errors										
2.6.2	LE:	log CS errors										
2.6.3	OU:	log CS errors										
		2.7 Ocular Dominance	<input type="checkbox"/> [1]Right Eye <input type="checkbox"/> [2]Left Eye									
		2.8 Pupil size (mm)	2.10.1 RE: 2.10.2 LE:									
3. REFERRAL & WAITING TIMES												
3.1 Who referred you for cataract surgery?	<input type="checkbox"/> [1]GP <input type="checkbox"/> [2]Optometrist <input type="checkbox"/> [3]Ophthalmologist <input type="checkbox"/> [4]Other (please specify):		3.5 Were you given a choice of public or private cataract surgery by your referring doctor or optometrist? <input type="checkbox"/> [0]No <input type="checkbox"/> [1]Yes – If yes, why did you choose one over the other (select all that apply):									
3.2 What is the postcode or suburb of the professional mentioned in Q4.1?	<table border="1" style="width:100%; height: 40px; border-collapse: collapse;"> <tr> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> </tr> </table>						<input type="checkbox"/> [1]Surgical costs <input type="checkbox"/> [2]Waiting time for initial appointment <input type="checkbox"/> [3]Waiting time for surgery <input type="checkbox"/> [4]Convenient location <input type="checkbox"/> [5]Other (please specify):					
3.3 How often do you have your eyes tested? (please specify in months or years)	Every _____ years											

3.4 How long did you have to wait for an appointment with the ophthalmologist? (please specify in weeks or months)?	<p>_____ months</p> <p><i>(6 weeks = 1.5 months, 2 weeks = 0.5 months)</i></p>	
4. LICENCE		
4.1 Do you have a current driver's licence?	<input type="checkbox"/> [1] Yes <input type="checkbox"/> [0] No	
4.2 What type of licence do you hold?	<input type="checkbox"/> [1] Heavy Rigid <input type="checkbox"/> [2] Medium Rigid <input type="checkbox"/> [3] Light Rigid <input type="checkbox"/> [4] Car <input type="checkbox"/> [5] Heavy combination <input type="checkbox"/> [6] Car and rider <input type="checkbox"/> [0] other	
4.3 Do you have any restrictions on your licence?	<input type="checkbox"/> [1] Yes <input type="checkbox"/> [0] No	If [1] yes, list the restrictions:
4.4 Have you stopped driving in the last 12 months/since your surgery?	<input type="checkbox"/> [1] Yes <input type="checkbox"/> [0] No	If [1] yes, explain the reason:
5. DRIVING HABITS QUESTIONNAIRE (DHQ)		
Current Driving:		
5.1 Do you currently drive?	<input type="checkbox"/> [1] Yes – go to 5.4 <input type="checkbox"/> [2] No – answer 5.2 & 5.3 ONLY <input type="checkbox"/> [3] Never driven – go to Section 6	5.7 How would you rate the quality of your driving? <input type="checkbox"/> [5] Excellent <input type="checkbox"/> [4] Good <input type="checkbox"/> [3] Average <input type="checkbox"/> [2] Fair <input type="checkbox"/> [1] Poor
5.2 Why did you stop driving?		
5.3 When is the last time you drove?	_____ / _____ (MM/YYYY) GO TO SECTION 6	5.8 How fast do you generally drive compared to the general flow of traffic? <input type="checkbox"/> [5] Much faster <input type="checkbox"/> [4] Somewhat faster <input type="checkbox"/> [3] About the same <input type="checkbox"/> [2] Somewhat slower <input type="checkbox"/> [1] Much slower
5.4 Do you wear glasses or contact lenses when you drive?	<input type="checkbox"/> [1] Yes <input type="checkbox"/> [0] No	
5.5 Do you wear a seatbelt when you drive?	<input type="checkbox"/> [1] Always <input type="checkbox"/> [2] Sometimes <input type="checkbox"/> [3] Never	5.9 Has anyone suggested over the past year/since your surgery that you limit your driving or stop driving? <input type="checkbox"/> [1] Yes <input type="checkbox"/> [0] No
5.6 Which way do you prefer to get around?	<input type="checkbox"/> [3] Drive yourself <input type="checkbox"/> [2] Have someone drive you <input type="checkbox"/> [1] Use public transport or taxi <input type="checkbox"/> [0] Other (please specify):	5.10 If you had to go somewhere and couldn't drive yourself, what would you do? <input type="checkbox"/> [1] Ask friend or relative to drive <input type="checkbox"/> [2] Call a taxi <input type="checkbox"/> [3] Take a bus or train <input type="checkbox"/> [4] Drive yourself regardless <input type="checkbox"/>

			[5]Cancel/postpone plans & stay home <input type="checkbox"/> [6]Other (please specify):
5.11 Do you own your own car?	<input type="checkbox"/> [1] Yes <input type="checkbox"/> [0] No	5.12 What is the make of your car? 5.13 What is the model of your car? 5.14 What is the year of your car?	
Exposure			
5.15 In an average week, how many days per week do you usually drive?		5.17 Total trips per week	
5.16 Please tell me all the places you drive in a typical week		Total km per trip	
Total places		5.18 Total km driven/week	
Dependence			
Is there anyone that relies on you to drive them around?	<input type="checkbox"/> [1] Yes <input type="checkbox"/> [2] No	If [1] yes what is their relationship?	Total Number of individuals
Please list your friends and/or family members that you regularly travel with in a car over the past year/since your surgery.			
When travelling with this individual, who usually drives? (Indicate in adjacent cell using: [1]I drive; [2>About half and half; [3]This person drives)			
Person 1:		Person 5:	
Person 2:		Person 6:	
Person 3:		Person 7:	
Person 4:		5.19 Total # people	
Difficulty			
During the past 3 months/since your surgery, have you:	[0]No <i>Is this because of visual problems?</i>	[1]Yes <i>Would you say that you drive in that situation with:</i> [5]no difficulty at all; [4]a little difficulty; [3]moderate difficulty; or [2]extreme difficulty	
5.20 Driven when it is raining?	<input type="checkbox"/> [0]No <input type="checkbox"/> [1]Yes		
5.21 Driven alone?	<input type="checkbox"/> [0]No <input type="checkbox"/> [1]Yes		
5.22 Parallel parked?	<input type="checkbox"/> [0]No <input type="checkbox"/> [1]Yes		
5.23 Made right hand turns	<input type="checkbox"/> [0]No <input type="checkbox"/> [1]Yes		

across oncoming traffic?		
5.24 Driven on highways or freeways?	<input type="checkbox"/> [0]No <input type="checkbox"/> [1]Yes	
5.25 Driven on heavy traffic roads?	<input type="checkbox"/> [0]No <input type="checkbox"/> [1]Yes	
5.26 Driven in peak hour traffic?	<input type="checkbox"/> [0]No <input type="checkbox"/> [1]Yes	
5.27 Driven at night	<input type="checkbox"/> [0]No <input type="checkbox"/> [1]Yes	
Crash & Citations		
5.28 How many accidents have you been involved in over the past year/since your surgery when you were the driver?		
5.29 How many accidents have you been involved in over the past year/since your surgery when you were the driver and the police were called?		
5.30 How many times in the past year/since your surgery have you been pulled over by the police, regardless of whether you received a ticket?		
5.31 How many times in the past year/since your surgery have you received a traffic ticket (other than parking ticket) where you were found to be guilty, regardless of whether or not you think you were at fault?		
Driving Space		
5.32 During the past year/since your surgery, have you driven in the streets immediately around your home?	<input type="checkbox"/> [1]Yes <input type="checkbox"/> [0]No	5.35 During the past year/since your surgery, have you driven to more distant towns (within 2 hours)? <input type="checkbox"/> [1]Yes <input type="checkbox"/> [0]No
5.33 During the past year/since your surgery, have you driven to places further from home, within your suburb?	<input type="checkbox"/> [1]Yes <input type="checkbox"/> [0]No	5.36 During the past year/since your surgery, have you driven to places outside of greater <i>[insert name of city]</i> (2 or more hours)? <input type="checkbox"/> [1]Yes <input type="checkbox"/> [0]No
5.34 During the past year/since your surgery, have you driven to places out of your suburb?	<input type="checkbox"/> [1]Yes <input type="checkbox"/> [0]No	5.37 Do you think that cataract has affected your driving? <input type="checkbox"/> [0]No <input type="checkbox"/> [1]Yes – If yes, how has it affected your driving? (select all that apply)

<input type="checkbox"/> [1]Reduced my confidence in driving <input type="checkbox"/> [2]Reduced the number of hours driven <input type="checkbox"/> [3]Reduced the distance driven <input type="checkbox"/> [4]Reduced speed compared to the general public <input type="checkbox"/> [6]I try to avoid driving in rain <input type="checkbox"/> [7]I try to avoid driving at night <input type="checkbox"/> [8]I try to avoid driving in crowded traffic <input type="checkbox"/> [9]I try to avoid driving in unfamiliar areas <input type="checkbox"/> [10]I try to avoid driving long distances <input type="checkbox"/> [11]Other, please specify:		
Alternate Transport		
<i>In the last month have you:</i>		[1] Yes How many trips have you taken?
6.1 Travelled in a bus?	<input type="checkbox"/> [1] Yes <input type="checkbox"/> [2] No	
6.2 Travelled on a train?	<input type="checkbox"/> [1] Yes <input type="checkbox"/> [2] No	
6.3 Travelled in a taxi?	<input type="checkbox"/> [1] Yes <input type="checkbox"/> [2] No	
6.4 Used door to door community transport for medical appointments?	<input type="checkbox"/> [1] Yes <input type="checkbox"/> [2] No	
6.5 Used door to door community transport for shopping trips?	<input type="checkbox"/> [1] Yes <input type="checkbox"/> [2] No	
6.6 Used door to door community transport for social outings?	<input type="checkbox"/> [1] Yes <input type="checkbox"/> [2] No	
6.7 Used a mobility scooter to get around the community?	<input type="checkbox"/> [1] Yes <input type="checkbox"/> [2] No	
6.8 Used any other form of transport?	<input type="checkbox"/> [1] Yes <input type="checkbox"/> [2] No	

Appendix E Travel Diary

E.1 Travel Diary



The CEDAR Study: Cataract Extraction and Driving Ability Research

TRAVEL DIARY

Participant ID _____

Instructions to Participants

Thank you for agreeing to participate in our project.

For this part of our study, we are asking you to complete this travel diary every time you drive for a period of 7 days.

At the same time, you will have a GPS based data recorder installed in your car which will gather other details about your driving trips and record them for the research team.

Please complete the Travel Diary for every trip you make. You will find it easier and more accurate if you make your recordings at the beginning and end of each trip. Please record your trips honestly, we're not interested in where you go or who you are with and will not disclose information to another party.

Some tips for completing the Travel Diary

Vehicle Make, Model & Year – this should describe the vehicle you are driving, for example Holden Commodore Sedan 2006; Toyota Corolla Hatch 2010; Hyundai i20 2012 etc.

Start time is the time you commence your driving trip. **End time** is the time you reach your destination.

Odometer – the odometer is the device in your instrument panel, generally behind the steering wheel, that records the number of kilometres your vehicle has travelled. Record whole numbers only and round up or down appropriately if you have a display that shows distances less than 1 km. Please record all stops and starts as separate trips, even if you are only stopping for a short time to collect a friend on the way to another destination. Use a separate line for each trip – see the example below.

On the vehicle representation, the blue triangle is the front of the vehicle and the dark shaded square is the driver. There are three rows of seating to represent those vehicles that have three rows of seating. If the car you are using has only one row of seating, use just the first row of squares; if it has two rows, use the first two rows etc.

Date	Vehicle Make, Model & Year	Start time	End time	Purpose of trip	# of Passengers	Please write ages of passengers in the squares representing where they were seated
21/10/14	Holden Commodore Sedan 2006	9.00am	9.15am	Going to shops	1	
		Start Odometer	End Odometer			
		95462	95488			
21/10/14	Holden Commodore Sedan 2006	Start time	End time	Going home from shops	1	
		10.15am	10.30am			
		Start Odometer	End Odometer			
		95488	95501			

Travel Diary

Participant ID _____

Date	Vehicle Make, Model & Year	Start time	End time	Purpose of trip	# of Passengers	Please write ages of passengers in the squares representing where they were seated
						
		Start Odometer	End Odometer			
		Start time	End time			
		Start Odometer	End Odometer			
		Start time	End time			
		Start Odometer	End Odometer			
		Start time	End time			
		Start Odometer	End Odometer			

Appendix F In-vehicle monitoring device instructions

F.1 In-vehicle monitoring devices' instructions: OBD II port



Curtin University

C-MARC
CURTIN-MONASH ACCIDENT RESEARCH CENTRE



THE GEORGE INSTITUTE
for Global Health

Instructions for data acquisition device

1. Your device will arrive assembled as displayed below:

Extension cord Device



2. Find the OBD II port in your car, usually situated under the dash, on the driver's side of your car. Please refer to your car's manual for more information on locating your OBD II port. Plug the device into the OBD II port of your car.



3. If needed, plug the device into the extension cord and plug the extension cord into the OBD II port of your car. Place the device somewhere convenient, where it will not interfere with your driving.



4. Please make sure that your device is firmly secured using the supplied zip tie or the self-adhesive Velcro, so that it will not interfere with your driving.

5. Once you have plugged your device in, start the car and let it run for about 1 minute. The red LED will illuminate, followed by the green and blue LED's. This means that the GPS knows its position. Ensure that your car is parked outside, where it can get a clear GPS signal.

6. The device will start working automatically as soon as the car engine starts and will stop when the car engine stops.

7. Please leave the device plugged into your car for **one week** and fill out the travel diary every time you drive.

8. After one week place the device, the travel diary and consent form in the reply paid envelope and mail it back to us.

9. If someone other than yourself drives the car, please remember to unplug the device from the cigarette lighter, then plug it back in the next time you drive.

10. If you drive more than one car during the week, please set the device up in every car you drive, each time you drive.

If you have any queries please contact Seraina Agramunt on 08 9266 9591 or seraina.agramunt@curtin.edu.au

F.2 In-vehicle monitoring devices' instructions: cigarette lighter port



Curtin University

C-MARC
CURTIN-MONASH ACCIDENT RESEARCH CENTRE



THE GEORGE INSTITUTE
for Global Health

Instructions for data acquisition device with cigarette plug

1. Your device will arrive assembled as displayed below:

DevicePower Supply



2. Plug the device's power supply into the cigarette lighter of the car, then place the device somewhere convenient e.g. the compartment under the cigarette lighter.



3. Please make sure that your device is firmly secured using the supplied self-adhesive Velcro, so that it will not interfere with your driving.
4. Once you have plugged your device in, start the car and let it run for about 1 minute. The red LED will illuminate, followed by the green and blue LED's. This means that the GPS knows its position. Ensure that your car is parked outside, where it can get a clear GPS signal.
5. The device will start working automatically as soon as the car engine starts and it will stop when the car engine stops.
6. Please leave the device plugged into your car for **one week** and fill out the travel diary every time you drive.
7. After one week place the device, the travel diary and consent form in the reply paid envelope and mail it back to us. Please do not pull the cable to disconnect the cigarette plug, as this could damage the cable.
8. If someone other than yourself drives the car, please remember to unplug the device from the cigarette lighter, then plug it back in the next time you drive.
9. If you drive more than one car during the week, please set the device up in every car you drive, each time you drive.

If you have any queries please contact Seraina Agramunt on 08 9266 9591 or seraina.agramunt@curtin.edu.au

Appendix G Ethics approval

G.1 Ethics approval: Curtin University



Memorandum

To	A/Professor Lynn Meuleners, Health Sciences
From	Professor Peter O'Leary, Chair, Human Research Ethics Committee
Subject	Protocol Approval HR 29/2014
Date	5 March 2014
Copy	Dr Lisa Keay, University of Sydney Professor Mark Young, Brunel University Dr Jonathon Ng, University of Western Australia A/Professor Nigel Morlet, University of Western Australia Professor Peter McCluskey, University of Sydney

Office of Research and Development
Human Research Ethics Committee

TELEPHONE 9266 2784
FACSIMILE 9266 3793
EMAIL hrec@curtin.edu.au

Thank you for your application (4639) submitted to the Human Research Ethics Committee (HREC) for the project titled "*Characterisation of deficits in driving performance and self-regulation practices among older drivers with bilateral cataract.*". Your application has been reviewed by the HREC and is **approved**.

- You have ethics clearance to undertake the research as stated in your proposal.
- The approval number for your project is **HR 29/2014**. Please quote this number in any future correspondence.
- Approval of this project is for a period of 4 years **05-03-2014 to 05-03-2018**.
- Your approval has the following conditions:
 - (i) Annual progress reports on the project must be submitted to the Ethics Office.
 - (ii) Please clarify if data will be transferred between the Universities.
 - (iii) Please apply for ethics approval with:
 - University of Sydney
 - University of Western Australia
- It is your responsibility, as the researcher, to meet the conditions outlined above and to retain the necessary records demonstrating that these have been completed.

Applicants should note the following:

It is the policy of the HREC to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the HREC considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the HREC may request the chief investigator to provide an outcomes report, including information on follow-up of participants.

The attached **Progress Report** should be completed and returned to the Secretary, HREC, C/- Office of Research & Development annually.

Our website https://research.curtin.edu.au/guides/ethics/non_low_risk_hrec_forms.cfm contains all other relevant forms including:

- Completion Report (to be completed when a project has ceased)
- Amendment Request (to be completed at any time changes/amendments occur)
- Adverse Event Notification Form (if a serious or unexpected adverse event occurs)

Yours sincerely

Professor Peter O'Leary
Chair Human Research Ethics Committee

Standard conditions of ethics approval

These standard conditions apply to all research approved by the Curtin University Human Research Ethics Committee. It is the responsibility of each researcher named on the application to ensure these conditions are met.

1. **Compliance.** Conduct your research in accordance with the application as it has been approved and keep appropriate records.
 - a. **Monitoring** - Assist the Committee to monitor the conduct of the approved research by completing promptly and returning all project review forms that are sent to you.
 - b. **Annual report** - Submit an annual report on or before the anniversary of the approval.
 - c. **Extensions** - If you are likely to need more time to conduct your research than is already approved, complete a new application six weeks before the current approval expires.
 - d. **Changes to protocol** - Any changes to the protocol are to be approved by the Committee before being implemented.
 - e. **Changes to researcher details** - Advise the Committee of any changes in the contact details of the researchers involved in the approved study.
 - f. **Discontinuation** - You must inform the Committee, giving reasons, if the research is not conducted or is discontinued before the expected completion date.
 - g. **Closure** - Submit a final report when the research is completed. Include details of when data will be destroyed, and how, or if any future use is planned for the data.
 - h. **Candidacy** - If you are a Higher Degree by Research student, data collection must not begin before your Application for Candidacy is approved by your Faculty Graduate Studies Committee.
2. **Adverse events.** Consider what might constitute an adverse event and what actions may be needed if an adverse event occurs. Follow the procedures for reporting and addressing adverse events (<http://research.curtin.edu.au/guides/adverse.cfm>). Where appropriate, provide an adverse events protocol. The following are examples of adverse events:
 - a. Complaints
 - b. Harm to participants. This includes physical, emotional, psychological, economic, legal, social and cultural harm (NS Section 2)
 - c. Loss of data or breaches of data security
 - d. Legal challenges to the research
3. **Data management plan.** Have a Data Management Plan consistent with the University's recordkeeping policy. This will include such things as how the data are to be stored, for how long, and who has authorised access.
4. **Publication.** Where practicable, ensure the results of the research are made available to participants in a way that is timely and clear (NS 1.5). Unless prohibited from doing so by contractual obligations, ensure the results of the research are published in a manner that will allow public scrutiny (NS 1.3, d). Inform the Committee of any constraints on publication.
5. **Police checks and other clearances.** All necessary clearances, such as Working with Children Checks, first aid certificates and vaccination certificates, must be obtained before entering a site to conduct research.
6. **Participant information.** All information for participants must be approved by the HREC before being given to the participants or made available to the public.
 - a. **University logo.** All participant information and consent forms must contain the Curtin University logo and University contact details for the researchers. Private contact details should not be used.
 - b. **Standard statement.** All participant information forms must contain the HREC standard statement.

This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 29/2014). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.

- c. **Plain language.** All participant information must be in plain language that will be easily understood by the participants.

Please direct all communication through the Research Ethics Office

G.2 Ethics approval: Fremantle Hospital



Government of Western Australia
Department of Health
South Metropolitan Health Service

cg
R/14/64
15 September 2014

Professor Lynn Meuleners
Curtin-Monash Accident Research Centre
Curtin University
GPO Box U1987
Perth WA 6845

Dear Professor Meuleners

Project Title: The Characterisation of deficits in driving performance and self-regulation practices among older drivers with bilateral cataract.
HREC Reference: REG 14-033 (RPH)

On behalf of the South Metropolitan Health Service, I give authorisation for your research project to be conducted at the following site(s):

Fremantle Hospital

The following documents have been approved for this project:

Document
<ul style="list-style-type: none">• Research Protocol, version 1 dated 4 January 2014• Invitation Letter, FH version dated 20 May 2014• Patient Information and Consent Form, FH version 4, 28 July 2014• Participant Information Brochure, FH version 3, 20 May 2014• Standardized Mini-Mental State Examination dated 19 January 2014• Travel Diary dated 19 January 2014• NASA Task Load Index (No version)• EQ-5D-5L (Version 2)• Low visual acuity letter (No version)

This authorisation is based on the approval from the Royal Perth Hospital Ethics Committee (HREC) and the review from the Research Governance Office at Fremantle Hospital. This authorisation is valid subject to the ongoing approval from the RPH HREC.

This authorisation is based on the ethical approval from the Lead HREC, and on the basis of compliance with the 'Conditions of Authorisation to Conduct a Research Project at Site' (attached) and with the compliance of all reports as required by the Research Governance Office and approving HREC. Non-compliance with these requirements could result in the authorisation be withdrawn.

Meuleners CEDAR study R_14_64 approval letter

Research Governance & Ethics Office
Fremantle Hospital
Demountable 3, G Block
Postal Address: PO 480 Fremantle WA 6959
Telephone: (08) 94312929 Facsimile: (08) 9431 3630
<http://www.fhs.health.wa.gov.au> ABN 13 983 250 709

The responsibility for the conduct of this project remains with you as the Principal Investigator at the site.

Yours sincerely

A handwritten signature in blue ink, appearing to be 'D. Blythe', written in a cursive style.

DR DAVID BLYTHE
EXECUTIVE DIRECTOR
FREMANTLE HOSPITAL & HEALTH SERVICE

cc: Dr Dimitri Yellachich, Head of Department, Ophthalmology, Fremantle Hospital
Seraina Agramunt, Research Assistant, Curtin Monash Accident Research Centre
Mark Woodman, Ethics Coordinator RPH (REG 14-033)

Letterhead

9. Complaints relating to the conduct of a project should be directed to the RGO and will be promptly investigated according to the site Standard Operating Procedures.
10. The PI is reminded that records of consent or authorisation for participation in a project form part of the Acute Hospital Patient Record and should be stored with that record in accordance with the WA *Health Patient Information Retention and Disposal Schedule (Version 2) 2000*. A copy of the 'Participant Information Sheet' should also be included in the medical records as part of informed consent documentation.
11. Once the project has been closed at site, the PI is required to submit to the RGO a copy of the final report that is submitted to the HREC. This should include the site specific information which should be completed by the site PI. If the report is not received within 30 days the project will be closed and archived. An outstanding final report could impact on the PI's ability to apply for approval for future projects.
12. If a project is suspended or terminated the PI must ensure that the RGO at site is informed of this and the circumstances necessitating the suspension or termination of the project. Such notification should include information as to what procedures are in place to safeguard participants.
13. If a project fails to meet these conditions the RGO will contact the investigator(s) to request they rectify the identified issues. If, after being contacted by the RGO, the issues are not addressed the site authorisation will be withdrawn.

G.3 Ethics approval: Royal Perth Hospital



Government of Western Australia
Department of Health
South Metropolitan Health Service

Royal Perth Hospital



8th May 2014

A/Prof Nigel Moriet
Ophthalmology
Royal Perth Hospital

Dear Nigel

Project Title: **Characterisation of deficits in driving performance and self-regulation practices among older drivers with bilateral cataract.**
Protocol No: **N/A**
HREC Reference: **REG 14-033**

The ethics application for the project referenced above has been **approved** by the Royal Perth Hospital Human Research Ethics Committee (EC00270).

The following documents have been approved for use in this project:

- Research Protocol (**Version 1, 04.01.2014**)
- Invitation Letter (**30/04/2014**)
- Patient Information and Consent Form (**Version 3, 30/04/2014**)
- Participant Information Brochure (**Version 2.0, 19/01/2014**)
- Standardized Mini-Mental State Examination (**19/01/2014**)
- Trial Making Test – Parts A&B (**No version**)
- DriveSafe/DriveAware Assessments (**19/01/2014**)
- Travel Diary (**19/01/2014**)
- NASA Task Load Index (**No version**)
- EQ-5D-5L (**Version 2**)
- Low visual acuity letter (**No version**)

The approval is **valid to 08/05/2017** and on the basis of compliance with the 'Conditions of HREC Approval for a Research Project' (attached).

The nominated participating site in this project is:

Royal Perth Hospital
Fremantle Hospital
Sir Charles Gairdner Hospital

- If additional sites are recruited prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the RPH HREC. Notification of withdrawn sites should also be provided to the HREC in a timely fashion.
- A copy of this ethical approval letter must be submitted by all site Principal Investigators to the Research Governance Office or equivalent body or individual at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site/s.

This letter constitutes ethical approval only. This project cannot proceed at any site until separate site authorisation has been obtained from the Chief Executive, or delegate, of the site under whose auspices the research will be conducted.

The RPH Ethics Committee is registered with the Australian Health Ethics Committee and operates according to the NHMRC National Statement on Ethical Conduct in Human Research and International Conference on Harmonisation – Good Clinical Practice.

Should you have any queries about the HREC's consideration of your project, please contact (08) 9224 2292. The HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Ethics Office, (08) 9224 2292 or rph.hrec@health.wa.gov.au.

Yours sincerely

PROF FRANK VAN BOCKXMEER
Chairman, RPH Human Research Ethics Committee



CONDITIONS OF HREC APPROVAL FOR A RESEARCH PROJECT

The following general conditions apply to the research project approved by the Human Research Ethics Committee (HREC) and acceptance of the approval will be deemed to be an acceptance of these conditions by all investigators involved in the research project:

1. The responsibility for the conduct of the projects lies with the Coordinating Principal Investigator (CPI). All correspondence with the Lead HREC should be signed by the CPI.
2. Projects that do not commence within 12 months of the approval date may have their approval withdrawn. The CPI must outline why the project approval should stand.
3. The submission of an application for HREC approval will be deemed to indicate that the investigator/s and any sponsor recognises the approving HREC is registered with the National Health and Medical Research Council (NH&MRC) and that it complies in all respects with the National Statement on Ethical Conduct in Human Research and all other national and international ethical requirements. **The HREC will not enter into further correspondence on this point.**
4. A list of attendance at a specific HREC meeting is available on request, but no voting records will be provided.
5. The CPI will notify the HREC of his or her inability to continue as CPI and will provide the name and contact information of their replacement. Failure to notify the HREC may result in the project being suspended or approval withdrawn.
6. The CPI will notify the HREC of any departures of named investigators. The CPI will also notify the HREC if any new investigators and/or sites join the project that will utilise the HREC's approval.
7. The CPI will inform the HREC about any changes to the project. The CPI is responsible for submitting any amendments to the approved documents listed on the approval letter, or any new documentation to be used in the project. Any new or amended documentation should be submitted in a timely manner and cannot be implemented at any participating site until they have received HREC approval.
8. The CPI is responsible for reporting adverse events, indicating whether or not the project should continue. Reporting requirements are as per the WA Health Research Governance and Single Ethical Review Standard Operating Procedures. Additional reports other than those outlined that are submitted to the HREC will be returned without acknowledgement. The HREC can request additional reporting requirements as a special condition of a research project.
9. Where a project requires a Data Safety Monitoring Board (DSMB) it is the CPI's responsibility to ensure this is in place before the commencement of the project and the HREC notified of this. All relevant reports from the DSMB should be submitted to HREC.
10. For projects where the site is acting as the sponsor (ie. investigator initiated project) it is the responsibility of the CPI to report serious and unexpected drug/device reactions, as well as other reactions/events to the Therapeutic Goods Administration (TGA). Please refer to TGA website for further information and the relevant forms (see <http://www.tga.gov.au/pdf/clinical-trials-guidelines.pdf> p71 for medications or p77 for devices).
11. If this project involves the use of an implantable device a properly monitored and up to date system for tracking participants is to be maintained for the life of the device in accordance with the National Statement section 3.3.22 (g).
12. The investigator is responsible for notifying the Therapeutic Drugs Administration of a device incident in accordance with the National Statement section 3.3.22 (g).
13. An annual report on an approved research project will be required on the anniversary date of the project's approval. HREC approvals are subject to the submission of these reports and approval may be suspended if the report is not submitted.
14. The HREC has the authority to audit the conduct of any project without notice. Exercise of this authority will only be considered if there are grounds to believe that some irregularity has occurred, if a complaint is received from a third party or the HREC decides to undertake an audit for Quality Improvement purposes.

The RPH Human Research Ethics Committee (HREC) is constituted and operates in accordance with NH&MRC Guidelines.

15. The HREC can conduct random monitoring of any project. The CPI will be notified if their project has been selected. The CPI will be given a copy of the monitor's report along with the HREC and Research Governance Office (RGO) at each site.
16. Complaints relating to the conduct of a project should be directed to the HREC Chair and will be promptly investigated according to the Committee's complaints procedures.
17. CPI are reminded that records of consent or authorisation for participation in a project form part of the Acute Hospital Patient Record and should be stored with that record in accordance with the WA Health Patient Information Retention and Disposal Schedule (Version 2) 2000. A copy of the "Participant Information Sheet" should also be included in the medical records as part of informed consent documentation.
18. The duration of HREC approval for a project is 3 year (with the option of 5 years) from the date of approval. The date of approval expiry is stipulated in the HREC approval letter.
19. If the project is to continue beyond the stipulated approval expiry date a request for an extension should be submitted prior to that expiry date. One extension of 3 years can be granted but approval beyond this time period may necessitate further review by the HREC.
20. Once the approval period has expired, the CPI is required to submit a final report. If the report is not received within 30 days the project will be closed and archived. An outstanding final report could impact on the CPI's ability to apply for approval for future projects.
21. If a project is suspended or terminated by the CPI, or a project sponsor, the CPI must immediately inform the HREC and the RGO at each site of this and the circumstances necessitating the suspension or termination of the project. Such notification should include information as to what procedures are in place to safeguard participants.
22. If a project fails to meet these conditions the HREC will contact the investigator(s) to request they rectify the identified issues. If, after being contacted by the HREC, the issues are not addressed the HREC approval will be withdrawn. The HREC will notify the RGO at each site within WA Health that work may no longer be conducted in relation to the project other than that concerning the participants safety.

The RPH Human Research Ethics Committee (HREC) is constituted and operates in accordance with NH&MRC Guidelines.

Ethics Office Level 5 Colonial House, Royal Perth Hospital, GPO Box X2213 Perth WA 6001
Tel (08) 9224 2292 | Fax (08) 9224 3688 | Email rph.hrec@health.wa.gov.au

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G.4 Ethics approval: Sir Charles Gairdner Hospital



Government of Western Australia
Department of Health

Our Ref: 2014-113-approval SCGOPHCG



Sir Charles
Gairdner Hospital

31 October 2014

Professor Lynn Meuleners
Curtin-Monash Accident Research Centre
Curtin University
GPO Box U1987
PERTH WA 6845

Dear Professor Meuleners

HREC No: 2014-113

Project Title: Characterisation of deficits in driving performance and self-regulation practices among older drivers with bilateral cataract (CEDAR study)

On behalf of the Sir Charles Gairdner Osborne Park Health Care Group, I give authorisation for your research project to be conducted at the following site(s):

Sir Charles Gairdner Hospital

The following site specific documents are to be used in addition to those approved by the Human Research Ethics Committee (HREC).

Document

SCGH Brochure - Participant Information, SCG version 3, 20 May 2014

This authorisation is based on the approval from the Royal Perth Hospital Human Research Ethics Committee and the review from the Research Governance Office. This authorisation is valid subject to the ongoing approval from the HREC, and on the basis of compliance with the 'Conditions of Site Authorisation to Conduct a Research Project' (attached) and with the compliance of all reports as required by the Research Governance Office and approving HREC. Noncompliance with these requirements could result in the authorisation be withdrawn.

The responsibility for the conduct of this project remains with you as the Principal Investigator at the site.

Yours sincerely

Dr Victor Cheng
A/EXECUTIVE DIRECTOR
SIR CHARLES GAIRDNER AND
OSBORNE PARK HEALTH CARE GROUP

CONDITIONS OF SITE AUTHORISATION TO CONDUCT A RESEARCH PROJECT

The following general conditions apply to the research project authorised to be conducted at the site(s) nominated in the accompanying letter. The acceptance of the site authorisation will be deemed to be an acceptance of these conditions by all investigators involved in the research project at the nominated site(s).

1. The responsibility for the conduct of project at a site lies with the nominated Principal Investigator (PI) at that site, all correspondence should be signed by PI.
2. The PI will inform the Research Governance Office (RGO) about any changes to the project. The PI is responsible for submitting any amendments to the approved documents listed on the approval letter, or any new documentation to be used in the project. Any new or amended documentation should be submitted in a timely manner and cannot be implemented at this site until they have received HREC approval for use at site(s).
3. The PI will notify the RGO of their inability to continue as PI at the site(s) and will provide the name and contact information of their replacement.
4. The PI will notify the RGO of any departures of named site investigators. The PI will also notify the RGO if any new site investigators join the project.
5. The PI is responsible for reporting site adverse events, using the standard forms available from the website. Reporting requirements are as per the WA Health Research Governance and Single Ethical Review Standard Operating Procedures. Additional reports, other than those outlined, that are submitted will be returned without acknowledgement.
6. The annual report that is submitted to the HREC should also be submitted to the RGO. This should include the site specific information which should be completed by the site PI.
7. The site has the authority to audit the conduct of any project without notice. Exercise of this authority will only be considered if there are grounds to believe that some irregularity has occurred, if a complaint is received from a third party or the site decides to undertake an audit for Quality Improvement purposes.
8. The site can conduct random monitoring of any project. The PI will be notified if their project has been selected. The PI will be given a copy of the monitor's report along with the HREC and RGO.
9. Complaints relating to the conduct of a project should be directed to the RGO and will be promptly investigated according to the site Standard Operating Procedures.
10. The PI is reminded that records of consent or authorisation for participation in a project form part of the Acute Hospital Patient Record and should be stored with that record in accordance with the *WA Health Patient Information Retention and Disposal Schedule (Version 2) 2000*. A copy of the 'Participant Information Sheet' should also be included in the medical records as part of informed consent documentation.
11. Once the project has been closed at site, the PI is required to submit to the RGO a copy of the final report that is submitted to the HREC. This should include the site specific information which should be completed by the site PI. If the report is not received within 30 days the project will be closed and archived. An outstanding final report could impact on the PI's ability to apply for approval for future projects.

12. If a project is suspended or terminated the PI must ensure that the RGO at site is informed of this and the circumstances necessitating the suspension or termination of the project. Such notification should include information as to what procedures are in place to safeguard participants.
13. If a project fails to meet these conditions the RGO will contact the investigator(s) to request they rectify the identified issues. If, after being contacted by the RGO, the issues are not addressed the site authorisation will be withdrawn.

Investigator Initiated Trials

Please note if you are the Principal Investigator of an Investigator Initiated Trial utilising a CTN for a medication or device where SCGOPHCG is the sponsor, it is a TGA requirement that you inform the TGA of trial completion, in addition to reporting to the HREC/RGO.

Please refer to the TGA website <http://www.tga.gov.au/pdf/clinical-trials-guidelines.pdf> for further information and a copy of the Clinical Trial Completion Advice form for completion.

Appendix H Participant information sheet and consent form

H.1 Participant information sheet and consent form: Fremantle Hospital



PARTICIPANT INFORMATION SHEET

The CEDAR Study: Cataract Extraction and Driving Ability Research

Invitation

You are invited to participate in a research study into how cataract surgery affects a person's driving performance.

The study is being conducted by Professor Lynn Meuleners, Curtin-Monash Accident Research Centre at Curtin University and the George Institute in Sydney.

The study is funded by the Australian Research Council and is part of a national collaborative study coordinated by Curtin University in Perth.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

If you agree participate in this study, you will be asked to sign the attached Consent Form.

1. 'What is the purpose of this study?'

The purpose is to investigate the impact of cataract and cataract surgery on driving performance and self-regulation practices.

2. 'Why have I been invited to participate in this study?'

You are eligible to participate in this study because you are aged 55 years or older, have a current driver's licence, drive at least twice a week, live in the Perth metropolitan area, are able to attend three assessment visits, have not had cataract surgery before and are now recommended for cataract surgery.

3. 'What if I don't want to take part in this study or if I want to withdraw later?'

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason. Withdrawing from this study will not affect your relationship with your doctors or any standard treatment you may be receiving. If you

want to withdraw notify one of the research team or complete the 'Revocation of Consent' which is attached here.

4. 'What does this study involve?'

This study will be conducted over 3 years. However, your involvement will last only from one month before your first eye surgery to six months after your second eye surgery.

If you agree to participate, you will be asked to attend three face to face visits at Curtin University. These will take place 1 month before your first eye surgery, 3 months after first eye surgery and 3 months after second eye surgery. At each visit you will be asked to undergo the following assessments:

- Visual tests: These include letter charts, visual fields, refraction, pupil size and measurement of your glasses
- Questionnaire: We will ask you some questions about your glasses, access to eye care and referral for surgery, attitudes to cataract surgery, difficulty with vision, your driving habits, self-regulation and driving difficulties, and collect information about your health, medical history, physical activity and risk of falls.
- Cognitive tests: We will ask you to complete three cognitive tests that involve answering questions and looking at pictures
- Driving simulator: You will drive a specific route in our state-of-the-art driving simulator
- In-vehicle driving device: We will ask you to plug a device into your car for one week to record confidential driving data, then post it back.

The researchers will also access your hospital medical records to obtain clinical information about your cataract and cataract surgery.

You may also be invited to participate in a panel formulating recommendations for older drivers with cataract at the completion of the study. It is your decision whether to choose to participate in this panel.

5. 'How is this study being paid for?'

The study is being sponsored by the Australian Research Council.

All of the money being paid by the sponsor to run the study will be deposited into a centrally managed account to cover the costs of running the study. No money is paid directly to individual researchers or your medical team.

6. 'Are there risks to me in taking part in this study?'

There are no risks associated with taking part in the study. All tests are non-invasive and safe. However, some people may feel sick while using the driving simulator. If this happens to you, we will stop the assessment immediately. Furthermore, if the study tests identify any issues such as depression or anxiety, you will be advised to seek help from a professional. If you are in need a help line number will provide immediate support to you (Lifeline 13 11 14).

7. 'What happens if the study tests indicate my vision is inadequate for safe driving?'

If the visual tests show that you do not meet the minimum correct visual standard for driving in at least one eye, you will be advised to consult your GP or Ophthalmologist. If you are about to undergo cataract surgery, you will be advised not to drive until you have seen your Ophthalmologist after surgery. A follow-up call will be made within 7 days to see if you have followed up with a medical appointment. In the event that you do not seek medical assistance from a GP or Ophthalmologist, you accept responsibility for your decision not to seek treatment.

8. 'Will I benefit from the study?'

This study aims to further medical knowledge and may improve future management of cataract, however it will not directly benefit you. Nevertheless, a personal summary report will be provided to you on completion of the study.

9. 'Will taking part in this study cost me anything, and will I be paid?'

Participation in this study will not cost you anything. You will be paid \$10 for the first assessment, \$15 for the second assessment and \$20 for the final assessment for your time and effort participating in research.

10. 'How will my confidentiality be protected?'

Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Data collected by the in-vehicle monitoring devices could be used in a court law following a traffic accident. Only the researchers named above will have access to your details and results that will be held securely at the Curtin-Monash Accident Research Centre, Curtin University. The information will be stored in password protected files with access limited to those involved in running the study. Any paper documents will be stored in locked filing cabinets. Information will not be passed onto your doctors, the Department of Transport or the WA Police.

11. 'What happens with the results?'

If you give us your permission by signing the consent document, we plan to discuss the results with The George Institute for Global Health and the Curtin University Ethics Committee for the purpose of monitoring the conduct of this research and to publish the results in peer reviewed journals, presentation at conferences or other professional forums.

In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish. If you wish to receive the study results you should contact Professor Lynn Meuleners, (08) 9266 4636 or Seraina Agramunt from Curtin University on (08) 9266 9591.

12. 'What should I do if I want to discuss this study further before I decide?'

When you have read this information, the researcher will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact Lynn Meuleners on (08) 9266 4636 or Seraina Agramunt from Curtin University on (08) 9266 9591.

13. 'Who should I contact if I have concerns about the conduct of this study?'

This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 29/2014). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.

The study has also been approved by the South Metropolitan Area Health Service Human Research Ethics Committee which can be contacted on (08) 9431 2929 or SMHS.HREC@health.wa.gov.au.

**Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached Consent Form.
This information sheet is for you to keep.**



**CONSENT FORM
IMPACT OF FIRST AND SECOND EYE SURGERY ON DRIVING OUTCOMES**

1. I,.....
of.....

agree to participate in the study described in the participant information statement set out above.

2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this Consent Form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to Curtin University or my treating hospital.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact Professor Lynn Meuleners on (08) 9266 4636 or Seraina Agramunt on (08) 9266 9591 who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the Curtin University Human Research Ethics Committee on (08) 9266 9223 or at hrec@curtin.edu.au or the South Metropolitan Area Health Service Human Research Ethics Committee on (08) 9431 2929 or SMHS.HREC@health.wa.gov.au.

Signature of participant	Please PRINT name	Date
_____	_____	_____

Signature of witness	Please PRINT name	Date
_____	_____	_____

Signature of investigator	Please PRINT name	Date
_____	_____	_____

H.2 Participant information sheet and consent form: Royal Perth Hospital



PARTICIPANT INFORMATION SHEET

The CEDAR Study: Cataract Extraction and Driving Ability Research

Invitation

You are invited to participate in a research study into how cataract surgery affects a person's driving performance.

The study is being conducted by Professor Lynn Meuleners, Curtin-Monash Accident Research Centre at Curtin University and the George Institute in Sydney.

The study is funded by the Australian Research Council and is part of a national collaborative study coordinated by Curtin University in Perth.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

If you agree participate in this study, you will be asked to sign the attached Consent Form.

1. 'What is the purpose of this study?'

The purpose is to investigate the impact of cataract and cataract surgery on driving performance and self-regulation practices.

2. 'Why have I been invited to participate in this study?'

You are eligible to participate in this study because you are aged 55 years or older, have a current driver's licence, drive at least twice a week, live in the Perth metropolitan area, are able to attend three assessment visits, have not had cataract surgery before and are now recommended for cataract surgery.

3. 'What if I don't want to take part in this study or if I want to withdraw later?'

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

If you wish to withdraw from the study once it has started, you can do so at any time

without having to give a reason. Withdrawing from this study will not affect your relationship with your doctors or any standard treatment you may be receiving. If you

want to withdraw notify one of the research team or complete the 'Revocation of Consent' which is attached here.

4. 'What does this study involve?'

This study will be conducted over 3 years. However, your involvement will last only from one month before your first eye surgery to six months after your second eye surgery.

If you agree to participate, you will be asked to attend three face to face visits at Curtin University. These will take place 1 month before your first eye surgery, 3 months after first eye surgery and 3 months after second eye surgery. At each visit you will be asked to undergo the following assessments:

- Visual tests: These include letter charts, visual fields, refraction, pupil size and measurement of your glasses
- Questionnaire: We will ask you some questions about your glasses, access to eye care and referral for surgery, attitudes to cataract surgery, difficulty with vision, your driving habits, self-regulation and driving difficulties, and collect information about your health, medical history, physical activity and risk of falls.
- Cognitive tests: We will ask you to complete three cognitive tests that involve answering questions and looking at pictures
- Driving simulator: You will drive a specific route in our state-of-the-art driving simulator
- In-vehicle driving device: We will ask you to plug a device into your car for one week to record confidential driving data, then post it back.

The researchers will also access your hospital medical records to obtain clinical information about your cataract and cataract surgery.

You may also be invited to participate in a panel formulating recommendations for older drivers with cataract at the completion of the study. It is your decision whether to choose to participate in this panel.

5. 'How is this study being paid for?'

The study is being sponsored by the Australian Research Council.

All of the money being paid by the sponsor to run the study will be deposited into a centrally managed account to cover the costs of running the study. No money is paid directly to individual researchers or your medical team.

6. 'Are there risks to me in taking part in this study?'

There are no risks associated with taking part in the study. All tests are non-invasive and safe. However, some people may feel sick while using the driving simulator. If this happens to you, we will stop the assessment immediately. Furthermore, if the study tests identify any issues such as depression or anxiety, you will be advised to seek help from a professional. If you are in need a help line number will provide immediate support to you (Lifeline 13 11 14).

7. 'What happens if the study tests indicate my vision is inadequate for safe driving?'

If the visual tests show that you do not meet the minimum correct visual standard for driving in at least one eye, you will be advised to consult your GP or Ophthalmologist. If you are about to undergo cataract surgery, you will be advised not to drive until you have seen your Ophthalmologist after surgery. A follow-up call will be made within 7 days to see if you have followed up with a medical appointment. In the event that you do not seek medical assistance from a GP or Ophthalmologist, you accept responsibility for your decision not to seek treatment.

8. 'Will I benefit from the study?'

This study aims to further medical knowledge and may improve future management of cataract, however it will not directly benefit you. Nevertheless, a personal summary report will be provided to you on completion of the study.

9. 'Will taking part in this study cost me anything, and will I be paid?'

Participation in this study will not cost you anything. You will be paid \$10 for the first assessment, \$15 for the second assessment and \$20 for the final assessment for your time and effort participating in research.

10. 'How will my confidentiality be protected?'

Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Data collected by the in-vehicle monitoring devices could be used in a court law following a traffic accident. Only the researchers named above will have access to your details and results that will be held securely at the Curtin-Monash Accident Research Centre, Curtin University. The information will be stored in password protected files with access limited to those involved in running the study. Any paper documents will be stored in locked filing cabinets. Information will not be passed onto your doctors, the Department of Transport or the WA Police.

11. 'What happens with the results?'

If you give us your permission by signing the consent document, we plan to discuss the results with The George Institute for Global Health and the Curtin University Ethics Committee for the purpose of monitoring the conduct of this research and to publish the results in peer reviewed journals, presentation at conferences or other professional forums.

In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish. If you wish to receive the study results you should contact Professor Lynn Meuleners, (08) 9266 4636 or Seraina Agramunt from Curtin University on (08) 9266 9591.

12. 'What should I do if I want to discuss this study further before I decide?'

When you have read this information, the researcher will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact Lynn Meuleners on (08) 9266 4636 or Seraina Agramunt from

Curtin University on (08) 9266 9591.

13. 'Who should I contact if I have concerns about the conduct of this study?'

This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 29/2014). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.

The study has also been approved by the Royal Perth Hospital Human Research Ethics Committee which can be contacted on (08) 6151 1180 or SIRO.REG@health.wa.gov.au.

**Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached Consent Form.
This information sheet is for you to keep.**



**CONSENT FORM
IMPACT OF FIRST AND SECOND EYE SURGERY ON DRIVING OUTCOMES**

1. I,.....
of.....

agree to participate in the study described in the participant information statement set out above.

2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this Consent Form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to Curtin University or my treating hospital.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact Professor Lynn Meuleners on (08) 9266 4636 or Seraina Agramunt on (08) 9266 9591 who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the Curtin University Human Research Ethics Committee on (08) 9266 9223 or at hrec@curtin.edu.au or the Royal Perth Hospital Human Research Ethics Committee on (08) 6151 1180 or SIRO.REG@health.wa.gov.au.

Signature of participant	Please PRINT name	Date
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_____	_____	_____
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Signature of witness	Please PRINT name	Date
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_____	_____	_____
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Signature of investigator	Please PRINT name	Date
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_____	_____	_____
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H.3 Participant information sheet and consent form: Sir Charles Gairdner Hospital



Curtin University



**Sir Charles
Gairdner Hospital**

PARTICIPANT INFORMATION SHEET

The CEDAR Study: Cataract Extraction and Driving Ability Research

Invitation

You are invited to participate in a research study into how cataract surgery affects a person's driving performance.

The study is being conducted by Professor Lynn Meuleners, Curtin-Monash Accident Research Centre at Curtin University and the George Institute in Sydney.

The study is funded by the Australian Research Council and is part of a national collaborative study coordinated by Curtin University in Perth.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

If you agree participate in this study, you will be asked to sign the attached Consent Form.

1. 'What is the purpose of this study?'

The purpose is to investigate the impact of cataract and cataract surgery on driving performance and self-regulation practices.

2. 'Why have I been invited to participate in this study?'

You are eligible to participate in this study because you are aged 55 years or older, have a current driver's licence, drive at least twice a week, live in the Perth metropolitan area, are able to attend three assessment visits, have not had cataract surgery before and are now recommended for cataract surgery.

3. 'What if I don't want to take part in this study or if I want to withdraw later?'

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason. Withdrawing from this study will not affect your

relationship with your doctors or any standard treatment you may be receiving. If you want to withdraw notify one of the research team or complete the 'Revocation of Consent' which is attached here.

4. 'What does this study involve?'

This study will be conducted over 3 years. However, your involvement will last only from one month before your first eye surgery to six months after your second eye surgery.

If you agree to participate, you will be asked to attend three face to face visits at Curtin University. These will take place 1 month before your first eye surgery, 3 months after first eye surgery and 3 months after second eye surgery. At each visit you will be asked to undergo the following assessments:

- Visual tests: These include letter charts, visual fields, refraction, pupil size and measurement of your glasses
- Questionnaire: We will ask you some questions about your glasses, access to eye care and referral for surgery, attitudes to cataract surgery, difficulty with vision, your driving habits, self-regulation and driving difficulties, and collect information about your health, medical history, physical activity and risk of falls.
- Cognitive tests: We will ask you to complete three cognitive tests that involve answering questions and looking at pictures
- Driving simulator: You will drive a specific route in our state-of-the-art driving simulator
- In-vehicle driving device: We will ask you to plug a device into your car for one week to record confidential driving data, then post it back.

The researchers will also access your hospital medical records to obtain clinical information about your cataract and cataract surgery.

You may also be invited to participate in a panel formulating recommendations for older drivers with cataract at the completion of the study. It is your decision whether to choose to participate in this panel.

5. 'How is this study being paid for?'

The study is being sponsored by the Australian Research Council.

All of the money being paid by the sponsor to run the study will be deposited into a centrally managed account to cover the costs of running the study. No money is paid directly to individual researchers or your medical team.

6. 'Are there risks to me in taking part in this study?'

There are no risks associated with taking part in the study. All tests are non-invasive and safe. However, some people may feel sick while using the driving simulator. If this happens to you, we will stop the assessment immediately. Furthermore, if the study tests identify any issues such as depression or anxiety, you will be advised to seek help from a professional. If you are in need a help line number will provide immediate support to you (Lifeline 13 11 14).

7. 'What happens if the study tests indicate my vision is inadequate for safe driving?'

If the visual tests show that you do not meet the minimum correct visual standard for driving in at least one eye, you will be advised to consult your GP or Ophthalmologist. If you are about to undergo cataract surgery, you will be advised not to drive until you have seen your Ophthalmologist after surgery. A follow-up call will be made within 7 days to see if you have followed up with a medical appointment. In the event that you do not seek medical assistance from a GP or Ophthalmologist, you accept responsibility for your decision not to seek treatment.

8. 'Will I benefit from the study?'

This study aims to further medical knowledge and may improve future management of cataract, however it will not directly benefit you. Nevertheless, a personal summary report will be provided to you on completion of the study.

9. 'Will taking part in this study cost me anything, and will I be paid?'

Participation in this study will not cost you anything. You will be paid \$10 for the first assessment, \$15 for the second assessment and \$20 for the final assessment for your time and effort participating in research.

10. 'How will my confidentiality be protected?'

Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Data collected by the in-vehicle monitoring devices could be used in a court law following a traffic accident. Only the researchers named above will have access to your details and results that will be held securely at the Curtin-Monash Accident Research Centre, Curtin University. The information will be stored in password protected files with access limited to those involved in running the study. Any paper documents will be stored in locked filing cabinets. Information will not be passed onto your doctors, the Department of Transport or the WA Police.

11. 'What happens with the results?'

If you give us your permission by signing the consent document, we plan to discuss the results with The George Institute for Global Health and the Curtin University Ethics Committee for the purpose of monitoring the conduct of this research and to publish the results in peer reviewed journals, presentation at conferences or other professional forums.

In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish. If you wish to receive the study results you should contact Professor Lynn Meuleners, (08) 9266 4636 or Seraina Agramunt from Curtin University on (08) 9266 9591.

12. 'What should I do if I want to discuss this study further before I decide?'

When you have read this information, the researcher will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact Lynn Meuleners on (08) 9266 4636 or Seraina Agramunt from

Curtin University on (08) 9266 9591.

13. 'Who should I contact if I have concerns about the conduct of this study?'

This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 29/2014). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.

The study has also been approved by the Sir Charles Gairdner Group Human Research Ethics Committee which can be contacted on (08) 6457 2999 or hrec.scgh@health.wa.gov.au

**Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached Consent Form.
This information sheet is for you to keep.**

**CONSENT FORM
IMPACT OF FIRST AND SECOND EYE SURGERY ON DRIVING OUTCOMES**

1. I,.....
of.....

agree to participate in the study described in the participant information statement set out above.

2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this Consent Form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to Curtin University or my treating hospital.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact Professor Lynn Meuleners on (08) 9266 4636 or Seraina Agramunt on (08) 9266 9591 who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the Curtin University Human Research Ethics Committee on (08) 9266 9223 or at hrec@curtin.edu.au or Sir Charles Gairdner Group Human Research Ethics Committee on (08) 6457 2999 or hrec.scgh@health.wa.gov.au

Signature of participant	Please PRINT name	Date
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_____	_____	_____
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Signature of witness	Please PRINT name	Date
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_____	_____	_____
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Signature of investigator	Please PRINT name	Date
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Appendix I Revocation of consent

I.1 Revocation of consent: Fremantle Hospital



REVOCAION OF CONSENT

IMPACT OF FIRST AND SECOND EYE SURGERY ON DRIVING OUTCOMES

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with Curtin University or my treating hospital.

Signature of participant

Please PRINT name

Date

The section for Revocation of Consent should be forwarded to Seraina Agramunt, Curtin-Monash Accident Research Centre, Curtin University, GPO Box U1987, Perth WA 6845.

I.2 Revocation of consent: Royal Perth Hospital



REVOCATION OF CONSENT

IMPACT OF FIRST AND SECOND EYE SURGERY ON DRIVING OUTCOMES

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with Curtin University or my treating hospital.

Signature of participant

Please PRINT name

Date

The section for Revocation of Consent should be forwarded to Seraina Agramunt, Curtin-Monash Accident Research Centre, Curtin University, GPO Box U1987, Perth WA 6845.

I.3 Revocation of consent: Sir Charles Gairdner Hospital



REVOCAION OF CONSENT

IMPACT OF FIRST AND SECOND EYE SURGERY ON DRIVING OUTCOMES

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with Curtin University or my treating hospital.

Signature of participant

Please PRINT name

Date

The section for Revocation of Consent should be forwarded to Seraina Agramunt, Curtin-Monash Accident Research Centre, Curtin University, GPO Box U1987, Perth WA 6845.

**Appendix J Letter sent to participants with
low vision**

J.1 Letter sent to participants with low vision



Professor Lynn Meuleners
Curtin-Monash Accident Centre
Curtin University
GPO Box U1987
Perth WA 6845

Name:
Address:

Date:

Dear Mr/Mrs

Re. Impact of first and second eye cataract surgery on driving outcomes study

Thank you kindly for participating in our study examining the impact of cataract and cataract surgery on driving.

As part of the study we examined your vision. The results of the test(s) suggest that **you should not drive until you have sought medical advice** from your GP or Ophthalmologist.

We will be calling you within 7 days to see whether you are seeking further medical advice about your result. Thereafter, Curtin University will have no continuing responsibility for your medical care and you are responsible for your medical decisions. In the event that you do not seek medical assistance from a GP or Ophthalmologist, you accept responsibility for your decision not to seek treatment.

If you wish to discuss these results please contact Professor Lynn Meuleners on 9266 4636.

Thank you very much for your time and we greatly appreciate your contribution to this important study.

Yours sincerely,

Professor Lynn Meuleners
Curtin University

Appendix K Permission statement

K.1 Permission statement: paper 1

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Title: Bilateral cataract, crash risk, driving performance, and self-regulation practices among older drivers

Author: Seraina Agramunt, Lynn B. Meuleners, Michelle L. Fraser, Nigel Morlet, Kyle C. Chow, Jonathon Q. Ng

Publication: Journal of Cataract & Refractive Surgery

Publisher: Elsevier

Date: May 2016

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K.2 Permission statement: paper 2

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Title: A validation study comparing self-reported travel diaries and objective data obtained from in-vehicle monitoring devices in older drivers with bilateral cataract

Author: Seraina Agramunt, Lynn Meuleners, Kyle Chi Chow, Jonathon Q. Ng, Nigel Morlet

Publication: Accident Analysis & Prevention
Publisher: Elsevier
Date: September 2017

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K.3 Permission statement: paper 3



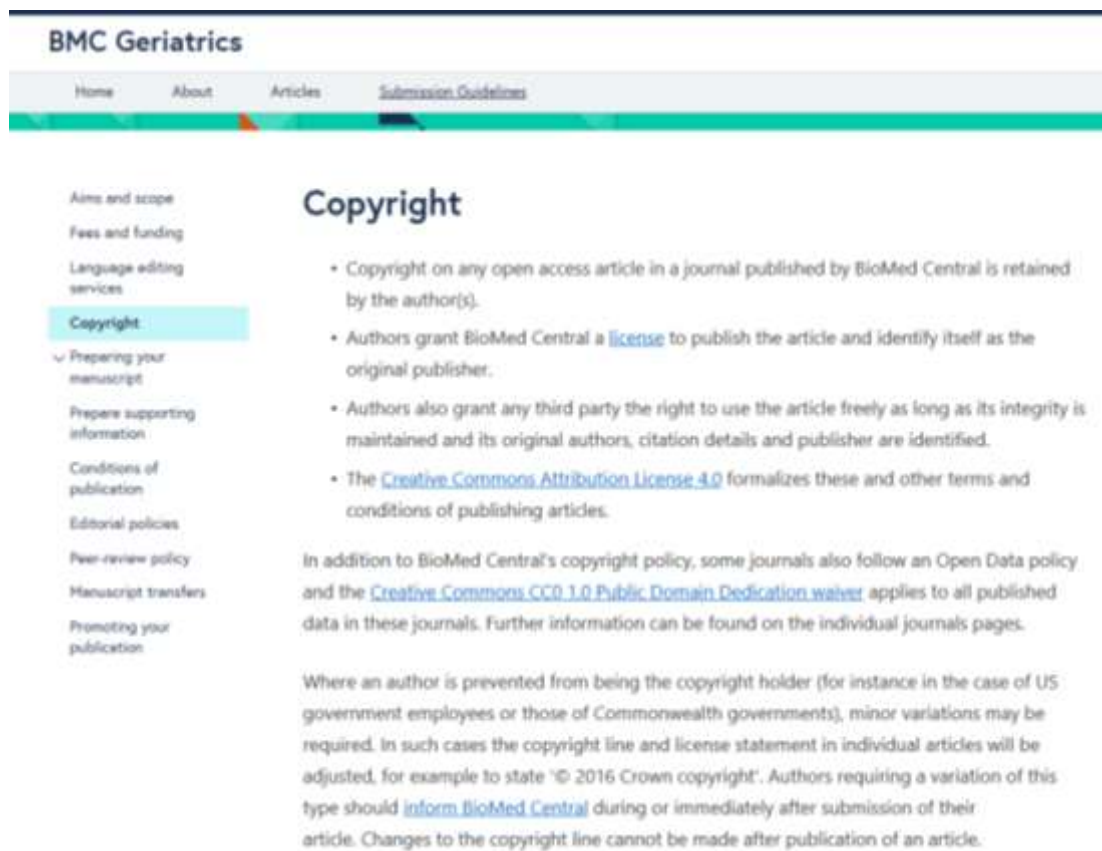
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K.4 Permission statement: paper 4



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The requesting person/organization	Seraina Agramunt
Title or numeric reference of the portion (s)	Do older drivers with bilateral cataract self-regulate their driving while waiting for first eye cataract surgery?
Title of the article or chapter the portion is from	Do older drivers with bilateral cataract self-regulate their driving while waiting for first eye cataract surgery?
Editor of portion(s)	Dr Richard Walker
Author of portion(s)	Agramunt S, Meuleners LB, Fraser ML, Chow KC, Ng JQ, Raja V, Morlet N
Volume of serial or monograph	Volume 2017:12
Page range of portion	
Publication date of portion	8 November 2017
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Instructor name	Seraina Agramunt
Institution name	Curtin-Monash Accident research Centre
Expected presentation date	Feb 2018

Appendix L Statements of contribution

L.1 Co-Author: Professor Lynn Meuleners

To Whom It May Concern

I, Seraina Agramunt, contributed to data collection, analysis, and interpretation of data, drafting, revising and approving the following manuscripts entitled:

- Agramunt, S., Meuleners, L. B., Fraser, M. L., Morlet, N., Chow, K. C., & Ng, J. Q. (2016). Bilateral cataract, crash risk, driving performance, and self-regulation practices among older drivers. *Journal of Cataract & Refractive Surgery*, 42(5), 788-794.
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- Agramunt, S., Meuleners, L., Fraser, M.L., Chow, K. C., Ng, J. Q., Raja, V., & Morlet, N. (submitted). An examination of driving exposure, habits and adverse events in older drivers with bilateral cataract using naturalistic driving data.
- Agramunt, S., Meuleners, L. B., Fraser, M. L., Chow, K. C., Ng, J. Q., Raja, V., & Morlet, N. (2017). Do older drivers with bilateral cataract self-regulate their driving while waiting for first eye cataract surgery? *Clinical Interventions in Aging*, 12, 1911.
- Agramunt, S., Meuleners, L., Fraser, M.L., Chow, K. C., Ng, J. Q., & Raja, V. (accepted for publication on 06/02/2018). First and second eye cataract surgery and driver self-regulation among older drivers with bilateral cataract: a prospective cohort study. *BMC Geriatrics*.

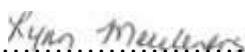
Seraina Agramunt, PhD candidate



.....

I, Professor Lynn Meuleners, as a Co-Author, endorse that this level of contribution by the candidate indicated above is appropriate.

Professor Lynn Meuleners



.....

L.2 Co-Author: Doctor Jonathon Ng

To Whom It May Concern

I, Seraina Agramunt, contributed to data collection, analysis, and interpretation of data, drafting, revising and approving the following manuscripts entitled:

- Agramunt, S., Meuleners, L. B., Fraser, M. L., Morlet, N., Chow, K. C., & Ng, J. Q. (2016). Bilateral cataract, crash risk, driving performance, and self-regulation practices among older drivers. *Journal of Cataract & Refractive Surgery*, 42(5), 788-794.
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Seraina Agramunt, PhD candidate



I, Doctor Jonathon Ng, as a Co-Author, endorse that this level of contribution by the candidate indicated above is appropriate.

Doctor Jonathon Ng



L.3 Co-Author: Doctor Kyle Chow

To Whom It May Concern

I, Seraina Agramunt, contributed to data collection, analysis, and interpretation of data, drafting, revising and approving the following manuscripts entitled:

- Agramunt, S., Meuleners, L. B., Fraser, M. L., Morlet, N., Chow, K. C., & Ng, J. Q. (2016). Bilateral cataract, crash risk, driving performance, and self-regulation practices among older drivers. *Journal of Cataract & Refractive Surgery*, 42(5), 788-794.
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Seraina Agramunt, PhD candidate



.....

I, Doctor Kyle Chow, as a Co-Author, endorse that this level of contribution by the candidate indicated above is appropriate.

Doctor Kyle Chow



.....

L.4 Co-Author: Michelle Fraser

To Whom It May Concern

I, Seraina Agramunt, contributed to data collection, analysis, and interpretation of data, drafting, revising and approving the following manuscripts entitled:

- Agramunt, S., Meuleners, L. B., Fraser, M. L., Morlet, N., Chow, K. C., & Ng, J. Q. (2016). Bilateral cataract, crash risk, driving performance, and self-regulation practices among older drivers. *Journal of Cataract & Refractive Surgery*, 42(5), 788-794.
- Agramunt, S., Meuleners, L., Chow, K. C., Ng, J. Q., & Morlet, N. (2016). A validation study comparing self-reported travel diaries and objective data obtained from in-vehicle monitoring devices in older drivers with bilateral cataract. *Accident Analysis & Prevention*.
- Agramunt, S., Meuleners, L., Fraser, M.L., Chow, K. C., Ng, J. Q., Raja, V., & Morlet, N. (submitted). An examination of driving exposure, habits and adverse events in older drivers with bilateral cataract using naturalistic driving data.
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- Agramunt, S., Meuleners, L. B., Fraser, M. L., Morlet, N., Chow, K. C., & Ng, J. Q. (2016). Bilateral cataract, crash risk, driving performance, and self-regulation practices among older drivers. *Journal of Cataract & Refractive Surgery*, 42(5), 788-794.
- Agramunt, S., Meuleners, L., Chow, K. C., Ng, J. Q., & Morlet, N. (2016). A validation study comparing self-reported travel diaries and objective data obtained from in-vehicle monitoring devices in older drivers with bilateral cataract. *Accident Analysis & Prevention*.
- Agramunt, S., Meuleners, L., Fraser, M.L., Chow, K. C., Ng, J. Q., Raja, V., & Morlet, N. (submitted). An examination of driving exposure, habits and adverse events in older drivers with bilateral cataract using naturalistic driving data.
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- Agramunt, S., Meuleners, L., Fraser, M.L., Chow, K. C., Ng, J. Q., Raja, V., & Morlet, N. (submitted). An examination of driving exposure, habits and adverse events in older drivers with bilateral cataract using naturalistic driving data.
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