School of Occupational Therapy, Social Work and Speech Pathology
Perth Children's Hospital - Kids Rehab WA
Centre for Research Excellence in Cerebral Palsy

Investigating the Use of Wearable Sensors to Measure Upper Limb Range of Motion in Young Children with Cerebral Palsy

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This thesis is presented for the degree of Doctor of Philosophy
of
Curtin University

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Declaration

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Human Ethics

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 in 2018. The proposed research studies in this thesis have received human research ethics approval from Curtin University Human Research Ethics Committee (RDHS-11-16; HR223/2015), Perth Children's Hospital Ethics Committee (2014061; 2014060), and the Australian Catholic University Human Research Ethics Committee (2014 318V; 2014 317V).

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Corrin Paige Walmsley

Candidate

29th January 2020

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Abstract

Cerebral palsy (CP) is one of the main causes of physical disability in childhood. Motor impairment in the upper limb is common, with potential for the wrist to be involved from an early age. Muscle over-activity, predominantly due to spasticity, combined with secondary musculoskeletal impairments, may cause limitations in joint range of motion (ROM). There is an increasing need for accurate measurement of joint ROM in early intervention to monitor impairment over time and as the child grows, and to determine efficacy of treatment. However, measurement of joint ROM in children <5 years old is beset with challenges. The overall aim of this research was to investigate the use of small custom wearable sensors to measure wrist joint ROM in young children with CP.

This thesis is written as a series of chapters charting the investigation of wearable sensors to measure upper limb joint ROM in young children with CP. Following an introduction to the topic in Chapter One, Chapter Two is a review of literature that focuses on the *body functions and structure* domain of the International Classification of Functioning Health and Disability (ICF). This literature review provides context to the common impairments in the upper limb (muscle tone, muscle weakness and contracture formation), their impact on ROM, and the available tools to objectively measure upper limb joint ROM. Subsequent to this, Chapter Three (Study One) is a systematic review of literature that investigates the use of wearable sensors for the measurement of joint ROM in the upper limb. The review identified the absence of the use of wearable sensors with children with CP and highlighted the need for small custom designed wearable sensors suitable for use with children.

Chapter Four (Study Two) outlines the trans-disciplinary approach to the development of small custom wearable sensors, with three versions undergoing feasibility testing. The final version of the custom wearable sensors (V3) was subject to further testing. The first phase of this testing is outlined in Chapter Five (Study Three) and explores the validation of the custom wearable sensors; demonstrating their ability to detect peak angles within 3° error from known angles on a robotic device for single plane movement (flexion/extension), at various movement speeds.

Due to this accuracy, a logical progression was to explore the interchangeability of the wearable sensors when compared to the goniometer; the most utilised tool to measure wrist joint ROM in clinical practice. Chapter Six (Study Four) compares the wearable

sensors to the goniometer to measure passive wrist extension in children with CP (1.75 to 17.5 years). For children with CP aged ≥5.75 years, high agreement was found between the wearable sensors and the goniometer, suggesting the wearable sensors may be used as an alternative to measure wrist ROM in a single plane (i.e. passive wrist extension). However, the level of agreement was not as strong for the group of younger children with CP. The lower levels of measurement agreement, in addition to measurement challenges encountered with obtaining joint ROM data, brought into question the applicability and accuracy of wearable sensors for this age group (those <5.5 years).

Chapter Seven outlines the proposed investigation of the wearable sensors to measure wrist joint ROM in its respective movement planes (i.e. flexion/extension and radial/ulna deviation) in young children with and without CP. The aim was to i) complete further criterion validation between the custom wearable sensors and three-dimensional motion analysis (3DMA), and ii) compare upper limb kinematics between both cohorts of children during play tasks designed to specifically elicit wrist extension. Building from the measurement challenges outlined within Chapter Six, Chapter Seven discusses the limitations in the design specification of the customised wearable sensors which led to the decision to exclude the wearable sensors throughout this trial. For this reason, the focus of Study Five is the comparison of upper limb kinematics in young children with and without CP, obtained using 3DMA. Outcomes from this work demonstrated that young children with CP (n = 8; mean age = 3.48 ± 1.47 years) use less wrist and elbow extension during play tasks compared with typically developing children (n = 10; mean age = 3.51 ± 1.65 years).

This body of work has identified challenges in measuring single and multi-plane joint ROM in the upper limb of young children with CP. It also simultaneously acknowledges the importance of measuring active joint ROM to identify early impairment in young children with CP. Measurement of upper limb joint ROM in young children with CP remains an area that requires additional exploration to determine whether it can be done accurately and reliably.

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Abbreviations

BoNT-A	Botulinum Neurotoxin Type-A
CI	Confidence Interval
CNS	Central Nervous System
COSMIN	COnsensus-based Standards for the selection of health Measurement INstruments
CP	Cerebral Palsy
DOF	Degree of Freedom
EACD	European Academy of Childhood Disability
EKF	Extended Kalman Filter
Hz	Hertz
ICC	Intraclass Correlation Coefficient
ICF	International Classification of Functioning, Disability and Health
KF	Kalman Filter
iWHOT	infant Wrist Hand Orthoses Trial
LOA	Limits of Agreement
MACS	Manual Ability Classification Scale
MAS	Modified Ashworth Scale
Mini-MACS	Mini-Manual Ability Classification Scale
MiT	Minimising impairment Trial
RMS	Root Mean Square
ROM	Range of Motion
SD	Standard Deviation
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
TD	Typically Developing
3DMA	Three-Dimensional Motion Analysis
UKF	Unscented Kalman Filter
V1	Version 1
V2	Version 2
V3	Version 3

List of Publications

The following is a list of publications to which I have contributed during the course of my candidature, arising both directly and indirectly from this thesis. The peer reviewed manuscripts and abstracts are included in Appendix A and Appendix B.

Peer review publications

Walmsley CP, Xu W, Ortega-Sanchez C, Campbell A, Imms C, Elliott C, Williams SA. Validation of custom wearable sensors to measure angle kinematics: A technical report. *Health and Technol*. 2019;9(5):887-892. doi: 10.1007/s12553-019-00360.

Walmsley CP, Williams SA, Grisbrook T, Elliott C, Imms C, Campbell A. Measurement of upper limb range of motion using wearable sensors: A systematic review. *Sports Med – Open*. 2018;4(53):1-22. doi: 10.1186/s40789-018-0167-7.

Walmsley CP, Taylor S, Parkin T, Carey L, Girdler S, Elliott C. What is the current practice of therapists in the measurement of somatosensation in children with cerebral palsy and other neurological disorders? *Aust Occup Ther J*. 2018;65(2): 89-97. doi: 10.1111.1440-1630.12431.

Manuscripts prepared for journal submission

Walmsley CP, Campbell A, Elliott C, Garbellini S, Imms C, Williams SA. Can wearable sensors be used as an alternative to the goniometer to measure passive wrist extension in children with cerebral palsy? 2019; Manuscript prepared for journal submission.

Walmsley CP, Campbell A, Elliott C, Imms C, Williams SA. A comparison of wrist and elbow kinematics in young children with and without cerebral palsy. 2020; Manuscript prepared for journal submission.

Fernando E, **Walmsley CP,** Wild C, Garbellini S, Grisbrook T, Williams SA. How much range of motion in the wrist is used during active tasks? Understanding and comparing the proportion of peak passive range of motion used during active upper limb task in children with and without cerebral palsy. 2019; Manuscript prepared for journal submission.

Presentations, Awards and Affiliations

Conference presentations

Fernando E, **Walmsley CP,** Wild CY, Williams SA (May 23rd – 25th, 2019). *Passive range of motion – is it useful? Understanding the relationship between passive and functional range of motion at the wrist in children with cerebral palsy*. Oral presentation, European Academy of Childhood Disability (EACD) Conference: Paris, France.

Walmsley CP, Williams SA, Grisbrook T, Elliott C, Imms C, Campbell A (March 21st-24th, 2018). *Measurement of upper limb range of motion using wearable sensors: A systematic review*. Oral presentation, Australasian Academy of Cerebral Palsy and Developmental Medicine (AusACPDM) Conference: Auckland, New Zealand

Walmsley CP, Taylor S, Parkin T, Carey L, Girdler S, Elliott C (1st – 3rd, July 2018). What is the current practice of therapists in the measurement of somatosensation in children with cerebral palsy and other neurological disorders? Oral presentation, Occupational Therapy Conference: Melbourne, Australia.

Professional development presentations

Walmsley CP, Williams SA, Grisbrook T, Elliott C, Imms C, Campbell A. (November 2017). *Measurement of upper limb range of motion using wearable sensors: A systematic review*. Presented at the Centre for Disability and Development Research (CeDDR)

Walmsley CP, Williams SA, Grisbrook T, Elliott C, Imms C, Campbell A. (February 2018). *Measurement of upper limb range of motion using wearable sensors: A systematic review*. Presented at the School of Physiotherapy and Exercise Science Musculoskeletal Interest Group at Curtin University.

Awards

2015 Perth Children's Hospital PhD Top-Up Scholarship (2015-2019)

2015 Australian Postgraduate Award Scholarship (2015-2018)

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2019 Curtin University PhD Completion Scholarship (2019-2020)

Affiliations

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Centre for Research Excellence in Cerebral Palsy (CRE-CP)

Centre for Disability and Development Research (CeDDR)

Statement of Author Contribution

The nature and extent of the intellectual input by the candidate and co-authors has been acknowledged and validated by all supervisors:

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Dr Amity Campbell
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Dr Tiffany Grisbrook
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Prof Christine Imms
(Associate supervisor)

Chapter One

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1.1 Introduction

This chapter lays the foundation as to what to expect from this thesis; outlining the thesis setting, the background to the research problem, the motivation and significance of the research, and an outline of the remaining chapters of the thesis.

1.2 Background

Cerebral palsy (CP) is a lifelong disorder of impaired motor function that arises from a lesion in the developing central nervous system (CNS).[1] In Australia, the incidence is estimated to be 1.4 – 2.1 cases per 1000 live births[2], making CP the leading cause of physical disability in childhood.[2] The term CP does not describe a single entity; but rather a large array of disorders that primarily impact movement and posture.[1] The timing, location and extent of injury to the CNS is highly variable between individuals; therefore different permutations of the disorder exist.[3] Although CP is a diverse disorder with substantial variation in impairments and severity, the manifestation of impairment in the upper limb is common.[4]

The International Classification of Functioning, Disability and Health (ICF)[5] framework can be used to help capture the myriad of impairments associated with CP and the aspects of a child's life that it may impact.[6] The ICF framework portrays a dynamic and bidirectional interaction between impairments in *body functions and structure*, with *activity* performance and *participation*.[5] Within the domain of *body functions and structure*, common impairments of the upper limb can be described in relation to CP. The co-occurrence of spasticity, hypertonia and muscle weakness are known to contribute to the alterations in the musculoskeletal system seen in children with CP.[3,4,7] Over time, additional structural changes within muscles and soft tissue can occur and an imbalance of bone to muscle growth, subsequent tissue shortening, contracture formation and loss of passive and active joint range of motion (ROM) in the upper limb may ensue.[3,4,7] Musculoskeletal changes may lead to increased impairment and decreased use of the upper limb in functional activity.

Despite the injury to the CNS being static, the secondary musculoskeletal impairments can change over time.[7] Upper limb impairments can manifest early, with asymmetrical upper limb use[8,9] and abnormal posturing of the wrist and thumb commonly providing early clinical indicators of a child being at risk of a diagnosis of CP.[9,10] In addition, asymmetries in global and segmental hand movements at 3 months of

age have shown to be predictive of a diagnosis of hemiplegic (or unilateral) CP.[11,12] It is, therefore, evident that motor impairment in the upper limb can occur from an early age and restrictions in ROM can become markedly apparent as the child ages and increases the complexity of their activity involvement.[13]

Flexion deformities in the wrist and elbow can be particularly pervasive in children with CP.[4] The onset of restrictions in passive movement have shown to occur in children with CP between 1 and 3 years of age, with restrictions in passive movement continuing as the child ages and develops.[13] In children with CP between 5 and 18 years of age, there is evidence for limitations in active ROM (wrist and elbow extension and forearm supination) when compared to typically developing children.[14-18] Despite a strong body of clinical knowledge to suggest that active ROM in the upper limb is also limited in young children with CP (i.e. <5 years of age), the research evidence to support this is currently limited. Irrespective of the paucity of documented evidence, improvement or maintenance of ROM in the wrist and elbow is often a goal in the clinical management of children with CP in early intervention. The ability to accurately measure active and passive ROM in children less than 5 years of age has the potential to help determine efficacy of treatment and to monitor impairment as the child grows.

In 2010 a Delphi survey of health professionals (i.e. clinicians, paediatricians and rehabilitation specialists) involved in the care of children with CP identified high priority research areas, and with the help of consumers, two major themes were identified: i) effective outcomes and ii) effective research and services.[19] Within these themes, research questions related to the effectiveness of interventions and the prevention of secondary deformities were identified as priorities.[19] The methodology in which interventions were tested for effectiveness was also considered, with the need for sensitive instruments highlighted.[19]

In an attempt to address these research priorities, two randomised control trials were initiated in Australia to evaluate the effectiveness and feasibility of the use of rigid wrist-hand orthoses in children with CP to prevent or reduce loss of wrist extension. The Minimising impairment Trial (MiT) included children aged between 5 and 15 years with a confirmed diagnosis of CP.[20] The infant Wrist-Hand Orthosis Trial (iWHOT) included children between 0 and 36 months at the time of recruitment that were identified with or ‘at risk’ of CP.[21] Within the context of the iWHOT, risk of CP was defined as presenting with abnormal muscle tone, increased reflexes and abnormal postures with or without asymmetrical limb use.[21,22] The primary outcome of interest for the iWHOT and MiT

was passive and active wrist extension.[20,21] Therefore, objective, accurate and reliable measurement of this movement was required.

For older children with CP, the goniometer is commonly utilised by clinicians to measure joint ROM.[23] Despite this, use of the goniometer has demonstrated wide variability for the inter and intra-rater reliability, and measurement errors are known to vary between 10° and 15°.[24] Nonetheless, the goniometer is the most reliable tool available to clinicians for the routine measurement of joint ROM.

For younger children with CP, finding a reliable tool to measure passive and active joint ROM in the upper limb poses more of a challenge. Clinometric testing of the goniometer for measurement of joint ROM in the upper limb has not included participants less than 4 years old; as such, the accuracy remains relatively un-documented in young children. Objective quantification of passive and active joint ROM using the goniometer is challenging as young children are less likely to follow instructions and voluntarily maintain a position long enough for the goniometer to be aligned with precision. This is a concern as accurate measurement of joint ROM is needed to closely monitor change over time, particularly as the child grows and musculoskeletal impairments manifest.

An alternative to the goniometer is three-dimensional motion analysis (3DMA). In children with CP over the age of 5 years, 3DMA has demonstrated high levels of within-session reliability (Intra-class Correlation Coefficient (ICC's) >0.70) to measure active upper limb ROM,[25-27] with angular errors between 5° and 9°.[26,27] However, the use of 3DMA to measure upper limb joint ROM is relatively unexplored in younger children and its complexity, characteristics and associated costs often make it infeasible for frequent use in the clinical setting.

In contrast to 3DMA, wearable sensors, or inertial measurement units, have potential to provide clinicians with an objective tool to quantify joint ROM and over recent years their application to the upper limb has become increasingly popular.[28-31] Typically, wearable sensors contain an accelerometer, gyroscope and magnetometer, and data are integrated using sophisticated algorithms to provide an output of joint angle.[28] Potential benefits of wearable sensors include being low in cost with respect to traditional motion analysis systems; portable; small size and light weight; simple application to the patient, and overall user-friendliness.[32-34] These factors could make wearable sensors ideal for measurement of upper limb joint ROM in a clinical context,

particularly for use with young children. Prior to the uptake of wearable sensors in clinical practice, their accuracy and reliability requires investigation. This research, therefore, aimed to create new knowledge by investigating the development, feasibility, and accuracy, of small custom designed wearable sensors to measure upper limb joint ROM in young children (<5 years) with CP.

1.3 Statement of the problem

In early intervention there is an increasing need for accurate and objective measurement of passive and active upper limb joint ROM to help detect and monitor movement deviations that may occur over time or with growth, and to determine efficacy of treatment. Despite this, there are limited valid and reliable tools that can offer an objective measurement of upper limb joint ROM in young children (<5 years) with CP. As such, our understanding of the effectiveness of upper limb therapeutic interventions (e.g. Botulinum Neurotoxin Type-A (BoNT-A) injections, serial casting, orthoses or activity-based intervention) in improving or maintaining passive and/or active joint ROM in this age group is largely based on subjective clinical observation or measures of functional hand use. New measurement instruments and/or approaches are needed.

1.4 Consumer involvement in the research program

Consumer involvement in research enables enhanced quality of research, ensures results are relevant to the target group, and accelerates the dissemination and implementation of findings.[35,36] The involvement of consumers was a key component of the iWHOT and MiT, with a national steering committee involved in all stages of the research process.[20] Additionally, two parent advisors guided the design, implementation and evaluation of the research undertaken in Perth, Western Australia.[20] Specific to this thesis, the two parent advisors provided input and feedback that guided the design, feasibility and validation of the wearable sensors.

1.5 Significance of the thesis

Wearable sensors have potential to provide clinicians with a non-invasive, quick, inexpensive, and user-friendly tool to measure passive and active upper limb joint ROM. If demonstrated to be accurate and reliable, wearable sensors could be integrated into routine clinical practice for regular measurement of upper limb joint ROM throughout childhood, allowing clinicians to easily monitor change in ROM with growth and

development, as well as change in response to interventions that aim to improve or maintain joint ROM.

For children with CP, regular measurement of upper limb joint ROM, particularly passive wrist extension, is considered to be imperative for the early detection of contracture formation.[13] Early restrictions in passive wrist extension have shown to appear within the first few years of life and continue to progressively deteriorate with age.[13] Wearable sensors may offer a solution to the early surveillance, and potentially prevention, of contracture in CP. In addition, early identification of movement restrictions in the upper limb could lead to timely referral and access to early intervention services during the most critical stages of child development.[37]

Information obtained about joint ROM from the wearable sensors could complement activity-based measures such as the Hand Assessment for Infants,[8] the Mini-Assisting Hand Assessment[38] or the Assisting Hand Assessment.[39] The combination of these measures may facilitate a holistic picture of the child's upper limb capacity and performance across two levels of the ICF: *body functions and structure*, and *activity*.

To our knowledge, the precise quantification of upper limb joint ROM with wearable sensors for young children with CP, particularly during active and functional movement, has not been explored previously. Outcomes from this thesis provide the first investigation, and insights, into the potential use of wearable sensor technology in clinical practice for the assessment of upper limb joint ROM in young children with CP.

1.6 Thesis overview

Three frameworks guide the structure of this thesis: the ICF framework,[5] a feasibility framework,[40] and the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN).[41] The ICF is used as a framework throughout this thesis to provide a structured approach to understanding upper limb impairment in CP. Although the *activity* domain of the ICF will be briefly discussed, the domain of *body functions and structure*, with particular attention to the consequence of upper limb impairments on ROM, is the core focus.[5] A feasibility framework proposed by Bowen et al[40] is also used. This framework outlines focus areas (Demand, Acceptability, Implementation, Practicality, Adaption, Integration and Expansion) that can be evaluated in feasibility studies.[40] Relevant focus areas were chosen to evaluate the feasibility of the wearable sensors for use with young children and to evaluate the feasibility of the play session to elicit maximum wrist extension in young children. Where relevant, the design

and methodology of the studies that comprise this thesis were guided by the COSMIN.[41] The COSMIN is a published, evidence-based framework that guided the design and reporting of the clinometric properties related to the wearable sensors.[41] In this thesis, the combination of the three frameworks provides a structured guide to the development and testing of the wearable sensors and play session.

The wearable sensors used in this thesis were developed in collaboration with engineers from the School of Electrical Engineering, Computing and Mathematical Sciences at Curtin University in Perth, Western Australia. The present body of work sought to investigate the clinical application of the wearable sensors to measure joint ROM in the upper limb of young children with CP, however it does not address the construction or technicalities of the hardware or software, including algorithm development or algorithm validation. These topics form the basis of a parallel PhD project[42] and acknowledgement is given where due throughout this research. All joint ROM data used in the current thesis are original and were collected by the PhD Candidate.

The original intention of this research was to measure wrist and elbow joint ROM in their respective degrees of freedom (DOF). However, due to the complexity of algorithms behind the use of wearable sensors and resources required to do this, it was increasingly evident that measuring elbow joint ROM and movement of the wrist in multiple DOF could no longer be priorities of this thesis. Therefore, this research focuses on the use of wearable sensors to measure wrist joint ROM in one DOF, limited to flexion and extension.

The data presented in this body of work was sourced specifically for the purpose of this research, but also sourced from two other studies; the iWHOT[21] and MiT.[20] Data from children with CP involved in Study Four of this research were sourced from the iWHOT and MiT, with young children with CP involved in Study Five sourced from only the iWHOT.

1.7 Chapter synopsis

This research aimed to investigate the development, feasibility and validity of custom wearable sensors to measure passive and active joint ROM in the upper limb of children with and without CP. This thesis is comprised of eight chapters. Chapter Two to Chapter Seven contain five standalone studies; two are published, one is under review and one is prepared for submission in a peer review journal. All studies, with the exception of Study Two, are prepared as manuscripts for full publication. See Table 1.1

for a summary. Different referencing styles are used to meet the requirements of each of the peer review journals to which papers have been submitted. It is acknowledged that there is some repetition of information reported across the five studies, however this was unavoidable as each paper needs to be readable in isolation. What follows is a synopsis of each chapter.

1.7.1 Chapter Two – Literature review

The review of literature builds the context of the research through a comprehensive appraisal of published research. The review starts with a brief introduction to CP and focuses on the ICF domain of *body functions and structure*, with an emphasis on three common upper limb impairments; muscle tone, muscle weakness and secondary musculoskeletal change. The extent to which these motor impairments pertain to limitations in joint ROM is discussed. The literature review then provides an overview of the measurement tools that are available to objectively quantify joint ROM in the upper limb. Conclusions drawn from the literature review identify avenues for potential research.

Table 1.1 A summary of the methods used in each of the studies included in this research

	Chapter Three: Study One	**Chapter Four: Study Two**	**Chapter Five: Study Three**	**Chapter Six: Study Four**	**Chapter Seven: Study Five**
Design	Systematic review	Feasibility	Experimental design; validation	Exploratory design, cross-sectional	Cross-sectional
Sample	2191 records identified; 66 studies met inclusion criteria	6 healthy adults, 10 TD children (age range: 2–6 years) and 25 children (age range: 2–14 years) with CP	Robotic device simulating wrist flexion and extension at various movement speeds	152 measurements of wrist extension from 39 children with CP (age range: 1.9–17.8 years)	8 children with CP (age range: 2.4–5.1 years) and 10 children without CP (age range: 1.8–4.8 years)
Source of sample	Medical databases	Convenience and iWHOT	Robotic device	iWHOT and MiT	Convenience and iWHOT
Data analysis	Included papers were assessed on: • whether the aim was clear and corresponded to the results, • the design/type of paper (i.e. conference paper), • the number of participants, as per the COSMIN[43] guidelines	Field note review	Mean and RMS error	ICC's, 95% CI, LOA, mean and RMS error	Between group analysis, 95% CI
Publication status	Published in Sports Medicine Open 2018 (Appendix A.1)	Not for publication	Published in Health and Technology 2019 (Appendix A.2)	Under review in a peer review journal	Manuscript prepared for submission to peer review journal
Relevant abstracts	Abstract is published as a conference proceeding (Appendix B.1)	Not presented	Not presented	Accepted for oral presentation at EACD in June 2020	Accepted for oral presentation at EACD in June 2020

CP = cerebral palsy, TD = typically developing, COSMIN = COnsensus-based Standards for the selection of health Measurement Instruments, iWHOT = infant Wrist Hand Orthoses Trial, MiT = Minimising impairment Trial, ICC = Intraclass Correlation Coefficient, RMS = Root Mean Square, CI = Confidence Interval, LOA = Limits of Agreement, EACD = European Academy of Childhood Disability

1.7.2 Chapter Three (Study One)

Title: Measurement of upper limb range of motion using wearable sensors: A systematic review.

Walmsley CP, Williams SA, Grisbrook T, Elliott C, Imms C, Campbell A. Measurement of upper limb range of motion using wearable sensors: A systematic review. *Sports Med – Open*. 2018;4(53):1-22. doi: 10.1186/s40789-018-0167-7.

The aim of this study was to:

1. Establish the evidence for the use of wearable sensors to calculate joint ROM in the upper limb, specifically:

    - The characteristics of commercially available and custom designed wearable sensors.
    - The populations that researchers use wearable sensors with and how they have been used.
    - The established psychometric properties for the wearable sensors to measure joint ROM in the upper limb.

1.7.3 Chapter Four (Study Two)

Title: Exploring the development of prototype custom wearable sensors and the feasibility of their use to measure upper limb joint range of motion in children with CP.

The aim of this study was to:

1. Document the development and evaluate the feasibility of three prototype versions of the wearable sensors prior to validation testing.

1.7.4 Chapter Five (Study Three)

Title: Validation of custom wearable sensors to measure angle kinematics: A technical report.

Walmsley CP, Xu W, Ortega-Sanchez C, Campbell A, Imms C, Elliott C, Williams SA. Validation of custom wearable sensors to measure angle kinematics: A technical report. *Health and Technol*. 2019;9(5):887-892. doi: 10.1007/s12553-019-00360.

The aims of this study were to:

1. Compare small custom designed wearable sensors (V3) to known angles of a robotic device to determine the true error when measuring peak angles, prior to *in vivo* testing.
2. Determine if the true error changes with increased movement speed.

1.7.5 Chapter Six (Study Four)

Title: Can wearable sensors be used as an alternative to the goniometer to measure passive wrist extension in children with cerebral palsy?

The aims of this study were to:

1. Assess the level of agreement between the goniometer and wearable sensors for the measurement of peak passive wrist extension in young (≤5.5 years) and older (≥5.75 years) children with CP.
2. Determine the difference between the goniometer and wearable sensors for the measurement of passive wrist extension; with fingers flexed and fingers extended.

Regarding to the first aim, it was hypothesised that:

- There would be less agreement between the goniometer and wearable sensors for the younger children due to: i) the increased amount of subcutaneous tissue on the dorsum of the hand, and ii) the ability of the younger children to follow instructions and tolerate the assessment procedure.

Regarding to the second aim, it was hypothesised that:

- There would be a smaller root mean square (RMS) error and mean difference between the two tools for wrist extension with fingers flexed as opposed to wrist extension with fingers extended, due to the difficulty of achieving the position for measurement.

1.7.6 Chapter Seven (Study Five)

Title: A comparison of wrist and elbow kinematics in young children with and without cerebral palsy.

The aims of this study were to:

1. Compare peak active wrist extension and flexion, and elbow extension and flexion, between young children with and without CP during movement/play tasks.

2. Compare the difference between peak active wrist extension and peak passive wrist extension in children with and without CP.

Regarding to the first and second aim, it was hypothesised that:

- Children with CP, who present with full passive wrist extension, will have reduced active wrist and elbow extension and will complete tasks in a more flexed position, compared to children without CP.

Regarding to the second aim, it was hypothesised that:

- Children with CP will complete tasks using less of their available passive wrist extension than children without CP.

1.7.7 Chapter Eight

This chapter provides a synthesis and summary of the findings, critically reviewing the strengths and limitations of the research and suggesting recommendations for future research.

Chapter Two

2

Literature Review

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The overarching aim of this body of work was to determine if custom wearable sensors could be used to objectively measure passive and active upper limb joint range of motion (ROM) in young children (<5 years of age) with cerebral palsy (CP). Prior to investigating this, an understanding of CP, its prevalence and the motor impairments (i.e. muscle tone, muscle weakness and the secondary development of contracture) limiting upper limb joint ROM is required. The International Classification of Functioning, Disability and Health (ICF)[5] is used to frame this review, with particular focus on the *body functions and structure* domain. The impact of *body functions and structure* impairments on passive and active joint ROM as presented in the literature are discussed, followed by the tools that can be used to objectively measure joint ROM in the upper limb.

2.1 Cerebral palsy

CP is the most common cause of physical disability in childhood, with an overall estimated prevalence of 2.11 per 1000 live births worldwide.[44] In Australia, the estimated prevalence is between 1.4 to 2.1 for every 1000 live births.[2] Although the incidence of CP in Australia has declined since 2006, it still remains one of the largest physical disorders treated in paediatric rehabilitation programs across the country. CP is described as:

> "a group of permanent disorders of the development of movement and posture causing activity limitation, that are attributed to non-progressive disturbances that occurred in the developing fetal or infant brain" (p.9).[1]

Motor impairment is a primary feature of CP[1,7] which can vary between individuals depending on the location and extent of injury to the brain.[3] The definition of CP has evolved over the years due to improved understanding of the condition, with the latest definition reflecting the increasing understanding that CP is more than a motor disorder.[1] Co-morbidities in the form of seizures, pain, visual and auditory impairment, learning disabilities, communication disorders, impaired sensation and secondary musculoskeletal problems are very common.[1] The clinical manifestations of CP are also progressive in nature, meaning they can change as the child grows and develops.[3,45,46] CP is, therefore, a broad term that encompasses a large array of complex and heterogeneous disorders, and the impairments and specific needs of children can vary widely.

Several methods exist that broadly describe the clinical presentation of a child with CP in attempt to provide a common language amongst clinicians. One common method is to describe the predominant motor type: spastic; dyskinetic (including dystonia and

choreo-athetosis); ataxic; and mixed.[47] The most common predominant motor type is spastic, accounting for over 85% of reported cases in Australia.[2]

Topographical or anatomical distribution is also used and describes areas of the body affected by CP.[48] Hemiplegia and monoplegia are characterised by impairment to one side of the body and often referred to as unilateral CP.[2] Hemiplegia is the most common distribution (i.e. involvement of an upper and lower limb on the same side of the body), accounting for approximately 40% of children diagnosed with CP in Australia.[2] Diplegia, triplegia and quadriplegia are characterised by impairment to both sides of the body, making up the proportion of children with bilateral CP. Diplegia is second most common distribution, occurring in 36% of children in Australia[2] and indicates predominant involvement of both lower limbs with the possibility of mild involvement of both upper limbs.[48] The distinction between diplegia and quadriplegia remains subjective, and dependent on the severity of upper limb involvement.[48] Nevertheless, it is evident in most topographical distributions of CP, that upper limb involvement is present to varying degrees.

Over the years, there has been a fundamental move towards describing the functional impact of upper limb impairment in children with CP.[48,49] The Manual Ability Classification Scale (MACS)[50] and the Mini-Manual Ability Classification Scale (Mini-MACS)[51] describe how children with CP use their hands in everyday activities. Both functional scales facilitate conversation between the therapist, parent and child (where possible) to determine the child's needs based upon how they use their hands and to guide intervention. The scales are divided into five levels, with children classified at Level I having the least functional impairment and children classified at Level V having the most severe functional impairment (Table 2.1).[50,51] The classification of manual ability combined with the topographical distribution and predominant motor type, provide a description of subgroups within the heterogeneous population of CP.

Table 2.1 Levels of the Manual Ability Classification Scale (MACS)[50] and the Mini-Manual Ability Classification Scale (Mini-MACS)[51]

Level	MACS	Mini-MACS
I	Handles objects easily and successfully. At most, limitations in the ease of performing manual tasks requiring speed and accuracy. However, any limitations in manual abilities do not restrict independence in daily activities.	Handles objects easily and successfully. The child may have slight limitation in performing actions that require precision and coordination between the hands, but they can still perform them. The child may need somewhat more adult assistance when handling objects compared with other children of the same age.
II	Handles most objects but with somewhat reduced quality and/or speed of achievement. Certain activities may be avoided or be achieved with some difficulty; alternative ways of performance might be used but manual abilities do not usually restrict independence in daily activities.	Handles most objects, but with somewhat reduced quality and/or speed of achievement. Some actions can only be performed and accomplished with some difficulty and after practice. The child may try an alternative approach, such as using one hand. The child needs adult assistance to handle objects more frequently compared with children of the same age.
III	Handles objects with difficulty; needs help to prepare and/or modify activities. The performance is slow and achieved with limited success regarding the quality and quantity. Activities are performed independently if they have been set up or adapted.	Handles objects with difficulty. Performance is slow and with limited variation and quality. Easily managed objects are handled independently for short periods. The child often needs adult help or support to handle objects.
IV	Handles a limited selection of easily managed objects in adapted situations. Performs parts of the activities with effort and with limited success. Requires continuous support and assistance and/or adapted equipment, for even partial achievement of the activity.	Handles a limited selection of easily managed objects in simple actions. The actions are performed slowly, with exertion, and/or with random precision. The child needs constant adult help and support to handle objects.
V	Does not handle objects and has severely limited ability to perform even simple actions. Requires total assistance.	Does not handle objects and has severely limited ability to perform even simple actions. At best, the child can push, touch, press or hold onto a few items while in constant interaction with an adult.

[50]Eliasson A, Krumlinde Sundholm L, Rosblad B, Beckung E. The manual ability classification system (MACS) for children with cerebral palsy: Scale development and evidence of validity and reliability. *Dev Med Child Neuol.* 2006;48(7):549-554.

[51]Eliasson AC, Ullenhag A, Wahlström U, Krumlinde-Sundholm L. Mini-MACS: Development of the manual ability classification system for children younger than 4 years of age with signs of cerebral palsy. *Dev Med Child Neuol.* 2017;59(1):72-78.

2.2 Prevalence and severity of upper limb involvement

A population based study that retrospectively analysed data from 367 children with CP (subtypes: spastic; ataxic; dyskinetic; and mixed) on the Swedish national register, reported that 60% of children (age range: 4 to 14 years) had more than minor problems with hand function as determined by the MACS (level of ≥I).[52] In another cross-sectional study at a specialist children's hospital, 83% of children with CP (n = 100, mean age 10.3 years) across three anatomical distributions (hemiplegia, diplegia and quadriplegia) had involvement of the upper limb indicated by a level of more than II on the MACS; with 54% of children classified by level III or higher.[53] Children with upper limb involvement, therefore, make up a significant portion of those with CP. As a result, a substantial amount of therapy time and resources are directed to the management of upper limb impairment in children with CP[54] and it is essential that this management is considered within a wider, more holistic context of the individual themselves.

2.3 Theoretical framework: The International Classification of Functioning, Disability and Health: Children and Youth Version (ICF)

The ICF, developed by the World Health Organisation, offers a framework to understand functioning and disability from a biopsychosocial perspective.[5] This framework is commonly adopted by health professionals as it provides a unified, international language to describe a health condition and the impact it may have on function.[5,55] The functioning of an individual is largely influenced by the interaction of the domains that make up the ICF; the *health condition*, *body functions and structure*, *activity* and *participation*, and *environment* and *personal factors* (Figure 2.1).[5] The interaction among these domains is dynamic and bidirectional.[5] As such, the ICF is considered the ideal framework to standardise the description of impairment, assessment and treatment of children with CP.[56,57]

This framework will be used in this thesis to discuss upper limb impairment in CP. Measurement of muscle and soft tissue length (passive and active joint ROM) is the overarching aim of this research, therefore the *body functions and structure* domain will be the focus and will be used to describe upper limb impairment and the measurement of joint ROM in children with CP.

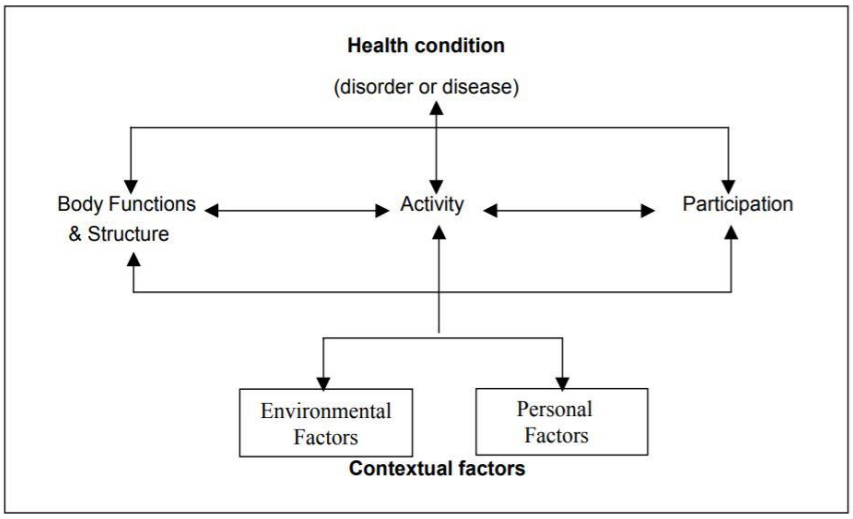

Figure 2.1 The International Classification of Functioning, Disability and Health (ICF).[5] Figure reproduced with permission

2.4 Body functions and structure domain of the ICF

The *body functions and structure* domain of the ICF encompasses the physiological and anatomical structures of the body.[5] In childhood, the most common cause of upper motor neurone syndrome is CP.[7] Upper motor neurone syndrome directly affects the physiological and anatomical structures of the body, causing positive and negative features of movement.[3,58,59] Positive features include hypertonia (including spasticity), hyper-reflexia, clonus and co-contraction of muscles[7] and generally occur due to reduced descending inhibitory signals from the brain.[48] Negative features are known to result from reduced descending excitatory signals, and are clinically observed as muscle weakness, loss of selective motor control and sensory deficits.[7,48] Assessment of positive and negative features includes the assessment of muscle tone, muscle imbalance due to weakness, joint structure and alignment changes, and changes in muscle and soft tissue length (passive and active joint ROM).[60]

2.4.1 Muscle tone

Muscle tone is the continuous partial contraction of muscles to maintain posture or movement against the force of gravity.[61] Normal muscle tone is a result of well-coordinated commands between the brain, spinal cord and muscles.[60] CP is characterised by damage to areas of the brain that control muscle tone and movement which can cause variations in muscle tone to occur. Hypertonia is an increase in muscle tone, described as tight or stiff muscles when passively moved.[62] The stiffness is thought to occur due to

several changes in the physical properties of the muscle, connective tissue (including ligaments, tendons and joint capsules), and synovial joint.[60]

Spasticity is the neurological component of hypertonia that is predominant in children with CP, and is described as:

> "A motor disorder characterized by velocity dependent increase in tonic stretch reflexes (muscle tone) with exaggerated tendon jerks, resulting from hyper excitability of the stretch reflex" [63](p.485).

Spasticity is dependent on the speed of movement and resistance occurs when the muscle is passively lengthened with a rapid external force.[64] The resistance on rapid passive movement is the key feature that distinguishes spasticity from other forms of hypertonia.[60] In the presence of spasticity, when a passive stretch is performed slowly, tone may feel relatively normal, however clear resistance occurs when the movement is performed quickly.[64,65] Differentiating spasticity from other forms of hypertonia can be challenging but is crucial to ensure correct treatment planning.[60]

In children with CP, spasticity is common in the flexor muscles of the elbow, wrist and fingers, and forearm pronators.[3,66] Subsequently, children with CP tend to adopt a common position of the upper limb; elbow flexion, forearm pronation, and wrist flexion often with ulnar deviation.[3,4] Over time, muscles adapt to the shortened positions due to the force not being able to be counteracted by weaker antagonistic muscles.[7] Persistent muscle over-activity combined with altered bone growth can result in changes to musculotendinous units and over time can become increasingly resistant to passive stretch.[7,67] Musculoskeletal changes that occur secondary to spasticity are probable, and tend to increase as the child gets older.[68] Eventually, muscles decrease in passive extensibility which can result in varying degrees of immobility.[69] The secondary effects of immobility can result in reduced passive and active joint ROM, contractures, rotational abnormalities of long bones, and joint instability.[7,60,69]

2.4.2 Muscle weakness

Muscle weakness is a pervasive clinical feature of CP that affects the ability to generate or maintain muscle force for voluntary movement.[60,70,71] Literature to support the presence of muscle weakness in the upper limb of children with CP is growing but remains somewhat limited compared to what is known about muscle weakness in the lower limb. A study by Klingels et al[66] documented upper limb muscle weakness in children with unilateral CP (n = 81; mean age: 9 years 11 months) in the forearm

pronators, wrist flexors and extensors, and finger flexors. Almost half (44%) of these children were unable to extend the wrist against minimal resistance (manual muscle testing score < 3+).[66] Despite increased muscle tone documented in the wrist and finger flexors, 41% of children with CP were unable to flex the wrist against minimal resistance.[66] Children with CP (n = 11; age range 6–11 years) have also recorded significantly lower strength values for the wrist extensors (mean difference: 42.71 newtons) and flexors (mean difference: 69.75 newtons) compared to TD children (n = 11; age range 6–11 years)[72], further reiterating the presence of underlying weakness in muscles predominantly thought to be impacted increased muscle tone.[72,73]

Given the documented weakness in muscles of the upper limb, it is not surprising to find impaired grip strength in children with CP.[66,68,72] Von Walden et al[68] demonstrated that children with CP have significantly (p <0.01) lower grip strength (10 second isometric contraction) (58.3 newtons ± 32.1) compared to TD children (167.5 newtons ± 93.5). The study by Klingels et al[66] compared grip strength of the non-hemiplegic hand to the hemiplegic hand and found the latter to be 40% weaker in grip strength. However, in children with hemiplegia it is not uncommon for the non-hemiplegic hand to present with motor impairments, including impaired grip strength. The study by Arnould et al[74] found that out of a sample of 50 children with hemiplegic CP, grip strength was impaired in the hemiplegic hand in 80% of children, with the non-hemiplegic hand also impaired in 34% of children.

There is increasing evidence that muscle weakness may hinder functional performance. Arnould et al[74] found grip strength in the hemiplegic hand to be moderately correlated with manual ability as measured by the ABILHAND-Kid questionnaire (r = 0.56, p = <0.001, n = 100).[74] A high correlation (r = 0.80) between grip strength and the Assisting Hand Assessment was also found by Braendvik et al[75] for children with spastic CP (n = 23; mean age 13 years; age range 8 - 18 years). Similarly, Klingels et al[66] found that wrist strength and grip strength of children with unilateral CP (n = 81; age range 5–15 years) to be highly correlated with the Assisting Hand Assessment (r_S = 0.88; r_S = 0.76) and the Melbourne Assessment of Unilateral Upper Limb Function (r_S = 0.88; r_S = 0.75). Muscle weakness, therefore, may have significant functional implications for children with CP, and may further limit the amount of active joint ROM used during voluntary movement.[76]

A critical review of literature by Rameckers et al[77] in 2015 identified six articles related to the effectiveness of strengthening interventions in the upper limb of children

with CP, highlighting the scarcity of research in this area. The critical review further reiterated the presence of muscle weakness in the wrist flexors and extensors in children with hemiplegic CP[77], and highlighted the need to include functional outcomes in future upper limb strength related studies.[77]

2.4.3 Musculoskeletal change

Muscle and joint stiffness can frequently lead to fixed contractures, which is described as soft tissue shortening and loss of extensibility.[78] The key determinant of contracture development is long term immobilisation, or disuse.[78] Over time, changes to the biomechanical and biochemical properties of soft tissue arise, including adaptations in the skin, subcutaneous tissue, muscles, tendons, ligaments, joint capsule, vessels and nerves.[78] Different types of contractures are described in the literature; mobile/dynamic, organic or fixed.[60] Mobile or dynamic contractures are characterised by resistance to passive movement, however full joint ROM can be achieved.[60,79] Organic contractures present as persistent stiffness that may be managed through interventions such as casting, however reoccurrence is probable in the absence of long term positioning.[60] In contrast, fixed contractures often require surgical intervention[60] due to changes in the biochemical composition of surrounding soft tissue.[3,60,78,79]

Flexion contracture of the elbow and/or wrist, and/or pronation contracture of forearm contribute to the typically observed elbow flexed and forearm pronated position of the upper limb in children with CP.[80] Evidence of the prevalence of contracture formation in the upper limb is growing, with a recent population-based study investigating the retrospective longitudinal development of passive ROM.[13] This study by Hedberg-Graff et al[13] included 771 children, and found that 34% of children with CP developed contractures of the upper limb (defined by ≤60° of wrist extension and <-10° (i.e. elbow flexion) of elbow extension). Contracture of wrist extension (with fingers extended) was most common (19.4%) followed by wrist extension (with fingers flexed) (9.9%) and elbow flexion (8.9%).[13] Contracture development was shown to first appear in the wrist, with reductions in passive wrist extension occurring in children between 1 and 3 years of age and becoming significant at 4 years of age.[13] This is arguably the largest population-based study to track the longitudinal contracture formation in the upper limb. Other studies with smaller sample sizes report a similar prevalence of contractures in the upper limb; one third of children with CP (n = 100; age range 3 - 18 years) had a demonstrable contracture, with contracture of the wrist and hand most common.[53]

Contractures of the elbow, wrist and/or forearm can result in issues related to hygiene, aesthetic appearance, pain and a loss of joint ROM.[4,60] Contractures therefore have potential to cause an array of functional difficulties.[78] A flexion contracture of the elbow may interfere with the ability to reach and a pronation contracture in the forearm may limit activities that require supination (i.e. hand to mouth).[79] Considered more problematic, is wrist flexion contracture.[13,79] Functionally, a flexed wrist may interfere with fine motor skills, weaken grip strength[66] and make grasp-and-release of objects difficult.[81] Therefore, contracture of the wrist has potential to impact many aspects of self-care and performance in daily activities.[13,79]

2.5 Range of motion

ROM is described as movement around a joint that can occur passively or actively.[82] Muscle strength, flexibility and musculotendon length are key contributors to joint ROM and each are often impaired in children with CP. Consequently, children with spastic CP can present with reduced active and passive elbow and wrist joint ROM that can be attributed to a combination of neural and muscular impairments.[83] The severity of motor impairment determines the extent to which ROM is reduced, and due to the heterogeneous nature of CP, each child presents differently. Therefore, it is necessary to consider limitations in both passive and active joint ROM.

2.5.1 Passive range of motion

Passive ROM is the maximum amount of movement around a joint that is achieved when applying an external force (i.e. clinician moving the limb) when muscles are not actively engaged.[82] In children with CP, the surveillance of passive ROM throughout childhood is recommended to assess for changes in muscle and/or soft tissue, and thus the early detection of contracture formation.[13] While infants with CP usually have full passive ROM, the onset of stiffness is thought to occur gradually, with restrictions in passive ROM tending to progressively worsen throughout childhood.[13]

A one year follow up period has been determined to not be long enough to detect statistically significant changes in passive ROM[84], however, data collected at multiple time points throughout childhood has demonstrated significant changes in passive ROM.[13] In the same previously mentioned longitudinal study (12 years; 2002 to 2014), Hedberg-Graff et al[13] documented changes in passive ROM in a large cohort of children with CP (n = 771; mean age 11 years 8 months; age range 1 - 18 years). Children with

dyskinetic CP (46%), and children within MACS levels IV (46%) and V (65%) constituted the largest proportions of children with restrictions in passive ROM.[13] With age, mean values for passive elbow extension decreased by approximately 30°, forearm supination by 50°, wrist extension with fingers extended by 65° and wrist extension with fingers flexed by 56°.[13]

In children with unilateral CP (n = 81; mean age 9 years 11 months), limitations in passive elbow extension have been reported to be most common (present in 25% of the participants), followed by limitations in passive forearm supination (present in 30% of the participants) and passive wrist extension (present in 12% of the participants).[66]

2.5.2 Active range of motion

Active ROM is the amount of voluntary movement around a joint that results from the timely contraction of agonist and antagonist muscles.[60] Movement through active joint ROM is beneficial to build and/or maintain muscle strength as well as maintain the health of joints and surrounding tissue.[82] Active joint ROM may be limited in children with CP due to a combination of muscle weakness, stiffness in the agonistic muscle and inappropriate co-contraction of antagonist muscle.[60]

To date, limitations in active joint ROM are only documented for children with CP between the ages of 5 and 18 years. Limitations in elbow extension, forearm supination and wrist extension are commonly observed during active movement of the upper limb of children with CP.[14-18,85,86] Quantification of active joint ROM is accurately and reliably described using three-dimensional motion analysis (3DMA) (details of which will be discussed later in this chapter) captured during various functional tasks (i.e. reaching, reach-grasp or simple functional movements such as hand-to-mouth or hand-to-head).[15-18,85,87,88] During reaching tasks, children with hemiplegic CP (n = 10; mean age = 13.3 years; age range = 10 – 17 years) demonstrated pronounced deficits in active elbow extension (difference of 21°), however active forearm supination was similar (difference of 2°) to healthy controls (n = 10; mean age = 9.8 years; age range = 6 – 12 years).[15] On average, children with hemiplegic CP (n = 20; mean age = 10.9 ± 2.9 years) used 18° more elbow flexion, 6.6° more forearm pronation and 22.5° more wrist flexion when reaching forward, sideward and upward compared to TD children.[16] In the same study, reach to grasp tasks were completed by children with CP with similar deficits in active ROM; 8.4° more elbow flexion, 6.6° more forearm pronation and 21.8° more wrist flexion.[16] Similar to reaching tasks, studies assessing active ROM during hand-to-mouth

tasks also show reductions in elbow extension, supination, and wrist extension.[16] Children with CP on average used 4.2°[16] to 12°[15] more active elbow flexion, 26° less active supination[15], similar active pronation (± 1°)[16] and 31.1° more active wrist flexion[16] than TD children. The magnitude of deficits in active ROM of the upper limb were similar between the hand-to-head and hand-to-shoulder tasks, with pronounced deficits observed in active forearm supination (26° difference)[15] and wrist flexion (differences ranged from 17.1° to 31.2°).[16] Collectively, these studies reflect that children with CP between 5 and 18 years of age complete functional tasks with restrictions in elbow extension, forearm supination and wrist extension.

In contrast to these findings, a study by Coluccini et al[89] reported less characteristic patterns of active upper limb movement, with marginal differences in elbow and wrist flexion between children with and without CP (n = 10; median age: 11 years). This study included a sample of children with more variation in their predominant motor type; both spastic and dyskinetic (n = 5 spastic, n = 5 dyskinetic), compared to prior studies, which may account for the less characteristic movement patterns observed.[89]

The correlation between limitations in active movement and MACS levels demonstrate that children classified at MACS level III have significant restrictions in maximum active forearm supination compared to children classified at MACS level I and TD children ($p < 0.05$).[18] Proximal compensatory strategies have also been reported to be employed by children with CP to counteract insufficient active ROM distally.[18,80] Compared to TD children, children with CP are found to complete tasks with increased flexion[15,16,18] and outward rotation of the trunk[16,90], anterior tilting, medial rotation and protraction of the scapular[80,90] and external rotation and decreased elevation of the shoulder.[90]

2.6 Measurement of range of motion

Routine measurement of passive and active joint ROM is recommended to indicate whether an intervention has worked as expected, and/or to monitor potential progression of secondary musculoskeletal impairment over time.[4,91,92] For children with CP, the most common methods employed by clinicians to objectively quantify upper limb joint ROM include the universal goniometer, and 3DMA.

2.6.1 Goniometer

In a 2016 systematic review of literature, the universal goniometer was identified as one of the most widely utilised tool to measure joint ROM by healthcare professionals

(i.e. occupational therapists and physiotherapists) working with children with CP.[93] This is likely due to its versatility (i.e. it can be used for numerous joints in the body), low cost, and because it is considered an easy-to-use instrument (though this can be largely dependent on the experience of the assessor).[94] These benefits make the goniometer a highly accessible measurement tool for clinicians in a busy setting. As such, measurement of passive joint ROM using the goniometer is often an outcome of interest in studies that evaluate change in response to interventions such as BoNT-A[95], upper limb orthoses[20,21], and surgery.[96]

An advantage reported with use of the goniometer in adult populations, is that it allows for the measurement of both passive and active joint ROM. Measurement of active limitations may be considered a better reflection of the dynamic restrictions in joint ROM experienced during functional activities, however, this is a more challenging measurement to obtain in younger people. Challenges are due to a number of reasons including (but not limited to) the: ability of the child to understand instructions; motivation to participate; acceptance of physical contact on the arm and hand; and the ability to sustain an upper limb position for measurement. As a result, passive measurement is utilised more often than active measurement in younger children.

The reliability of the goniometer to measure passive ROM varies widely, however it is widely accepted that measurements taken by the same clinician are more consistent than measurements taken by multiple clinicians at different time points.[91,97-99] Given that measurements of wrist and elbow ROM are routinely completed for children with CP, it is recommended that children be measured by the same clinician at follow up time points to ensure consistency of measures.[100] However, a busy clinical setting does not always allow for this, and awareness of potential error is needed when interpreting measures obtained by a goniometer, even when completed by the same rater.

Inter and intra-rater reliability of the goniometer is well established for measurement of joint ROM in the lower limb of children with CP (age range: 3 – 21.2 years)[24,97,98,101-104] and measurement errors between 10° to 15° can be expected depending on the joint being measured.[24,101] In part, the measurement error is believed to be due to the visual estimation required to complete goniometric measurements, leading to incorrect measurements with limited repeatability.[101,105] Few studies report on the reliability of the goniometer for the upper limb, despite measurements of the wrist and elbow being used as a common indication of soft tissue shortening in children with CP.[13,52] The most substantial evidence for reliability of passive measurement of the wrist

and elbow comes from Klingels et al[100] who investigated the inter and test-retest reliability in a sample of 30 children with hemiplegic CP between the ages of 5 and 15 years. In this study, the goniometer showed moderate inter-rater reliability for elbow extension and wrist supination (ICC = 0.69 and 0.73, respectively); however, reliability was lower for measurement of wrist extension (ICC = 0.48).[100] Test-retest reliability was found to be high across all joints in the upper limb (ICC = 0.81 to 0.94)[100], however this study did not report intra-rater reliability.

Using Pearson's correlation coefficient, a strong positive relationship between two occasions of measurement was found for the measurement of elbow and wrist extension with coefficients ranging from 0.92 and 0.85, respectively (n = 19 spastic CP; age range 2.5 to 9 years.[106] Caution is required, however, when interpreting these results as this analysis does not provide a robust measure of agreement.[107] Unfortunately, the results of this study are limited to what is reported in a conference abstract, with no full text available. This was the only study found to include children under 4 years of age; therefore, the reliability and accuracy of the goniometer in this age group is still largely unknown. Despite the lack of demonstrated reliability for use of the goniometer with children with CP less than 5 years and the difficulties of obtaining measurement of active movement, the goniometer continues to be used in clinical settings and research applications.

2.6.2 Three-dimensional motion analysis (3DMA)

Three-dimensional motion analysis (3DMA) is a measurement system capable of objectively quantifying active movement of the upper limb in multiple degrees of freedom.[14,16,26] This system is considered the 'gold standard' in movement analysis for gait and employs multiple video cameras to visualise retro-reflective markers placed at specific locations on the body. In adults, this system has demonstrated an error in the order of 0.5mm, and an angular error less than 5°.[108] For children with CP, the uptake of 3DMA to analyse gait parameters is common and evidence for use in the upper limb is growing.

Jaspers et al[25] reported within-and-between session reliability of 3DMA in an observational study during reaching, reach to grasp and gross motor tasks for children with hemiplegic CP aged between 6 and 15 years. They reported high to very high levels of reliability for joint angles at endpoint (ICC >0.70), with most within and between session measurement errors between 5° and 7°, respectively.[25] Similarly, in a sample of children with spastic CP (age range 6 – 11 years) measurement error between 5° and 9°

was found for elbow joint angle, with good test-retest reliability (ICC = 0.87 to 0.94).[27] Excellent within and between session reliability was reported for elbow flexion/extension (coefficient of multiple correlation = 0.93 to 0.96), with slightly lower reliability values found for elbow supination/pronation (coefficient of multiple correlation = 0.63 to 0.90).[26] To date, only one study investigated the reliability of 3DMA to measure wrist joint ROM. This study included children with CP between 9 and 15 years (n = 7), with coefficient of multiple correlation values varying between 0.19 and 0.45 depending on the task completed.[85] Despite most of the other studies concluding adequate levels of reliability for the measurement of upper limb joint ROM during active movement, the complexity, characteristics, availability and associated costs of 3DMA make it often impossible or impractical for frequent use in the clinical setting.[109]

As previously discussed, limitations in active elbow and forearm joint ROM are frequently documented for children with CP; however few studies report on joint ROM of the wrist.[16,89] Kinematic analysis of the wrist joint tends to either focus on spatio-temporal parameters (i.e. movement duration and velocity)[14,110] or present data in graph format as a movement trajectory (i.e. discrete joint kinematics are not reported).[85] Notably, reporting of joint kinematics within the literature are also limited to children with CP over the age of 5 years. While restrictions in active ROM are observed clinically in young children with CP, to date no study has objectively quantified these differences.

2.7 Summary

Children with CP may have limitations in passive and active upper limb joint ROM which is a result of a combination of factors including spasticity, muscle weakness, and subsequent progressive secondary musculoskeletal impairments.[13,16,52,111] Depending on the severity of the impairments, reduced active joint ROM is considered to be associated with functional difficulties in older children with CP.[14-16] Given there are several treatment options that target upper limb impairment at the *body functions and structure* level, particularly joint ROM, there is a need for clinicians to have access to valid and reliable tools to measure change in response to intervention or to monitor secondary musculoskeletal impairment over time. Therefore, this research will seek to investigate whether wearable sensors can be used to measure passive and active upper limb joint ROM in young children with CP.

Chapter Three

3

Measurement of upper limb joint angle using wearable sensors: A systematic review

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Foreword

Chapter One outlined the need for objective measurement of joint ROM in the upper limb for the ongoing management and monitoring of secondary musculoskeletal impairments. Goniometry is the most utilised tool in clinical practice, however its use with young children is limited to the measurement of passive joint ROM. There is also a lack of psychometric properties for the use of the goniometer to measure joint ROM in the upper limb of young children (<5 years of age) with CP. With technology rapidly evolving, the use of wearable sensors has gained considerable interest due to their ability to measure unrestricted movement. In children with CP, wearable sensors have been used to determine gait parameters and used in the assessment of spasticity within the literature, however, less is known about their application to the upper limb to measure joint ROM. In exploring the use of wearable sensors to measure upper limb joint ROM, Study One involved a comprehensive and systematic review of literature specific to the use of wearable sensors to measure joint ROM in the upper limb. This study aimed to synthesise literature relating to the physical characteristics of wearable sensors, their established psychometric properties to measure joint ROM in the upper limb and the populations with which they have been utilised. In doing so, this paper identifies gaps in current literature and provides directions for future research, some of which form the basis of research reported in subsequent chapters.

Abstract

Background: Wearable sensors are portable measurement tools that are becoming increasingly popular for the measurement of functional movement. With many brands emerging on the market, each with variations in hardware and protocols, evidence to inform selection and application is needed. Therefore, the objectives of this review were related to the use of wearable sensors to calculate upper limb joint angle. We aimed to describe: i) the characteristics of commercial and custom wearable sensors, ii) the populations for whom researchers have adopted wearable sensors, and iii) their established psychometric properties.

Methods: A systematic review of literature was undertaken using the following data bases: MEDLINE, EMBASE, CINAHL, Web of Science, SPORTDiscus, IEEE and Scopus. Studies were eligible if they met the following criteria: i) involved humans and/or robotic devices, ii) involved the application or simulation of wearable sensors on the upper limb, and iii) calculated a joint angle.

Results: Of 2191 records identified; 66 met the inclusion criteria. Eight studies compared wearable sensors to a robotic device and 22 studies compared wearable sensors to a motion analysis system. Commercial (n = 13) and custom (n = 7) wearable sensors were identified, each with variations in placement, calibration methods and fusion algorithms, which were demonstrated to influence accuracy.

Conclusion: Wearable sensors have potential as viable instruments for measurement of joint angle in the upper limb during active movement. Currently, customised application (i.e. calibration and angle calculation methods) is required to achieve sufficient accuracy (error <5°). Additional research and standardisation is required to guide clinical application.

Registration: This systematic review was registered with Prospero (CRD42017059935).

3.1 Background

Clinicians and researchers often seek information about the way people move. Range of motion (ROM), defined as movement around a joint, is measured in a variety of clinical populations including those with orthopaedic, musculoskeletal and neurological disorders. Measurement of ROM forms a valuable part of clinical assessment; therefore, it is essential that it is completed in a way that provides accurate and reliable results [1, 2].

In clinical practice, the goniometer is a widely used instrument to measure ROM [2 - 4]. Despite being considered a simple, versatile and an easy-to-use instrument, reports of reliability and accuracy are varied. Intra-class correlation coefficients (ICC's) range from 0.76-0.94 (intra-rater) [3, 4] and 0.36-0.91 (inter-rater) [4] for shoulder and elbow ROM. Low inter-rater reliability is thought to result from the complexity and characteristics of the movement, the anatomical joint being measured, and the level of assessor experience [5, 6]. The goniometer is also limited to measuring joint angles in single planes and static positions, thus, critical information regarding joint angles during functional tasks cannot be measured.

In research settings, three-dimensional motion analysis (3DMA) systems, such as Vicon (Vicon Motion Systems Ltd., Oxford, UK) and Optitrack (NaturalPoint, Inc., Corvallis, OR, USA) are used to measure joint angles during dynamic movement in multiple degrees of freedom (DOF). Such systems are considered the 'gold standard' for evaluating lower limb kinematics, with a systematic review reporting errors <4.0° for movement in the sagittal plane and <2.0° in the coronal plane; higher values have been reported for hip rotation in the transverse plane (range: 16 to 34°) [7]. Measurement in the upper limb is considered more technically challenging due to the complexity of shoulder, elbow and wrist movements [8]. Given the demonstrated accuracy in the lower limb, 3DMA systems are used as the 'ground truth' when validating new upper limb measurement tools [9]. However, 3DMA does have limitations. Most notably, these systems are typically immobile, expensive and require considerable expertise to operate, and therefore rarely viable for use with clinical populations [10, 11].

Wearable sensors, or inertial movement units, are becoming increasingly popular for the measurement of functional joint angle [12]. In this review we were interested in wearable sensors that contained accelerometers and gyroscopes, with or without a magnetometer, to indirectly derive orientation. The software typically utilised three main

steps: i) calibration; using system (offset of the hardware on a flat surface), static (pre-determined pose) and/or functional (pre-determined movement) [13, 10]; ii) filtering; using fusion algorithms including variations of the Kalman filter (KF) [14, 15], and iii) segment and angle definition; using Euler angle decompositions and/or Denavit-Hartenberg Cartesian coordinates.

Wearable sensors are an increasingly popular surrogate for laboratory based 3DMA due to their usability, portability, size and cost. Systematic reviews have detailed their use during swimming [16], whole body analysis [17] and in the detection of gait parameters and lower limb biomechanics [18]. However, their validity and reliability must be established and acceptable prior to their application [19]. Accuracy of the wearable sensors is dependent on the joint and movement being measured; therefore, a systematic review specific to the upper limb is required. This study aimed to establish the evidence for the use of wearable sensors to calculate joint angle in the upper limb, specifically:

- What are the characteristics of commercially available and custom designed wearable sensors?
- What populations are researchers applying wearable sensors for and how have they been used?
- What are the established psychometric properties for the wearable sensors?

3.2 Methods

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines [20] and registered with the International Prospective Register of Systematic Reviews on the 23rd March 2017 (CRD42017059935).

3.2.1 Search terms and data bases

Studies and conference proceedings were identified through scientific databases relevant to the fields of biomechanics, medicine and engineering, from their earliest records to September 2017: MEDLINE via PROQUEST, EMBASE via OVID, CINAHL via EBSCO, Web of Science, SPORTDiscus, IEEE and Scopus. Reference lists were searched to ensure additional relevant studies were identified. The search was updated in October 2017 to identify new studies that met the inclusion criteria.

The following search term combinations were used: *("wearable sens*"*OR *"inertial motion unit*"* OR *"inertial movement unit*"* OR *"inertial sens*" OR sensor)* AND *("movement* analysis"* OR *"motion analysis*"* OR *"motion track*"* OR *"track* motion*"* OR *"measurement system*" OR movement)* AND *("joint angle*"* OR *angle** OR *kinematic** OR *"range of motion*")* AND *("upper limb*"* OR *"upper extremit*"* OR *arm** OR *elbow** OR *wrist** OR *shoulder** OR *humerus**). Relevant MeSH terms were included where appropriate. All references were imported into Endnote X6 (Thomson Reuters, Carlsbad, California, USA) and duplicates were removed.

3.2.2 Study selection criteria and data extraction

The title and abstracts were screened independently by two reviewers (CW and AC). Full texts were retrieved if they met the following inclusion criteria: i) included human participants and/or robotic devices, ii) applied/simulated use of wearable sensors on the upper limb, and iii) calculated an upper limb joint angle. The manuals of commercial wearable sensors were located, with information extracted when characteristics were not reported by study authors. Studies were excluded based on the following criteria: i) used a single wearable sensor, ii) included different motion analysis systems (i.e. WiiMove, Kinetic and smart phones), ii) used only an accelerometer, iv) calculated segment angle or position, v) studied the scapula, or vi) were not published in English.

Two reviewers (CW and AC) extracted data independently to a customised extraction form. Discrepancies were discussed and a third reviewer (TG) involved when consensus was not reached. Extracted parameters of the wearable sensor characteristics included: custom and commercial brands, the dimensions (i.e. height and weight), components used (i.e. accelerometer, gyroscope and magnetometer), and the sampling rate (measured in Hertz (Hz)). Sample characteristics included the number of participants, their age and any known clinical pathology. To determine if authors of the included studies customised aspects of the wearable sensors system, the following parameters were extracted: the type of calibration (i.e. system, static and dynamic), the fusion algorithms utilised, how anatomical segments were defined and how joint angle was calculated.

To understand the validity and reliability of the wearable sensors, information about the comparison system, marker placement, and psychometric properties were extracted. The mean error, standard deviation (SD) and root mean square (RMS) error reported in degrees were extracted where possible from the validation studies. The RMS error represents the error or difference between the wearable sensor and the comparison

system (e.g., 3DMA system). The larger the RMS error, the greater the difference (in degrees) between the two systems. Further, to report on the validity of the wearable sensors, studies that did not delineate error between the wearable sensor and soft tissue artefact (movement of the markers with the skin) by not using the same segment tracking were not further analysed. Reliability was assessed using ICC's, with values <0.60 reflecting poor agreement, 0.60-0.79 reflecting adequate agreement and 0.80-1.00 reflecting excellent agreement [21].

The following parameters were used to guide the interpretation of measurement error; with <2.0° considered acceptable, between 2.0 and 5.0° regarded as reasonable but may require consideration when interpreting the data, and >5.0° of error was interpreted with caution [7].

3.2.3 Assessment of risk of bias and level of evidence

Due to the variability between research disciplines (i.e. health and engineering) in the way that studies were reported, and the level of detail provided about the research procedures, the available assessments of risk of bias and levels of evidence were not suitable for this review. Therefore, the following criteria were used to evaluate the quality of the reporting in the included studies:

- The aim of the study was clear and corresponded to the results that were reported.
- The study design and type of paper (i.e. conference proceeding) was considered.
- Number of participants included in the study was considered in relation to the COSMIN guidelines which indicate that adequate samples require 50-99 participants [19].

3.3 Results

The initial search (2016) identified 1759 studies eligible for inclusion, with an additional 432 studies identified 12 months later (2017). A total of 66 studies met the inclusion criteria (Figure 3.1). Eight studies reported on validation against a robotic device and 22 studies reported on the validation against a motion analysis system with human participants. One study assessed the reliability of the wearable sensors, with the remaining 36 studies using wearable sensors as an outcome measure in an experimental design.

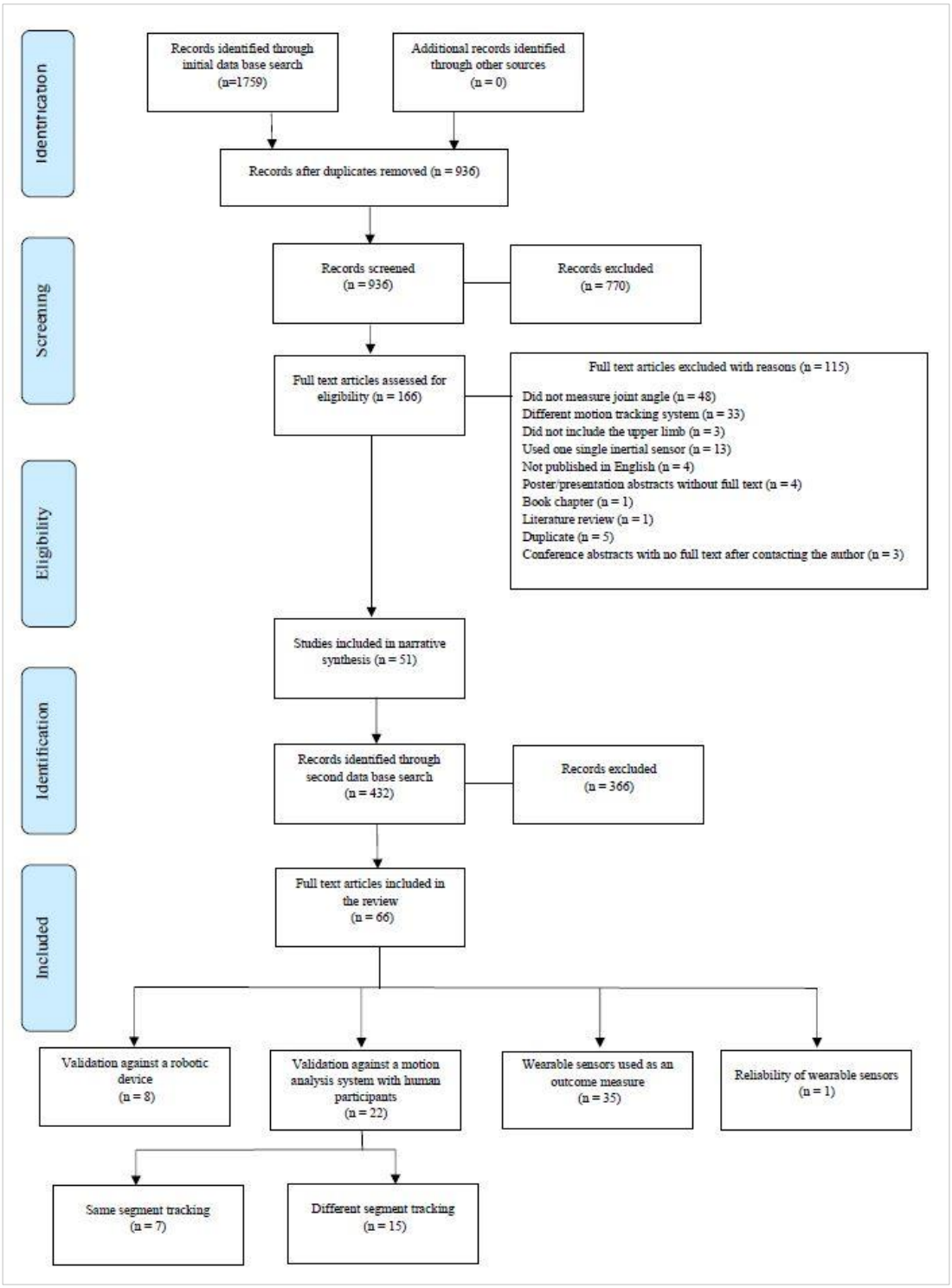

Figure 3.1 A PRISMA diagram of the search strategy

3.3.1 Characteristics and placement of the wearable sensors

The characteristics of the wearable sensors are summarised in Table 3.1. A total of seven custom wearable sensors and 13 commercial brands were identified. The level of detail provided for the placement of the wearable sensors on the upper limb varied significantly, as did the mode of attachment (Table 3.1).

3.3.2 Calibration methods

Forty-seven studies reported on a calibration procedure prior to data acquisition. System calibration was reported on 12 occasions, with two procedures described for the wearable sensors; i) placement on a flat surface and/or ii) movement in a predetermined order while attached to a flat surface [56, 62]. The aim of system calibration was reported to be to align coordinate systems [56, 39] and account for inaccuracies in the orientation of wearable sensor chip relative to its case/packaging [62]. Static anatomical calibration was performed often (n = 34), with dynamic calibration performed sometimes (n = 10) [23, 45, 30, 41, 57, 49, 36]. Only one study used system, static and dynamic calibrations together [47].

3.3.3 Populations assessed using wearable sensors

Most studies (n = 52) recruited healthy adults; participants with known pathology were reported in nine studies (Table 3.1). One study recruited children (<18 years) [49]. Sample sizes ranged from 1 to 54 participants, with a median sample of 7.6 participants per study. Twenty-nine studies recruited less than five participants, with 20 studies recruiting one single participant.

Table 3.1 Summary of the descriptive characteristics of the wearable sensors

Study							Components					Participants		
First Author	Conference/ full text	Brand	No of sensors used	Dimensions (mm) L x W x H	Weight (grams)	Wireless	Acc	Gyr	Mag	Sample rate (Hz)	Method of attachment	Population	*N*	Mean age ± SD (years)
Muller et al. [22]	Full	Xsens – MTw Awinda	2	47 x 30 x 13*	16*	Y*	✓	✓	✓	-	DS tape	Healthy	1	25
Bouvier et al. [23]	Full	Xsens – MTw	4	34.5 x 57.8 x 14.5	27	Y	✓	✓	✓	60	DS tape & elastic	Healthy	10	29 ± 3.4
Robert-Lachaine et al. [24]	Full	Xsens - MVN	17	-	50*	N	✓	✓	✓	30	Velcro	Healthy	12	26.3 ± 4.4
Robert-Lachaine et al. [25]	Full	Xsens - MVN	17	-	50*	N	✓	✓	✓	30	Velcro	Healthy	12	26.3 ± 4.4
Eckardt et al. [26]	Full	Xsens - MVN	17	-	50*	N	✓	✓	✓	120	Body suit	Healthy	20	20.2 ± 5.7
Eckardt et al. [27]	Full	Xsens - MVN	17	-	50*	N	✓	✓	✓	120	Body suit	Healthy	10	23.4 ± 5.3
Alvarez et al. [28]	Full	Xsens - MTx	4	38 x 53 x 21 *	30 *	N	✓	✓	✓	50	Velcro & elastic	Robot & Healthy	1	-
Quinones et al. [29]	Con	Xsens - MTx	7	38 x 53 x 21 *	30 *	N	✓	✓	✓	50	-	SCI	15	37.4 ±7.3
Gil-Agudo et al. [30]	Full	Xsens – MTx	5	38 x 53 x 21 *	30 *	N	✓	✓	✓	25	-	Healthy	1	30
Alvarez et al. [31]	Full	Xsens – MTx	4	40 x 55 x 22	30*	-	✓	✓	✓	50	Elastic	Robot & Healthy	2	-
Bai et al. [32]	Con	Xsens – MTx	3	38 x 53 x 20.9	30	N	✓	✓	-	100	-	-	-	-
Bai et al. [33]	Con	Xsens – MTx	2	38 x 53 x 21 *	30*	-	✓	✓	✓	120	Velcro	Healthy	1	-
Zhang et al. [34]	Full	Xsens – MTx	3	38 x 53 x 21 *	30*	-	✓	✓	✓	100	-	Healthy	4	-

Study							Components					Participants		
First Author	Conference/ full text	Brand	No of sensors used	Dimensions (mm) L x W x H	Weight (grams)	Wireless	Acc	Gyr	Mag	Sample rate (Hz)	Method of attachment	Population	*N*	Mean age ± SD (years)
Rodriques-Anglese et al. [35]	Con	Xsens - MTx	2	38 x 53 x 21 *	30*	N	✓	✓	✓	100	-	Robot & Healthy	1	-
Cutti et al. [36]	Full	Xsens – MT9B	4	39 x 54 x 28	38	N	✓	✓	✓	100	DS tape & elastic	Healthy	1	23
Zhou et al. [37]	Full	Xsens - MT9B	2	-	-	N	✓	✓	✓	25	Velcro	Healthy	4	20-40
Zhou et al. [38]	Full	Xsens – MT9B	2	-	-	N	✓	✓	-	25	-	Healthy	1	-
Perez et al. [39]	Full	Xsens - MTi	4	58 x 58 x 22*	50	-	✓	✓	✓	50	Fabric	Healthy	1	-
Miezal et al. [15]	Full	Xsens	3	-	-	-	✓	✓	✓	120	-	Healthy	1	30
Miguel-Andres et al. [40]	Full	Xsens	3	-	-	N	✓	✓	✓	75	Velcro & DS tape	Healthy	10	29.3 ± 2.21
Luinge et al. [41]	Full	Xsens	2	-	-	N	✓	✓	-	-	DS tape & Leukoplast	Healthy	1	-
Morrow et al. [42]	Full	ADPM Opal	6	43.7 x 39.7 x 13.7 *	<25 *	Y	✓	✓	✓	80	Strap	Surgeons	6	45 ± 7
Rose et al. [43]	Full	ADPM Opal	6	43.7 x 39.7 x 13.7 *	<25 *	Y	✓	✓	-	128	Strap	Surgeons	14	-
Bertrand et al. [44]	Con	ADPM Opal	3	48 x 36 x 13	<22	Y	✓	✓	✓	-	DS tape	Astronauts	2	-
Fantozzi et al. [45]	Full	ADPM Opal	7	43.7 x 39.7 x 13.7 *	<25 *	Y	✓	✓	✓	128	Velcro	Swimmers	8	26.1 ± 3.4
Kirking et al. [46]	Full	ADPM Opal	3	43.7 x 39.7 x 13.7 *	22	-	✓	✓	✓	-	DS tape & strap	Healthy	5	-
Ricci et al. [47]	Full	ADPM Opal	6	43.7 x 39.7 x 13.7 *	<25*	Y	✓	✓	-	128	Velcro	Robot	-	-
El-Gohary et al. [48]	Full	ADPM Opal	3	43.7 x 39.7 x 13.7 *	<25*	-	✓	✓	-	128	Velcro	Robot	-	-

Study							Components					Participants		
First Author	Conference/ full text	Brand	No of sensors used	Dimensions (mm) L x W x H	Weight (grams)	Wireless	Acc	Gyr	Mag	Sample rate (Hz)	Method of attachment	Population	*N*	Mean age ± SD (years)
Ricci et al. [49]	Con	ADPM Opal	5	43.7 x 39.7 x 13.7 *	<22	Y	✓	✓	-	128	Velcro	Healthy	4 & 4	7 ± 0.3 & 27 ± 1.9
El-Gohary et al. [50]	Full	ADPM Opal	2	43.7 x 39.7 x 13.7 *	<25*	-	✓	✓	-	128^	Velcro	Healthy	8	-
El-Gohary et al. [51]	Con	ADPM Opal	2	43.7 x 39.7 x 13.7 *	<25*	Y	✓	✓	-	-	Strap	Healthy	1	-
Mazomenos et al. [52]	Full	Shimmer 2r	2	-	-	Y	✓	✓	✓	50	Custom holders & elastic	Healthy & Stoke	18 & 4	25-50 & 45-73
Tran et al. [53]	Con	Shimmer 2r	2	-	-	Y	✓	✓	✓	18	Strap	Healthy	1	-
Daunoravicene et al. [54]	Full	Shimmer	3	-	-		✓	✓	-	51.2	Strap	Stroke	14	60.8 ± 12.5
Bertomu-Motos et al. [55]	Full	Shimmer	2	51 x 34 x 14 *	-	Y	✓	✓	✓	-	Strap	Healthy	4 & 50	21-51 & 20 - 72
Meng et al. [56]	Con	Shimmer	2	51 x 34 x 14 *	-	Y	✓	✓	✓	20	Velcro	Spherical coordinate system & Healthy	1	-
Peppoloni et al. [57]	Con	Shimmer	3	51 x 34 x 14 *		Y	✓	✓	✓	100	Velcro	Healthy	1	-
Ruiz-Olaya et al. [58]	Full	InvenSense MPU9150 chip	2	-	-	N	✓	✓	✓	50	Straps	Healthy	3	-
Callejas –Curervo et al. [59]	Full	InvenSense MPU9150 chip	2	-	-	N	✓	✓	✓	30	DS tape	Robot & Healthy	3	-

Study							Components					Participants		
First Author	Conference/ full text	Brand	No of sensors used	Dimensions (mm) L x W x H	Weight (grams)	Wireless	Acc	Gyr	Mag	Sample rate (Hz)	Method of attachment	Population	*N*	Mean age ± SD (years)
Li et al. [60]	Full	InvenSense MPU9150 chip	2	-	-	N	✓	✓	✓	-	-	Stroke & Healthy	35 & 11	-
Gao et al. [61]	Con	InvenSense MPU9150 chip	2	26.2 x 39.2 x 14.8	-	Y	✓	✓	✓	-	-	Healthy	1	25
Lambretcht et al. [62]	Full	InvenSense MPU9150 chip	4	12 x 12 x 6	-	N	✓	✓	✓	50	-	Healthy	1	-
Peppoloni et al. [63]	Con	InvenSense MPU9150 chip	4	-	-	-	✓	✓	✓	-	Velcro	Healthy	1	-
Eom et al. [64]	Full	InvenSense MPU6050 chip	2	-	-	Y	✓	✓	-	-	Straps	Robot & Goniometer		
Roldan-Jimenez et al. [65]	Full	InterSense InertiaCube3	3	26.2 x 39.2 x 14.8	17	N	✓	✓	✓	-	DS tape & elastic cohesive bandage	Healthy	15	18-35
Roldan-Jimenez et al. [66]	Full	InterSense InertiaCube3	4	26.2 x 39.2 x 14.8	17	N	✓	✓	✓	1000	DS tape & elastic cohesive bandage	Healthy	11	24.7 ± 4.2
Nguyen et al. [67]	Con	BioKin WMS	2	-	-	Y	✓	✓	✓	200	Straps	Healthy	15	20 - 60
Karunarathne et al. [68]	Con	BioKin WMS	2	-	-	Y	✓	✓	-	-	Straps	Healthy	4	-
Ligorio et al. [69]	Full	YEI Technology	2	-	-	N	-	✓	-	220	Velcro	Healthy	15	28 ± 3

Study							Components					Participants		
First Author	Conference/ full text	Brand	No of sensors used	Dimensions (mm) L x W x H	Weight (grams)	Wireless	Acc	Gyr	Mag	Sample rate (Hz)	Method of attachment	Population	*N*	Mean age ± SD (years)
Vignais et al. [70]	Full	CAPTIV Motion	5	60 x 35 x 19	32	Y*	✓	✓	✓	64	Straps	Healthy	5	41.2 ± 11
Chen et al. [71]	Con	L-P Research Motion Sensor B2	8	39 x 39 x 8*	12	Y	✓	✓	✓	-	-	Goniometer	-	-
Matsumoto et al. [72]	Full	Noraxon Myomotion	13	37.6 x 52 x 18.1	<34	-	✓	✓	✓	200	-	Healthy & Stoke	10 & 1	32.2 ± 9.3 & 27
Schiefer et al. [73]	Full	CUELA	13	-	-	-	✓	✓	✓	50	Velcro	Healthy	20	37.4 ± 9.9
Balbinot et al. [74]	Full	ArduMuV3 chip	9	-	-	Y	✓	✓	✓	20	Straps	-	-	-
Huang et al. [75]	Full	MSULS	4	30 x 35 x 12	-	-	✓	✓	✓	50	Fabric	Healthy & Stoke	11 & 22	53 ± 8 & 62 ± 10
Salam et al. [76]	Full	Custom	3	44.45 x 44.45	-	Y	✓	✓	-	150	-	Cricketers	10	-
Chang et al. [77]	Full	Custom	2	-	-	N	✓	✓	✓	-	-	Robot	-	-
Borbely et al. [78]	Con	Custom	2	-	-	N	✓	✓	✓	200	Velcro	-	1	-
Kumar et al. [79]	Full	Custom	14	66.6 x 28.2 x 18.1*	22*	Y*	✓	✓	✓	25	Custom holders & Velcro	Healthy & un-healthy	19 & 19	24.6 ± 6.7 & 68.4 ± 8.9
Lee et al. [80]	Full	Custom	7	66.6 x 28.2 x 18.1	22	Y	✓	✓	✓	25	Straps	Goniometer & Stroke	5	68
Cifuentes et al. [81]	Con	Custom	2	43 x 60	-	-	✓	✓	✓	60	Straps	Healthy	9	-
Kanjanapas et al.[82]	Full	Custom	2	-	-	N	✓	✓	✓	100	Orthosis	Healthy	1	25

Study							Components					Participants		
First Author	Conference/ full text	Brand	No of sensors used	Dimensions (mm) L x W x H	Weight (grams)	Wireless	Acc	Gyr	Mag	Sample rate (Hz)	Method of attachment	Population	*N*	Mean age ± SD (years)
Zhang et al. [83]	Con	-	2	-	-	Y	✓	✓	✓	-	-	Healthy	1	-
Lin et al. [84]	Full		2	-	-	Y	✓	✓	✓	-	Straps	Stroke	25	52.2 ± 10.2 & 62.2 ± 7.1
El-Gohary et al. [85]	Con	-	2	-	-	-	✓	✓	-	-	-	-	-	-
Hyde et al. [86]	Full	-	-	-	-	-	✓	✓	-	-	-	Robot	-	-

The table is organised by the brand of the wearable sensor followed by the date that the study was published. This allows direct comparison to be made within the brand of the wearable sensors and trends to be identified between more recently published studies.

Abbreviations - Gms = grams, Y = Yes, N = No, Acc = accelerometer, Gyr = gyroscope, Mag = magnetometer, Hz = Hertz (unit of frequency), Sd = standard deviation, SCI = spinal cord injury, PD = Parkinson's Disease, Full = full text, Con = conference paper, mm = millimetre, DS = double sided

Wireless – The wearable sensor system was considered wireless if the wearable sensors did not have wires connecting them to an external source, even if that external source was also mounted on the subject.

Sample rate – The number of data samples collected per second by the wearable sensor measured in Hertz (Hz) which is the unit of frequency.

Custom - defined as a newly developed wearable sensor or modifications have occurred to the pre-existing hardware of the wearable sensor.

Symbols:

***** = The information was obtained from the manufacturer procedure manual or other referenced papers.

^ = The sample rate was down sampled (reduced) to allow comparison to the MOCAP system.

- = Information was not reported and/or unclear in the study and/or unable to be obtained from the manufacturer manual

3.3.4 Psychometric properties of wearable sensors

Validity

Validation studies were split into two categories: i) studies that compared the wearable sensor output to simulated upper limb movement on a robotic device (Table 3.2) and ii) studies that compared wearable sensor output to a 3DMA system on a human participant (Table 3.3). The term 'error' is used to describe the difference between the capture systems, however, we acknowledge that comparisons between the wearable sensors and a robotic device are the only true measures of error.

Robot comparisons

Eight studies reported the error of wearable sensors when compared to simulated upper limb movement on a robotic device (Table 3.2). A mean error between 0.06-1.8° for flexion and 1.05-1.8° for lateral deviation of the wrist was reported using Xsens [28, 31]. For elbow flexion/extension, the difference between Invensence and the robotic device was between 2.1-2.4° [59]. For finger flexion/extension, RMS errors ranged from 5.0-7.0° using a customised wearable sensor system [77].

Three studies reported the error associated with use of different fusion algorithms. Using the Unscented Kalman Filter (UKF) to fuse data from Opal wearable sensors, the RMS error range was: 0.8-8.1° for 2 degrees of freedom (DOF) at the shoulder, 0.9-2.8° for 1DOF at the elbow, 1.1- 3.9° for 1DOF of the forearm, and 1.1-2.1° for 2DOF at the wrist [48, 46]. Rotation of the shoulder and twist of the wrist resulted in more error compared to single plane movements of flexion/extension and pronation/supination [48, 46]. When the UKF was compared to a modified UKF, lower RMS errors were found across all 6DOF using the modified UKF [46]. One study investigated the effects that speed of movement had on measurement error. Using Opal wearable sensors, the UKF was compared to the Extended Kalman Filter (EKF) under three speed conditions; slow, medium and fast. For slow movements both fusion algorithms were comparable across all 6DOF (RMS error: 0.8-7.8° for the UKF, and 0.8-8.8° for the EKF). The UKF resulted in less error across 6DOF for the medium (RMS error: 1.2-3.0°) and fast (RMS error: 1.1-5.9°) speeds compared to the EKF (RMS error: 1.4-8.6°; 1.4-9.7°) [48].

Table 3.2 List of the 8 articles organised by first author, and containing information related to the validation of wearable sensors for the measurement of joint angle for simulated movements of the upper limb when compared to a robotic device

					Calibration							
First Author	**Aim of the study**	**Brand of wearable sensors**	**Description of robotic device**	**Sensor fusion algorithm**	**System**	**Static**	**Functional**	**Segment(s)**	**DOF's**	**Simulated movements**	**RMSE**	**Mean error (sd)**
Callejas –Cuervo et al. [59]	System Validation	Invensense MPU-9150	Industrial robotic arm (ABB IRB 120)	KF	-	✓	-	Elbow	1DOF	Flex/ext	2.12-2.44°	-
Chang et al. [77]	System Validation	Custom	Rehabotics Medical Technology Corporation	-	-	-	-	Finger	1DOF	Flex/ext	5-7°	-
Alvarez et al. [28]	System Validation	Xsens	Pan and tilt unit (Model PTU-D46)	–	-	✓	-	Wrist	2DOF	Flex Lat dev	– –	0.06° (9.20) 1.05° (2.18)
Alvarez et al. [31]	System Validation	Xsens	Pan and tilt unit (Model PTU-D46)	–	-	✓	-	Wrist	2DOF	Flex Lat dev	– –	1.8° for each axis, with a max error ± 6°
Rodriguez-Angleseet et al. [35]	System validation	Xsens	Plantar robot	KF*	-	✓	-	Elbow	2DOF	–	Did not report discrete statistics	

First Author	Aim of the study	Brand of wearable sensors	Description of robotic device	Sensor fusion algorithm	Calibration			Segment(s)	DOF's	Simulated movements	RMSE	Mean error (sd)
					System	Static	Functional					
Kirking et al. [46]	Validation/comparison of senor fusion methods	Opal	Industrial Epson C3 robot arm	UKF*	-	✓	-	Shoulder	2DOF	Int/ext rot	8.1°	-
										Flex/ext	2.4°	-
								Elbow	1DOF	Flex/ext	2.6°	-
								Forearm	1DOF	Pro/sup	2.1°	-
								Wrist	2DOF	Flex/ext	2.2°	-
										Twist	3.9°	-
				Modified UKF*	-	✓	-	Shoulder	2DOF	Int/ext rot	3.0°	-
										Flex/ext	1.6°	-
								Elbow	1DOF	Flex/ext	2.0°	-
								Forearm	1DOF	Pro/sup	1.2°	-
								Wrist	2DOF	Flex/ext	1.5°	-
										Twist	2.8°	-
Ricci et al. [47]	Validation/comparison of senor fusion methods	Opal	LWR 4+ (KUKA GmbH)	KF*	-	✓		Shoulder	7DOF			
								Elbow				
								Forearm		–	Unable to determine exact values from box plot	
								Wrist				
				GNF*	-	✓	-	Shoulder	7DOF			
								Elbow		–		
								Forearm				
								Wrist				

First Author	Aim of the study	Brand of wearable sensors	Description of robotic device	Sensor fusion algorithm	Calibration			Segment(s)	DOF's	Simulated movements	RMSE			Mean error (sd)
					System	Static	Functional				Slow	Med	Fast	
El-Gohary et al. [48]	Validation/comparison of senor fusion methods	Opal	Not described	UKF*	-	✓	-							
								Shoulder	2DOF	In/ext rot	7.8°	3.0°	5.9°	-
								Elbow	1DOF	Flex/ext	0.8°	1.6°	2.5°	-
								Forearm	1DOF	Flex/ext	0.9°	2.0°	2.8°	-
								Wrist	2DOF	Pro/sup	1.3°	1.2°	1.1°	-
										Flex/ext	1.1°	1.5°	1.8°	-
										Twist	1.7°	2.8°	2.2°	-
				EKF*	-	✓	-	Shoulder	2DOF	In/ext rot	8.8°	8.6°	9.7°	-
								Elbow	1DOF	Flex/ext	1.2°	1.9°	2.5°	-
								Forearm	1DOF	Flex/ext	1.3°	2.1°	3.1°	-
								Wrist	2DOF	Pro/sup	0.8°	1.4°	1.4°	-
										Flex/ext	1.2°	1.9°	2.9°	-
										Twist	1.8°	3.7°	3.4°	-

RMSE = root mean square error, SD = standard deviation, CMC = coefficient of multiple correlation, KBF = Kalman-based Filter, KF = Kalman filter, EKF = Extended Kalman Filter, UKF = Unscented Kalman Filter, WLS = Weighted Least Squares, Flex = flexion, Ext = extension, Pro = pronation, Sup = supination, Ab = abduction, Ad= adduction, Dev = deviation, Rad = radial, Uln = ulnar, In = internal, Ex = external, Rot = rotation, Elev = elevation, Dep = depression, DOF = degrees of freedom C = Customised, M = Manufacture, ^ = Statistics obtained from graph/figure, no explicit statistics reported

3DMA comparisons

Twenty-two studies compared the joint angles calculated by wearable sensors, both custom and commercial, to a 'gold standard' 3DMA system (Table 3.3). Studies that used same segment tracking (i.e. motion analysis markers directly on the wearable sensors) were reported in 7 studies. Opal wearable sensors were compared to a 3DMA system during simulated swimming (multiplane movement). The largest difference between the two systems occurred at the elbow (RMS error: 6-15°), with the least occurring at the wrist (RMS error: 3.0-5.0°) [45]. When Xsens was compared to Codamotion during single plane movement, with the addition of a dynamic calibration trial, the largest difference occurred at the elbow (5.16° ± 4.5 to 0.54° ± 2.63), and the least different at the shoulder (0.65°± 5.67 to 0.76° ± 4.40) [30]. Xsens was compared to Optotrack with consistent differences between systems across all DOF's of the shoulder (RMS error: 2.5-3.0°), elbow (RMS error: 2.0-2.9°) and wrist (RMS error: 2.8-3.8°) [24].

Three studies investigated the performance of wearable sensors using different fusion methods to amalgamate the data and compared this to a 'gold standard' system. Zhang and colleagues [34] compared the accuracy of their own algorithm to two pre-existing algorithms. Comparing Xsens to the BTS Optoelectronic system, their methodology resulted in less error (RMS error = 0.08°, CC = 0.89 to 0.99) across 5DOF compared the two other methods [34]. The addition of a magnetometer in the analysis of data was also investigated using the EKF and non EKF based fusion algorithm [15]. The latter produced the least difference between the two systems, irrespective of the speed of the movement and whether or not a magnetometer was included. In contrast, the EKF fusion algorithm resulted in the largest difference from the reference system, particularly for fast movements where magnetometer data was included (7.37° ± 4.60 to 11.91° ± 6.27) [15]. The level of customisation to achieve these results are summarised in Table 3.4.

One study compared the difference between YEI Technology (YEI technology, Portsmouth, OH) wearable sensors and Vicon during three customised calibration methods for the elbow, which resulted in RMS errors that ranged from 3.1 to 7.6° [69].

Table 3.3 List of the selected 22 articles organised by first author, and containing information related to the validation of wearable sensors for the measurement of joint angle in upper limb when compared to a three-dimensional motion analysis system.

Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	DOF	Movements	Mean error(sd)	RMSE	Correlation	Calibration: System	Calibration: Static	Calibration: Functional
Robert Lachaine et al. [24]															
Validate Protocol	Xsens	KF	**S1**: Upper arm **S2** Forearm **S3**: Hand	Optotrak	Yes	Elbow flex/ext, pro/sup; wrist flex/ext, ul/rad deviation, rotation & manual handling tasks				*Optotrak ISB to Xsens ISB*			-	✓	-
							Shoulder	3	Flex/ext	-	3.0°	-			
									Ab/ad		2.9°				
									Rotation		2.5°				
							Elbow	3	Flex/ext		2.9°				
									Ab/ad		2.0°				
									Pro/sup		2.6°				
							Wrist	3	Flex/ext		3.8°				
									Rad/ul dev		2.8°				
									Rotation		3.6°				
Ligorio et al. [69]															
Validate Calibration method	YEI tech-nology	-	-	Vicon	Yes	Flex/ext and pro/sup				*Method A*			-	✓	✓
							Elbow	2	Flex/ext	-	8.5 - 11.1°	-			
									Pro/sup		11.9 - 13.3°				
										Method B					
								2	Flex/ext	-	3.4 – 3.6°	-			
									Pro/sup		6.8 – 7.6°				
										Method C – Proposed					
								2	Flex/ext	-	3.1 – 3.3°	-			
									Pro/sup		3.8 – 4.0°				

Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	DOF	Movements	Mean error(sd)	RMSE	Correlation	Calibration		
													System	Static	Functional
Fantozzi et al. [45]															
Validate Protocol	Opal	KBF	**S1**: Flat portion of the sternum. **S2**: Laterally on the humerus above the centre and posteriorly. **S3**: Distal forearm above the ulnar and radial styloid. **S4**: Back of the hand.	Stereo-photogram-metric system (SMART-DX 7000)	Yes	Simulated front crawl	Shoulder	3	Flex/ext	-	5.0° (4-6)	0.99	-	✓	-
									Ab/ad		10.0° (7-11)	0.97			
									In/ext rot		7.0° (5-8)	0.99			
							Elbow	2	Flex/ext		15.0° (12-17)	0.95			
									Pro/sup		10.0° (7-11)	0.93			
							Wrist	2	Flex/ext		5.0° (4-5)	0.95			
									Rad/ul dev		3.0° (2-4)	0.90			
						Simulated breaststroke	Shoulder	3	Flex/ext	-		-			
									Ab/ad		5.0° (3-7)	0.99			
									In/ext rot		3.0° (3-4)	0.99			
							Elbow	2	Flex/ext		8.0° (5-10)	0.98			
									Pro/sup		6.0° (5-10)	0.97			
							Wrist	2	Flex/ext		5.0° (4-7)	0.98			
									Rad/ul dev		4.0° (3-5)	0.93			
Gil-Agudo et al. [30]															
Validate Protocol	Xsens	KF	**S1**: Trunk **S2**: Back of the head **S3**: Right arm **S4** Distal forearm **S5**: Hand.	CODA	Yes	Shoulder rot, flex/ext and ab/ad; elbow flex/ext and pro/sup, wrist flex/ext and ul/rad deviation.	Shoulder	3	Flex/ext	0.76° (4.4)	-	-	-	-	✓
									Ab/ad	0.69° (10.47)					
									In/ext rot	0.65° (5.67)					
							Elbow	2	Flex/ext	0.54° (2.63)					
									Pro/sup	5.16° (4.5)					
							Wrist	2	Flex/ext	3.47° (9.43)					
									Rad/ul dev	2.19° (4.64)					

Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	DOF	Movements	Mean error(sd)	RMSE	Correlation	Calibration		
													System	Static	Functional
Miezal et al. [15]															
Validate Sensor fusion/ algorithm	Xsens	EKF, WLS	Not described	Natural Point Optitrack system 13 cameras	Yes	Eight-shaped movements at varied speeds, smooth parts imitating reaching and steering in the case of real-slow, and agile parts with quick starts and stops, as well as, parts reminding of sportive movements, such as boxing, in the case of real-fast.				*Chaintracker (real fast w/mag)*			-	✓	-
							Shoulder	1	-	9.38° (5.79)	-	-			
							Elbow	1		11.91° (6.27)					
							Wrist	1		7.37° (4.60)					
										Chaintracker (real slow w/mag)					
							Shoulder	1	-	4.76° (2.24)	-	-			
							Elbow	1		8.83° (4.64)					
							Wrist	1		4.72° (2.61)					
										Optitracker (real fast w/mag)					
							Shoulder	1	-	1.88° (0.91)	-	-			
							Elbow	1		2.22° (1.38)					
							Wrist	1		2.28° (1.15)					
										Optitracker (real fast w/mag)					
							Shoulder	1	-	1.27° (0.81)	-	-			
							Elbow	1		2.16° (1.35)					
							Wrist	1		2.32° (1.37)					

Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	DOF	Movements	Mean error(sd)	RMSE	Correlation	Calibration		
													System	Static	Functional
Lambretcht et al. [62]															
Validate Sensor fusion/ algorithm	Custom	DMP algor-ithm	**S1**: Sternum **S2** Upper arm **S3**: Distal forearm **S4**: Hand	Optotrack	Yes	Reaching movements	Shoulder	3	Azimuth	-	4.9°	0.99	✓	-	-
									Elev		1.2°	0.99			
									Int rot		2.9°	0.99			
							Elbow	2	Flex		7.9°	0.99			
									Pro		1.5°	0.99			
							Wrist	2	Flex/Ext		5.5°	0.97			
									Dev		2.6°	0.94			
Zhang et al. [34]															
Validate Sensor fusion/ algorithm	Xsens	UKF	**S1**: Sternum **S2**: Lateral side above the elbow **S3**: Lateral and flat side of the forearm near the wrist	BTS SMART-D optoelectronic tracking system	Yes	Move the upper limb arbitrarily.				*Independent Estimation*			-	✓	-
							Shoulder	3	Flex/ext	0.070° (0.083)	0.11°	0.99			
									Ab/ad	0.023° (0.042)	0.04°	0.99			
									Int/ext rot	0.061° (0.061)	0.08°	0.99			
							Elbow	2	Flex/ext	0.052° (0.155)	0.16°	0.81			
									Pro/sup	0.321° (0.265)	0.41°	0.96			
										Constraints method					
							Shoulder	3	Flex/ext	0.040° (0.039)	0.05°	0.99			
									Ab/ad	0.013° (0.018)	0.02°	0.99			
									Int/ext rot	0.029° (0.032)	0.04°	0.99			
							Elbow	2	Flex/ext	0.046° (0.100)	0.11°	0.88			
									Pro/sup	0.155° (0.143)	0.21°	0.96			

Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	DOF	Movements	Mean error(sd)	RMSE	Correlation	Calibration		
													System	Static	Functional
										Papers proposed method					
							Shoulder	3	Flex/ext	0.028° (0.029)	0.04°	0.99			
									Ab/ad	0.007° (0.013)	0.01°	0.99			
									Int/ext rot	0.035° (0.036)	0.05°	0.99			
							Elbow	2	Flex/ext	0.054° (0.093)	0.10°	0.89			
									Pro/sup	0.168° (0.153)	0.22°	0.96			
Morrow et al [4															
Validate protocol	Opal	-	Bilateral: **S1**: Lateral aspect upper arms **S2**: Forearms	Raptor 12 Digital Real-time Motion Capture System	No	Peg transfer task using straight laparoscopic surgical instruments.	Shoulder Elbow	1 1	Elevation Flexion	3.0° (2.1) 2.2° (1.6)	6.8° (2.7) 8.2° (2.8)	-	-	✓	✓
Callejas-Cuerro et al. [59]															
Validate protocol	Invensense MPU-9150	KF	**S1**: External arm aligned with the humerus. **S2**: Between the radial styloid and ulnar styloid, aligned with external part of the hand.	Qualisys Oqus 5	No	Flex/ext.	Elbow	1	Flex/ext	< 3.0° - < 5.0°	2.44%	-	-	✓	✓

Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	DOF	Movements	Mean error(sd)	RMSE	Correlation	Calibration		
													System	Static	Functional
Meng et al. [56]															
Validate protocol	Shimmer	KF	Not described	Vicon Mocap System	No	1) Raise shoulder. 2) Move shoulder right then left. 3) Clockwise axial rotation to its max, then rotate the upper arm counter clockwise. 4) Elbow extension move into flexion.	Shoulder	3	Flex/ext Ab/ad In/ext rot	0.50° (1.79) 0.18° (1.34) 0.16° (1.96)	1.85° 1.35° 1.96°	-	✓	-	-
							Elbow	2	Flex/ext Pro/sup	1.86° (1.85) 1.22° (2.87)	2.62° 3.12°				
Cifuentes et al. [81]															
Validate protocol	Custom	-	**S1**: Arm **S2**: Forearm	Optical tracking system	No	Reaching and grasping from the rest position with the forearm on the table, at angle of approximately 90 degrees with respect to the arm before reaching and grasping an object, and then returning it to starting position.	Elbow	1	Flex/ext	No discrete data reported only figures of continuous data			-	-	-

Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	DOF	Movements	Mean error(sd)	RMSE	Correlation	Calibration		
													System	Static	Functional
Muller et al. [22]															
Validate Sensor fusion/ algorithm	Xsens	KF*	**S1**: Thorax. **S2**: Lateral side of the arm **S3**: Posterior side of the wrist	Vicon	No	1) Flex/ext in a horizontal plane with the shoulder abducted 90° flex/ext in a sagittal plane while standing with the elbow close to the trunk. 2) Flex/ext in a sagittal plane with the spine bent forward 90° and the upper arm aligned horizontally and parallel to the ground sup/pro with the elbow flexed 90°	Elbow	2	Flex/ext Pro/sup	*Proposed Algorithm*			✓	✓	-
										-	2.7° 3.8°	-			
										Manual Alignment					
							Elbow	2	Flex/ext Pro/sup	-	3.8° 8.7°	-			

Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	DOF	Movements	Mean error(sd)	RMSE	Correlation	Calibration		
													System	Static	Functional
Bertomu-Motos et al. [55]															
Validate sensor fusion/ algorithm	Shimmer	EKF	**S1**: Shoulder **S2**: Upper arm	Optitrak	No	The activity consisted of taking a box from the perimeter and placing it in the centre of the screen.				*Without compensation Filter*			-	-	-
							Shoulder	5	Unclear	5.24° (3.38) 0.5° (1.6) 3.6° (2.1) 1.8° (1.0) 1.60° (0.6)	-	-			
										Compensation filter					
							Shoulder	5	Unclear	1.69° (2.1) 1.1° (0.8) 5.9° (2.3) 2.6° (1.7) 0.9° (1.2)	-	-			
Karunarathne et al. [68]															
Validate sensor fusion/ algorithm	BioKin WMS	KF*	**S1**: Near the elbow **S2**: Wrist	Vicon	No	Lifting a water bottle				*High pass filter - Gyroscope*			-	-	-
							Elbow	1	Flex/ext	-	10.18°	-			
										Low pass filter - Accelerations					
							Elbow	1	Flex/ext	-	18.30°	-			
										Tradition complementary filter					
							Elbow	1	Flex/ext	-	10.30°	-			
										Adaptive complementary filter					
							Elbow	1	Flex/ext	-	8.77°	-			

Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	DOF	Movements	Mean error(sd)	RMSE	Correlation	Calibration		
													System	Static	Functional
El-Gohary et al. [50]															
Validate Sensor fusion/ algorithm	Opal	UKF	**S1**: Upper arm **S2**: Forearm	Vicon motion analysis system	No	Single movements: Shoulder flex/ext, ab/ad, Elbow flex/ext and forearm sup/pro.	Shoulder	2	Flex/ext	-	5.5°	0.98	-	✓	
									Ab/ad		4.4°	0.99			
							Elbow	2	Flex/ext		6.5°	0.98			
									Pro/sup		0.95°	0.95			
						Complex tasks:	Shoulder	1	-	9.8°	6.5°	0.94			
						1) touching nose and	Elbow	1		8.8°	5.5°	0.95			
						2) reaching for door									
El-Gohary et al. [51]															
Validate Sensor fusion/ algorithm	Opal	UKF	**S1**: Between the shoulder and elbow **S2**: Near the wrist	Eagle Analog System, Motion Analysis	No	Single movements at different speeds: Shoulder flex/ext, ab/ad, Elbow flex/ext, sup/pro				*Normal speed*			-	-	-
							Shoulder	2	Flex/ext	-	-	0.97			
									Ab/ad			0.94			
							Elbow	2	Flex/ext			0.92			
									Pro/sup			0.96			
										Fast speed					
							Shoulder	2	Flex/ext	-	-	0.94			
									Ab/ad			0.91			
							Elbow	2	Flex/ext			0.89			
									Pro/sup			0.93			

Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	DOF	Movements	Mean error(sd)	RMSE	Correlation	Calibration		
													System	Static	Functional
Perez et al. [39]															
Validate Sensor fusion/ algorithm	Xsens	-	**S1**: Back **S2**: 18 cm from acromion **S3**: 25 cm from epicondyle S4: 5.5 cm from distal radio-cubital joint.	BTS SMART-D optoelectronic tracking system	No	Single movements: Shoulder flex/ ext, horizontal ab/ad, and internal rotation. Elbow flex, pro/sup and wrist flex/ext.	Shoulder	3	Flex/ext	13.4°	-	0.99	✓	-	-
									Ab/ad	17.2°		0.71			
									In rot	60.4°		0.99			
							Elbow	2	Flex	5.8°		0.98			
									Pro/sup	24.1°		0.96			
							Wrist	1	Flex/ext	11.6°		0.98			
						Pouring water from a glass jar into a glass	Shoulder	3	Flex/ext	13.8°	-	0.99			
									Ab/ad	7.4°		0.90			
									In rot	28.8°		0.85			
							Elbow	2	Flex/ext	18.6°		0.97			
									Pro/sup	11.7°		0.92			
							Wrist	1	Flex/ext	26.8°		0.92			
Zhou et al. [37]															
Validate Sensor fusion/ algorithm	Xsens	KF	**S1**: Lateral aspect of upper arm between the lateral epicondyle and the acromion process (5cm from the AP) **S2**: Wrist centre on the palmer aspect	Codamtion	No	Reaching, shrugging, forearm rotation	Elbow	2	Flex/ext Rot	0.4° (2.34) 0.06° (4.82)	2.4° 4.8°	-	-	✓	-

Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	DOF	Movements	Mean error(sd)	RMSE	Correlation	Calibration		
													System	Static	Functional
Luinge et al. [41]															
Validate Sensor fusion/ algorithm	Xsens	KF	**S1**: Lateral upper arm near the elbow **S2**: Dorsal side of the forearm near the wrist.	Vicon	No	1) Mimicking eating routines (pouring a glass eating soup, eating spaghetti, eating meat, drinking). 2) Mimicking morning routines (splashing water on face and drying it using a towel, applying deodorant, buttoning a blouse, combing hair, brushing teeth).	Elbow	2	-	No discreet data reported			-	✓	✓

Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	DOF	Movements	Mean error(sd)	RMSE	Correlation	Calibration		
													System	Static	Functional
Peppoloni et al. [57]															
Validate kinematic model	Shimmer	UKF	**S1**: Scapula beside the angulus acromialis **S2**: Lateral side of the upper arm above the elbow. **S3**: Lateral side of forearm a few centimetres far from the wrist.	Vicon	No	Single movements: Scapula elev/dep, ante-position/retro-position. Shoulder flex/ext, ab/ad, and int/ext rotation. Elbow flex/ext, pro/sup.	*7DOF model*						-	✓	✓
							Scapula	2	Elev/dep	-	6.19°	0.65			
									Prof/retr		3.43°	0.74			
							Shoulder	3	Flex/ext		8.19°	0.94			
									Ab/ad		10.68°	0.63			
									In/ext rot		8.79°	0.97			
							Elbow	2	Flex/ext		5.00°	0.99			
									Pro/sup		9.61°	0.85			
							5DOF model								
							Shoulder	3	Flex/ext	-	7.03°	0.95			
									Ab/ad		6.03°	0.87			
							Elbow	2	In/ext rot		4.95°	0.99			
									Flex/ext		9.93°	0.98			
									Pro/sup		11.29°	0.85			
Robert-Lachaine et al. [25]															
Validate calibration method	Xsens	KF	-	Optotrack	No	Single plane movements	-	-	-	No discrete data reported			-	-	-

Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	DOF	Movements	Mean error(sd)	RMSE	Correlation	Calibration		
													System	Static	Functional
Bouvier et al. [23]															
Validate calibration method	Xsens	KF	**S1**: Sternum **S2**: Central third of upper arm laterally (or slightly posterior) **S3**: Dorso-distally on the forearm **S4**: Dorsum hand	Eagle 4 Optoelectric system	No	Move through 9 calibration trials for each joint.	Shoulder	3	Flex/ext	-	-	-	-	✓	✓
									Ab/Ad	-	-	-			
									Wheel	-	-	-			
							Elbow	2	Flex/ext	-	20.46°	0.84			
									Pro/sup	-	14.76°	0.94			
							Wrist	2	Flex/ext	-	14.21°	0.93			
									Ab/sd		13.9°	0.68			

RMSE = root mean square error, SD = standard deviation, CMC = coefficient of multiple correlation,
KBF = Kalman-based Filter, KF = Kalman filter, EKF = Extended Kalman Filter, UKF = Unscented Kalman Filter, WLS = Weighted Least Squares
Flex = flexion, Ext = extension, Pro = pronation, Sup = supination, Ab = abduction, Ad= adduction, Dev = deviation, Rad = radial, Uln = ulnar, In = internal, Ex = external, Rot = rotation, Elev = elevation, Dep = depression
DOF = degrees of freedom C = Customised, M = Manufacture
^ = Statistics obtained from graph/figure, no explicit statistics reported.

Table 3.4 Summary of the software customisation reported by the authors for validation studies that used the same segment tracking

		Software			
First Author	Sensor hardware	Sensor fusion algorithm	Calibration	Anatomical segment definition	Kinematic calculation
Robert Lachaine et al. [24]	Commercial – Xsens MVN	Manufacturer	Manufacturer	Custom	Custom
Ligorio et al. [69]	Commercial - YEI Technology	Custom	Custom	Custom	Custom
Fantozzi et al. [45]	Commercial - ADPM Opal	Custom	Custom	Custom	Custom
Gil-Agudo et al. [30]	Commercial - Xsens MTx	Custom	Custom	Custom	Custom
Miezal et al. [15]	Commercial - Xsens	Did not report	Did not report	Custom	Custom
Lambretcht et al. [62]	Commercial – InvenSense MPU9150 chip	Custom	Custom	Custom	Custom
Zhang et al. [34]	Commercial - Xsens MTx	Custom	Manufacturer	Custom	Custom

Reliability

Adequate to excellent agreement was reported for 2DOF at the shoulder (ICC: 0.68-0.81) and poor to moderate agreement for the 2DOF at the elbow (ICC: 0.16-0.83). The wrist demonstrated the highest overall agreement with ICC values ranging from 0.65-0.89 for 2DOF [73].

3.3.5 Risk of bias

The sample sizes of the included studies were mostly inadequate, with 30% including single participants (Table 3.1). Twenty-eight percent of the included studies were conference papers, providing limited information.

3.4 Discussion

This systematic review described the characteristics of wearable sensors that have been applied in research and clinical settings on the upper limb, the populations with whom they have been used with, and their established psychometric properties. The inclusion of 66 studies allowed for a comprehensive synthesis of information.

Similar to other systematic reviews on wearable sensors, commercial wearable sensors, as opposed to custom designed, were reported in most studies (83%) [17]. One benefit for users of commercial wearable sensors is the user-friendly nature of the associated manufacturer guidelines and processing software, including in-built fusion algorithms and joint calculation methods. However, the studies that utilised commercial hardware often customised aspects of the software (i.e. fusion algorithm, calibration method, anatomical segment definition and the kinematic calculation). Therefore, the validity and reliability of an entirely commercial system (hardware and software) for use in the upper limb remains unknown. Customisation impacts the clinical utility of the wearable sensor systems, especially if there are no support personnel with appropriate knowledge and expertise.

Of the studies reviewed, there was no consensus on the procedures to follow for using wearable sensors on the upper limb. The placement of the wearable sensors varied, and in some cases was poorly described. Manufacturer guidelines for placement of commercial wearable sensors were not referred to, which lead to apparent differences in placement for studies that utilised the same commercial brand. Multiple fusion algorithms were reported, with no clear outcome about which was best suited to a specific joint or movement. The level of customisation of fusion algorithms makes it difficult to compare between studies and often the specifics of the algorithm were not readily available, limiting replication. Similar inconsistencies and a lack of consensus were reported in other systematic reviews investigating use of wearable sensors [16, 89]. Without clear guidelines, measurement error can be introduced and/or exacerbated depending on the procedures followed.

The methods of calibration also varied between studies, with a static calibration the most commonly utilised method (typically adopting a neutral pose, standing with arms by the side and palms facing forward, as recommended by most manufacturers). Functional calibration was often customised to suit the needs of the study and the joint being measured. For example, functional calibration of the elbow varied from repetitions of flexion and extension at various speeds [59], to the rapid movement of the arm from 45 degrees to neutral [42]. Details of the functional calibrations were omitted in some studies, limiting replication. The influence of calibration on measurement error has been investigated, with the type of calibration (i.e., static or functional) and movements of the functional calibration, having a significant impact on the accuracy of wearable sensors [69].

Of the 66 studies included in this review, almost half (45%) were validation studies with the remaining studies using wearable sensors as an outcome measure. Over one third (29%) were conference proceedings in the field of engineering, thus limiting the amount of information available. The median sample size was 7.6 participants per study; only one study was considered to have an adequate sample size for the validation of a measurement tool as per the COSMIN guidelines [19]. The majority (78%) of the results were obtained from healthy adults, with clinical populations (12%) and those under the age of 18 (1.5%) not well represented. Research investigating the use of wearable sensors to measure lower limb kinematics has demonstrated a level of accuracy with clinical populations and children. Errors <4° were reported for elderly individuals with hemiparesis [90] and RMS errors between 4.6 and 8.8° for children with spastic cerebral palsy [10]. There is potential for wearable sensors to be applied to the upper limb of these populations, however, more research is required to determine the optimal procedures prior to implementation in clinical practice.

The validity and reliability of wearable sensors when applied to the upper limb has not been clearly described to date. When compared to a robotic device, the commercial wearable sensors with customised software recorded errors below McGinley's [7] suggested 5.0° threshold. Less than 3.9° was reported for replica/simulated movements of the wrist in 3DOF [28, 48, 46, 56], <3.1° for 2DOF at the elbow [48, 46, 56] and <2.5° for 1DOF (flexion/extension) at the shoulder [48]. Shoulder internal and external rotation resulted in the largest error (3.0-9.7°) [48], and therefore results for this movement should be interpreted with caution.

The next section will discuss *in vivo* studies with 3DMA as a pseudo-gold standard. Studies that made a direct comparison between the wearable sensors and 3DMA system (i.e. used the same segment tracking) demonstrated differences that exceeded the suggested 5.0° threshold, with up to 15.0° difference reported for the elbow. However, depending on the software specifications and level of customisation, a difference of <0.11° (3DOF shoulder), <0.41° (2DOF elbow) and <2.6 (2DOF wrist) was achievable. The range in difference observed between the two systems is indicative that wearable sensors are still largely in a 'developmental phase' for the measurement of joint angle in the upper limb.

Consistent with prior findings, error values were unique to the joint and movement tasks being measured. Most of the tasks involved movements in multiple planes (i.e. reaching tasks), which resulted in more error compared to studies that assessed isolated

movement in a single plane (i.e. flexion and extension). Measuring multiple planes of movement poses a further challenge to motion analysis and needs careful consideration when interpreting the results [91].

3.5 Limitations

Due to the heterogeneity in the reported studies, a meta-analysis was not appropriate given the variance in sample sizes, movement tasks, different procedures and statistical analyses used. It was also not possible to apply a standard assessment of quality and bias due to the diversity of the studies. The inclusion of small samples (30% single participant) is a potential threat to validity; with single participant analysis insufficient to support robustness and generalisation of the evidence. The inclusion of conference papers (28%) meant that many papers provided limited detail on the proposed system and validation results. Small sample sizes and the inclusion of mostly healthy adults mean the results of this review cannot be generalised to wider clinical populations. In addition, studies that utilised different segment tracking (i.e. 3DMA markers were not mounted on the wearable sensor) were not further analysed as it was not possible to delineate between the sources of error.

3.6 Conclusion

Wearable sensors have become smaller, more user friendly and increasingly accurate. The evidence presented suggests that wearable sensors have great potential to bridge the gap between laboratory-based systems and the goniometer for the measurement of upper limb joint angle during functional tasks. A level of acceptable accuracy was demonstrated for the measurement of elbow and wrist flexion/extension when compared to a robotic device. Error was influenced by the fusion algorithm and method of joint calculation, which required customisation to achieve errors <2.9° from known angles on a robotic device. Higher error margins were observed *in vivo* when compared to a 3DMA system, but <5° was achievable with a high level of customisation. The additional level of customisation that was often required to achieve results with minimal error is particularly relevant to clinicians with limited technical support, and critically, when using a system 'off the shelf' the expected level of accuracy may not be comparable to the findings reported in this review.

With this technology rapidly evolving, future research should establish standardised protocol/guidelines, and subsequent reliability and validity for use in the upper limb, and in various clinical populations. Direct comparisons with the gold standard (i.e. same segment tracking) is needed to produce results that are most meaningful. We recommend and encourage the use of wearable sensors for the measurement of flexion/extension in the wrist and elbow, however, this should be combined with outcome measures that have demonstrated reliability and validity in the intended population.

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Chapter Four

4

Exploring the development of prototype custom wearable sensors and the feasibility of their use to measure upper limb joint range of motion in children with cerebral palsy

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Foreword

The systematic review (Chapter Three), titled '*Measurement of upper limb range of motion using wearable sensors: A systematic review'*, identified the use of wearable sensors for the measurement of upper limb joint range of motion (ROM) for clinical and research purposes, but highlighted notable variability in their application.[28] Furthermore, the use of wearable sensors with children (<18 years of age) was reported in only one study, and of a typically developing cohort[28], highlighting a gap for the potential application of wearable sensors both clinically and for research purposes. It is possible that the reason why little work has been done in this is area was owed to the hardware characteristics (i.e. the size) of available wearable sensors being incompatible for use with children. The availability commercial wearable sensors small enough for the present research purposes was also identified as an issue at the time of planning. Therefore, the purpose of this chapter was to describe the trans-disciplinary collaboration lead by the PhD Candidate of this thesis to develop small custom designed wearable sensors and investigate their feasibility for use with young children.

4.1 Introduction

Wearable sensors, also known as inertial measurement units, are an innovation that have gained popularity for their proposed ability to provide objective, quantified and continuous information about movement in a variety of environments.[32] Wearable sensors integrate the use of accelerometers, gyroscopes and magnetometers to estimate joint ROM[112], however system specifications can differ depending on their intended application.[28] Wearable sensor technology was developed to meet the clinical demand and need for a portable, field-based and low-cost system, relative to laboratory-based optical tracking systems, which could offer an accurate method of kinematic analysis. Over the years, wearable sensors have been utilised with a wide range of clientele; from individuals with neurological pathology to high performance athletes.[28] While measurement of joint ROM in the lower limb and position of the trunk is commonly documented[113,114], measurement of upper limb joint ROM and position is gradually gaining more attention.[28,30]

Within the *body functions and structure* domain of the International Classification of Functioning, Disability and Health, accurate measurement of passive and active upper limb joint ROM forms an important component of routine assessment for children with cerebral palsy (CP). Repeat measurement of wrist and elbow joint ROM is often required throughout childhood to monitor and assess for muscle shortening and the development of contractures.[115] Measurements of ROM can also be used to indicate whether interventions (i.e. Botulinum Neurotoxin Type-A (BoNT-A) and/or rigid wrist-hand orthoses[20]) are effective in improving or maintaining active joint ROM, however in young children with CP (i.e. ≤5 years of age) this is relatively unexplored. This is largely due to a lack of valid and reliable tools that can objectively measure active upper limb joint ROM in this age group, and is of particular relevance given that limitations in passive wrist and elbow extension are suggested to manifest within the first few years of life.[13] Therefore, having accurate and reliable tools to measure early limitations in passive and active upper limb joint ROM may provide important clinical indications for early intervention.

The demand and clinical interest for a measurement tool, such as wearable sensors, that can objectively measure joint ROM in the upper limb of young children with CP originated in this research program from the infant Wrist Hand Orthoses Trial (iWHOT).[21] This multicentre randomised control trial (U1111-1164-0647) aimed to determine the effectiveness of rigid wrist-hand orthoses to improve or maintain wrist

extension in children with or considered at risk of CP aged between 0 to 36 months (age at the time of recruitment).[21] While the goniometer can be used to measure passive wrist extension of young children with CP (with inherent difficulty and varied reliability[100]), the goniometer cannot measure active wrist extension during play as it is too challenging. Younger children will rarely comply to performing/completing a task on demand, nor are they able to maintain the position long enough for the measurement to be taken. Therefore, alternative methods of measuring active joint ROM required exploration.

The process of finding a suitable measurement system for use with children for the above-mentioned trial began in 2014. With wearable sensor technology ever-growing, we liaised with companies that manufactured commercial 'off the shelf' and 'ready to use' systems. Companies that specialise in the development of wearable sensors such as Xsens (Xsens Technologies B.V., Enschede, Netherlands), Noraxon (Noraxon, Scottsdale, USA) and DorsaVi (DorsaVi, Melbourne, Victoria, Australia) were contacted in an effort to find a commercial wearable sensor system that would meet the size and weight requirements to use with small children. The main limitation of the commercial wearable sensors at the time was their size (length, width and height), which covered the entire dorsum of the hand and restricted passive and active movement of the wrist into extension (Figure 4.1).

Figure 4.1 The size of Noraxon commercial wearable sensors on the arm of a small child.

DorsaVi (DorsaVi, Melbourne, Victoria, Australia) were in the preliminary stages of developing a wearable sensor system potentially small enough to use with children, however, this is still yet to be released. Another disadvantage of commercial systems was their cost; ranging from $6500 to in excess of $30,000 (AUD) for the wearable sensor system (with the number of wearable sensors required for measurement varying) and the software required to collect and analyse data. In addition to using the wearable sensors in the iWHOT, the wearable sensors also have potential for use in clinical practice, which further reiterated the need for a cost effective system to support potential implementation into clinical practice.

The demand for small wearable sensors prompted a systematic review of literature (Chapter Three) in efforts to collate information on the characteristics and specifications of wearable sensor systems that measured joint ROM in the upper limb and their established psychometric properties. Additional specifications of the commercially available wearable sensors were also sought through manuals.[28] The main findings of this review identified that for the measurement of joint ROM in the upper limb wearable sensors were: i) still largely in a developmental phase in terms of their accuracy, ii) scarcely used with paediatric populations, and iii) commercially available wearable sensors were designed for intended use with adults, and as a result would not be appropriate in terms of size for use with young children[28]. Therefore, in order for wearable sensors to be used with young children a new system needed to be: i) custom designed to be small and light enough to not restrict or alter typical movement[116], ii) wireless to enable unrestricted movement[116], iii) demonstrate feasibility for end-users (i.e. children, clinicians and researchers), and iv) demonstrate adequate validity and reliability to measure joint ROM in the upper limb.

A trans-disciplinary approach was required to transform this concept into a prototype product. Clinicians, who are also the end-users of this product, sought the expertise of engineers to collaboratively develop small custom prototype wearable sensors. As with any new innovation, people must want to use it and it must be acceptable to those with whom it is being used[117], therefore this chapter is a feasibility study to determine whether iterations of the prototype wearable sensors were acceptable and practical for use by end-users with children prior to further validation and *in vivo* testing.

4.2 Methods

The development of three prototype wearable sensors and associated software occurred over a three-year period, from early 2015 to 2018. Frequent face to face meetings, on a fortnightly and/or monthly basis, occurred over the three-year period to assess the feasibility of each version of the wearable sensors.

A feasibility framework proposed by Bowen et al[40] is used to describe the development and pilot of each version of the wearable sensors. This feasibility framework recommends the inclusion of focus areas that are typically employed within a feasibility study.[40] This study evaluated the feasibility each version of the wearable sensors in relation to the following focus areas: Demand (addressed in the introduction), Aim, Implementation, Practicality, Acceptability, Efficacy and Adaptation. Table 4.1 presents the definition of terms used to establish feasibility. The findings for each of the focus areas in relation to each version of the wearable sensors will be presented and final synthesis of information tabulated.

Table 4.1 Key feasibility focus areas relevant to pilot of wearable sensors and associated software

Area of focus	Application to wearable sensors and software
Implementation	
'Who were they used by'	Factors affecting implementation (i.e. trans-disciplinary approach) End-users (i.e. clinicians and researchers) Test population (i.e. children)
Practicality	
'What were the physical characteristics'	Size Shape Weight Mode/rate of communication (i.e. radio frequency or Bluetooth) Charging method Battery life Sample rate External switches Placement on the upper limb Software interface features
Acceptability	
'How were they tolerated by all parties'	User observations Ease of application by administrator Comfort of the child (i.e. crying) Child compliance Restriction of movement Software stability (i.e. crashes/errors)

Area of focus	Application to wearable sensors and software
Efficacy	
'Could they be used to produce the desired result and if not, why not'	Preliminary analysis of data Completeness of data
Adaptation	
'Recommendations for future versions'	Improvements or further testing

4.2.1 Participants/setting

Participants within this study were 'end-users' (i.e. the personnel to be administering the use of the wearable sensors and software), and the 'test population' (i.e. the individuals wearing the wearable sensors for assessment). The potential end-users included occupational therapists, physiotherapists and biomechanists involved in paediatrics (i.e. research and/or clinical). The wearable sensors were piloted with a convenience sample of; i) healthy adults (>18 years old), and/or ii) typically developing children (age range: 2 – 14 years), and/or iii) children diagnosed with CP (age range: 2 – 14 years). Adults and typically developing children were recruited via convivence. Adults were included to initially test the concept and each prototype of the wearable sensors to make sure they worked and measured what they intended to before trialling them on children. The children with CP were recruited by a senior occupational therapist at Princess Margaret Hospital for Children, or enrolled in the iWHOT[21] or Minimising impairment Trial (MiT).[20] Data collection took place at Curtin University or at Princess Margaret Hospital for Children in Perth, Western Australia.

4.2.2 Instruments/software

The wearable sensors and associated software used for this feasibility study were developed by the School of Electrical Engineering, Computing and Mathematical Sciences at Curtin University[42], with end-users of this technology (i.e. clinicians and clinical researchers) providing clinical input throughout the process. Over the course of the development of the wearable sensors, three prototypes, or versions, were developed. Each version sought to build on the previous version based on the feedback provided, and observations made by the research team.

The consistent factor across all versions of the wearable sensors was the use of an accelerometer (±2g) and gyroscope (±250°/s) which collected data about the acceleration and angular velocity of the movement. The use of an external receiver to communicate with the wearable sensors was required for prototype Version 1 (V1) and Version 3

(V3), which connected to a laptop. Prototype V1 and V3 also used the same custom developed software package to collect and store data, with minor adjustments and updates made to the software.

4.2.3 Placement of the wearable sensors

To measure joint ROM, at least two wearable sensors are needed, one on each segment. For the calculation of wrist joint ROM, one wearable sensor on the hand and another on the forearm is required. To capture elbow joint ROM, a wearable sensor is required on the mid upper arm, and another on the forearm. Placement of the wearable sensors on the upper limb followed the standardised procedure outlined in Table 4.2 and Figure 4.2.

Table 4.2 Description of the placement of the wearable sensors on the upper limb

Segment	Surface	Placement
Hand	Dorsal	With the child's fingers in flexion, the clinician places the wrist into passive, end of range extension to determine the dorsal wrist crease. The midpoint between the dorsal wrist crease and the 3rd metacarpal is measured using a fabric tape measure. The wearable sensor is placed at the midpoint with the switch facing distally (i.e. towards fingers).
Forearm	Dorsal	The midpoint from the dorsal wrist crease and elbow crease is measured. The wearable sensor is placed at the midpoint, parallel to long bones of forearm and perpendicular to the wearable sensor on the hand. The wearable sensor is placed so that the switch is facing distally (i.e. towards hand).
Upper arm	Lateral	The midpoint between the elbow crease and the acromion process is measured. The wearable sensor is placed at the midpoint with the switch facing distally (i.e. towards elbow)

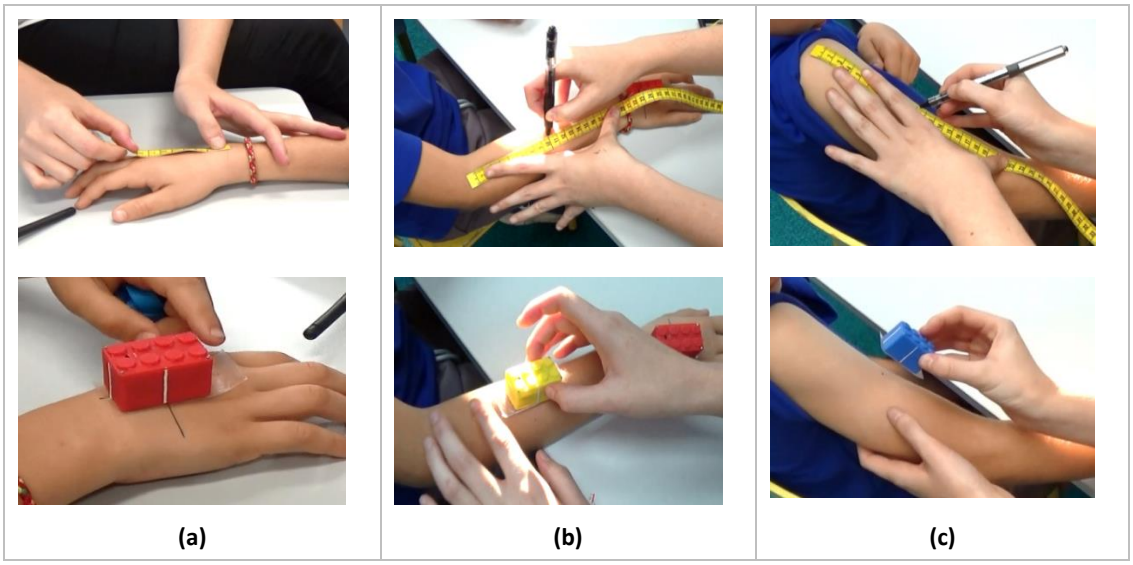

Figure 4.2 Placement of the wearable sensors on the (a) hand, (b) forearm and (c) upper arm

4.2.4 Wearable sensor data processing

Raw acceleration and gyroscope data were exported to Excel. Where usable data were available, they were processed in MATLAB® (Mathworks Inc., Natick, USA - R2014b) using sophisticated filtering algorithms (Kalman filtering)[42] to output joint ROM.

4.2.5 Feasibility data synthesis

Information was gathered in the form of field notes which were recorded by an occupational therapist who had direct involvement in the pilot sessions (CW). The field notes included observations from the pilot sessions, feedback from the end-users and feedback from a consumer representative (i.e. a mother of a child with CP).

4.2.6 Ethical approval

Ethical approval was gained for each stage of the feasibility testing (Curtin University: RDHS-11-16; Perth Children's Hospital; 2014060, 2014061; Australian Catholic University; 2014318V; 2014317V).

4.3 Results

4.3.1 Participants

The end-users included occupational therapists (n = 6), physiotherapists (n = 3) and biomechanists (n = 3). The occupational therapists (with the exception of one) and one physiotherapist had over five years of clinical experience working with children with CP. The remaining occupational therapist and physiotherapists had a background in research. The biomechanists had approximately nine years of experience in their respective field, with one having previous experience with the use of wearable sensors.

The test participants are outlined in Table 4.3 and included a combination of adults and children, as considered appropriate for the stage of feasibility testing.

Table 4.3 Participant characteristics

Version of wearable sensor	Population	Sample (n)	Age range
V1 (2015)	TD children	3	2 - 4 years
		2	5 - 14 years
	Children with CP	15	5 - 14 years
		10	2 - 4 years
V2 (2017)	Healthy adult	1	30 years
V3 (2017)	Healthy adults	5	25 - 30 years
	TD children	5	2 - 6 years

TD = typically developing, CP = cerebral palsy

4.3.2 Version 1 (V1)

Implementation

V1 of the wearable sensors was used with typically developing children and children with CP (refer to Table 4.4). Two end-users were involved in the application and collection of data using the wearable sensor system and parent/guardians were present. Engineer's involved in the development of the wearable sensors also attended some of the pilot sessions.

Practicality

V1 prototypes measured 38 x 24 x 27mm, were rectangular in design and resembled Lego blocks in three colours (red, yellow and blue) (Figure 4.3). This design concept was employed to make the wearable sensors less intimidating and more familiar to young children. Each wearable sensor weighed approximately 20 grams, had an average sample rate of 35Hz and used radio frequency to transmit data from the wearable sensors to the receiver. Each wearable sensor had an external on/off switch and an external micro USB charging port.

Acceptability

The design was very appealing to the young children, resulting in children wanting to touch and pull the wearable sensors off their arm to play with them. The large external switch and micro USB charging port were also tempting to touch. It was observed that once the wearable sensors were affixed to the arm, the child favoured the use of the arm without wearable sensors. This was likely due to the weight and bulkiness of the wearable

sensors. The surface area of the wearable sensor covered the entire dorsum of the hand in the younger children. In turn, this resulted in a deviation from the placement protocol with the need for the wearable sensor on the hand to be rotated medially (i.e. from the switch facing distally, to the switch facing medially) to fit on the hand. Peak passive and active wrist extension was restricted due to the forearm and hand wearable sensor contacting each other during the movement. Double sided tape was used to affix the wearable sensors to the arm for the duration of the sessions, however moisture on the skin (i.e. sweat or saliva) could cause the wearable sensors to come off the skin. Removal of the wearable sensors did not cause any adverse reactions, however a small proportion of children appeared to experience slight redness of the skin which resolved shortly after.

Figure 4.3 V1 wearable sensors; (a) on the hand and forearm of a young child, (b) receiver dongle the wearable sensors transmit data to, (c) size of the V1 wearable sensors compared to a 10c coin (AUD) which measures 23mm in diameter.

Efficacy

Preliminary analysis revealed dropout of data (i.e. missing data) that was due to interrupted communication between the wearable sensors and receiver as a result of loose internal wiring and incorrect placement of internal components. Measurement accuracy was also highly influenced by a phenomenon known as 'drift' which sees the accumulation of small errors when the 'integration' is used to calculate orientation/angle from the raw acceleration and velocity data. Essentially, this causes the integrated output of the wearable sensors to move (or 'drift') away from the true value[118], and is thought to occur linearly over time (i.e. the longer the trial, the more 'drift'). The occurrence of drift is commonly reported in literature with use of this technology, with efforts frequently directed towards minimising its effects.[118] To help mitigate the effects of drift, movement trials were reduced from 5 minutes to 2 minutes and the development of more sophisticated filtering techniques was required from the engineering team to help cancel the drift bias.[42] Rotation of the wearable sensor on the hand was documented each time by the clinician to ensure post processing of data was modified to account for the change in position. Additional time and algorithm development were needed to process data related to the elbow; therefore, wrist ROM was prioritised to align the prototype development with the needs of the iWHOT (i.e. measurement of wrist extension).

Recommendations for adaption

The primary recommendations for adaptation were to: i) focus on measurement of the wrist in one plane of movement, ii) reduce the size and weight of the wearable sensors, iii) increase the sample rate to ensure fast movements were captured, iv) improve fixation of wiring between internal components, and vi) improve the communication between the wearable sensors and receiver to prevent loss of data. Secondary to these, was to adopt a new design concept. The design needed to be a balance between the wearable sensors being less appealing so that children would not want to play with them, but not so unappealing that children would not want to wear them.

4.3.3 Version 2 (V2)

Implementation

This prototype was trialled with one adult participant and did not progress to being tested with children due to the hardware not being appropriate for use with children. Only researchers were involved in the application and collection of data using this version of the wearable sensor system, with engineer representatives also in attendance.

Practicality

Commercial hardware was purchased and then customised to try and save resource and development time. The hardware was encased in a custom printed circular case which measured 27 x 23 mm (Figure 4.4). This version had no external switches or charging ports and data from each wearable sensor were transmitted to a separate android device (i.e. mobile phone) using Bluetooth communication, captured at a sample rate of 60Hz.

Acceptability

V2 was small and compact, therefore unlikely to restrict peak active wrist extension if used with children. However, there was difficulty with two wearable sensors communicating simultaneously with one android device. This resulted in a significant dropout of data and the need to reduce the sample rate to accommodate for two wearable sensors communicating at the same time. A reduction in the sample rate below 60Hz meant that fast movements would likely result in lost data. To avoid reducing the sample rate, each wearable sensor required its own android device for the transmission of data (i.e. two wearable sensors required to capture wrist joint ROM; therefore, two android devices were required).

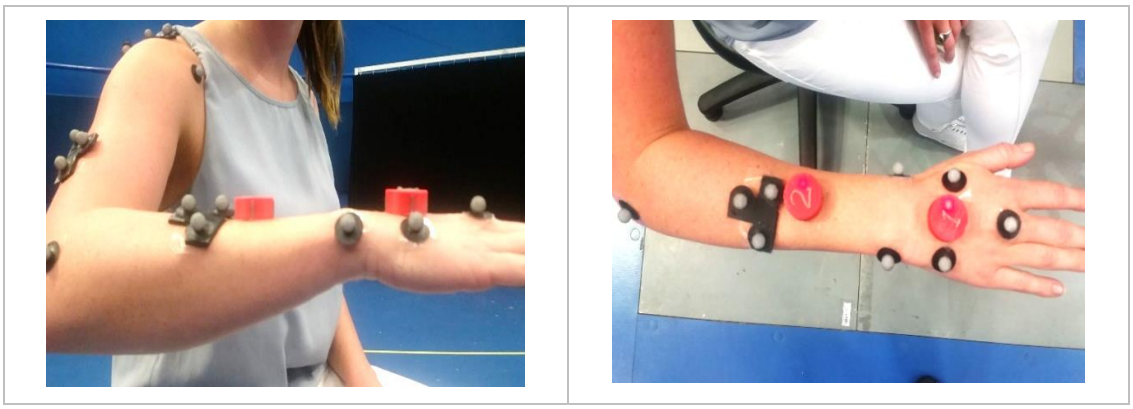

Figure 4.4 V1 wearable sensors on the hand and forearm of an adult

Efficacy

As a measurement tool with potential clinical use, the purchase of an android device per wearable sensor was not realistic in terms of cost or practicality. It was also time consuming for the researchers to navigate two android devices during data collection; the complexity of which would likely be amplified if used with children. The Bluetooth-to-Android communication only allowed collection of data for a brief period of time, which was considerably less than the anticipated two minute movement trial. Due to incomplete software associated with the android system, the data captured using V2 was not processed.

Recommendations for adaption

Several months was estimated to be needed to develop a system that supported effective communication (at an appropriate capture frequency) of multiple wearable sensors with one android device. Recommendations were made to revert to radio frequency communication as utilised in V1. Given that the use of this system was not user friendly or practical, reconsideration of the design, hardware and software was required, which was out of the scope of this thesis.

4.3.4 Version 3 (V3)

Implementation

Clinicians and researchers were involved in the application and collection of data using the wearable sensor system, with engineer representatives in attendance for a few of the pilot sessions. Two end-users and parent/guardians were present for the collection of data with younger children, with one end-user present for the collection with adults.

Practicality

V3 reverted to the original design that utilised radio frequency to communicate and transmit data. Several months were required to design and custom print circuit boards. The custom printed boards eliminated the need for internal wiring; the main cause of data loss from V1. The wearable sensors were black, measured 22mm × 24mm × 18mm, weighed approximately 10 grams and had an external on/off switch (much smaller than V1) and external micro USB port for charging (Figure 4.5). The sample and communication rate was approximately 100Hz, and the battery allowed three hours of nonstop use from one charge. The communication range between the wearable sensors and receiver was approximately 10 meters.

Figure 4.5 V3 wearable sensors; a) receiver dongle the wearable sensors transmit data to; b) external switch and charging usb port; c) size of the wearable sensor compared to a 10c coin; d) size of V3 compared to V1 and 10c coin, and e) V3 wearable sensor on the hand and forearm of a young child.

Acceptability

The size of the wearable sensors did not restrict active ROM when piloted with the adults or typically developing children. However, there was potential for the hand and forearm wearable sensors to contact each other during peak passive wrist extension, particularly for the young children with small hands. In most cases this was avoidable with careful placement of the wearable sensors. The colour and shape of the wearable sensors reduced their appeal to young children who did not appear to want to play with them. The smaller surface area of the wearable sensor reduced the contact areas of the double sided tape used to affix the wearable sensor which lessened the area of potential discomfort that occurred for some of the children.

Efficacy

Minimal dropout of data occurred over a consecutive 10-minute period and during active movement trials with children. In order to process data, a member of the clinical team received additional training in MATLAB®.

Recommendations for adaption

The size of V3 is considerably smaller than prior versions (see Figure 4.5d), however the ongoing clinical need for smaller wearable sensors with more robust casing is warranted to prevent obstruction of movement in very young children. The stability and reliability of the connection in V3 improved, allowing for a more streamline data collection and processing of data, therefore it was a collaborative decision to progress V3 to further validation testing.

A summary of the feasibility characteristics for each version of the prototypes is provided in Table 4.4.

Table 4.4 Feasibility characteristics of each version of the wearable sensor system

		Results		
	Methods	**V1 (2015)**	**V2 (2017)**	**V3 (2017)**
Aim	What the WS's aimed to measure	Wrist and elbow ROM	Wrist ROM	Wrist ROM
	Number of WS's required	Three WS	Two WS	Two WS
	Trial timeframes:			
	Passive ROM	Passive ROM – 1 min trials	Passive ROM – 1 min trials	Passive ROM – 1min trials
	Active ROM	Active ROM – 5 min trials	Active ROM – 2 min trials	Active ROM – 2 min trials
Implementation	End-users	Occupational therapists, physiotherapists, biomechanists	Occupational therapists, physiotherapists, biomechanists	Occupational therapists, physiotherapists, biomechanists
	Test population	2 TD children, 15 children with CP (5 – 14 years) 3 TD children (2 – 4 years) 10 children with CP (2 – 4 years)	1 adult (30 years)	5 adults (20 – 30 years) 5 TD children
Practicality	Size	38mm x 24mm x 27mm	27mm x 23mm	22mm × 24mm × 18mm
	Shape	Rectangular (Lego block)	Circular	Square
	Mode of communication between WS's and receiver	RF (±100Hz)	BT, requiring an android device per WS	RF (±100Hz)
	Sample Rate	±30Hz	±60Hz	±100Hz
	External features	Large external on/off switch and charging port		Small external on/off switch and micro USB port
	Battery life			±3 hours nonstop measuring from one charge
	Communication range			±10m

	Methods	Results		
		V1 (2015)	**V2 (2017)**	**V3 (2017)**
Acceptability	Observations from researcher (comfort of child, and compliance)	No adverse effects Lego appearance encouraged child to touch and play with WS Size of WS restricted peak ROM Child did not use arm with WS's on as much as they did without	Small and compact No adverse effects Did not appear to restrict peak ROM	No adverse effects Did not appear to restrict peak ROM
Efficacy	Preliminary analysis of data Outcomes	Drop of data due to loose wiring between internal components of the WS Difficulty with three WS's communicating simultaneously Rotation of WS due to size which impacted analyses Errors (i.e. crashes) occurring in the software	Data not analysed due to incomplete software development Could not collect data for 2 min period due to insufficient memory on android devices Errors (i.e. crashes) occurring in the software	Two WS could communicate simultaneously over a 10 min period
Recommendations for adaption	Recommendations based on the above clinical observations and preliminary analysis of data	Reduce size Reconsider design (Lego & colour) Improve communication for multiple WS Improve sample rate Improve charging system Fix errors with the software	Avoid use of multiple android devices Develop charging system Extend the length of time that data can be collected Improve sample rate	Progress to further testing

Key: WS = wearable sensor, Hz = hertz, ROM = range of motion, mm = millimetres, RF = radio frequency, BT = Bluetooth

4.3.5 Associated software

Approximately six versions of the software were piloted, with each version varying slightly in the user-interface. The initial purpose of the software was to collect and store data as opposed to process the data. This meant that data were collected with no immediate feedback as to whether there was any dropout of data or whether all wearable sensors were communicating with the receiver. Instead, after data were collected there was a delay (weeks to months) for the clinical team to have access to the output of the processed data. Software with a live feature (i.e. immediate visual feedback with the ability to provide results in real-time (during assessment) or shortly thereafter was anticipated to be ready in 2016, however due to unforeseen difficulties this was put on hold. The key clinical recommendations for the software are outlined in Table 4.5. Software crashes were reported to the engineering team and software updates were made to rectify them when possible.

Table 4.5 Clinical recommendations for data capture software features

Initial concept	• Real-time live data that provided immediate visual feedback and processed results during or shortly after the assessment. • Stop/start feature to collect short movement trials during play. • Section for participant characteristics (i.e. participant identification number, side of body assessed, type of session (i.e. baseline, 6-month etc.). • Ability to retrieve returning participants demographic characteristics.
V1 to V6	• Reiteration of stop/start feature. • In-built timer to indicate length of data collection. • Flashing light added to each wearable sensor to indicate whether data were being collected or to indicate interrupted connection. • Ability to differentiate between the types of calibration (i.e. table and static). • Option to save or disregard collected data as opposed to saving automatically. • Pre-saved/loaded trial names to avoid inserting information each time the software is used (i.e. play session or PROM wrist extension). • Updates to fix software crashes.

4.4 Discussion

The purpose of this feasibility study was to outline the development and evaluate the feasibility (i.e. Demand, Acceptability, Practicality and Efficacy) of prototype wearable sensors and associated software when used by end-users to measure single plane joint ROM in the upper limb of children with CP. Three versions of the wearable sensors were developed, along with six versions of the software. Each version of the wearable sensors and software sought to improve on the prior version's design, practicality and

acceptability. The development and feasibility testing occurred over a three-year period, beginning in early 2015. V3 was considered feasible for use by end-users with young children in early 2018. Adopting the feasibility focus areas proposed by Bowen et al[40] enabled the evaluation of the wearable sensors and software in relation to their Demand, Implementation, Practicality, Acceptability, Efficacy and Adaption.

4.4.1 Demand

The clinical and research demand for a tool to measure upper limb joint ROM within the domain of *body functions and structure* of the ICF was outlined in the introduction of this chapter. CP is a prevalent neurological disorder that is characterised by neuromuscular and secondary musculoskeletal impairments to the upper limb.[4,115] These impairments can manifest in the first few years of life and have potential to restrict joint ROM of the wrist and elbow.[13] As such, measurement of passive and active joint ROM is required to: i) monitor change over time[13], and ii) determine efficacy of treatment.[20,21] Currently, objective measurement of joint ROM in children with CP <5 years old is limited by a lack of available tools suitable for use with this age group.

4.4.2 Implementation

The implementation of a small custom wearable sensor system was a partnership between two distinct academic disciplines: clinical researchers with a background working with children with CP, and engineers with an interest in biomedical technology. This trans-disciplinary approach was essential for the innovative concept to come into fruition. Frequent and ongoing face to face meetings, at times required on a fortnightly to monthly basis, were required over the three-year period. The meetings provided a platform for communication between disciplines and an opportunity to discuss: i) clinical feedback from piloting the wearable sensor system, ii) modifications and adjustments needed, iii) demonstration of new features, and iv) analysis of data that had been collected. The trans-disciplinary approach brought together various expertise and different perspectives to the design concept which helped to mitigate biases and work towards practical solutions.

The implementation of the wearable sensor system, however, was not without its challenges. Combining multiple disciplines to design wearable sensors that meet end-user expectations of higher functionality and small size was at times a demanding and laborious task. Different expectations and priorities for the wearable sensor system needed to be addressed. On one hand, the clinical team prioritised the size of the wearable sensors, portability and wireless feature to allow movement to occur freely, and a high

sampling rate to ensure collection of movement at fluctuating speeds. On the other hand, these end goals were not necessarily shared by the engineering team and priority was given to the cost of the system, the simultaneous communication of multiple wearable sensors, and need for a wireless feature.[42] At times, this meant that concerns highlighted by the clinical team were not immediately addressed or were compromised for other system specifications. For example, prior to piloting V1 and its associated software, the clinical team advised that a stop/start feature within the software would be needed for clinicians to capture and analyse short movement trials with children. However, this was not prioritised until engineer representatives attended a practical trial and established that capturing continuous data with children makes for very challenging and onerous post processing of specific data points to match target movements. As a result, timeframes were protracted for changes to be made that were initially suggested by the clinical team in the beginning stages. The concept of 'user-drive innovation' or 'co-design' is well documented in literature[119,120] and the importance was reiterated in the development of these small wearable sensors. It is important to involve end-users from conception to implementation to ensure what is created is relevant for its intended use and addresses the user needs. Had end-user involvement not occurred it may have resulted in time, effort and funding being utilised on something that was not necessarily considered important, thus running the risk of the end product not being user-friendly or as relevant as intended.

Although the original aim of the wearable sensor system was to measure elbow and wrist joint ROM, the complexity of algorithms and resources required to achieve this were underestimated. Additional time, manpower, resources and funding (beyond the scope and availability of the present project) were needed for this to be attainable, and end-user expectations of the wearable sensor system needed to be adjusted to reflect this. To reflect the clinical demand, priority was given to measurement of the wrist.

4.4.3 Practicality

Practicality was addressed in relation to the characteristics of the wearable sensor hardware (i.e. size, shape, battery, sample rate) and software (i.e. interface features). In this focus area, key elements were identified that require careful consideration when using, or choosing a suitable wearable sensor system for use with children. The more obvious considerations include the size, shape and weight of the wearable sensors which have already been discussed in depth, with the main goal being that wearable sensors, when affixed to the upper limb, should not prevent movement or result in abnormal movement patterns.

Another factor that requires consideration is the battery life of the wearable sensors. The required battery life will be largely dictated by the frequency of assessments, and the anticipated time in between each assessment. Ideally, the battery life should be able to sustain non-stop use over several hours to allow multiple children to be measured in a single day without the need for recharging in-between sessions. The memory capacity of the wearable sensors also warrants consideration. Some systems automatically transmit data from the wearable sensors to the laptop, however other systems may store data directly on the wearable sensors. Given it may take longer to get the desired movement from children, it is important to make sure that the wearable sensor memory capacity is sufficient to store/hold data without the need to offload between measurements with the same child, or in between participants. If the purpose was to use the wearable sensors to monitor joint ROM throughout an entire day while the child was in their natural environment, then the memory capacity would need to be considerably increased to allow for this.

The communication range between the wearable sensors and receiver will also be largely dictated by the intended use of the wearable sensor system. In most clinical settings, the distance that the laptop is set up away from the child may not be an issue as measurement is likely to be contained to a relatively small space (i.e. 2 – 5m).[116] However, for research purposes where wearable sensors might be used in a motion analysis laboratory, a communication range above five meters is recommended. This is likely to be sufficient to allow the wearable sensors to continue communicating with the receiver despite the equipment being set up on one side of the room. In addition, the need for healthcare technology to be wireless for use with young children has also been highlighted in literature.[116] Certain wearable sensor systems require electrical wires which have potential to impede the child's movement, become tangled and difficult to organise, as well as hinder the device's portability.[116] To ensure safety and comfort of the child, a wireless system is recommended.

Software that provides a 'real time' snap shot of the data being collected would be ideal in a clinical setting where there is limited time for later analysis. However, in circumstances where this may not be possible it is critical that there is support from personnel to post-process the data or clinical staff be upskilled with appropriate training in programs such as MATLAB®. In a busy clinical setting, it is unlikely that staff would have the time to post process data. Therefore, a sophisticated user friendly software program that reports movement parameters of interest at the time of the session or shortly after is necessary if the intent is for the wearable sensors to be used clinically.

4.4.4 Acceptability

V3 of the wearable sensors appeared to be acceptable and tolerated by both the end-users and test participants. The application and removal of the wearable sensors using double sided tape did not cause any adverse reactions and children appeared to tolerate the removal with minimal discomfort. For the younger children, removal of the wearable sensors from the arm when distracted (i.e. playing) proved effective. Removal of the wearable sensor in one quick movement while holding the skin taut was the best approach, with the application of pressure straight after. To ensure the safety of the younger children (i.e. not mouthing equipment), the collection of data was completed by two end-users, with the parent or guardian also present. Navigating the software, receiver and wearable sensors, troubleshooting any problems and ensuring safety of the child would be challenging for one clinician if the system does not allow a streamline process.

4.4.5 Efficacy

The quality of data improved from V1 to V3 of the wearable sensors which was reflective of a more stable and reliable connection between the: i) internal components of the wearable sensor, and ii) wearable sensors and receiver.[42] Minimal dropout of data in V3 also indicated that sophisticated algorithms were somewhat effective in mitigating the effects of drift.[42]

4.4.6 Recommendations for adaption

There are aspects of V3 that require further refinement (i.e. size, robustness of casing and software stability), however this version demonstrated adequate feasibility for use by two clinicians with young children in the context of a research study. The collection of data with this wearable sensor system by one clinician is possible in the older children. For use with younger children, it is recommended that the parent and/or guardian are present as well as the clinician to ensure the child's safety (i.e. not mouthing equipment).

In line with the COnsensus-based Standards for the selection of health Measurement INstruments[41] (COSMIN), the next step would be to evaluate the validity of the wearable sensors (their ability to measure the intended movements) and reliability (how consistent they are)[107] to measure joint ROM at the wrist. A wearable sensor system small enough for use with young children and with acceptable psychometric parameters has potential to constitute as an accessible measurement tool for clinicians to: i) detect early movement deviations, ii) determine the effectiveness of intervention targeting movement range, and iii) monitor change over time.

4.5 Strengths and limitations

The feasibility of the wearable sensors was determined using researcher field notes and although they provided valuable information, they are subjective. The researchers involved in this study were occupational therapists, physiotherapists and biomechanists with a background in paediatrics, and therefore do represent the end-users of this product. The opinions, perspectives and recommendations of researchers involved in this study are, therefore, justified and were useful in supporting iterative development of the device.

Children with CP are often recruited to many research studies, therefore careful consideration is needed to minimise burden on the child and family. Even though the omission of children with CP in the pilot of V3 may be perceived as a limitation, V1 was piloted with a diverse age range of children both with and without CP and no notable difference in the collection process was observed between populations. As such, use of the wearable sensors with typically developing children was an adequate reflection of the process and deemed a good representation of the wider population of children.

4.6 Conclusion

V3 of the prototype wearable sensors was the most acceptable and practical version to measure upper limb joint ROM in young children. The small size, colour, shape, stable communication with minimal dropout of data, and high sample rate provided the ideal combination for use with children. The findings of this feasibility study provide valuable information to inform the development of future wearable sensors and outline factors that require consideration when choosing wearable sensors for use with children.

Additional research is required to establish the psychometric properties of the wearable sensors. Utilising the COSMIN guidelines[41], future research is anticipated to establish the validity of the wearable sensors against a criterion (i.e. precise angles of a robotic device) and gold standard (i.e. three-dimensional motion analysis), and to determine how V3 compares to current clinical methods (i.e. goniometer) to measure joint ROM in upper limb of children with CP.

Chapter Five

5

Validation of custom wearable sensors to measure angle kinematics: A technical report

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Foreword

The feasibility of V3 wearable sensors for use with young children was established in Chapter Four. The next step was to establish the accuracy of the wearable sensors to measure distinct angles (i.e. peak angles at end of range). Commonly, validation studies testing for accuracy achieve this by comparing wearable sensor output to known angles on a robotic device to provide a level of true error associated with use of the wearable sensors. As such, this study compares V3 wearable sensors to known angles on a robotic device which simulates movement in a single plane (i.e. flexion/extension). In doing so, this study established the error associated with the use of V3 wearable sensors when measuring peak angles, which is an important and necessary step prior to *in vivo* testing.

The reliability/consistency of the associated wearable sensor software was investigated by the engineering team within a parallel thesis. The methodology, outcomes and discussion of this software testing are beyond the scope of the current thesis and, as such, are not reported.

Abstract

Objective: The objective of this study was to determine the accuracy of custom designed wearable sensors when compared to a robotic device to measure: i) peak angles in a single plane (flexion/extension), and ii) the extent of error associated with speed of movement.

Methods: Two experimental procedures were undertaken: i) one wearable sensor was mounted on the arm of a step motor that simulated wrist flexion/extension at the speed of 90°/s with the other wearable sensor static (flat surface), and ii) two wearable sensors were each mounted on a step motor which was programmed to move at two movement speeds 30°/s and 90°/s.

Findings: When compared to predetermined angles of the robotic device, the wearable sensors detected peak angles with mean error ranging from -0.95° to 0.11° when one wearable sensor was static and the other dynamic. When two wearable sensors were moving, movement at the higher speed (90°/s) had a mean error range of -2.63° to 0.54, and movement at the slower speed (30°/s) had a mean error range of -0.92° to 2.90°.

Conclusion: The custom wearable sensors demonstrated the ability to measure peak angles comparable to the robotic device and demonstrated acceptable to reasonable error when tested at two movement speeds. The results warrant future *in vivo* testing.

5.1 Introduction

Accurate measurement of range of motion (ROM) forms an important part of clinical assessment, with the information used to guide treatment plans, determine efficacy of treatment and monitor patients' progress [1]. Clinical measurement of passive and active ROM is typically completed using a universal goniometer [2]. Use of this instrument is reliant on the clinician's ability to accurately palpate bony landmarks and visually estimate the alignment of the axis and arms of the goniometer to the joint being measured. It remains the most versatile, reliable and widely used instrument for the measurement of ROM in clinical practice irrespective of measurement errors up to 15° [3] reported in literature. For static and single plane movements, the universal goniometer provides quantified insight into the ROM at a joint. However, for active movement, use of the goniometer is very difficult, and not always possible in some populations; particularly those who are unable to reliably respond to movement instructions, for example young children or those with cognitive impairments.

Three-dimensional motion analysis (3DMA) systems provide alternative methods to measure active ROM in multiple planes of movement and are considered a pseudo gold standard, with measurement errors up to 0.5mm, and angular errors less than 5° [4]. Although accurate, these systems are largely unused by clinicians because they are expensive, require expertise to operate along with dedicated laboratory space and equipment [5].

Wearable sensors have potential to overcome these limitations. Lightweight, portable and relatively low in cost in comparison to 3DMA systems, wearable sensors are emerging as favourable instruments for quantifying joint angle and position in the upper limb [6 - 8]. Wearable sensors typically contain a miniaturised accelerometer, gyroscope and magnetometer [9], data from which are integrated using sophisticated sensor fusion algorithms to determine the three-dimensional orientation of each wearable sensor with respect to its global coordinate system [10]. When used to quantify joint angle in the upper limb, wearable sensors have demonstrated an acceptable level of accuracy in adult populations [11].

In this paper, small, custom designed, wearable sensors were utilised. The wearable sensors were developed collaboratively by a multidisciplinary team, and are novel in their small size (22 x 24 x 18 mm) and light weight casing. The small size of the wearable sensors is a necessary characteristic as we intend to use them with young children with a

brain injury. In a systematic review of the literature, commercial wireless wearable sensors ranged in size (length, width and height) from 34.5 x 57.8 x 14.5mm to 58 x 58 x 22 mm, with size varying depending on their intended application [11]. Various commercial wearable sensors were piloted on the hand and forearm of infants less than two years of age prior to the development of the custom wearable sensors used in this study. It was observed that the larger wearable sensors either: i) did not fit on the dorsal surface of a small hand; ii) restricted wrist ROM, particularly in wrist extension when the hand and forearm wearable sensors came into contact; and iii) the weight of some wearable sensors impacted the child's normal spontaneous use of the hand.

Given the vulnerability of the population of interest (i.e. children), it was not reasonable to use the wearable sensors prior to accuracy being established due to potential inherent insurmountable measurement error associated with the custom wearable sensors, and thus inconveniencing children and families. Determining the accuracy of the wearable sensors on a rigid static device or robotic device prior to use with human participants is common [12 – 17], therefore, the aim of this study was to compare the small custom designed wearable sensors to known angles of a robotic device and determine the true error of the wearable sensors when measuring peak angles, prior to *in vivo* testing.

5.2 Methods

5.2.1 Instruments

Two custom wearable sensors containing an inertial measurement unit with the dimensions of 22 x 24 x 18 mm were used. Each contained a tri-axial accelerometer, tri-axial gyroscope and a tri-axial magnetometer. Further details on the engineering specifications of each unit are published elsewhere [18]. The acceleration and angular velocity of the movement was sampled at 100Hz and transmitted from the wearable sensors to a personal computer using radio frequency at the rate of 100Hz. The magnetometer was not used in the calculation of angles due to likelihood of interference with the environment [19]; however, it was used to assist with the calibration of the wearable sensors [18]. The receiver has an approximate communication range of 10m. A custom developed software program was used to collect, store and process the data.

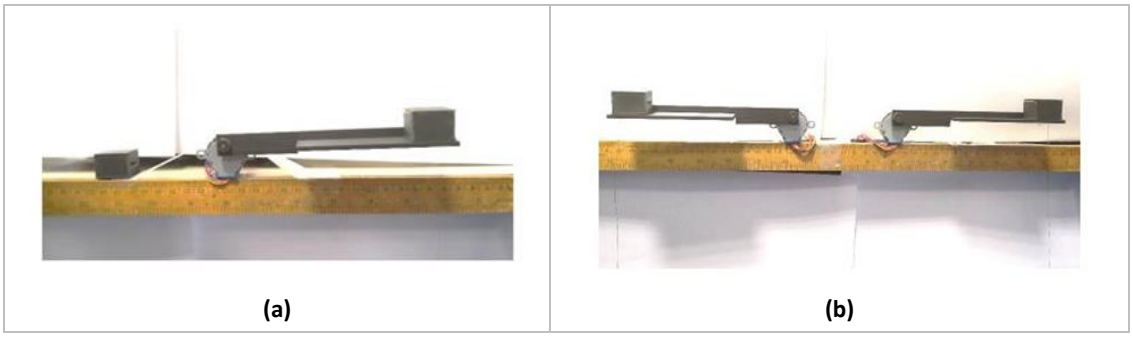
Two step motors (28BYJ-48) were used to simulate movement of the wrist joint, specifically wrist joint flexion and extension. The step motors were programmed to perform synchronized circular movements.

5.2.2 Experimental set up

Data were collected using the wearable sensors for one degree of freedom (DOF) (flexion/extension) in two separate experiments. The wearable sensors were calibrated prior to collecting data [18]. Double sided tape was used to attach the wearable sensors to the devices.

Experiment one

The objective of this experiment was to determine the accuracy of the angular measurements recorded by the wearable sensors compared with the robotic device in a condition whereby one sensor was static and the other was moving. The wearable sensors were set up with a step motor, as shown in Figure 5.1(a), with one wearable sensor static on the table and the other placed on the step motor arm that moved to simulate flexion and extension. The step motor started at neutral (0°) and was programmed to move in approximately 15° increments returning to 0° between each increment (i.e. 0, 15, 0, 30, 0, 45, 0, 60, 0, 75). This was repeated for five trials at the movement speed of 90 °/s.



(a) (b)

Figure 5.1 Experimental set-up: (a) one wearable sensor attached to the mechanical arm of a step motor and the other attached to a static surface acting as the forearm, (b) two wearable sensors mounted on separate mechanical arms of two step motors.

Experiment two

The objective of this experiment was to determine the accuracy of measurement using the wearable sensors when both sensors are moving, and whether this accuracy is influenced by speed of movement. The wearable sensors were mounted on the arm of

each step motor, as shown in Figure 5.1(b). The starting angle of each step motor was set to neutral (0°) and programmed to move in 30° increments returning to 0° between each increment (i.e. 0, 30, 0, 60, 0, 90, 0, 120, 0, 150°). Exact robot angles are outlined in Table 5.1. This was repeated for five trials at two movement speeds: 30°/s and 90°/s.

5.2.3 Data processing

Raw data from the wearable sensors were exported into an Excel spreadsheet and analysed in MATLAB® (R2014b) using the sensor fusion algorithms and filtering techniques outlined in [18].

5.2.4 Statistical analysis

The mean and standard deviation (SD) of the peak angles were manually determined in Excel. To help guide the clinical interpretation of the measurement error, the following parameters were considered: <2.0° error was considered acceptable, between 2.0 and 5.0° was regarded as reasonable but requires consideration when interpreting the data, and >5.0° of error should be interpreted with caution [20].

5.3 Results

5.3.1 Experiment one

The mean error between the robot and wearable sensor when detecting peak angle ranged from -0.95° (± 0.34) to 0.11°(± 0.56) (Table 5.1).

Table 5.1 Experiment one: The mean error between the wearable sensors and the robot to detect peak angles at 90º/s movement speed.

Target robot angle	Robot angle (º)	WS angle (º)						Mean error (Robot – WS) (± SD)
		Trial 1	Trial 2	Trial 3	Trial 4	Trial 5	Mean	
15	15.24	14.41	14.64	15.52	15.58	15.49	15.13	0.11 (± 0.56)
30	29.16	30.10	31.55	26.67	28.65	29.80	29.35	-0.19 (± 1.82)
45	44.08	45.06	44.54	45.48	45.11	44.96	45.03	-0.95 (± 0.34)
60	60.00	60.64	60.02	60.96	61.61	60.90	60.82	-0.83 (± 0.58)
75	76.14	76.82	76.53	76.77	77.14	76.44	76.74	-0.60 (± 0.27)

WS = wearable sensor, SD = standard deviation

5.3.2 Experiment two

The mean error between the robot and the wearable sensors ranged from -0.92° (±0.94) to 2.90° (±6.47) when the movement speed was set at 30°/s and ranged from -2.63° (±0.96) to 0.54 (±1.24) at a movement speed of 90°/s (Table 5.2).

Table 5.2 Experiment Two: The mean error between the robot and the WS at two movement speeds.

Target robot angle	Robot angle (°)	WS angle (°)						Mean error (Robot – WS) (± SD)
		Trial 1	Trial 2	Trial 3	Trial 4	Trial 5	Mean	
Movement speed (°/s): 30								
30	30.48	29.74	31.02	16.05	30.22	30.90	27.58	2.90 (±6.47)
60	59.96	60.08	59.46	58.54	60.93	61.81	60.16	-0.20 (±1.27)
90	88.74	89.55	90.19	90.95	89.02	88.58	89.66	-0.92 (±0.94)
120	119.53	119.39	119.28	117.06	119.41	119.35	118.90	0.63 (±1.03)
150	150.20	150.05	148.66	150.50	150.61	150.25	150.01	0.19 (±0.79)
Movement speed (°/s): 90								
30	30.48	31.14	29.24	31.26	28.38	29.65	29.94	0.54 (±1.24)
60	59.96	61.84	60.20	59.19	58.97	59.84	60.00	-0.04 (±1.13)
90	88.74	92.32	92.26	91.24	91.06	89.98	91.37	-2.63 (±0.96)
120	119.53	122.45	121.26	121.55	120.84	121.46	121.51	-1.98 (±0.59)
150	150.20	152.96	152.24	151.94	152.32	152.45	152.38	-2.18 (±0.37)

WS = wearable sensor, SD = standard deviation

5.4 Discussion

The purpose of this study was to determine the error in the measurement of angles associated with custom designed wearable sensors when compared to a robotic device. The comparison of wearable sensor output to known angles from a robotic device provides a measure of 'true error' and is commonly undertaken in studies as the first step towards the validation of wearable sensors [12-17].

In experiment one, an acceptable mean error (range: -0.95° to 0.11°) was demonstrated when one wearable sensor was static and the other dynamic. The largest mean error (-0.95°) was observed for the 44.08° angle measurement. The mean error associated with smaller angle measurements of 15.25° and 29.16° (range: -0.19° to 0.11°) was less than the mean error associated with larger angle measurements of 60° and 76.14°. The error, however, was not constant. Similar results have been achieved when comparing wearable sensors to a pan and tilt unit that simulated wrist flexion, with mean error between 0.06° (±9.20) [21] and 1.8° (±6.0) [12]. This type of movement task

can be likened to measuring passive wrist range of motion, whereby the forearm wearable sensor is static, and the hand wearable sensor is dynamic. This is a common clinical assessment completed by therapists using visual estimation or a goniometer [22]. Given the demonstrated potential accuracy, further *in vivo* research is required to determine the agreement between the wearable sensors and the goniometer - the tool typically used clinically.

Whether or not speed of movement influences the accuracy of wearable sensors on the upper limb is debatable. One study that utilised wearable sensors to measure wrist flexion/extension and twist on a robotic device demonstrated a slight increase in error from the slow (root mean spare (RMS) error range: 1.1° - 1.8°) to the fast movement speed (RMS error range: 1.8° - 3.4°) [16]. However, Zhou and Hu [23] found that when wearable sensors were used to determine wrist position on human participants; no significant change in error was associated with speed variations. The current study also found that the speed of movement (i.e. slow and fast) did not significantly affect measurement error. Rather, variability in the magnitude and direction of the error was observed across the different measurement angles, with no systematic or constant error apparent. The custom wearable sensors also had a slight tendency to over-estimate the angle, reflected by the negative sign (-).

The largest mean error reported for the slow movement speed (30°/s) was 2.90° (± 6.47) at the 30.48° angle. The increase in error observed at this angle was due to a drop in communication between one of the wearable sensors and the receiver device for approximately one second. The mean error is reduced when the outlier is removed (0.01° ± 0.60). For the fast movement speed (90°/s) the largest mean error reported was -2.63° (± 0.96) at the 88.74° angle.

Overall, the custom wearable sensors demonstrated similar error across both experimental conditions irrespective of whether one or two wearable sensors were moving, and error did not appear to be significantly influenced by movement speed. Therefore, we anticipate that the custom wearable sensors could be used with confidence to measure flexion/extension of the wrist at slow and controlled movement speeds, and further *in vivo* testing is now required. Data that are collected for populations whose speed may be faster and more sporadic (i.e. young children) needs to be interpreted with knowledge that increased speed of movement may be associated with an increase in error. Analysis of error associated with use of the custom wearable sensors *in vivo* with children of typical development and children with a brain injury will provide further evidence of this accuracy and is currently underway.

5.5 Limitations

The robotic devices used in this study were limited to single plane movement (i.e. flexion/extension). The error associated with movement in multiple planes of movement is likely to be greater than that demonstrated in this study but requires further investigation.

5.6 Conclusion

The custom wearable sensors utilised in this study have demonstrated an acceptable level of error to measure peak angles (1DOF: flexion/extension) when compared to known angles from a robotic device, with mean error ranging from -2.63° to 2.90° across both experiments. Further to this, they also demonstrate acceptable to reasonable error at both a fast and slow movement speeds. The results are positive and warrant further investigation of the accuracy of the wearable sensors when used *in vivo* for single and multiplane movement.

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Chapter Six

6

Can wearable sensors be used as an alternative to the goniometer to measure passive wrist extension in children with cerebral palsy?

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Foreword

Chapter Five established the accuracy of custom wearable sensors (V3) to measure angles in a single movement plane, mimicking the movement of flexion and extension at the wrist joint. Building from this, Chapter Six discusses the further testing of V3 wearable sensors, specifically exploring the potential interchangeability with the goniometer, the current tool used in clinical practice to measure joint ROM. To investigate this, both the wearable sensors and the goniometer were used to measure peak passive wrist extension of a cohort of children with CP (n = 39; mean age 7.89 ± 4.71). Outcomes from this study indicate promising levels of agreement between the measures for children with CP within an older age range (>5.75 years old), but highlights the challenges of measuring ROM in young children. Possible explanations for why agreement between wearable sensors and goniometer were lower for younger children are proposed.

Abstract

Background: Clinical management of children with cerebral palsy (CP) may include repeat measurement of passive wrist extension, typically assessed via goniometry. Wearable sensors, however, are an increasingly popular clinical measurement tool.

Objective: To assess the agreement between wearable sensors and goniometry for measurement of peak passive wrist extension, and assess the absolute difference between the two tools for measuring wrist extension both with fingers flexed and extended.

Design: Cross-sectional.

Method: Data were collected from children in two separate trials which enrolled children with CP ≤ 3 years old, and between 5 – 15 years. Passive wrist extension was measured using custom wearable sensors and the goniometer. Agreement was assessed using intra-class correlation coefficients (ICC's), limits of agreement and root mean square (RMS) error.

Results: 152 measurements of wrist extension were collected (n children = 39; age range: 1.9 – 17.8 years; Manual Ability Classification System Levels I to IV). Excellent agreement between the two tools was found for older children (ICC = 0.97; 95%CI: 0.94 to 0.98; p<.001), with poor agreement found for younger children (ICC 0.37; 95%CI: 0.06 to 0.62; p=.011). The smallest RMS error was for wrist extension with fingers flexed (10.63°) compared to fingers extended (12.13°).

Limitations: A relatively small sample of children was included, particularly in the younger age group.

Conclusion: Wearable sensors may be used interchangeably with the goniometer to measure passive wrist extension in older children with CP. The presence of increased subcutaneous tissue and the ability of the younger children to follow instructions and tolerate the assessment procedure are thought to impact the agreement for younger children.

6.1 Introduction

Cerebral palsy (CP) is a term used to describe a variety of musculoskeletal impairments that result from non-progressive disturbances to the developing brain.[1,2] The condition is multi-faceted however motor impairment is foremost[2-4], with most children with upper limb involvement having impaired motor control of the wrist and fingers.[5,6] Active and passive wrist extension in particular may be limited; a common cause of reduced wrist range of movement (ROM) is the presence of spasticity in the wrist/finger flexor muscles and/or weak wrist extensors, and secondary musculoskeletal impairments, such as muscle shortening, that may have progressed.[7] The inability to extend the wrist through full ROM has significant functional implications, including impeding the ability to grasp, release and manipulate objects.[8]

Clinical assessment of CP includes monitoring wrist passive ROM from an early age.[8] Although most young children with CP have full passive wrist ROM, a gradual onset of stiffness can present within the first few years.[8] Over time this has potential to advance to joint deformities with fixed, painful contractures.[2,3,8] Regular measurement of passive wrist extension is recommended to detect the early development of contracture by assessing for soft tissue shortening.[3,8,9] Passive ROM values are routinely used to guide appropriate management, and to evaluate the effectiveness of intervention[10], such as rigid hand orthoses[11], serial casting, Botulinum Neurotoxin Type-A[12] or surgery. Therefore, it is important that wrist ROM is measured with tools that provide a consistent measure.

Clinically, the goniometer is routinely used to measure ROM in children with CP.[13] Goniometric measurements taken by an experienced therapist in the same session and on the same day are reported to be more reliable than measurements taken by multiple therapists.[10,13-18] However, the nature of a clinical setting means that children with CP are often assessed by multiple therapists over multiple time-points which potentially increases the amount of measurement error. Hypertonicity has also been shown to influence the reliability of lower limb goniometric measurements in children with CP.[16,19-21] Whilst it is presumed the same issues may exist for the upper limb, very limited evidence exists for the reliability of the goniometer to measure wrist joint ROM in children with CP. Only one study demonstrated inter-rater (intraclass correlation coefficients (ICC) = 0.48) and test-retest reliability (ICC = 0.88) for measurement of passive wrist extension in children with spastic CP between the ages of 5 and 15 years.[22] For children younger than 5 years, the reliability of the goniometer to measure passive wrist extension is unknown, however, it remains a widely used clinical assessment for this age group.

A limitation to the use of goniometry to measure passive ROM in children is the common need for two therapists (one to hold the child in maximal range, and the other to align the goniometer).[23] Instead, therapists may prefer to visually estimate passive ROM. This can be achieved by one person, and leaves the hands free to hold the joint being measured.[10] Visual estimation of joint ROM in the upper limb has not been explored in children with CP; however there is a growing body of literature exploring the accuracy in adult populations. Research investigating the visual accuracy of static wrist extension of 164 final year medical students, orthopaedic residents and orthopaedic specialists' reported a mean error of 15.5°.[24] This study concluded that caution is required when visually estimating wrist extension, suggesting when accuracy within 10° is important, wrist extension should be measured rather than visually estimated.[24] Basing clinical judgement upon the inconsistency of the goniometer or visual estimation, particularly when tracking change over time, is problematic for treatment planning and evaluation, and highlights the need for exploring alternative methods of measuring ROM.

Wearable sensors, or inertial measurement units, have potential to offer an alternative method to the goniometer to measure passive and active joint ROM. Containing accelerometers, gyroscopes and magnetometers, wearable sensors are wireless portable devices that allow measurement of joint ROM. Most research thus far has compared wearable sensors to criterion (i.e. robotic devices) or pseudo gold standards (3-dimensional motion analysis) to measure upper limb joint ROM in adult populations, predominantly for the shoulder and elbow during active movement.[25] In a recent systematic review, five studies compared commercial wearable sensors to known angles of a robotic device that simulated wrist flexion/extension; root mean square (RMS) errors ranged from 1.5° to 2.2° and mean errors ranged from 0.06 to 1.8°.[25] This level of accuracy suggests wearable sensors are worthy of further investigation to measure wrist joint ROM.

Wearable sensors have potential to be used as an alternative to the goniometer for measurement of passive wrist extension. Particularly important for children with CP, wearable sensors may reduce the time the child must sustain an uncomfortable position that would be required for correct alignment of the goniometer. Exploring whether wearable sensors are consistent in measuring passive wrist extension for use with children in clinical practice is important given the lack of data making comparison to current clinical methods.

The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) provided guidelines for the design and reporting of this

measurement study.[26] Our intent was to build evidence about the measurement properties of the custom wearable sensors. However, given the sources of error inherent with goniometric measurement[27] and the paucity of information related to its validity for measurement of wrist extension in children with CP, goniometry is not considered a gold standard in this study. The absence of a gold standard prevented the ability to complete criterion validation according to the design requirements on the COSMIN.[26] Instead, this study proposes wearable sensors as an alternative to the traditional established method to measure passive wrist ROM using a goniometer.

6.1.1 Study aims

The primary aim of this study was to assess the level of agreement between the goniometer and wearable sensors for the measurement of peak passive wrist extension in younger and older children with CP. It was hypothesised there would be less agreement between the goniometer and wearable sensors for the younger children due to: i) the presence of subcutaneous tissue on the dorsum of the hand, and ii) the ability of the younger children to follow instructions and tolerate the assessment procedure.

The secondary aim was to determine the difference between the goniometer and wearable sensors for measurement of wrist extension; with fingers flexed and fingers extended. It was hypothesised that there would be a smaller RMS error and mean difference between the two tools for wrist extension with fingers flexed as opposed to wrist extension with fingers extended. This is based on the phenomenon of passive insufficiency. Passive wrist extension with fingers flexed measures isolated length of the wrist flexor muscles while eliminating the influence of the finger flexors. Passive insufficiency in the long finger flexors, that cross multiple joints, may limit the ability to achieve the same amount of wrist extension as with the fingers flexed.[28]

6.2 Methods

This study employed an exploratory cross-sectional design and was reported following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[29] Ethical approval was gained by the Human Research Ethics Committee of Perth's Children's Hospital (2014061; 2014060), and reciprocal approval by Curtin University in Western Australia (HR223/2015) and the Australian Catholic University in Victoria (2014 318V; 2014 317V). Written informed consent, and/or assent where appropriate, were obtained.

6.2.1 Setting/participants

Included data were collected between November 2016 and May 2019, from children with CP enrolled in two Australia-wide multicentre randomised control trials; the Infant Wrist Hand Orthoses Trial (iWHOT) and the Minimising Impairment Trial (MiT). Data were utilised from one participating site, Perth Children's Hospital in Perth, Western Australia. Both trials aim to assess the effectiveness of rigid wrist-hand orthosis for children with CP, and each recruited children from different age groups.[11,30]

At the time of the present study, the iWHOT had recruited 21 children at the site, aged between 0 – 36 months at the time of enrolment, with a diagnosis of CP or identified to be at risk of CP. These children presented with abnormal wrist flexion postures and full passive ROM at the wrist.[30] The grouped data from the iWHOT will be referred to as 'younger children'. The MiT had recruited 35 children at the site, aged between 5 and 15 at the time of enrolment, with a confirmed diagnosis of CP. This group presented with stiffness in the flexor muscles of the wrist, with a score of ≥1 on the Modified Ashworth Scale (MAS) at the time of enrolment. MiT grouped data will be referred to as 'older children'.[11] Children either had one or two arms eligible for inclusion in the studies.

6.2.2 Measurement instruments

Peak passive wrist extension was measured using a 15cm two-axis goniometer (Elite Medical Instruments, Fullerton, California) and two custom wearable sensors (developed at Curtin University, School of Electrical Engineering, Computing and Mathematical Sciences, V3, 22.8 x 25.2 x 21.5 mm). The wearable sensors were designed to be small enough for use with children and have established accuracy within 3° of a robotic device[31]; additional specifications are published elsewhere.[31,32] Raw data were captured at the rate of 100Hz and transmitted to a computer laptop using radio frequency. Prior to use, the wearable sensors were calibrated on a flat surface (i.e. table) and a custom software interface was used to collect and store the data.

6.2.3 Procedure

Measurements took place at a tertiary hospital clinic. A standardised protocol with detailed descriptions of all procedures and measurements was followed. Three experienced therapists were involved in the data collection; two occupational therapists and one physiotherapist. Appropriate training involving the placement of the wearable

sensors and goniometer, as well as reliability testing for administration of the goniometer, was completed with therapists prior to the study to ensure the reliable administration and consistency of assessment techniques between therapists. The same physiotherapist was present at all assessments, accompanied by one occupational therapist - a blinded assessor for the trial.

For the goniometer placement, the occupational therapist palpated and marked the triquetrum, and a line along the ulnar aspect of the longitudinal axis of the 5th metacarpal bone, and the longitudinal axis of the ulnar. These marks were used to align the axis, dynamic and stationary arm of the goniometer to the child's arm (Figure 6.1). For the placement of the wearable sensors, the midpoint between the wrist crease and head of the metacarpal bone of the middle finger, and the midpoint between elbow crease and wrist crease on the dorsum of the forearm were measured and marked using a fabric tape measure. These marked the placement of the wearable sensors, which were adhered using hypoallergenic double-sided tape to minimise displacement during movement (Figure 6.2).

Figure 6.1 Example mark-up of the position of the goniometer to measure wrist extension.

(a) (b)

Figure 6.2 Example of the placement of the wearable sensors on the hand and forearm of (a) a young child and (b) an older child.

Measurement of wrist extension, with fingered flexed and extended, was completed by two therapists. With the wearable sensors affixed to the arm, therapist 1 started the wearable sensor software; therapist 2 moved the child's wrist at a slow velocity beyond spastic resistance until end range was achieved, i.e. wrist extension. The wrist position of

the participant was maintained while the therapist 1 aligned the goniometer with the pre-determined marks to measure peak passive wrist extension. To synchronise the joint angle measurement taken by the wearable sensor with the measurement taken by the goniometer, the forearm wearable sensor was gently tapped three times (resulting in three clear 'spikes' in the data to orient the team to the section of the wearable sensor data that corresponded with the time of interest). The tapping of the wearable sensors occurred immediately prior to the therapist reading the joint angle measured by the goniometer. Therapist 2 read and recorded the degrees of movement. The same procedure was followed to measure fingers flexed and fingers extended. Both therapists were blinded to the measurement obtained by the wearable sensor.

The measurements were also videorecorded to provide a visual reference for the measurement and to allow synchronisation of data where needed. The camera was positioned approximately 1 meter to the side of the child's included hand. If the child had both hands included, the camera was repositioned accordingly to capture the other arm.

Younger children were seated in one of the following ways: i) a chair at a height adjustable table, ii) highchair with tray, iii) wheelchair at a height adjustable table, iv) pram with insert, or v) on parent/guardian's lap. Older children were seated in a chair or wheelchair at a height adjustable table, or on the parent/guardian's lap; the latter only utilised after other options had been trialled.

6.2.4 Data processing

Wearable sensor data were not included in this study if: i) an older version of the of the custom wearable sensors was used (the prototype wearable sensors that were initially implemented in this study were larger and restricted movement), ii) there was no calibration trial to determine the offset, and iii) data were not captured or there were missing data due to loss in connectivity of radio frequency (i.e. transmission of data). Raw acceleration and gyroscope data were exported to Excel and processed in MATLAB® (Mathworks Inc., Natick, USA - R2014b) using sophisticated filtering algorithms to output wrist joint angle.[33] A customised Labview program (National Instruments, Austin, Texas) was then applied to output maximum passive wrist extension. Three spikes in the acceleration data determined the peak that corresponded with the goniometer data collection point. If multiple peaks occurred in the same data set, video data was inspected to identify the peak that correlated with the goniometer reading. Multiple peaks could occur because children were not compliant with the task,

or the therapist needed more than one attempt to move through spasticity and tone to achieve full passive ROM.

6.2.5 Statistical analysis

Statistical analysis was performed using SPSS, version 26 (IMB Corp, Armkonk, NY). Agreements between the goniometer and wearable sensors were analysed using ICC with their 95% confidence intervals (CI's). ICC's greater than 0.90 reflect excellent agreement, with values less than 0.50 indicative of poor agreement.[34] Values were considered statistically significant at $p \leq 0.05$.[35] Bland-Altman limits of agreement (LOA; SD x 1.96 + mean difference) were assessed by plotting the difference in ROM (goniometer minus wearable sensor) against the average value of the ROM.[36-38] The mean difference was calculated by averaging each individual difference (goniometer - wearable sensor = difference). The absolute difference was calculated using root mean square (RMS) error.

6.3 Results

A total of 152 measurements of passive wrist extension were recorded from a sample of 39 children with CP. Categorisation of children in this study was based on their enrolment in the iWHOT and MIT. Fifteen children were included from the iWHOT (n = 74 measures, age range: 1.92 to 5.50 years) and 24 children from the MiT (n = 78 measures, age range: 5.75 to 17.83 years) (Table 6.1). One or two measurements of wrist extension were completed for each included arm: wrist extension with fingers flexed (n = 76) and fingers extended (n = 76). Fifteen of the 39 children completed multiple assessments (maximum of 3) that were six months apart (depending on their entry time point into the larger study). Seventeen children had both arms included in the study.

The agreements between measures are outlined in Table 6.2. Data from the older children group had excellent and statistically significant agreement for wrist extension with fingers flexed (ICC: 0.97; 95% CI 0.94 to 0.98; p<.001) and fingers extended (ICC: 0.97; 95% CI 0.94 to 0.98; p<.001). Data from the younger children had poor agreement with wide 95% confidence intervals, with ICC's for wrist extension fingers flexed slightly higher (ICC: 0.42; 95% CI 0.12 to 0.65) than those found for wrist extension with fingers extended (ICC: 0.37; 95% CI 0.06 to 0.62).

Limits of agreement (LOA) analyses show mean differences below 0° (range -4.25° to -7.08°): wearable sensor ROM tended to be greater than goniometer ROM (see Figure 6.3). LOA were wide, with upper LOA consistently greater than +10° and lower LOA consistently below -20° for both measures of wrist extension and across both age groups.

For the older children, LOA were wider for wrist extension with fingers extended as opposed to fingers flexed, showing the expected greater variability.

The least difference and least RMS errors were found for the older children; and for the measure of wrist extension with fingers flexed across both age groups (Table 6.3).

Table 6.1 Participant characteristics

	Trials Combined	**iWHOT Younger**	**MiT Older**
n children	39	15	24
n measures	152	74	78
Mean age ± SD	7.89 ± 4.71	3.64 ± 0.93	11.74 ± 3.17
Gender			
Male : Female	17:22	9:06	8:16
Involvement			
Unilateral : Bilateral	22:17	6:09	16:08
Hand measured			
Left : Right	34:39	16:19	18:20
GMFCS			
I	13	5	8
II	7	1	6
III	6	1	5
IV	3	2	1
V	10	6	4
MACS*			
I	14	0	14
II	6	3	3
III	4	3	1
IV	5	3	2
V	10	6	4

iWHOT= infant Wrist Hand Orthoses Trial, MiT = Minimising impairment Trial, SD = standard deviation, GMFCS = Gross Motor Function Classification System, MACS = Manual Ability Classification System
*Mini-MACS was used for children in the iWHOT.

Table 6.2 Agreement between the goniometer and wearable sensors

	Wrist extension (fingers flexed) ICC (95% CI) p value	**Wrist extension (fingers extended) ICC (95% CI) p value**
All	0.94 (0.91 – 0.96) p<.001*	0.94 (0.91 – 0.96) p<.001*
Older	0.97 (0.94 – 0.98) p<.001*	0.97 (0.94 – 0.98) p<.001*
Younger	0.42 (0.12 – 0.65) p=.004*	0.37 (0.06 – 0.62) p=.011*

ICC = Intraclass Correlation Coefficient; CI = Confidence Interval
*statistically significant (p = ≤0.05)

Table 6.3 Mean values, standard deviation, mean difference and RMS error between the goniometer and wearable sensors

	Wrist Extension (fingers flexed)				Wrist Extension (fingers extended)			
	Goniometer Mean ± SD	**Wearable Sensor Mean ± SD**	**Mean Difference**	**RMS error**	**Goniometer Mean ± SD**	**Wearable Sensor Mean ± SD**	**Mean Difference**	**RMS error**
All	89.13 ± 26.04°	94.37 ± 27.59°	-5.25 ± 9.31°	10.63°	80.83 ± 29.13°	86.48 ± 33.42°	-5.65 ± 10.80°	12.13°
Older	80.71 ± 34.38°	84.68 ± 35.47°	-4.25 ± 8.99°	9.84°	72.90 ± 38.13°	77.26 ± 42.72°	-4.35 ± 10.39°	11.15°
Younger	97.55 ± 6.86°	103.81 ± 10.65°	-6.25 ± 9.63°	11.37°	89.64 ± 6.79°	96.72 ± 12.44°	-7.08 ± 11.21°	13.13°

SD = Standard Deviation, RMS = Root Mean Square

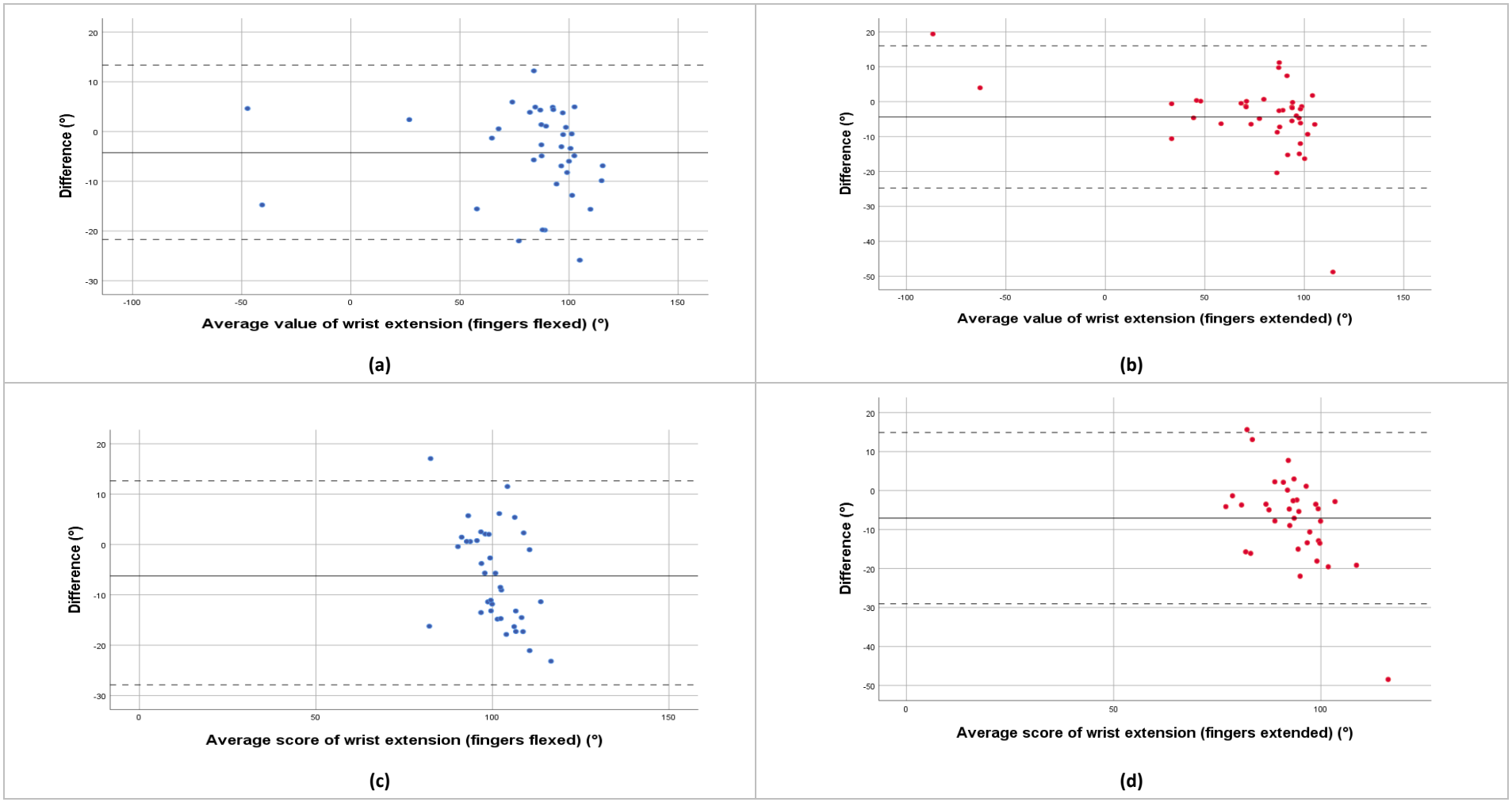

Figure 6.3 (a) Bland-Altman plot for wrist extension (fingers flexed) and (b) wrist extension (fingers extended) showing the agreement and LOA for older children; (c) wrist extension (fingers flexed) and (d) wrist extension (fingers extended) showing the agreement and LOA for younger children.

6.4 Discussion

This study explored the level of agreement, and therefore potential interchangeability, of custom wearable sensors and the goniometer to measure peak passive wrist extension in children with CP. When comparing such tools, it is important to acknowledge that both the wearable sensors and the goniometer have inherent error associated with their use and it is currently unknown which of these tools is more accurate. In addition, both tools have different measurement approaches which may also lead to measurement variation; the goniometer assessed ROM from mid segment to mid segment, while wearable sensors are adhered to the surface of the skin. Despite these differences, an excellent level of agreement was found between the wearable sensors and the standard goniometer for older children with CP. This suggests that wearable sensors are able to produce similarly meaningful results to that of the goniometer.

This level of interchangeability was not found with younger children and there are a few plausible factors that may contribute to the poor agreement and wide CI's. As hypothesised, increased subcutaneous tissue in younger children might have contributed to greater variability compared to older children where structures of the hand are closer to the skin's surface. Movement of the wearable sensors with respect to underlying soft tissue and bone, known as soft tissue artefact[39], is a well-known source of error in the estimation of joint kinematics.[40] The additional subcutaneous tissue in younger children may also occlude bony landmarks for accurate placement of the goniometer. Despite the wearable sensors being smaller than most that are commercially available[25], they sometimes covered the dorsum of small hands, making it difficult for the therapist move the wrist into extension without touching the wearable sensor. In addition, there were instances where the forearm and hand wearable sensors contacted each other in peak extension. It is known that contact (i.e. by another wearable sensor or the therapist) can alter the acceleration or gyroscope readings, thereby impacting the value obtained. It was also sometimes difficult for younger children to tolerate the assessment procedure increasing the difficulty of obtaining a measure. The older children tended to tolerate the assessment procedure, likely owing to their familiarity and understanding of the need for the measurements. The fundamental problem is the inability to exactly pin point the source of variability. Thus, there are multiple sources of variability related to a combination of factors inherent to the measurement tools, the therapist and the child. Addressing each of these sources of variation will be required to increase the accuracy of measurement.

It was expected that measures of wrist extension with fingers flexed would be greater than with fingers extended, and this was confirmed using both the goniometer and wearable sensors. It was also our expectation that RMS error would be less when taking measures with fingers flexed because this measure is easier to achieve, and this too was confirmed. Controlling the fingers in extension while extending the wrist can be more clinically challenging than measuring wrist extension with fingers flexed. To achieve the wrist extension fingers extended measure, the clinician needs to control more than one joint and the goniometer at the time of measurement. While the presence of two assessors was intended to support obtaining this measure, it remains a more complex measure to achieve.

The average difference between the wearable sensors and the goniometer in this study varied by up to 7°. However, the LOA show the extent of variability in the differences; with values ranging from 0.12° to 48.80° across both age groups. To remain unbiased, outliers were not removed from the data set. From a clinical perspective, the upper range in differences cannot be overlooked as a difference in ROM of ≥30° may lead to alternate intervention approaches.

The limited research in this area makes direct comparison between the current and previous research difficult. Only one study was found that compared wearable sensors to the goniometer to measure peak active wrist extension in adults. This study found moderate correlation between the two tools (r = 0.68 in healthy, and r = 0.79 in 'newly disabled').[41] Measuring active wrist movement in multiple planes of motion is likely to increase variability, however different statistical approaches mean results are not directly comparable, and correlation analyses do not provide a robust measure of agreement.

6.4.1 Implications for clinical practice

Therapists could use the wearable sensors and the goniometer interchangeably with confidence in their ability to produce similarly meaningful results for older children with CP for measurement of passive wrist extension. Measurement is more clinically challenging with younger children and interpreting results from wearable sensors in this age group needs to be done so with caution because the presence of increased subcutaneous tissue may influence the measurement.

6.4.2 Implications for research

Wearable sensors are likely the way of the future for accurate measurement of ROM. One benefit is their potential application for measurement of active movement.

The next step in understanding the role of wearable sensors clinically will be to establish their reliability and determine the error when compared to pseudo gold standards such as 3-dimensional movement analysis for measurement of wrist joint ROM during active movement. Exploring this in relation to other joints and movements of the upper limb is also required. Before this can be done in younger children, further exploration is required to determine how best to achieve accurate measurement using wearable sensors with younger children. The development of smaller wearable sensors (that will not come into contact with each other during wrist movement) may reduce some of this variability.

6.5 Strengths and limitations

This study has highlighted the challenges of measuring passive wrist extension in young children with CP and identified future research directions. The main limitation of this study is the categorisation of children by enrolment in the iWHOT or MiT rather than age per se. There was less than 6 months between the age of the oldest child in the iWHOT and the youngest child in the MiT. Given the poor agreement between the wearable sensors and the goniometer for the younger children, a secondary exploratory analysis (removing the 'grouping') was completed, however no noteworthy relationship between age of the children and level of agreement was found. The inclusion of a larger sample of young children is likely needed for this age relationship to be determined. To minimise participant burden on top of an already lengthy assessment procedure in the iWHOT and MiT, only one measure of wrist extension was completed with fingers flexed and fingers extended for each child. As such, reliability of measures could not be reported.

6.6 Conclusion

This study explored the interchangeability of the wearable sensors with the goniometer for measuring passive wrist extension in children with CP. Excellent agreement was found for older children with CP, with poor agreement found for the younger children with CP. The smallest RMS error and difference between the goniometer and wearable sensor values was found for wrist extension fingers flexed, compared to wrist extension fingers extended.

Wearable sensors have potential to provide an alternative method for measuring passive wrist extension in older children within the parameters of accuracy and objectivity of that of the goniometer. Further exploration is required to address the poor agreement between the wearable sensors and goniometer with younger children with CP.

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Chapter Seven

7

Exploring solutions to the measurement of wrist and elbow range of motion in young children with and without cerebral palsy

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Foreword

Chapter Six identified that V3 wearable sensors and the goniometer had excellent agreement for the measurement of passive wrist extension in older children with cerebral palsy (CP). However, for younger children with CP, poor agreement was found between the wearable sensors and goniometer. The lack of agreement is likely owing to the inherent error associated with use of the goniometer but may also stem from error associated with the use of the wearable sensors. Although Chapter Five established that the wearable sensors could detect peak angles within <3° from the robotic device, this was tested at relatively consistent speeds and movement that occurred in one plane. In order to investigate this further and delineate how much error was associated with use of the wearable sensors, we sought to explore their accuracy when compared to three-dimensional motion analysis (3DMA) during active movement. The comparison of wearable sensors and 3DMA has been undertaken predominantly in adult populations and done so while participants complete a series of functional tasks with pre-defined start and stop points.[28] In younger children, pre-defined movement tasks are not possible, giving rise for the need to capitalise on play-like activities. 'Play-like activities' describes using play as a means to achieve other outcomes, in this case, using play to elicit certain movements of interest. This approach was chosen as play is regarded as a familiar and meaningful occupation of young children.[121]

This chapter reports on a study conducted in three parts. Part One outlines the development of a play session for young children that was designed specifically with the goal to elicit active wrist extension. Part Two reports on the unanticipated intricacies and challenges of data capture with V3 of the wearable sensors during active movement with young children which lead to the decision to not utilise data from the wearable sensors in Part Three. Part Three therefore, is a prepared manuscript which compares the upper limb movement parameters obtained using 3DMA, between children with and without CP during the outlined play session in Part Two.

PART ONE: PLAY SESSION DEVELOPMENT

7.1 Introduction

Active range of motion (ROM) of the wrist and elbow in children with CP is of interest to health professionals as it is a movement often restricted due to neuromuscular and secondary musculoskeletal changes.[14,16,89] Restricted movement at the wrist and elbow joint have potential to impact reach, hand placement and efficiency of grasp and release. Subsequently, difficulty with independently completing everyday tasks may ensue, such as dressing and feeding, and participation in meaningful activities, such as playing with peers.[122] It is believed that upper limb restrictions to ROM emerge throughout early childhood over periods of rapid growth and development, as such, routine monitoring of passive wrist and elbow extension should also commence within the first few years of life.[13,52] In young children with CP, it is unknown if restrictions in passive movement translate to limited ROM during functional use. Active upper limb ROM is relatively unexplored in young children with CP due to the lack of available tools to objectively measure ROM in this age group. This thesis thus far has investigated the potential application of wearable sensors as a viable option to measure active wrist and elbow extension; however, how these movements were going to be elicited in young children required consideration.

In older children, maximal active extension of the wrist and elbow can be measured by asking the child to hold their arm out straight in front with their fingers *pointing to the sky* or by *making a stop sign*. There are a number of difficulties in trying to achieve this with young children which highlights the need to explore alternative age and developmentally appropriate approaches to measure ROM. A popular approach to obtaining information about upper limb performance in young children with CP is to use play-based assessments. The Mini-Assisting Hand Assessment is a standardised, criterion referenced assessment that employs a set of specific toys to provoke bimanual play in children with CP between 8 and 18 months.[38] More recently, the Hand Assessment for Infants has become available for use with infants with or at risk of CP aged between 3 and 12 months.[8] The Hand Assessment for Infants looks at a combination of uni-manual and bi-manual play behaviours, and can be used to identify upper limb asymmetry for early diagnostic purposes.[8] The Mini-Assisting Hand Assessment and the Hand Assessment for Infants are examples of how play and the

selection of specific toys can be used to facilitate a variety of upper limb behaviours and actions in infants with CP.

The play session procedures for the Mini-Assisting Hand Assessment and Hand Assessment for Infants were not entirely appropriate for use in the present study for several reasons. First, during the initial planning of this study, the Hand Assessment for Infants was still under early development and not yet available for use. Second, although movement of the upper limb is elicited, the assessments do not focus on purposely provoking maximal wrist and elbow movement. Third, the research team needed the assessment to span the ages of 6 months to 5 years, for which neither the Mini-Assisting Hand Assessment or the Hand Assessment for Infants were appropriate. The need to develop a uni-manual play session that utilised specific toys to elicit maximal movement of the wrist and elbow was warranted, with the end goal of using this play session while the child wore wearable sensors and/or three-dimensional motion analysis (3DMA) markers on the upper limb. With the strong evidence-base for early intervention to maximise neuroplasticity[9,37,123], the ability to objectively measure maximal active movement of the wrist and elbow may be of benefit to describe: i) the amount of active ROM used functionally, ii) to measure change in active ROM throughout early development, and iii) to evaluate therapeutic management and targeted interventions.

7.2 Aims

The primary aim was to develop a uni-manual play session using specific toys to elicit maximum active wrist extension in young children (≤5 years) with and without CP. The secondary aim was to elicit maximal elbow extension. The achievement of these aims would allow for the (previously unreported) objective measurement of active wrist and elbow ROM during age relevant activity.

7.3 Methods

7.3.1 Procedures

The development of the play session was an iterative process with the initial concept formulated through ongoing working-group meetings. The working-group consisted of research and clinical occupational therapists and biomechanists involved in paediatric rehabilitation. The play session and selection of toys were guided and further refined by input from expert paediatric occupational therapists involved in the development of the Mini-Assisting Hand Assessment[38] and the Hand Assessment for Infants.[8] Dr Susan

Greaves (Royal Children's Hospital in Melbourne, Australia; Mini-Assisting Hand Assessment[38]) had an active and ongoing role in the development of this play session from the initial stages, with Professor Ann-Christin Eliasson (Astrid Lindgren Hospital, Karolinska Institute, Stockholm, Sweden; Hand Assessment for Infants[8]) also providing input during a visit to Perth, Western Australia in March 2015.

It was from the working-group meetings, liaison with experts in the field, and a review of recent literature on the development of the Mini-Assisting Hand Assessment and Hand Assessment for Infants[8,38,124], that core concepts relevant to the selection of toys to elicit maximum wrist and elbow extension were identified. These included: i) the properties of toys (including size, shape and weight), ii) how the toys should be presented to the child to provoke maximum movement (i.e. midline, to the side, distance and height away from the child), iii) appropriate seating to support upper limb movement, iv) the duration of the play session, and v) placement of the camera/s to capture the play session. Refinement of these concepts was achieved through ongoing discussion with the working-group, consultation with experts, and piloting of the play session and use of toys with six typically developing children. The video footage was visually inspected and reviewed by the working-group each time the play session was piloted with a child which allowed further refinement prior to additional piloting of the play session. When the working group reached consensus on the set up and selection of toys, a protocol was devised that outlined the pertinent details to enable replication of the uni-manual play session in a standardised manner with each child (Appendix E).

7.3.2 Participants

The selected toys and facilitation of the play session were piloted with typically developing children (aged 6 months to 2 years) who were recruited via a convenience sample.

7.3.3 Feasibility framework

The feasibility framework by Bowen et al[40] is used to describe the development of a play protocol. The play sessions with children were used to evaluate the feasibility of using the protocol to elicit the movements of interest in relation to the following focus areas: Implementation, Practicality and Adaptation. The definition of terms used to establish feasibility are outlined in Table 7.1. Information pertinent to each focus area will be presented, followed by a final synthesis of information.

Table 7.1 Key feasibility focus areas relevant to the development of the play session

Area of focus	Application to the play session
Implementation	Toy selection
	Seating
	Duration of the play session
	Camera set up
Practicality	Elicitation of wrist and elbow extension
	Position of the play facilitator
	Duration of the play session
	Camera view
	Engagement (child and toys)
Adaptation	Aspects of the play session that required adaption
	(i.e. toys, placement of the toys, timing of the play)

7.4 Results

Different iterations of the play session were trialled with six typically developing children between 6 months and 2 years of age (2 boys; 4 girls). Children had no history of upper limb impairment or injury.

7.4.1 Implementation

Initially, ten different toys were piloted for their ability to elicit active wrist and elbow ROM (see Table 7.2). Some toys were modelled from assessments such as the Mini-Assisting Hand Assessment[38] or the Hand Assessment for Infants[8] with permission from the developers. Depending on the child's age and postural stability, different seating options were considered for the facilitation of the play session; i) on the floor, ii) in a floor seat, iii) in a highchair, or iv) on the parent's lap. The use of two cameras were trialled to capture the play session and were set up from a sagittal and frontal perspective. Additional toys were available for the child to play with pre and post the play session to keep their interest and attention.

7.4.2 Practicality

Video footage was visually inspected by a team of occupational therapists (n = 6) and biomechanists (n = 2) to determine the extent to which the toys provoked the movements of interest. Uni-manual play was more often provoked when the toy was presented to one side of the body as opposed to the midline. Active wrist and elbow

extension were elicited by certain toys, however this was dependent on the height and distance that the toys were presented to the child.

Gentle restriction of the other hand by the play facilitator or parent was sometimes required to promote active movement of one side of the body as the play session focused on eliciting uni-manual movement. The toys, how they were presented to the child to elicit maximal ROM, and the child's level of engagement with the toys, were recorded (see Table 7.2). The length of the play was influenced by: i) how long the child maintained interest in the toys, and ii) the optimal length of time that the wearable sensors could collect data without being influenced by drift (i.e. 2 minutes, as outlined in Chapter Three).

The first play session was conducted with a child (age: 1.5 years old) while seated unsupported on the floor. This was trialled to see if the child would engage in play while the measurement tools (i.e. wearable sensors and 3DMA markers) were on their upper limb. The remaining play sessions were completed with the child in supported seating. The highchair interfered the least with the measurement tools (i.e. least obstruction of the markers). The sagittal camera view was most useful when viewing the data, with the frontal camera view often obstructed by the play facilitator.

7.4.3 Adaptation

Four of the 10 trialled toys were selected based on their perceived ability to provoke maximum active wrist and elbow extension, whilst simultaneously being able to engage the child. Active wrist extension and elbow extension were best elicited when the toys were held in front of the child, at the child's shoulder height, and at the child's arm length. The required movement was facilitated best when the child was seated in a highchair which provided sufficient postural support. In circumstances when the child was not settled, the option to sit on the parent's lap was utilised. The parent was asked to support the child's hips and not interfere with upper limb movements. A maximum of 2 minutes per toy was shown to be optimal for the child's engagement (i.e. a total of 4 x 2 minutes of play).

Table 7.2 Description of the toys

	Toy selection	Wrist and elbow extension response	Engagement of the child	Included in the final selection
1		Picking up and placing balls in the basket tended to elicit mostly wrist flexion and elbow extension.	Children did not appear engaged with this task, and would throw the balls elsewhere.	No
2		Reaching for the ball and placing the ball on the Velcro frog at different heights and distances away from the child elicited both wrist and elbow extension.	Children engaged well with this toy; however some children would throw the ball elsewhere.	Yes
3		Building with Duplo™ blocks did not elicit maximum wrist and elbow extension, and rather elicited bi-manual play.	Children appeared relatively engaged in the Duplo™ blocks.	No
4		The approach to grasping this frog elicited wrist extension however the ability to grasp was somewhat awkward and wrist extension appeared to be better elicited with the maracas.	Children were engaged with this toy possibly due to the noise.	No

	Toy selection	Wrist and elbow extension response	Engagement of the child	Included in the final selection
5		Elicited both wrist flexion and extension; however children predominantly maintained elbow flexion.	Children were engaged with this toy.	No
6		Reaching for the beads at different heights and distances away from the child elicited both wrist and elbow extension.	Children were very engaged with the beads.	Yes
7		Using the hammer and xylophone resulted in more global upper arm movements as opposed to isolated wrist and elbow extension.	Children were engaged with using the hammer and the noise of the xylophone.	No
8		Elicited a more neutral and flexed wrist when pressing/turning the buttons and elbow flexion was maintained.	Children were engaged with the different pop-up animals.	No

	Toy selection	Wrist and elbow extension response	Engagement of the child	Included in the final selection
9		Reaching for the maracas elicited both wrist and elbow extension. Wrist extension was elicited when approaching the maraca as well as when initially grasping the maraca.	Children engaged well with the maracas. Using two maracas also occupied the other hand.	Yes
10		Placing the magnet animals on and off the vertical surface elicited both wrist and elbow extension.	Children engaged well with the animal magnets. They were soft material and included noise components when squeezed.	Yes

7.5 Discussion

The aim was to develop a play session using specific toys with the purpose of provoking maximum active wrist and elbow extension in young children with and without CP. The need to develop a play protocol to elicit uni-manual maximum movement was highlighted as available tools tended to focus on bi-manual actions and did not aim to provoke maximal movement. A working-group of research and clinical paediatric occupational therapists and biomechanists sought to develop a play session with the intent that the desired maximal active movement in young children could then be measured objectively using wearable sensors or 3DMA. The objective measurement of maximal active upper limb ROM during functional movement in young children with and without CP has not previously been reported. The ability to do so has the potential to identify early restrictions in active movement which may facilitate early intervention.

The selection of toys and set up was adapted after each pilot of the play session. Following ongoing revision of the play sessions and further refinement by experts in the development of play-based upper limb assessments for children with CP, a play session protocol was developed. The protocol outlined the selection of four toys and the optimal methods of presenting them to the child to best elicit a large range of active wrist and elbow extension, with the elicitation of wrist extension the main priority. Preliminary evidence of the play session to provoke maximum active wrist and elbow extension was obtained using video footage, and supports the further investigation as to whether the amount of active ROM can be measured objectively (and quantified) using wearable sensors and/or 3DMA.

This study piloted the play session with typically developing children which was required to establish if active wrist and elbow extension could be elicited by the toys in this age group. Further testing is required to determine if: i) the play session can repeatedly elicit maximal active ROM in typically developing children measured objectively using wearable sensors and/or 3DMA, ii) the play session can elicit maximal active ROM in children with motor and potentially perceptual/cognitive difficulties, and iii) whether movement of the upper limb during the play session can be objectively measured using wearable sensors and/or 3DMA.

7.6 Conclusion

The chosen toys and play session protocol have potential to engage children and elicit maximal active wrist and elbow extension in typically developing children, with further investigation required in the CP population.

PART TWO: UTILITY OF THE WEARABLE SENSORS TO MEASURE ACTIVE UPPER LIMB RANGE OF MOVEMENT

The aim of this section is to outline the technological difficulties associated with V3 wearable sensors and the events that lead to the exclusion of the wearable sensors in Part Three.

After the play protocol was deemed appropriate for use with children to provoke maximal active wrist and elbow extension (Part One), the play session was performed with children while wearable sensors and 3DMA markers were on the upper limb. The intention was to determine the accuracy of V3 wearable sensors when compared to 3DMA to detect peak active wrist and elbow extension in children with and without CP while the child participated in the play session (outlined in Part One). Simultaneously, it aimed to compare wrist and elbow ROM in children with and without CP (outlined in Part Three). However, a number of unanticipated limitations of the wearable sensors were detected during data analysis that eventually precluded the use of the wearable sensors. The purpose of this section is to explain these events.

Data were collected from 10 typically developing children during the play session using V3 wearable sensors and 3DMA. On review of the wearable sensor raw data, it was apparent that usable data from only one wearable sensor was captured due to a fault in the hardware of one of the wearable sensors. The software had an in-built feature that was designed to alert to the clinician if data were not being collected, however, an additional fault in the software prevented this. Unaware of this, data was collected for all 10 typically developing children, and it was not until post processing that the loss of data was identified. To determine joint kinematics, data needs to be integrated from two wearable sensors; therefore the data that were collected from the 10 typically developing children were not usable. A new wearable sensor was made to replace the faulty wearable sensor and the software was rectified to ensure that loss of data would be identified immediately.

Data collection using the wearable sensors and 3DMA proceeded, with data for an additional 10 typically developing children and 10 children with CP (further described in Part Three) collected. At this point in time, software to analyse the data was not developed therefore processing of the data needed to be completed by the engineering team. However, due to time constraints the engineers were unable to process the data concurrently with data collected. In an attempt to streamline the analysis of data, and the

PhD candidate was upskilled in the use of MATLAB®, a computer engineering program. Upon analysis of the wearable sensor data it was evident that the wrist flexion/extension angles were significantly erroneous, with peaks and troughs often beyond the range of physiological capabilities. Further inspection of the raw data revealed that the hardware utilised were not suitable for the purpose of collecting movement of young children. The accelerometer specification in particular were consistently 'clipping', that is that they were not recording movements beyond a speed threshold that the young children were consistently using. Figure 7.1 shows the accelerometer data 'clipping' during fast movement. Figure 7.2 then demonstrates the corresponding flexion and extension angles of the wrist that are clearly erroneous/physiological impossible (e.g. >180° of flexion).

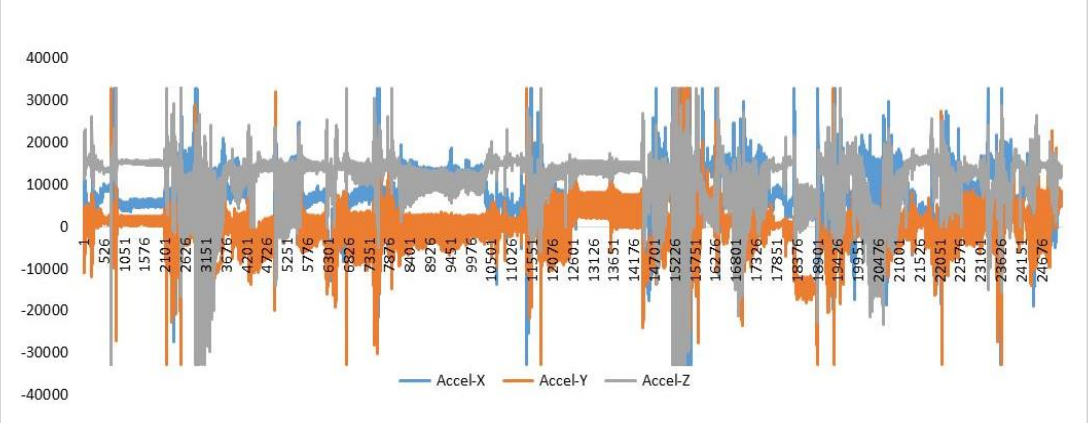

Figure 7.1 Example of raw acceleration data captured while the child played with a maraca, note the flat cut off of data at the maximal ranges, demonstrating a 'clipping' of the data.

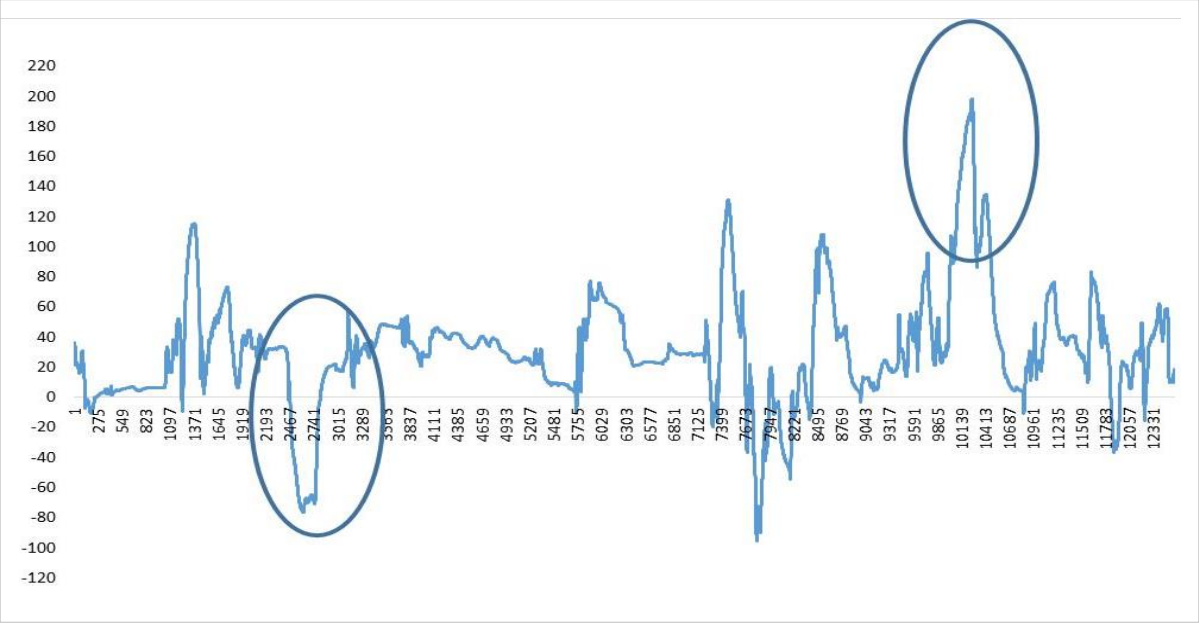

Figure 7.2 Corresponding wrist flexion/extension (°)

When the development of small custom wearable sensors began in 2015, the hardware specifications were largely modelled off commercial brands which contained a tri-axial digital accelerometer (± 2g) and tri-axial digital gyroscope (± 250°). These specifications were adequate to capture controlled movement at slow speeds (i.e. passive movement of the wrist outlined in Chapter Six). These specifications were also not highlighted as problematic in the preliminary analysis of data in Chapter Four when used with children, or in Chapter Three when tested at different movement speeds on a robotic device. This is likely owing to the movement of children in Study Five during the play session being faster and more sporadic than what was previously accounted for. Since 2015, commercial brands of wearable sensors have increased their accelerometer range to 8g, which is one solution to the use of the custom wearable sensors outlined in this thesis. Increasing the accelerometer range would require changes to the hardware and additional validation testing which, after four years of work, was deemed beyond the scope of this thesis. Another possibility was to mathematically interpolate the missing peaks and troughs in the acceleration data, however the accuracy of this would be unknown. Therefore, the decision was made to exclude further use of the wearable sensors with young children until the issues had been rectified and the wearable sensors re-tested for validity and reliability. Study Five, therefore omits the use of wearable sensors, and instead reports peak active movement of the wrist and elbow in young children with and without CP using 3DMA.

PART THREE: THREE-DIMENSIONAL MOTION ANALYSIS

Manuscript details

Title:

A comparison of wrist and elbow kinematics in young children with and without cerebral palsy.

Reference:

Walmsley, CP, Campbell A, Elliott C, Imms C, Williams SA. Wrist and elbow kinematics in children with cerebral palsy compared to typically developing children. 2019; Manuscript prepared for submission in peer review journal.

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The PhD Candidate, Corrin P Walmsley, accounted for 80% of the intellectual property associated with the final manuscript (the primary individual involved in the study design, data collection and analysis and manuscript preparation and revision). Collectively, the remaining authors contributed 20%.

Referencing Convention:

The referencing convention in this chapter follows the guidelines specified for submission to the specific peer review journal.

Abstract

Background: Musculoskeletal impairments associated with cerebral palsy (CP) can limit upper limb active range of motion (ROM), often resulting in activity limitations. It is not known how early impairments in active movement begin to occur. This study aimed to assess wrist and elbow kinematics in young children with and without CP during play tasks.

Research Question: Do young children (<5 years) with and without CP show differences in wrist and elbow ROM? How much active wrist ROM do children (with and without CP) use compared to their available passive ROM?

Methods: Three-dimensional motion analysis captured data from children with CP (presenting with abnormal flexion postures of the hand and full passive ROM at the wrist), and age matched children without CP. Play tasks aimed to elicit maximum active extension of the wrist and elbow. Peak wrist and elbow flexion/extension were compared between groups, as were measures of passive wrist extension (via goniometry).

Results: Eight children with CP (mean: age 3.5 ± 1.0; 5 male; Mini-Manual Ability Classification System levels II-V) and ten children without CP (mean: 3.4 ± 1.1 years; 5 male) participated. On average across all movement tasks, children with CP used less wrist extension (mean diff = 15.8°), more wrist flexion (mean diff = 10.6°), and less elbow extension (mean diff = 15.4°) than children without CP. Passive wrist extension was similar (CP; n = 8; average 89.1° ± 9.6; TD; n = 9; 96.3° ± 7.7).

Significance: Reduced active wrist and elbow extension is apparent in children with CP less than five years old, even in the presence of full passive wrist extension. Early identification of movement restrictions during the first few years of a child's life, and subsequent targeted intervention, may help to improve the long-term functional outcomes for children with CP.

7.7 Introduction

Cerebral palsy (CP) occurs as a result of a non-progressive injury to the developing brain, causing a group of disorders that affect movement and posture [1]. Motor impairments to the upper limb are common to varying degrees, and may include spasticity, muscle weakness, loss of selective motor control, co-contraction of muscles, and secondary changes to the musculoskeletal system [2-4]. Over time and with developmental growth, these impairments can result in reduced range of motion (ROM) at the wrist and elbow.

Three-dimensional motion analysis (3DMA) has provided valuable insight into the movement of the upper limb for children with CP, articulating the relationship between impaired active ROM and functional ability in children over 5 years of age [6-12]. During upper limb tasks, children with CP (>5 years) display reduced movement speeds, longer overall movement durations, and reductions in the smoothness and trajectory straightness of their movements compared to children without CP [7-9, 11, 13, 14]. Children with CP (5-15 years) also display reduced active wrist and elbow extension, and forearm pronation [7, 15, 16]. Beyond what is known from clinical experience, the evaluation of upper limb ROM in children with CP under the age of five years is limited. Given the first three years of life are considered most critical in terms of neurological development [18], early identification of impairment in active upper limb ROM is needed to facilitate timely intervention. This is particularly relevant given the plethora of evidence to support the functional consequences resulting from impaired active upper limb ROM in older children with CP [7-9, 11, 13-16].

What is known for this young age group is that a gradual onset of stiffness at the wrist can present within the first few years, which can lead to a progressive decrease in passive ROM over time [17]. Hedberg et al [17] investigated the retrospective longitudinal development of passive wrist ROM (n=771) and found that contracture development first appeared at the wrist (indicated by reductions in passive extension) between the ages of 1-3 years, and becoming significant at 4 years [17]. It is unclear, however, if reduced passive wrist ROM translates to limitations in active wrist ROM during functional tasks, but it is logical to presume a reduction in passive ROM will at least in part be linked with a reduction in active ROM. It also may be possible that identifying the amount of active ROM used compared to the amount of passive ROM available may allow for a more targeted intervention to improve or maintain the ROM that is used actively.

Aims and Hypotheses

The primary aim of this study was to compare peak active wrist and elbow extension and flexion, between young children with and without CP during movement tasks. The secondary aim compared the difference between peak *active* wrist extension and peak *passive* wrist extension. Based on what is known for older children with CP, it was hypothesised that compared to children without CP, children with CP (<5 years) would i) have reduced active wrist and elbow extension; ii) conduct tasks in a more flexed joint position; and iii) complete tasks using less of their available passive wrist extension.

7.8 Method

This cross-sectional study is reported following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [19]. Approval was obtained from the Human Research Ethics Committee of Perth's Children's Hospital (2014061) with reciprocal approval from Curtin University (RDHS-11-16). Informed consent was obtained from the parent/guardians.

7.8.1 Participants

Eligible children were those enrolled in the infant Wrist Hand Orthosis Trial (iWHOT) (U1111-1164-0647) (Perth, Western Australia). Children met the following eligibility criteria for the iWHOT at the time of recruitment; i) ≤ 3 years old with, or at risk of, CP, ii) persistent abnormal flexion postures of the wrist, and/or fingers/thumb, and iii) full passive wrist ROM [20]. Passive wrist extension was defined using the CP Follow-up Programme (CPUP) traffic light system, with good to normal wrist extension being ≥ 60° [17]. From a database of 20 enrolled children, 15 children were identified as being suitable by a senior occupational therapist and invited to partake. Five children were not deemed appropriate due to additional medical reasons or living in rural Western Australia. The iWHOT aimed to assess the effectiveness of rigid wrist-hand orthoses; therefore, children who underwent kinematic analysis may have received a wrist-hand orthosis as well as standard care. The involved upper limb was included for children with unilateral CP and for bilateral involvement the upper limb that was most active and that the child could most ably self-initiate movement was included as identified through consultation with the parents/guardian.

Children with CP were age-matched to a convenience sample of children without CP, who did not have a history of musculoskeletal or neurological disorders. The

dominant upper limb was included, as identified by the parent based on the upper limb the child used 'most frequently' in daily activity (i.e. during play and eating).

7.8.2 Instrumentation

3DMA

An 18 infra-red camera capture system (Vicon© Nexus; Oxford Metrics Inc., 250 Hz) and two optical Bonita™ cameras (Vicon© Motion Systems Ltd UK, 125 Hz) were used. The marker set comprised of 16 spherical retro-reflective markers (4 mm diameter) affixed to the hand, forearm and shoulder using double-sided tape. Placement of the markers, by the same investigator, followed a modified version of the University of Western Australia's upper limb model [21].

Goniometer

Passive wrist extension with fingers extended was measured using a 15cm two-axis goniometer (Elite Medical Instruments, Fullerton, California).

7.8.3 Experimental procedure

Participants attended the Motion Analysis Laboratory at Curtin University once between January and August 2018. Markers were placed on the upper limb specific to bony landmarks. Children were seated in a highchair, height adjustable table with hips and knees flexed at approximately 90°, wheelchair at a height adjustable table, or the parent's lap. Seating was dependent on age, independence, and postural stability, with the aim to achieve an upright posture with the arms free to move.

Passive ROM

Passive wrist extension was completed by an assistant (final year physiotherapy or sport science degree) and an occupational therapist (CW). The assistant moved the wrist until end range was achieved and CW aligned the goniometer axis with the triquetrum, the dynamic arm with the longitudinal axis of the 5th metacarpal bone, and static arm with the longitudinal axis of the ulnar.

Active ROM

Children completed four movement tasks which consisted of 'playing' with four toys (detailed in Table 7.3) to elicit maximum active movement of the wrist and elbow, with a focus on wrist extension. The toys were piloted with six children without CP and selected in consultation with the authors of the Mini-Assisting Hand Assessment [22] and the Hand Assessment for Infants [23].

The same occupational therapist (CW) administered the tasks in a randomised order. Guidelines were developed and followed to ensure the toys were presented to elicit greatest wrist and elbow extension (Table 7.3), and each child had equal opportunity to demonstrate the movements. For continuity, 3DMA data were collected for approximately two minutes for each task (i.e. the flow of the child's play was not disrupted) and the toys were offered again after all four tasks were completed.

Table 7.3 Description of the toys and their placement to elicit movements of interest

Abbreviated Task	Toy	Desired movement	Description
Frog	Velcro frog with removable ball	Wrist and elbow extension	The ball was placed on the Velcro frog to allow the child to pull it off. The frog was held at arm's length away from the child to encourage the child to reach out and grasp/touch ball. If the child was able to grasp and pull the ball off the frog, they were encouraged to place it back on the frog.
Beads Reaching	Plastic string beads	Wrist and elbow extension	The beads were held out vertically at an arm's length away from the child. The height was varied, encouraging the child to reach low, middle and high.
Beads Picking Up	Plastic string beads	Wrist and elbow flexion and extension	The beads were placed on the table in front of the child. The distance away from the child varied to elicit reaching close to body and away from the body. The child was asked to pick the beads up and place them in the therapist's hands.
Magnet	Magnetised fabric animal and a small white board	Wrist and elbow extension	The magnet board was held vertically at arm's length away from the child. The child was encouraged to pull off or touch the animal. If the child was able to pull the animal off the board, they were encouraged to place it back on.
Maraca	Wooden maraca	Wrist and elbow extension	The maraca was held out at an arm's length away from the child at varying heights; low, medium and high. The child was encouraged to reach and grasp the maraca.

7.8.4 Data Processing

Passive ROM

Passive ROM measurements were recorded, with group means and standard deviations (SD) calculated.

Active ROM

The 3DMA data were visually inspected and a maximum of three samples of representative movement (referred to as 'trials') were selected from the two minutes of data captured for each task. The representative trials were selected if: i) active movement was self-initiated (i.e. no passive assistance from the occupational therapist); ii) at least one segment moved (i.e. upper arm, forearm, and/or hand); and iii) movement was related to the task (e.g. video was inspected to ensure it was not during a unrelated activity). Observation of wrist extension was the priority when selecting the movement trials. The repeated trial was accessed when representative movement was not sufficient due to: i) occlusion/drop out of markers, and/or ii) the child was distracted or not interested in the toy.

Vicon Nexus 2.7 software was used to process (label and interpolate) the data (Oxford metrics, Oxford, England). A fourth-order zero-lag Butterworth low-pass filter (4Hz for children with CP, 4 Hz TD children; determined using residual analysis) was used to filter marker trajectories. A customised LabVIEW program (National Instruments, Austin, Texas) output total active ROM (difference between minimum and maximum angles), and minimum/maximum joint angles for the wrist and elbow (flexion/extension). Extension (negative) and flexion (positive) joint angles were output relative to anatomical zero position.

7.8.5 Statistical analysis

The mean difference (CP minus TD), SD and 95% CI of the mean difference were calculated. Independent *t*-tests assessed the differences in ROM between groups (alpha set at 0.05). Hedges G estimated the effect sizes due to the unequal and small sample sizes, and interpreted using the criteria: ≤ 0.2 = small effect, 0.5 = medium effect and ≥ 0.8 = large effect. Statistical analyses were performed with SPSS Statistics 23.0 (SPSS Inc., Chicago, Illinois).

7.9 Results

Ten children with CP took part in the study. Reasons for declining participation included; i) other medical concerns (i.e. scheduled surgery or recent hospital admissions), or ii) other therapy engagements and appointments. Data from two children with CP were excluded due to not demonstrating active self-initiated movement during the session, and due to drop out of markers precluding the processing of data.

Data from 18 children were analysed; 8 children with CP (mean age 3.5 ± 1.0 years; Mini-Manual Ability Classification or Manual Ability Classification II to IV) (Table 7.4) and 10 children without CP (mean age 3.4 ± 1.1) (Table 7.5). Four children with CP received Botulinum Neurotoxin Type A (BoNT-A) injections to the upper limb within the period of 6 months prior to 3D kinematics being collected, one child received BoNT-A to muscles that would impact the wrist ROM (Table 7.4). In addition to receiving standard care, four children had rigid wrist-hand orthoses for nocturnal wear as per their allocation in the iWHOT and three children had BoNT-A and orthosis wear (Table 7.4).

Table 7.4 Characteristics of children with CP

Child	Anatomical Presentation	Arm	Mini MACS	GMFCS	Gender	Age (years)	Passive wrist extension (fingers ext)	Allocation in iWHOT*	Seating
1	Uni	Left[a]	III	I	Male	2.8	86°	No orthosis	Highchair
2	Uni	Left	III	I	Female	2.4	83°	Orthosis	Highchair
3	Uni	Left[b]	II	I	Male	3.6	79°	No orthosis	Highchair
4	Bi	Left	IV	V	Male	2.5	93°	No orthosis	Parents lap
5	Uni	Right[c]	II	I	Female	3.1	109°	Orthosis	Chair at a table
6	Bi	Left[d]	IV	IV	Male	3.7	82°	Orthosis	Highchair
7	Uni	Left	II†	I	Male	5.1	94°	Orthosis	Chair at a table
8	Bi	Right[e]	IV†	V	Female	4.8	87°	No orthosis	Parents lap
Total	**Uni: 5** **Bi: 3**	**Right: 2** **Left: 5**	**II: 3** **III: 2** **IV: 3**	**I: 5** **II: 0** **III: 0** **IV:1** **V: 2**	**F: 3** **M:5**	**3.5 ± 1.0**	**89.1° ± 9.6°**	**Orthosis: 4** **No orthosis: 4**	

Uni = Unilateral, Bi = Bimanual, Mini MACS = Mini Manual Ability Classification, GMFCS = Gross Motor Functional Classification Scale, ext = extension, iWHOT = infant Wrist Hand Orthoses Trial, Botulinum Neuro Toxin Type-A = BoNT-A.

†Manual Ability Classification (MACS) was completed due to the child's age.

*allocation to orthosis or control group in the iWHOT was randomised.

[a] Received BoNT-A to infraspinatus (10 units), triceps (10 units), brachialis (10 units); 10.9 weeks prior.

[b] Received BoNT-A to pronator teres (5 units), flexor carpi ulnaris (5 units); 16.4 weeks prior.

[c] Received BoNT-A to brachialis (5 units), flexor pollicus brevis (5 units), adductor pollicus (5 units); 25.7 weeks prior.

[d] Received BoNT-A to brachialis (15 units), triceps (15 units); 15.7 weeks prior.

[e] Received BoNT-A to subscapularis (10 units); 16.0 weeks prior.

Table 7.5 Characteristics of children without CP (TD)

Child	Arm	Gender	Age (years)	Passive wrist extension (fingers ext)	Seating
1	Right	Male	4.2	94°	Chair at a table
2	Right	Male	4.8	97°	Chair at a table
3	Right	Female	4.2	91°	Chair at a table
4	Right	Male	4.8	91°	Chair at a table
5	Right	Male	3.1	98°	Chair at a table
6	Right	Male	3.0	-	Highchair
7	Right	Female	1.8	98°	Highchair
8	Left	Male	4.1	94°	Chair at a table
9	Right	Female	2.5	89°	Chair at a table
10	Right	Female	1.8	115°	Highchair
Total	**Right: 9** **Left: 1**	**F: 4** **M: 6**	**3.4 ± 1.1**	**96.3° ± 7.7°**	

Comparison between children with and without CP

No physical assistance was provided from the occupational therapist or parent. Joint angles were calculated for the wrist and elbow in the sagittal plane (flexion and extension). Table 7.6 outlines the minimum and maximum values and the total active ROM (defined as maximum flexion to maximum extension).

Passive wrist extension (end range)

Children with and without CP (n = 8) on average had similar passive wrist extension, 89.1° (SD: 9.6) and 96.3° (SD: 7.7) respectively.

Active wrist ROM

Extension of the wrist is denoted by a negative sign (-) (Figure 7.3).

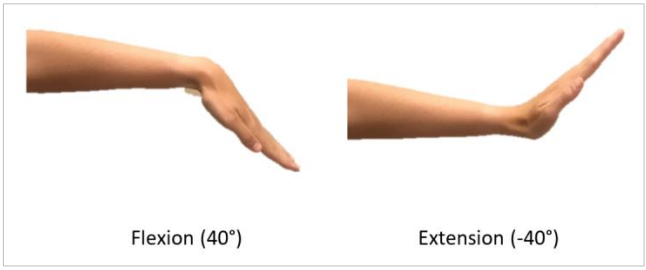

Figure 7.3 Example of wrist flexion and extension

Children with CP used more wrist flexion during the frog (mean difference = 27.8°; 95% CI = 13.1 to 42.5) and magnet (mean diff = 20.8°; 95% CI = 2.5 to 39.1) tasks, and less wrist extension during the frog (mean diff = 24.4°; 95% CI = 11.6 to 37.3), beads reaching (mean diff = 16.9°, 95% CI = 2.3 to 31.5), maraca (mean diff = 18.3°; 95% CI = 1.3 to 35.4) and magnet (mean diff = 10.2°; 95% CI = 0.4 to 20.1) tasks.

Active elbow ROM

Hyper-extension of the elbow denoted by a negative sign (-) (Figure 7.4).

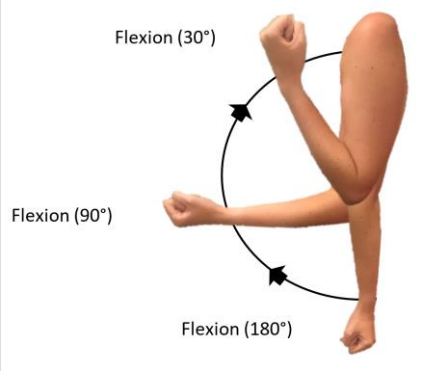

Figure 7.4 Example of elbow flexion, note that movement beyond 180° of Flexion at the elbow joint moves the elbow into hyperextension

The largest difference between groups for total elbow ROM was recorded in the frog task (mean diff = -28.7°; 95% CI = -42.4 to -15.8). Children with CP used less elbow extension during the frog (mean diff = 27.4°; 95% CI = 9.4 to 45.4) and picking up beads (mean diff = 19.1°; 95% CI = 2.4 to 35.8) tasks.

Comparison of peak passive and peak active wrist extension

On average, children with CP completed the tasks using the first 26° (SD: 15) or 28% of their available passive wrist extension, compared to children without CP who used 42° (SD: 13) or 44% of their available wrist extension.

Table 7.6 Mean (SD) for the discrete joint angles (degrees) of children with and without CP; and mean difference (95% Confidence Interval (CI)) and p value of the group comparison.

Toy/Movement	Without CP mean (SD)	CP mean (SD)	Mean diff (95% CI)	*p*	Effect size (Hedges G)
Frog					
Wrist Flex (max)	10.7 (7.5)	38.5 (20.4)	27.8 (13.1 to 42.5)	0.001	1.81
Wrist Ext (min)	-50.8 (9.9)	-26.3 (15.7)	24.4 (11.6 to 37.3)	0.001	-1.83
Wrist ROM	61.4 (9.3)	64.8 (20.1)	3.4 (-11.7 to 18.5)	0.641	0.22
Elbow Flex (max)	116.2 (19.0)	114.9 (21.2)	-1.3 (-22 to 19.4)	0.894	-0.06
Elbow Flex (min)	35.4 (15.4)	62.8 (19.3)	27.4 (9.4 to 45.4)	0.005	1.50
Elbow ROM	80.8 (11.9)	52.1 (14.4)	-28.7 (-42.4 to -15.8)	0.000	-2.08
Beads – Reach					
Wrist Flex (max)	31.3 (21.4)	30.7 (21.0)	-0.6 (-21.9 to 20.7)	0.953	-0.03
Wrist Ext (min)	-38.3 (13.0)	-21.4 (16.3)	16.9 (2.3 to 31.5)	0.026	-1.11
Wrist ROM	69.6 (27.0)	52.0 (18.7)	-17.5 (-41.4 to 6.3)	0.139	-0.71
Elbow Flex (max)	102.5 (11.9)	94.6 (28.0)	-7.9 (-28.6 to 12.8)	0.432	-0.37
Elbow Ext (min)	31.2 (13.6)	43.8 (23.9)	12.6 (-6.3 to 31.6)	0.177	0.64
Elbow ROM	71.3 (23.2)	50.8 (24.8)	-20.5 (-44.5 to 3.6)	0.090	-0.82
Beads - Picking Up					
Wrist Flex (max)	32.9 (17.9)	27.8 (17.6)	-5.1(-23.5 to 13.3)	0.563	-0.27
Wrist Ext (min)	-32.1 (13.6)	-23.1 (15.7)	9.0 (-6.1 to 24.1)	0.224	-0.58
Wrist ROM	65.1 (9.6)	51.0 (21.5)	-14.1 (-30 to 2.8)	0.095	-0.82
Elbow Flex (max)	88.4 (15.0)	108.8 (27.6)	20.4 (-3.9 to 44.7)	0.093	0.88
Elbow Flex (min)	39.5 (7.2)	58.6 (20.5)	19.1 (2.4 to 35.8)	0.028	1.21
Elbow ROM	48.9 (13.8)	50.2 (30.5)	1.27 (-24.5 to 27.0)	0.917	0.05
Maraca					
Wrist Flex (max)	16.2 (5.6)	26.0 (24.0)	9.9 (-6.7 to 26.4)	0.223	0.57
Wrist Ext (min)	-43.6 (15.7)	-25.3 (18.4)	18.3 (1.3 to 35.4)	0.037	-1.03
Wrist ROM	59.8 (13.4)	51.3 (13.4)	-8.5 (-21.9 to 5.0)	0.201	-0.61
Elbow Flex (max)	102.1 (12.0)	102.5 (16.5)	0.4 (-13.8 to 14.7)	0.949	0.03
Elbow Flex (min)	37.8 (14.7)	54.9 (26.0)	17.1 (-3.5 to 37.6)	0.098	0.80
Elbow ROM	64.2 (21.6)	47.6 (16.8)	-16.6 (-36.3 to 3.1)	0.093	-0.80
Magnet					
Wrist Flex (max)	11.0 (16.1)	31.9 (20.6)	20.8 (2.5 to 39.1)	0.028	1.10
Wrist Ext (min)	-43.0 (7.4)	-32.7 (12.2)	10.2 (0.4 to 20.1)	0.042	-1.02
Wrist ROM	57.0 (11.8)	64.6 (15.9)	7.6 (-6.3 to 21.4)	0.264	0.53
Elbow Flex (max)	107.7 (16.3)	114.0 (14.6)	6.3 (-10.1 to 22.8)	0.425	0.38
Elbow Flex (min)	46.4 (14.0)	46.9 (24.8)	0.5 (-19.5 to 20.5)	0.957	0.02
Elbow ROM	61.3 (13.2)	67.1 (30.7)	5.8 (-17.2 to 28.8)	0.599	0.28

max = maximum, min = minimum, ROM = range of motion, flex = flexion, ext = extension Note: negative effect sizes indicate ROM used is greater in children without CP.

7.10 Discussion

This study examined the differences in wrist and elbow ROM between young children with and without CP. The primary aim was to capture active movement of the wrist and elbow during movement that focused on provoking wrist extension. As

hypothesised, limitations in active extension of the wrist and elbow were found for children with CP younger than five years of age. The secondary aim was to compare peak active wrist extension relative to the available peak passive wrist extension. Despite both groups having full passive wrist extension, children with CP completed the tasks using a smaller amount of their available wrist extension compared to children without CP.

The most discernible difference was noted for active wrist extension, with children with CP displaying a reduction in peak passive wrist extension between 9° and 24° across the upper limb movement tasks. This reiterates that musculoskeletal changes begin to occur early and can impact active movement even in the presence of full passive wrist extension. The young children with CP use more wrist extension than what is reported elsewhere for older children (5 – 15 years) [7]. Though it may be that the younger cohort of children are yet to demonstrate significant limitations in active ROM, it is also possibly owing to explicitly including movement/play tasks to promote wrist extension, suggesting the toys did what was intended in terms of provoking active wrist extension.

Young children with CP were found to complete tasks with more elbow and wrist flexion than children without CP. This is not surprising given that flexion deformity is a common impairment and it is well documented that older children with CP (5 – 18 years) complete tasks with more wrist flexion and less elbow extension [7, 9, 15, 16] which translates to functional consequences such as reduced ability to reach, weakened grip strength and compensatory trunk and shoulder movements. It is concerning that the flexion pattern is already evident in young children with CP during active movement, which highlights the need for early surveillance of upper limb ROM to ensure timely referral for early intervention to minimise future the functional consequences.

This study also found that young children with and without CP used a similar amount of total wrist active ROM (flexion + extension) despite children with CP having reduced active wrist and elbow extension. This finding is consistent with what is reported for older children with CP (>5 years of age) [7, 12]. Young children with CP used more active wrist flexion during the play session, evident even in tasks that aimed to explicitly elicit wrist extension (i.e. frog task). Children with CP also used, on average, between 9.0° and 24.4° less wrist extension than children without CP. Not using the available active extension of the wrist and elbow in one activity, or only occasionally, is unlikely to be problematic. However, habitually not using the available range is likely to contribute to a loss of passive and active ROM over time. Therapeutic intervention therefore may need to encourage children to move through all their available ROM.

The available passive wrist extension in children with and without CP was similar, which is reassuring, and expected, in this age group. Decreased passive ROM (and potentially subsequent contracture) are proposed to develop throughout childhood when there is an imbalance of bone to muscle growth and subsequent secondary musculoskeletal changes [17]. It is likely, therefore, that the structural adaptations were yet to have developed in the young children with CP in this study, who were aged between two and five years. In support of this concept, structural deformities impacting hand function are reported to occur in the wrist around the age of four years [17, 25], and only two children in this study were over the age of four.

7.11 Strengths and limitations

Measuring upper limb kinematics in this age group is not without its challenges. Despite careful camera placement, there was occlusion of some markers by body parts or toys. The ability to follow direction and tolerate the assessment procedure also influenced data capture, with some children attempting to remove the 3D markers. To compensate for potential loss of data, each movement task was repeated twice.

Sample size was small, though comparable to other studies that have investigated 3D kinematics in children with CP [7-15] and was sufficient to detect the medium-large effect sizes. The sample was one of convenience so it is unclear if findings can be generalised, particularly given the heterogeneity of the small sample. Peak movement variables were the focus; as such, differences in joint angle along the movement path were not explored. The same start and end point for each movement was not possible, nor would we expect a fixed movement trajectory in the play tasks. Therefore, data were not time normalised as they are in kinematic studies including older children with CP.

Children with CP received a range of upper limb interventions (e.g. orthoses and BoNT-A) which may have impacted their ROM. Outcomes of this study, therefore, do not reflect the natural progression of CP; though they are reflective of clinical reality. It would be rare, particularly with the recognition of the importance of early intervention, for children with CP living in a large metropolitan city in Australia, to not be receiving upper limb intervention targeted at improving or maintaining ROM.

7.12 Conclusion

Most of what we know about upper limb movement in CP is derived from children over the age of five years. To our knowledge, this is the first study to use 3DMA to quantify upper limb joint ROM in young children with CP. In doing so, restrictions in active wrist and elbow ROM have been identified, with children with CP demonstrating restricted maximum active wrist and elbow extension during functional tasks compared to age matched children without CP. Restrictions in range were more pronounced in the wrist than the elbow. Early identification of active movement restrictions during the first few years of a child's life, and subsequent intervention, may improve the long-term functional outcomes for children with CP.

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Chapter Eight

8

Synthesis of Results

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Chapter Eight provides an overall synthesis and summary of the key findings of this body of research. The strengths and limitations, significance of the findings, future avenues for research and clinical implications will be discussed in this chapter.

8.1 Summary

Cerebral palsy (CP) is a health condition that describes an array of motor impairments that are caused by a static encephalopathy in the immature brain.[1] Secondary to spasticity, a myriad of adaptive changes to the musculoskeletal system in the upper limb can ensue.[4,7] Upper limb range of motion (ROM), particularly wrist extension, can be restricted to varying degrees.[14,16] There is research evidence to suggest that reductions in passive wrist extension manifest in the first few years of life[13], however, documented evidence of early impaired active ROM, beyond what is clinical knowledge, is limited for children with CP younger than 5 years of age.

Measurement of passive ROM using the goniometer can provide an indication of muscular shortening and thus subsequent development of contracture.[60] Obtaining measurements of passive wrist and/or elbow extension in young children with CP can be challenging, and, even when achieved, does not provide a true indication of the child's functional limitations. Further to this, measurement of passive wrist and elbow ROM in children with CP younger than 5 years using the goniometer is yet to be established as reliable. Not only are there inherent limitations in obtaining measurement of passive ROM, but there is currently no tool that can objectively measure active joint ROM in young children with CP. Given the importance of early identification of muscular changes, attention is shifting to new measurement tools that can be used accurately and reliably in this age group to assist with clinical assessment and treatment planning. The application of wearable sensors may offer a potential solution. The popularity of wearable sensors is owed to their portability, their relatively small size and low cost compared to traditional laboratory based motion capture systems, but can they be used with young children with CP?

This research focused on the International Classification of Functioning Health and Disability (ICF) domain of *body functions and structure*, with the overall purpose to investigate the development, feasibility and accuracy of wearable sensors to measure wrist and elbow ROM in young children (<5 years) with CP. The research problem was addressed by first undertaking a systematic review of literature, followed by four original studies. To outline the development and feasibility of the wearable sensors and play

session, a feasibility framework proposed by Bowen et al[40] was utilised. Subsequent study design and tool development was further guided by the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN)[41] where relevant. The COSMIN was selected due to being a comprehensive and evidence-based framework that is widely used by health professionals to examine the rigour of clinical tools.

Investigating the use of wearable sensors poses the idea of a tool that can objectively measure impairment at the level of *body functions and structure*. Given one of the favourable aspects of wearable sensors are their portability and ability to be used in various environments, there is also considerable future applicability for the measurement of ROM within the context of the *activity* domain of the ICF.

8.1.1 Chapter Three: Study One

Title: *Measurement of upper limb joint angle using wearable sensors: A systematic review.*

A systematic review of literature was undertaken to establish the evidence for the use of wearable sensors to measure joint ROM in the upper limb. This review synthesised research that reported on the: i) characteristics of commercial and custom wearable sensors systems (i.e. size, sample rate), ii) the populations wearable sensors had been used with, and iii) their established psychometric properties.

The key findings from this systematic review were:

- The size, weight, sample rate and placement of the wearable sensors on the upper limb varied across studies.
- The smallest wearable sensors from the main commercial brands were; Xsens (L 38 x W 53 x H 21 mm), ADPM Opal (L 43 x W 39.7 x H 13.7 mm), and Shimmer (L 51 x W 34 x H 14 mm).
- The wearable sensors were predominantly used with adult populations, with one study reporting their use with children.
- Collectively, wearable sensors achieved error <2.9° when compared to a robotic device for simulated movement of the wrist and elbow in all degrees of freedom.
- Higher error margins were reported when the wearable sensors were used *in vivo* and compared to pseudo gold standards (i.e. 3DMA) likely owing to the complexity of the movements. Error <5° was possible with a high level of software customisation (i.e. filtering and algorithms).

- Using wearable sensors 'off the shelf' may result in more error than what was reported in this review due to the high level of software customisation that occurred within the studies.

The systematic review revealed an adequate level of accuracy to support the use of wearable sensors to measure joint ROM in the wrist and elbow of adults. Commercially available (i.e. 'off the shelf') wearable sensors had elements of the software that were customised to achieve low error margins. The absent reporting of the use of wearable sensors with children was highlighted, with further research required to determine if the size of the available wearable sensors was a limitation to their use with this population.

8.1.2 Chapter Four: Study Two

Title: *Exploring the development of prototype custom wearable sensors and the feasibility of their use to measure upper limb joint range of motion in children with cerebral palsy.*

In children with CP, the measurement of upper limb joint ROM using wearable sensors is an area of research that, until now, had not been explored.[28] As identified in the systematic review, the size of commercially available wearable sensors likely prevented the uptake with children. This was confirmed after trialling several commercial branded wearable sensors on the hands of young children. The size of the commercial wearable sensors covered the entire dorsum of the hand, and restricted peak passive and active extension of the wrist. As such, an alternative avenue of developing small custom wearable sensors was explored.

Chapter Four adopted a feasibility framework[40] to document the trans-disciplinary approach to the development and pilot of three versions of custom wearable sensors to measure joint ROM in the upper limb of children.

The key findings specific to each version of the wearable sensors are as follows:

Version 1 (V1)

- V1 was smaller than most commercial wearable sensors outlined in the systematic review, but were still too large for use with young children. Peak passive and active wrist extension was restricted and the dorsum of the hand was almost entirely covered, which resulted in a deviation to the placement protocol and further complicated the processing of data.

- Children tended to favour use of the arm without the wearable sensors possibly due to the weight and bulkiness.
- Incorrect placement of internal components and loose internal wiring within the wearable sensors resulted in loss of data.
- Sophisticated algorithms needed to be developed to mitigate the effects of drift.

Version 2 (V2)

- V2 were smaller but required the use of multiple android devices to collect data which limited the user-friendliness, practicality and cost effectiveness of the system.

Version 3 (V3)

- The size did not restrict active wrist extension in the children they were piloted with, however there was potential for the hand and forearm wearable sensor to come into contact and restrict peak passive wrist extension in young children with small hands.
- The development of sophisticated algorithms and new design eliminating the need for internal wiring resulted in the stable and reliable collection of data with minimal loss.

The development and feasibility testing occurred over a three-year period and identified previously unreported factors that warrant consideration by clinicians and researchers when using wearable sensors with young children. The positive outcomes of V3 with young children supported the further investigation of their validity.

8.1.3 Chapter Five: Study Three

Title: *Validation of custom wearable sensors to measure angle kinematics: A technical report.*

Chapter Five established the accuracy of V3 wearable sensors comparing their output to known angles of robotic device. This has been undertaken in many published papers[125-128] with the purpose of determining the 'true error' associated with use of the wearable sensors without the influence of soft tissue artefact, an inevitable factor when used *in vivo*.

The key findings of this study were:

- V3 wearable sensors detected peak angles within 3° of a robotic device when one wearable sensor was static and the other was dynamic. This was designed to mimic passive movement of the wrist (i.e. the forearm is static, while the hand is moved at a constant controlled speed) which forms part of routine assessment for a large proportion of children with CP.
- Movement speed did not significantly influence the error of V3 wearable sensors when tested at two speeds which is promising as children's movement can be unpredictable or sporadic.

The ability of the wearable sensors to detect peak angles within accuracy of 3° across both experiments in this study was promising and warranted further investigation to measure upper limb joint ROM in children with CP.

8.1.4 Chapter Six: Study Four

Title: *Can wearable sensors be used as an alternative to the goniometer to measure passive wrist extension in children with cerebral palsy?*

Given the accuracy of the wearable sensors outlined in Chapter Five, Chapter Six explored whether wearable sensors could be an alternative to the most commonly utilised tool to measure joint ROM, the goniometer.

The key findings of this study were:

- Excellent agreement was found between the wearable sensors and goniometer for the measurement of passive wrist extension in older children (>5.75 years), suggesting potential uptake of these wearable sensors for this measurement.
- Poor agreement and wide confidence intervals were found for the younger children (<5.5 years). While it is difficult to ascertain the exact causes of variability for the younger children, factors related to the child, therapist and measurement tools are thought to play a significant role.
- A smaller RMS error and mean difference between the goniometer and wearable sensors was found for the measurement of passive wrist extension with fingers extended. This is believed to be largely owing to wrist extension with fingers flexed being a clinically easier measure to achieve especially in the presence of increased muscle tone.

For young children with CP, the results of this study questioned the applicability of wearable sensors, and in general the ability to accurately and reliability measure ROM given the inherent limitations with use of the goniometer. The use of wearable sensors with young children with CP in isolation is cautioned, with further investigation into the cause of poor agreement between tools warranted.

8.1.5 Chapter Seven: Study Five

Title: *A comparison of wrist and elbow kinematics in young children with and without cerebral palsy.*

Study Five utilised 3DMA to measure upper limb joint ROM in children with and without CP during a play session that used a variety of toys to provoke maximum movement of the wrist and elbow, with a particular focus on wrist extension.

The key findings of this study were:

- Similar to what has been established for older children with CP; this study demonstrated that children with CP younger than 5.1 years of age had notable differences in peak active wrist and elbow extension when compared to children without CP.
- In the presence of full passive wrist extension, children with and without CP were found to use a similar amount of total active ROM, however children with CP tended to use less of the available extension and more of their flexion range.

This study documented early active restrictions in wrist and elbow extension in children with CP less than 5.1 years of age, highlighting the need to identify early impairment and reiterating the importance of valid, reliable and readily available measurement tools that are capable of objectively measuring ROM in this age group.

8.2 Strengths and limitations

Strengths and limitations are discussed within each individual study of this thesis. In this section, the overall strengths and limitations of the thesis will be discussed, including the study design, research team, sample and populations, and data collection tools.

8.2.1 Study design/s

Feasibility and exploratory designs were used to investigate the development and use of new wearable sensors. These methods were appropriate to the stage of the development

and knowledge of the issue under investigation. Limitations to the use of wearable sensors with young/small children were identified in a systematic matter, with the results of early studies in this thesis informing future studies. This iterative approach resulted in a lengthy process to ensure satisfactory results were achieved in one study, prior to undertaking the next study. On occasion, the findings of one study changed the originally intended sequence and focus of the studies within the thesis.

8.2.2 Research team

This research involved multiple disciplines collaborating across three schools at Curtin University: i) School of Occupational Therapy, Social Work and Speech Pathology, ii) School of Physiotherapy and Exercise Science, and iii) School of Electrical Engineering, Computing and Mathematical Sciences, along with clinicians and researchers in two multi-centre trials across Australia. The different expectations and priorities that each discipline and team had for the wearable sensors, and differing terminology between disciplines, made communication complex and ultimately prolonged the development of the technology, highlighting the complexity of interdisciplinary work. An undeniable strength of this research is that researchers and clinicians across multiple disciplines were able to collaborate to turn an idea and concept into a product that could be tested for its clinical applicability. No discipline would be able to achieve what this thesis has in isolation, highlighting the value of trans-disciplinary partnerships.

8.2.3 Population and sample size

The recruitment of children with CP in this thesis occurred via the iWHOT and MiT, both of which had specific eligibility criteria for participation. Children with CP in the iWHOT were between 0-36 months at the time of recruitment, with a diagnosis of CP or identified to be at risk of CP, have abnormal wrist flexion postures and full passive ROM at the wrist.[21] Children with CP in the MiT had a confirmed diagnosis of CP, stiffness in the flexor muscles of the wrist and a score of ≥1 on the MAS at the time of recruitment.[20] Children with CP outside of these parameters are not represented in this thesis. Despite this, a heterogeneous sample of children with CP across most MACS and Gross Motor Function Classification Scale levels was achieved. Although a disproportionate number of children with CP classified by each level were assessed, the bias towards children classified by lower classification levels is representative of the population.[129]

Recruitment from the iWHOT and/or MiT means children with CP included in this thesis may have received rigid wrist-hand orthoses in addition to evidence informed standard care. For some children with CP, evidence informed standard care included upper limb BoNT-A. Rigid wrist-hand orthoses and/or BoNT-A are interventions that aim to improve or maintain upper limb ROM. Given this, efforts were made to note and report on individual participant's receipt of intervention that targeted wrist joint ROM which may have confounded outcomes of greater joint ROM. It needs to be acknowledged that this was not controllable, nor was this the intent, or within the scope, of the thesis. In Australia, it would be rare, particularly with the recognition of the importance of early intervention, for young children with CP to not be receiving some form of upper limb intervention. Although this is a reflection of clinical reality in Australia, the generalisability of findings from Study Five, to children with CP that do not receive upper limb intervention is also cautioned.

The feasibility studies within this thesis had a relatively small sample, however they were an adequate number to reflect the feasibility of the wearable sensors and to provide sufficient evidence to warrant future testing. Study Four was limited to data available in Western Australia and would have likely benefitted from analysis of a larger sample of data from other participating sites of the iWHOT and MiT. The inclusion of additional data might have allowed further analyses to more definitively define the age at which the wearable sensors showed less agreement. Study Five of this thesis is a kinematic study that included a sample of <10 children per group (with and without CP). Although comparable to many other kinematic studies (Reid et al[85] n=7, Elliott et al[130] n=16 (8 per group), Coluccini et al[89] n=5 CP, 5 dyskinetic movement disorders, Butler et al n=12[14]), this small sample is a limitation when studying heterogeneous populations.

8.2.4 Data collection tools

The goniometer does not have established validity and reliability to measure wrist joint ROM in children with or without CP less than 5 years of age. Despite this, the goniometer was considered both appropriate and highly relevant for inclusion within this study due to its frequent and often routine use in clinical practice to measure joint ROM. As a result, the data presented in this study requires interpretation with knowledge that error is associated with the use of the goniometer, and the error reported cannot be attributed to the wearable sensors in isolation. The utilisation of 3DMA in Study Five was based on the established accuracy reported in literature to measure joint ROM in adults and older children with CP. Similarly, results of Study Five need to be interpreted

with knowledge that error may be associated with use of 3DMA to measure upper limb joint ROM in young children and the extent of this error is currently unknown.

8.3 Significance of research

In an attempt to address the increasing need to accurately and objectively measure active and passive upper limb joint ROM for young children with CP, this thesis investigated the development and use of custom wearable sensors as a new measurement tool. Wearable technology is at the forefront of health innovation and has fast become one of the leading industries in the world. The uptake of wearable sensors in healthcare in particular has become increasingly pervasive as they offer a cheaper alternative to laboratory restricted movement analysis systems (i.e. 3DMA), and the potential to allow for unrestricted measurement or monitoring of performance.

Early intervention is an area of health care that has the potential to benefit from the use of wearable sensors, if they are able to contribute to identifying and monitoring early impairment within the *body functions and structure* domain of the ICF. Wearable sensors have considerable potential clinical utility to monitor active and passive upper limb joint ROM as the child grows, and to inform the efficacy of intervention. The objective measurement of active upper limb ROM has not been possible due to a lack of available tools that can be used with children under 5 years of age. This thesis aimed to capitalise on the rise of wearable sensor technology, and for the first time, lays the foundations for using wearable sensors to measure upper limb joint ROM in young children with CP. In doing so, it highlights favourable characteristics of wearable sensors that require consideration by end-users prior to their uptake with children, and simultaneously identifies limitations to their use with this population.

Within the *body functions and structure* domain of the ICF, wearable sensors have a promising future for the application with older children with CP to measure passive wrist extension. This research supports the future uptake of wearable sensors to measure passive wrist extension in children with CP >5.75 years, providing an alternative to the use of goniometry and increasing the repertoire of tools for clinicians to use. Despite the wearable sensors not being able replicate the same results when used with young children with CP, this thesis documented several challenges in measuring passive ROM in young children with CP which may inform future practice.

The objective measurement of active movement in young children with CP was found to be technically challenging, with the need for the hardware specifications of the

wearable sensors to reflect the population (i.e. the person and the specific body part) and movement tasks (i.e. speed of movement, and plane/s of movement) in which they intend to be used. The wearable sensors developed and tested within this thesis require more development and investigation prior to their application during active movement in young children. Despite this, an extremely promising outcome of this body of work was that the wearable sensors (V3) were shown to be feasible for use young children. In terms of feasibility, the wearable sensors were tolerated by children as young as 6 months of age when affixed on the upper limb and no adverse events were encountered with their use. This is encouraging and validates the potential applicability of using wearable sensors with children with CP younger than 5 years of age.

An appealing feature of wearable sensors is the potential to objectively measure active ROM during functional and everyday tasks. In clinical practice, information about ROM might be captured during tasks that are not particularly relevant or of interest to the child and therefore may not capture the child's true upper limb performance and capacity. The use of wearable sensors outside of the clinical environment during functional tasks that are relevant to the child may offer a more accurate and true reflection of performance and capacity. Therefore, although wearable sensors are principally a measure of impairment within the ICF domain of *body functions and structure*, their future use in the context of *activity* may contribute to a holistic depiction of the child's upper limb function.

Through the use of 3DMA, this thesis also documented early active upper limb movement restrictions in children with CP younger than 5 years of age, contributing to the paucity of literature that reports on measuring upper limb ROM in young children with CP. Notable differences in active extension of the wrist and elbow were identified. Given the implications that loss of joint ROM can have on upper limb function in older children with CP, the findings of this study reiterate the importance of monitoring active ROM in young children. The significance of the results of this particular study are twofold. The quantification of active upper limb joint ROM using 3DMA has shown to be possible with young children with CP, and may offer an alternative measurement tool for clinicians and researchers in the future, when accuracy for use with this population has been established. The findings of this study also warrant further research into the use of wearable sensors with this age group, particularly as the technological capabilities of wearable sensors continue to advance. The ability to detect and objectively measure

early movement restrictions may facilitate the ability to intervene early and ultimately improve the functional outcomes of children with CP long-term.

This thesis provides valuable insight into the development of wearable sensors and their feasibility to measure upper limb joint ROM in young children with and without CP. In doing so, it has contributed to the evidence-base by establishing key areas for improvement and areas of future development that are required if wearable sensors are to be used with young children.

8.4 Directions for future research

This thesis articulates the challenges of accurately and reliably measuring upper limb joint ROM in young children with and without CP. Beyond the challenges of using wearable sensors with young children, this thesis also acknowledges the inherent difficulty in obtaining a reliable measure of passive wrist extension using the goniometer and the challenges of using 3DMA with young children. Although this body of work simultaneously highlights the importance of early surveillance of active ROM in the upper limb, the solution of how to accurately and reliably do so in this young age group remains unanswered. The foundations for the use of wearable sensors with young children, from a clinical perspective, are outlined in this thesis and overall indicate that wearable sensors are feasible and tolerated when affixed on the upper limb; a positive outcome that indicates the possibility of a future for the use of wearable sensors with young children. However, a substantial amount of additional research is warranted and should capitalise on the foundations outlined in this thesis prior to their uptake in clinical practice.

Prior to further psychometric testing, the foremost recommendation for these custom wearable sensors is to increase their accelerometer reading. Increasing the accelerometer reading will ensure fast and unpredictable movements, often seen in young children during play tasks, are captured in their entirety. The lower accelerometer reading was a major limitation of the current wearable sensors used in this thesis and precluded the collection of active upper limb joint ROM in the final study. Secondary to this, from a clinical, rather than engineering perspective, the following recommendations are made:

In regards to the hardware:

- Reduce the size of the wearable sensors, particularly the height. Reducing the height may prevent the wearable sensors contacting each other in passive and active wrist extension in the very young children.
- Robust and rigid casing is required that can withstand: i) frequent travel and manual handling, and ii) the unpredictable behaviour of children. The casing of V3 wearable sensors was repaired on a number of occasions which delayed the collection of data.

Recommendations for the hardware, from an engineering perspective, are outlined in a related doctoral thesis.[42] Those recommendations aim to increase the stability of the internal components of the wearable sensors to ensure the collection of data with minimal loss.[42]

In regards to the software associated with the collection and analysis of the data, the following are recommended for clinical use:

- Visual feedback of real-time live data collection. Whether that be in the form of a graph (y axis joint angle and x axis time) and/or animation of the data.
- Data processing features to enable the processing of data without the need to upskill in MATLAB® codes. Ideally, software that can process and report movement parameters of interest (i.e. peak wrist extension) immediately or shortly after the movement. This feature ensures that data were collected and enables the clinician to provide immediate feedback to the child and family, or record the results for further interpretation.

The challenges of post processing the wearable sensor data have been clearly articulated in this thesis as being a significant barrier to their use. The software features outlined above are recommended if wearable sensors are to be adopted in a busy clinical setting, and are the features that would be available to clinicians if a commercial wearable sensors system was to be used. The recommended changes to the hardware and software will enhance the feasibility and overall clinical utility of the wearable sensor system for end-users.

Once newly engineered wearable sensors have been developed, psychometric testing of the revised wearable sensors is required. It is recommended that the measurement properties reported in this thesis are re-tested and where relevant, the COSMIN guidelines[41] should be followed. Criterion-related validity remains difficult

when there is no true gold-standard for comparison[41], however as undertaken in this thesis, efforts should be made to delineate the error of the wearable sensors against the best available (i.e. robotic device and 3DMA) and what is used clinically (i.e. goniometer). Prior to *in vivo* testing, the wearable sensors should be subject to conditions that account for high movement speeds of young children. After this, the wearable sensors should be tested *in vivo* to determine the validity (concurrent) and reliability (inter and intra rater reliability) of the wearable sensors. *In vivo* testing should include a heterogeneous group of children with different clinical presentations of CP and the COSMIN guidelines recommend a sample size of at least 50 participants.[41]

In addition to measuring wrist and elbow flexion and extension, the measurement of other distal upper limb movements should also be explored. For children with CP, it is also common to see limitations in active forearm supination, as well as persistent ulnar deviation.[13] Wearable sensors have the potential to be feasible to measure these movements, however extensive testing, as outlined above, is required prior to doing so. Typically, measurement of joint ROM in this population occurs in a single plane of movement despite limitations occurring across multiple planes of movement (i.e. wrist extension, ulnar deviation, and forearm supination). Consideration as to whether wearable sensors can accurately capture joint ROM occurring in multiple planes of movement in this young population is warranted and may provide a more rounded picture of upper limb function.

This thesis demonstrated that wearable sensors have considerable potential to measure upper limb joint ROM in children with CP. At the time of this thesis, no commercial branded wearable sensors were suitable for use on the upper limb of young children. With technology rapidly evolving, commercial brands are likely to be closer to the development of a small wearable sensor and associated software in the near future. In the meantime, and building on from the research outlined in this thesis, the accuracy and reliability of the wearable sensors will continue to be explored.

In terms of the play session, further research is warranted to determine if the play session using the specific toys and following the developed protocol can repeatedly elicit wrist extension in young children with CP. In doing so, the play session could be an option for clinicians to utilise to monitor and promote maximal active wrist and elbow movement in young children with CP.

Given that reduced peak active wrist and elbow extension has now been identified in young children with CP, future research should continue to be directed towards the early assessment of upper limb ROM. Early identification of movement restrictions promotes early intervention within the *body functions and structure* domain of the ICF, and may help to facilitate better long-term functional outcomes for children with CP.

8.5 Implications for clinical practice

The findings of this thesis suggest that wearable sensors, custom or commercial, are currently not at a stage where they can be used accurately and reliably to measure active joint ROM in the upper limb of young children with CP (<5 years). The future use of wearable sensors, however, is promising. This body of work is the first to contribute to the development and use of wearable sensors with this population and launches the field into this advancement. Following on from this research and expertise in this area, the technological capabilities are likely to advance enough to the support their use with young children in the near future.

In the meantime, best practice for the objective measurement of active upper limb joint ROM in young children with CP remains unclear. 3DMA is not widely used with young populations to measure upper limb joint ROM, the psychometrics to support its use with children with CP <5 years is unknown, and the laboratory-based system is not easily accessible for clinicians. Despite this, active upper limb joint ROM should still be monitored and although objective measurement has proven to be difficult, clinicians can still gain subjective insight using standardised functional assessments such as the Hand Assessment for Infants[8] and the Mini-Assisting Hand Assessment.[38] Passive upper limb joint ROM should continue to be monitored using the goniometer, with the results interpreted carefully and with knowledge of measurement error.

For older children with CP, the wearable sensors (V3) presented in this thesis have demonstrated an acceptable level of accuracy compared to the goniometer for the measurement of passive wrist extension. This suggests V3 of the wearable sensors used in this thesis could be used clinically to obtain this measurement, however this is not recommended until the associated software is at the user-friendly stage of being able to process data during or immediately after it has been collected. The generalisation of the findings of V3 wearable sensors to other custom or commercial wearable sensors is not recommended. The systematic review completed in Chapter Three of this thesis reiterates, that currently, other custom or commercial wearable

sensors do not have established psychometrics to measure joint ROM in the upper limb of children (<18 years). Therefore, it is recommended that objective measurement of active and passive joint ROM in older children with CP continue to be obtained using the goniometer, or the former using 3DMA. Standardised assessments such as the Assisting Hand Assessment[39], Quality of Upper Extremity Skills Test[131], or the Melbourne Assessment of Unilateral Upper Limb Function[132] can be used to gain subjective information about active upper limb joint ROM.

8.6 Thesis conclusion

This thesis achieved its aim to investigate the development and use of small custom wearable sensors to measure upper limb joint ROM in young children with CP. The objective measurement of upper limb joint ROM in young children with CP was found to be challenging, but also necessary to detect early impaired movement. Although this body of work contributed to the evidence-base and lays the foundations for future research in this area, the question remains as to how measures of upper limb joint ROM can be achieved accurately and reliably in this age group. Wearable sensors, custom and commercial, are still largely in a developmental phase for use with children and more research is required prior to their uptake in clinical practice.

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APPENDICES

Appendix A Published Manuscripts

A.1 Measurement of upper limb range of motion using wearable sensors: A systematic review

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Sports Medicine - Open

SYSTEMATIC REVIEW Open Access

Measurement of Upper Limb Range of Motion Using Wearable Sensors: A Systematic Review

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Abstract

Background: Wearable sensors are portable measurement tools that are becoming increasingly popular for the measurement of joint angle in the upper limb. With many brands emerging on the market, each with variations in hardware and protocols, evidence to inform selection and application is needed. Therefore, the objectives of this review were related to the use of wearable sensors to calculate upper limb joint angle. We aimed to describe (i) the characteristics of commercial and custom wearable sensors, (ii) the populations for whom researchers have adopted wearable sensors, and (iii) their established psychometric properties.

Methods: A systematic review of literature was undertaken using the following data bases: MEDLINE, EMBASE, CINAHL, Web of Science, SPORTDiscus, IEEE, and Scopus. Studies were eligible if they met the following criteria: (i) involved humans and/or robotic devices, (ii) involved the application or simulation of wearable sensors on the upper limb, and (iii) calculated a joint angle.

Results: Of 2191 records identified, 66 met the inclusion criteria. Eight studies compared wearable sensors to a robotic device and 22 studies compared to a motion analysis system. Commercial ($n = 13$) and custom ($n = 7$) wearable sensors were identified, each with variations in placement, calibration methods, and fusion algorithms, which were demonstrated to influence accuracy.

Conclusion: Wearable sensors have potential as viable instruments for measurement of joint angle in the upper limb during active movement. Currently, customised application (i.e. calibration and angle calculation methods) is required to achieve sufficient accuracy (error < 5°). Additional research and standardisation is required to guide clinical application.

Trial Registration: This systematic review was registered with PROSPERO (CRD42017059935).

Keywords: Kinematics, Wearable sensor, Inertial movement unit, Joint angle, Motion analysis, Upper limb

Key Points

- Both commercially available and custom wearable sensors have some evidence of validity in the literature. Although commercial wearable sensors were validated against pseudo gold standards, each study customised the commercial software to do so.
- Wearable sensors demonstrated errors < 5° for all degrees of freedom at the wrist and elbow joints when compared to a robotic device. The range in error is greater when measured in vivo and compared to a pseudo gold standard.
- The measured errors are within margins that warrant future use of wearable sensors to measure joint angle in the upper limb.

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Background

Clinicians and researchers seek information about the quality and quantity of patients' movement as it provides

useful information to guide and evaluate intervention. Range of motion (ROM), defined as rotation about a joint, is measured in a variety of clinical populations including those with orthopaedic, musculoskeletal, and neurological disorders. Measurement of ROM forms a valuable part of clinical assessment; therefore, it is essential that it is completed in a way that provides accurate and reliable results [1, 2].

In clinical practice, the goniometer is a widely used instrument to measure ROM [2–4]. Despite being considered a simple, versatile, and an easy-to-use instrument, reports of reliability and accuracy are varied. Intra-class correlation coefficients (ICCs) range from 0.76 to 0.94 (intra-rater) [3, 4] and 0.36 to 0.91 (inter-rater) [4] for shoulder and elbow ROM. Low inter-rater reliability is thought to result from the complexity and characteristics of the movement, the anatomical joint being measured, and the level of assessor experience [5, 6]. The goniometer is also limited to measuring joint angles in single planes and static positions; thus, critical information regarding joint angles during dynamic movement cannot be measured.

In research settings, three-dimensional motion analysis (3DMA) systems, such as Vicon (Vicon Motion Systems Ltd., Oxford, UK) and Optitrack (NaturalPoint, Inc., Corvallis, OR, USA), are used to measure joint angles during dynamic movement in multiple degrees of freedom (DOF). Such systems are considered the 'gold standard' for evaluating lower limb kinematics, with a systematic review reporting errors < 4.0° for movement in the sagittal plane and < 2.0° in the coronal plane; higher values have been reported for hip rotation in the transverse plane (range 16 to 34°) [7]. Measurement in the upper limb is considered more technically challenging due to the complexity of shoulder, elbow, and wrist movements [8]. However, given the demonstrated accuracy in the lower limb, 3DMA systems are used as the 'ground truth' when validating new upper limb measurement tools [9]. However, 3DMA does have limitations. Most notably, these systems are typically immobile, expensive, require considerable expertise to operate, and therefore rarely viable for use with clinical populations [10, 11].

Wearable sensors, or inertial measurement units, are becoming increasingly popular for the measurement of joint angle in the upper limb [12]. In this review, we were interested in wearable sensors that contained accelerometers and gyroscopes, with or without a magnetometer, to indirectly derive orientation. The software typically utilised three main steps: (i) calibration, using two approaches: (1) system, also referred to as 'factory calibration' (offset of the hardware on a flat surface), and (2) anatomical calibration including both static (pre-determined pose) and dynamic (pre-determined movement) [10, 13]; (ii) filtering, using fusion algorithms including variations of the Kalman filter (KF) [14, 15]; and (iii) segment and angle definition, using Euler angle decompositions and/or Denavit-Hartenberg Cartesian coordinates.

Wearable sensors are an increasingly popular surrogate for laboratory-based 3DMA due to their usability, portability, size, and cost. Systematic reviews have detailed their use during swimming [16] and whole body analysis [17] and in the detection of gait parameters and lower limb biomechanics [18]. However, their validity and reliability must be established and acceptable prior to their application [19]. Accuracy of the wearable sensors is dependent on the joint and movement being measured; therefore, a systematic review specific to the upper limb is required. This study aimed to establish the evidence for the use of wearable sensors to calculate joint angle in the upper limb, specifically:

i. What are the characteristics of commercially available and custom designed wearable sensors?
ii. What populations are researchers applying wearable sensors for and how have they been used?
iii. What are the established psychometric properties for the wearable sensors?

Methods

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines [20] and registered with the International Prospective Register of Systematic Reviews on 23 March 2017 (CRD42017059935).

Search Terms and Data Bases

Studies and conference proceedings were identified through searches in scientific data bases relevant to the fields of biomechanics, medicine, and engineering, from their earliest records to November 1, 2016: MEDLINE via PROQUEST, EMBASE via OVID, CINAHL via EBSCO, Web of Science, SPORTDiscus, IEEE, and Scopus. Reference lists were searched to ensure additional relevant studies were identified. The search was updated on 9 October 2017 to identify new studies that met the inclusion criteria.

The following search term combinations were used: ("wearable sens*"OR "inertial motion unit*" OR "inertial movement unit*" OR "inertial sens*" OR sensor) AND ("movement* analysis" OR "motion analysis*" OR "motion track*" OR "track* motion*" OR "measurement system*" OR movement) AND ("joint angle*" OR angle* OR kinematic* OR "range of motion*") AND ("upper limb*" OR "upper extremit*" OR arm* OR elbow* OR wrist* OR shoulder* OR humerus*). Relevant MeSH terms were included where appropriate, and searches were limited to title, abstract, and key words. All

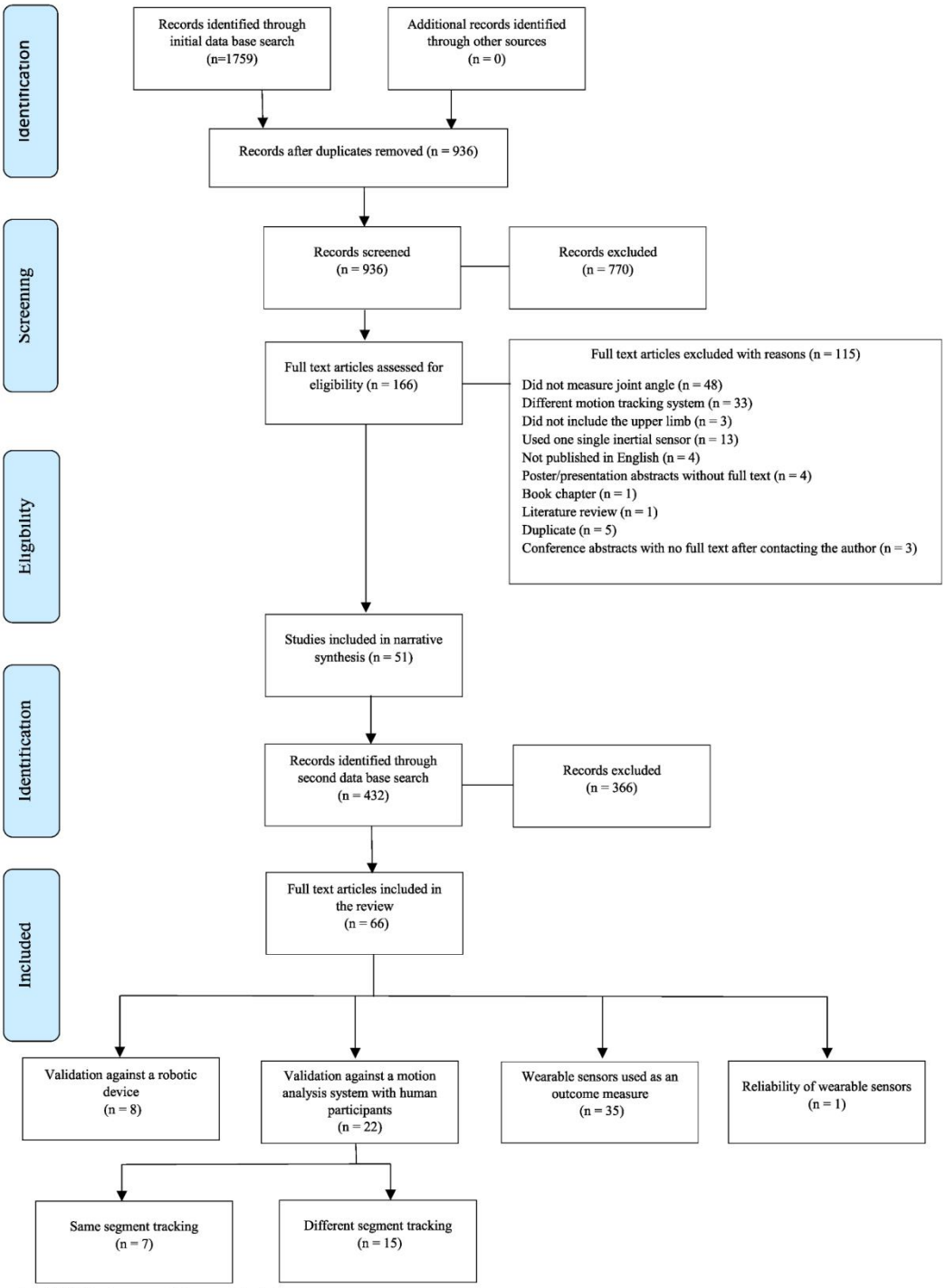

Fig. 1 A PRISMA diagram of the search strategy

references were imported into Endnote X6 (Thomson Reuters, Carlsbad, CA, USA), and duplicates were removed.

Study Selection Criteria and Data Extraction

The title and abstracts were screened independently by two reviewers (CW and AC). Full texts were retrieved if they met the inclusion criteria: (i) included human participants and/or robotic devices, (ii) applied/simulated use of wearable sensors on the upper limb, and (iii) calculated an upper limb joint angle. The manuals of commercial wearable sensors were located, with information extracted when characteristics were not reported by study authors. Studies were excluded based on the following criteria: (i) used a single wearable sensor, (ii) included different motion analysis systems (i.e. WiiMove, Kinetic, and smart phones), (iii) used only an accelerometer, (iv) calculated segment angle or position, (v) studied the scapula, or (vi) were not published in English.

Two reviewers (CW and AC) extracted data independently to a customised extraction form. Discrepancies were discussed, and a third reviewer (TG) was involved when consensus was not reached. Extracted parameters of the wearable sensor characteristics included custom and commercial brands, the dimensions (i.e. height and weight), components used (i.e. accelerometer, gyroscope, and magnetometer), and the sampling rate (measured in hertz (Hz)). Sample characteristics included the number of participants, their age, and any known clinical pathology. To determine if authors of the included studies customised aspects of the wearable sensors system, the following parameters were extracted: the type of calibration (i.e. system and anatomical), the fusion algorithms utilised, how anatomical segments were defined, and how joint angle was calculated.

To understand the validity and reliability of the wearable sensors, information about the comparison system, marker placement, and psychometric properties were extracted. The mean error, standard deviation (SD), and root mean square error (RMSE) reported in degrees were extracted where possible from the validation studies. The RMSE represents the error or difference between the wearable sensor and the comparison system (e.g. 3DMA system). The larger the RMSE, the greater the difference (in degrees) between the two systems. Further, to report on the validity of the wearable sensors, studies that did not delineate error between the wearable sensor and soft tissue artefact (movement of the markers with the skin) by not using the same segment tracking were not further analysed. Reliability was assessed using ICCs, with values < 0.60 reflecting poor agreement, 0.60–0.79 reflecting adequate agreement, and 0.80–1.00 reflecting excellent agreement [21].

The following parameters were used to guide the interpretation of measurement error, with $< 2.0°$ considered acceptable, between 2.0 and 5.0° regarded as reasonable but may require consideration when interpreting the data, and $> 5.0°$ of error was interpreted with caution [7].

Assessment of Risk of Bias and Level of Evidence

Due to the variability between research disciplines (i.e. health and engineering) in the way that studies were reported, and the level of detail provided about the research procedures, the available assessments of risk of bias and levels of evidence were not suitable for this review. Therefore, the following criteria were used to evaluate the quality of the reporting in the included studies:

- The aim of the study was clear and corresponded to the results that were reported.
- The study design and type of paper (i.e. conference proceeding) were considered.
- Number of participants included in the study was considered in relation to the COSMIN guidelines which indicate that adequate samples require 50–99 participants [19].

Results

The initial search (2016) identified 1759 studies eligible for inclusion, with an additional 432 studies identified 12 months later (2017). A total of 66 studies met the inclusion criteria (Fig. 1). Eight studies reported on the validation against a robotic device, and 22 reported on validation against a motion analysis system with human participants. One study assessed the reliability of the wearable sensors, with the remaining 35 studies using wearable sensors as an outcome measure in an experimental design.

Characteristics and Placement of the Wearable Sensors

The characteristics of the wearable sensors are summarised in Table 1. A total of seven customised wearable sensors and 13 commercial brands were identified. The level of detail provided for the placement of the wearable sensors on the upper limb varied significantly, as did the mode of attachment (Table 1).

Calibration Methods

Forty-seven studies reported on a calibration procedure prior to data acquisition. System calibration, also commonly known as 'factory calibration', was reported on 12 occasions, with two procedures described for the wearable sensors: (i) placement on a flat surface and/or (ii) movement in a pre-determined order while attached to a flat surface [56, 62]. The aim of system calibration was

Table 1 Summary of the descriptive characteristics of the wearable sensors

Study		Brand	No. of sensors used	Dimensions (mm) $L \times W \times H$	Weight (grams)	Wireless	Components			Sample rate (Hz)	Method of attachment	Participants		
First author	Conference/ full text						Acc	Gyr	Mag			Population	*N*	Mean age ± SD (years)
Muller et al. [22]	Full	Xsens—MTw Awinda	2	47 × 30 × 13*	16*	Y*	✓	✓	✓	–	DS tape	Healthy	1	25
Bouvier et al. [23]	Full	Xsens—MTw	4	34.5 × 57.8 × 14.5	27	Y	✓	✓	✓	60	DS tape and elastic	Healthy	10	29 ± 3.4
Robert-Lachaine et al. [24]	Full	Xsens—MVN	17	–	50*	N	✓	✓	✓	30	Velcro	Healthy	12	26.3 ± 4.4
Robert-Lachaine et al. [25]	Full	Xsens—MVN	17	–	50*	N	✓	✓	✓	30	Velcro	Healthy	12	26.3 ± 4.4
Eckardt et al. [26]	Full	Xsens—MVN	17	–	50*	N	✓	✓	✓	120	Body suit	Healthy	20	20.2 ± 5.7
Eckardt et al. [27]	Full	Xsens—MVN	17	–	50*	N	✓	✓	✓	120	Body suit	Healthy	10	23.4 ± 5.3
Alvarez et al. [28]	Full	Xsens—MTx	4	38 × 53 × 21*	30*	N	✓	✓	✓	50	Velcro and elastic	Robot and healthy	1	–
Quinones et al. [29]	Con	Xsens—MTx	7	38 × 53 × 21*	30*	N	✓	✓	✓	50	–	SCI	15	37.4 ± 7.3
Gil-Agudo et al. [30]	Full	Xsens—MTx	5	38 × 53 × 21*	30*	N	✓	✓	✓	25	–	Healthy	1	30
Alvarez et al. [31]	Full	Xsens—MTx	4	40 × 55 × 22	30*	–	✓	✓	✓	50	Elastic	Robot and healthy	2	–
Bai et al. [32]	Con	Xsens—MTx	3	38 × 53 × 20.9	30	N	✓	✓	–	100	–	–	–	–
Bai et al. [33]	Con	Xsens—MTx	2	38 × 53 × 21*	30*	–	✓	✓	✓	120	Velcro	Healthy	1	–
Zhang et al. [34]	Full	Xsens—MTx	3	38 × 53 × 21*	30*	–	✓	✓	✓	100	–	Healthy	4	–
Rodriques-Anglese et al. [35]	Con	Xsens—MTx	2	38 × 53 × 21*	30*	N	✓	✓	✓	100	–	Robot and healthy	1	–
Cutti et al. [36]	Full	Xsens—MT9B	4	39 × 54 × 28	38	N	✓	✓	✓	100	DS tape and elastic	Healthy	1	23
Zhou et al. [37]	Full	Xsens—MT9B	2	–	–	N	✓	✓	✓	25	Velcro	Healthy	4	20–40
Zhou et al. [38]	Full	Xsens—MT9B	2	–	–	N	✓	✓	–	25	–	Healthy	1	–
Perez et al. [39]	Full	Xsens—MTi	4	58 × 58 × 22*	50	–	✓	✓	✓	50	Fabric	Healthy	1	–
Miezal et al. [15]	Full	Xsens	3	–	–	–	✓	✓	✓	120	–	Healthy	1	30
Miguel-Andres et al. [40]	Full	Xsens	3	–	–	N	✓	✓	✓	75	Velcro and DS tape	Healthy	10	29.3 ± 2.21
Luinge et al. [41]	Full	Xsens	2	–	–	N	✓	✓	–	–	DS tape and leukoplast	Healthy	1	–

Table 1 Summary of the descriptive characteristics of the wearable sensors *(Continued)*

Study		Brand	No. of sensors used	Dimensions (mm) $L \times W \times H$	Weight (grams)	Wireless	Components			Sample rate (Hz)	Method of attachment	Participants		
First author	Conference/ full text						Acc	Gyr	Mag			Population	*N*	Mean age ± SD (years)
Morrow et al. [42]	Full	ADPM Opal	6	43.7 × 39.7 × 13.7*	< 25*	Y	✓	✓	✓	80	Strap	Surgeons	6	45 ± 7
Rose et al. [43]	Full	ADPM Opal	6	43.7 × 39.7 × 13.7*	< 25*	Y	✓	✓	–	128	Strap	Surgeons	14	–
Bertrand et al. [44]	Con	ADPM Opal	3	48 × 36 × 13	< 22	Y	✓	✓	✓	–	DS tape	Astronauts	2	–
Fantozzi et al. [45]	Full	ADPM Opal	7	43.7 × 39.7 × 13.7*	< 25*	Y	✓	✓	✓	128	Velcro	Swimmers	8	26.1 ± 3.4
Kirking et al. [46]	Full	ADPM Opal	3	43.7 × 39.7 × 13.7*	22	–	✓	✓	✓	–	DS tape and strap	Healthy	5	–
Ricci et al. [47]	Full	ADPM Opal	6	43.7 × 39.7 × 13.7*	< 25*	Y	✓	✓	–	128	Velcro	Robot	–	–
El-Gohary et al. [48]	Full	ADPM Opal	3	43.7 × 39.7 × 13.7*	< 25[a]	–	✓	✓	–	128	Velcro	Robot	–	–
Ricci et al. [49]	Con	ADPM Opal	5	43.7 × 39.7 × 13.7*	< 22	Y	✓	✓	–	128	Velcro	Healthy	4 and 4	7 ± 0.3 and 27 ± 1.9
El-Gohary et al. [50]	Full	ADPM Opal	2	43.7 × 39.7 × 13.7*	< 25*	–	✓	✓	–	128^	Velcro	Healthy	8	–
El-Gohary et al. [51]	Con	ADPM Opal	2	43.7 × 39.7 × 13.7*	< 25*	Y	✓	✓	–	–	Strap	Healthy	1	–
Mazomenos et al. [52]	Full	Shimmer 2r	2	–	–	Y	✓	✓	✓	50	Custom holders and elastic	Healthy and stoke	18 and 4	25–50 and 45–73
Tran et al. [53]	Con	Shimmer 2r	2	–	–	Y	✓	✓	✓	18	Strap	Healthy	1	–
Daunoravicene et al. [54]	Full	Shimmer	3	–	–		✓	✓	–	51.2	Strap	Stroke	14	60.8 ± 12.5
Bertomu-Motos et al. [55]	Full	Shimmer	2	51 × 34 × 14*	–	Y	✓	✓	✓	–	Strap	Healthy	4 and 50	21–51 and 20–72
Meng et al. [56]	Con	Shimmer	2	51 × 34 × 14*	–	Y	✓	✓	✓	20	Velcro	Spherical coordinate system and healthy	1	–
Peppoloni et al. [57]	Con	Shimmer	3	51 × 34 × 14*		Y	✓	✓	✓	100	Velcro	Healthy	1	–
Ruiz-Olaya et al. [58]	Full	InvenSense MPU9150 chip	2	–	–	N	✓	✓	✓	50	Straps	Healthy	3	–
Callejas –Curervo et al. [59]	Full	InvenSense MPU9150 chip	2	–	–	N	✓	✓	✓	30	DS tape	Robot and healthy	3	–
Li et al. [60]	Full	InvenSense MPU9150 chip	2	–	–	N	✓	✓	✓	–	–	Stroke and Healthy	35 and 11	–
Gao et al. [61]	Con	InvenSense MPU9150 chip	2	26.2 × 39.2 × 14.8	–	Y	✓	✓	✓	–	–	Healthy	1	25

Table 1 Summary of the descriptive characteristics of the wearable sensors *(Continued)*

Study		Brand	No. of sensors used	Dimensions (mm) $L \times W \times H$	Weight (grams)	Wireless	Components			Sample rate (Hz)	Method of attachment	Participants		
First author	Conference/ full text						Acc	Gyr	Mag			Population	*N*	Mean age ± SD (years)
Lambretcht et al. [62]	Full	InvenSense MPU9150 chip	4	12 × 12 × 6	–	N	✓	✓	✓	50	–	Healthy	1	–
Peppoloni et al. [63]	Con	InvenSense MPU9150 chip	4	–	–	–	✓	✓	✓	–	Velcro	Healthy	1	–
Eom et al. [64]	Full	InvenSense MPU6050 chip	2	–	–	Y	✓	✓	–	–	Straps	Robot and goniometer		
Roldan-Jimenez et al. [65]	Full	InterSense InertiaCube3	3	26.2 × 39.2 × 14.8	17	N	✓	✓	✓	–	DS tape and elastic cohesive bandage	Healthy	15	18–35
Roldan-Jimenez et al. [66]	Full	InterSense InertiaCube3	4	26.2 × 39.2 × 14.8	17	N	✓	✓	✓	1000	DS tape and elastic cohesive bandage	Healthy	11	24.7 ± 4.2
Nguyen et al. [67]	Con	BioKin WMS	2	–	–	Y	✓	✓	✓	200	Straps	Healthy	15	20–60
Karunarathne et al. [68]	Con	BioKin WMS	2	–	–	Y	✓	✓	–	–	Straps	Healthy	4	–
Ligorio et al. [69]	Full	YEI Technology	2	–	–	N	–	✓	–	220	Velcro	Healthy	15	28 ± 3
Vignais et al. [70]	Full	CAPTIV Motion	5	60 × 35 × 19	32	Y[a]	✓	✓	✓	64	Straps	Healthy	5	41.2 ± 11
Chen et al. [71]	Con	L-P Research Motion Sensor B2	8	39 × 39 × 8*	12	Y	✓	✓	✓	–	–	Goniometer	–	–
Matsumoto et al. [72]	Full	Noraxon Myomotion	13	37.6 × 52 × 18.1	< 34	–	✓	✓	✓	200	–	Healthy and stoke	10 and 1	32.2 ± 9.3 and 27
Schiefer et al. [73]	Full	CUELA	13	–	–	–	✓	✓	✓	50	Velcro	Healthy	20	37.4 ± 9.9
Balbinot et al. [74]	Full	ArduMuV3 chip	9	–	–	Y	✓	✓	✓	20	Straps	–	–	–
Huang et al. [75]	Full	MSULS	4	30 × 35 × 12	–	–	✓	✓	✓	50	Fabric	Healthy and stoke	11 and 22	53 ± 8 and 62 ± 10
Salam et al. [76]	Full	Custom	3	44.45 × 44.45	–	Y	✓	✓	–	150	–	Cricketers	10	–
Chang et al. [77]	Full	Custom	2	–	–	N	✓	✓	✓	–	–	Robot	–	–
Borbely et al. [78]	Con	Custom	2	–	–	N	✓	✓	✓	200	Velcro	–	1	–
Kumar et al. [79]	Full	Custom	14	66.6 × 28.2 × 18.1*	22*	Y*	✓	✓	✓	25	Custom holders and Velcro	Healthy and un-healthy	19 and 19	24.6 ± 6.7 and 68.4 ± 8.9
Lee et al. [80]	Full	Custom	7	66.6 × 28.2 × 18.1	22	Y	✓	✓	✓	25	Straps	Goniometer and stroke	5	68

Table 1 Summary of the descriptive characteristics of the wearable sensors *(Continued)*

Study		Brand	No. of sensors used	Dimensions (mm) $L \times W \times H$	Weight (grams)	Wireless	Components			Sample rate (Hz)	Method of attachment	Participants		
First author	Conference/ full text						Acc	Gyr	Mag			Population	*N*	Mean age ± SD (years)
Cifuentes et al. [81]	Con	Custom	2	43 × 60	–	–	✓	✓	✓	60	Straps	Healthy	9	–
Kanjanapas et al. [82]	Full	Custom	2	–	–	N	✓	✓	✓	100	Orthosis	Healthy	1	25
Zhang et al. [83]	Con	–	2	–	–	Y	✓	✓	✓	–	–	Healthy	1	–
Lin et al. [84]	Full	–	2	–	–	Y	✓	✓	✓	–	Straps	Stroke	25	52.2 ± 10.2 and 62.2 ± 7.1
El-Gohary et al. [85]	Con	–	2	–	–	–	✓	✓	–	–	–	–	–	–
Hyde et al. [86]	Full	–	–	–	–	–	✓	✓	–	–	–	Robot	–	–

Table 1 is organised by the brand of the wearable sensor followed by the date that the study was published. This allows direct comparison to be made within the brand of the wearable sensors and trends to be identified between more recently published studies

Abbreviations: *Gms* grams, *Y* yes, *N* no, *Acc* accelerometer, *Gyr* gyroscope, *Mag* magnetometer, *Hz* hertz (unit of frequency), *SD* standard deviation, *SCI* spinal cord injury, *PD* Parkinson's disease, *Full* full text, *Con* conference paper, *mm* millimetre, *DS* double sided

Key:

Wireless—the wearable sensor system was considered wireless if the wearable sensors did not have wires connecting them to an external source, even if that external source was also mounted on the subject

Sample rate—the number of data samples collected per second by the wearable sensor measured in hertz (Hz) which is the unit of frequency

Custom—defined as a newly developed wearable sensor or modifications have occurred to the pre-existing hardware of the wearable sensor

Symbols:

*The information was obtained from the manufacturer procedure manual or other referenced papers

^The sample rate was down sampled (reduced) to allow comparison to the MOCAP system

¯Information was not reported and/or unclear in the study and/or unable to be obtained from the manufacturer manual

reported to be to align coordinate systems [39, 56] and account for inaccuracies in the orientation of wearable sensor chip relative to its case/packaging [62]. Static anatomical calibration was performed often ($n = 34$), with dynamic anatomical calibration performed sometimes ($n = 10$) [23, 30, 36, 41, 45, 49, 57]. Only one study used system calibration alongside both static and dynamic anatomical calibrations to compute joint kinematics [47].

Populations Assessed Using Wearable Sensors

Most studies ($n = 52$) recruited healthy adults; participants with known pathology were reported in nine studies (Table 1). One study recruited children (< 18 years) [49]. Sample sizes ranged from 1 to 54 participants, with a median sample of 7.6 participants per study. Twenty-nine studies recruited less than five participants, with 20 studies recruiting one single participant.

Psychometric Properties of Wearable Sensors

Validity

Validation studies were split into two categories: (i) studies that compared the wearable sensor output to simulated upper limb movement on a robotic device (Table 2) and (ii) studies that compared wearable sensors output to a 3DMA system on a human participant (Table 3). The term 'error' is used to describe the difference between the capture systems; however, we acknowledge that comparisons between the wearable sensors and a robotic device are the only true measures of error.

Robot Comparisons

Eight studies reported the error of wearable sensors when compared to simulated upper limb movement on a robotic device (Table 2). A mean error between 0.06 and 1.8° for flexion and 1.05 and 1.8° for lateral deviation of the wrist was reported using Xsens [28, 31]. For elbow flexion/extension, the difference between Invensence and the robotic device was between 2.1 and 2.4° [59]. For finger flexion/extension, RMSEs ranged from 5.0 to 7.0° using a customised wearable sensor system [77].

Three studies reported the error associated with the use of different fusion algorithms. Using the unscented Kalman filter (UKF) to fuse data from Opal wearable sensors, the RMSE range was 0.8–8.1° for 2DOF at the shoulder, 0.9–2.8° for 1DOF at the elbow, 1.1–3.9° for 1DOF of the forearm, and 1.1–2.1° for 2DOF at the wrist [46, 48]. The rotation of the shoulder and twist of the wrist resulted in more error compared to single plane movements of flexion/extension and pronation/supination [46, 48]. When the UKF was compared to a modified UKF, lower RMSEs were found across all 6DOF using the modified UKF [46]. One study investigated the effects that speed of movement had on measurement error. Using Opal wearable sensors, the UKF was compared to the extended Kalman filter (EKF) under three speed conditions: slow, medium, and fast. For slow movements, both fusion algorithms were comparable across all 6DOF (RMSE 0.8–7.8° for the UKF and 0.8–8.8° for the EKF). The UKF resulted in less error across 6DOF for the medium (RMSE 1.2–3.0°) and fast (RMSE 1.1–5.9°) speeds compared to the EKF (RMSE 1.4–8.6°; 1.4–9.7°) [48].

3DMA Comparisons

Twenty-two studies compared the joint angles calculated by wearable sensors, both custom and commercial, to a 'gold standard' 3DMA system (Table 3). Studies that used same segment tracking (i.e. motion analysis markers directly on the wearable sensors) were reported in 7 studies. Opal wearable sensors were compared to a 3DMA system during simulated swimming (multiplane movement). The largest difference between the two systems occurred at the elbow (RMSE 6–15°), with the least occurring at the wrist (RMSE 3.0–5.0°) [45]. Xsens was compared to codamotion during single plane movement, with the addition of a dynamic anatomical calibration trial [30]. The largest difference occurred at the elbow (5.16° ± 4.5 to 0.54° ± 2.63), and the least difference at the shoulder (0.65° ± 5.67 to 0.76° ± 4.40) [30]. Xsens was compared to Optotrak with consistent differences between systems across all DOFs of the shoulder (RMSE 2.5–3.0°), elbow (RMSE 2.0–2.9°), and wrist (RMSE 2.8–3.8°) [24].

Three studies investigated the performance of wearable sensors using different fusion methods to amalgamate the data and compared this to a 'gold standard' system. Zhang and colleagues [34] compared the accuracy of their own algorithm to two pre-existing algorithms. Comparing Xsens to the BTS Optoelectronic system, their methodology resulted in less error (RMSE = 0.08°, CC = 0.89 to 0.99) across 5DOF compared to the two other methods [34]. The addition of a magnetometer in the analysis of data was also investigated using the EKF- and non-EKF-based fusion algorithm [15]. The latter produced the least difference between the two systems, irrespective of the speed of the movement and whether or not a magnetometer was included. In contrast, the EKF fusion algorithm resulted in the largest difference from the reference system, particularly for fast movements where magnetometer data was included (7.37° ± 4.60 to 11.91° ± 6.27) [15]. The level of customisation to achieve these results is summarised in Table 4.

One study compared the difference between YEI Technology (YEI technology, Portsmouth, OH) wearable sensors and Vicon during three customised calibration methods for the elbow, which resulted in RMSEs that ranged from 3.1 to 7.6° [69].

Table 2 List of the 8 articles organised by first author and containing information related to the validation of wearable sensors for the measurement of joint angle for simulated movements of the upper limb when compared to a robotic device

First author	Aim of the study	Brand of wearable sensors	Description of robotic device	Sensor fusion algorithm	Calibration			Segment(s)	DOFs	Simulated movements	RMSE	Mean error (SD)
					System	Static	Dynamic					
Callejas–Cuervo et al. [59]	System validation	Invensense MPU-9150	Industrial robotic arm (ABB IRB 120)	KF	–	✓	–	Elbow	1DOF	Flex/ext	2.12–2.44°	–
Chang et al. [77]	System validation	Custom	Rehabotics Medical Technology Corporation	–	–	–	–	Finger	1DOF	Flex/ext	5–7°	–
Alvarez et al. [28]	System validation	Xsens	Pan and tilt unit (Model PTU-D46)	–	–	✓	–	Wrist	2DOF	Flex Lat dev	– –	0.06° (9.20) 1.05° (2.18)
Alvarez et al. [31]	System validation	Xsens	Pan and tilt unit (Model PTU-D46)	–	–	✓	–	Wrist	2DOF	Flex Lat dev	– –	1.8° for each axis, with a max error ± 6°
Rodriguez-Angleseet et al. [35]	System validation	Xsens	Plantar robot	KF	–	✓	–	Elbow	2DOF	–	Did not report discrete statistics	
Kirking et al. [46]	Validation/comparison of sensor fusion methods	Opal	Industrial Epson C3 robot arm	UKF	–	✓	–	Shoulder Elbow Forearm Wrist	2DOF 1DOF 1DOF 2DOF	Int/ext rot Flex/ext Flex/ext Pro/sup Flex/ext Twist	8.1° 2.4° 2.6° 2.1° 2.2° 3.9°	– – – – – –
				Modified UKF	–	✓	–	Shoulder Elbow Forearm Wrist	2DOF 1DOF 1DOF 2DOF	Int/ext rot Flex/ext Flex/ext Pro/sup Flex/ext Twist	3.0° 1.6° 2.0° 1.2° 1.5° 2.8°	– – – – – –
Ricci et al. [47]	Validation/comparison of sensor fusion methods	Opal	LWR 4+ (KUKA GmbH)	KF	–	✓		Shoulder Elbow Forearm Wrist	7DOF	–	Unable to determine exact values from box plot	
				GNF	–	✓	–	Shoulder Elbow Forearm Wrist	7DOF	–		

Table 2 List of the 8 articles organised by first author and containing information related to the validation of wearable sensors for the measurement of joint angle for simulated movements of the upper limb when compared to a robotic device *(Continued)*

First author	Aim of the study	Brand of wearable sensors	Description of robotic device	Sensor fusion algorithm	Calibration			Segment(s)	DOFs	Simulated movements	RMSE			Mean error (SD)
					System	Static	Dynamic							
El-Gohary et al. [48]	Validation/comparison of sensor fusion methods	Opal	Not described	UKF	–	✓	–	Shoulder	2DOF	In/ext rot	Slow	Med	Fast	–
								Elbow	1DOF	Flex/ext	7.8°	3.0°	5.9°	–
								Forearm	1DOF	Flex/ext	0.8°	1.6°	2.5°	–
								Wrist	2DOF	Pro/sup	0.9°	2.0°	2.8°	–
										Flex/ext	1.3°	1.2°	1.1°	–
										Twist	1.1°	1.5°	1.8°	–
											1.7°	2.8°	2.2°	
				EKF	–	✓	–	Shoulder	2DOF	In/ext rot	8.8°	8.6°	9.7°	–
								Elbow	1DOF	Flex/ext	1.2°	1.9°	2.5°	–
								Forearm	1DOF	Flex/ext	1.3°	2.1°	3.1°	–
								Wrist	2DOF	Pro/sup	0.8°	1.4°	1.4°	–
										Flex/ext	1.2°	1.9°	2.9°	–
										Twist	1.8°	3.7°	3.4°	–

Abbreviations: *RMSE* root mean square error, *SD* standard deviation, *CMC* coefficient of multiple correlation, *KBF* Kalman-based filter, *KF* Kalman filter, *EKF* extended Kalman filter, *UKF* unscented Kalman filter, *WLS* weighted least squares, *Flex* flexion, *Ext* extension, *Pro* pronation, *Sup* supination, *Ab* abduction, *Ad* adduction, *Dev* deviation, *Rad* radial, *Uln* ulnar, *In* internal, *Ex* external, *Rot* rotation, *Elev* elevation, *Dep* depression, *DOF* degrees of freedom, *C* customised, *M* manufacture

–Information was not reported and/or unclear in the study and/or unable to be obtained from the manufacturer manual

Table 3 List of the selected 22 articles organised by first author and containing information related to the validation of wearable sensors for the measurement of joint angle in upper limb when compared to a three-dimensional motion analysis system

First Author	Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	Degrees of Freedom	Movements	Mean error (SD)	RMSE	Correlation coefficients	Calibration		
														System	Static	Dynamic
Robert Lachaine et al. [24]	Validate protocol	Xsens	KF	S1: Upper arm S2: Forearm S3: Hand	Optotrak	Yes	Elbow flex/ext, pro/sup; wrist flex/ext, ul/rad deviation, rotation and manual handling tasks	Shoulder Elbow Wrist	3DOF 3DOF 3DOF	Flex/ext Ab/ad Rotation Flex/ext Ab/ad Pro/sup Flex/ext Rad/ul dev Rotation	Optotrak ISB to Xsens ISB – 	 3.0° 2.9° 2.5° 2.9° 2.0° 2.6° 3.8° 2.8° 3.6°	 –	–	✓	–
Ligorio et al. [69]	Validate calibration method	YEI technology	–	–	Vicon	Yes	Flex/ext and pro/sup	Elbow	2DOF 2DOF 2DOF	Flex/ext Pro/supFlex/ext Pro/supFlex/ext Pro/sup	Method A – Method B – Method C – Proposed –	 8.5–11.1° 11.9–13.3° 3.4–3.6° 6.8–7.6° 3.1–3.3° 3.8–4.0°	 – – –	–	✓	✓
Fantozzi et al. [45]	Validate protocol	Opal	KBF	S1: Flat portion of the sternum. S2: Laterally on the humerus above the centre and posteriorly. S3: Distal forearm above the ulnar and radial styloid. S4: Back of the hand.	Stereo-photogrammetric system (SMART-DX 7000)	Yes	Simulated front crawl Simulated breaststroke	Shoulder Elbow Wrist Shoulder Elbow Wrist	3DOF 2DOF 2DOF 3DOF 2DOF 2DOF	Flex/ext Ab/ad In/ext rot Flex/ext Pro/sup Flex/ext Rad/ul dev Flex/ext Ab/ad In/ext rot Flex/ext Pro/sup Flex/ext Rad/ul dev	– – 	5.0° (4–6) 10.0° (7–11) 7.0° (5–8) 15° (12–17) 10.0° (7–11) 5.0° (4–5) 3.0° (2–4) 5.0° (3–7) 3.0° (3–4) 8.0° (5–10) 6.0° (5–10) 5.0° (4–7) 4.0° (3–5)	0.99 0.97 0.99 0.95 0.93 0.95 0.90 - 0.99 0.99 0.98 0.97 0.98 0.93	–	✓	–
Gil-Agudo et al. [30]	Validate protocol	Xsens	KF	S1: Trunk S2: Back of the head S3: Right arm S4: Distal forearm S5: Hand.	CODA	Yes	Shoulder rot, flex/ext and ab/ad; elbow flex/ext and pro/sup, wrist flex/ext and ul/rad deviation.	Shoulder Elbow Wrist	3DOF 2DOF 2DOF	Flex/ext Ab/ad In/ext rot Flex/ext Pro/sup Flex/ext Rad/ul dev	0.76° (4.4) 0.69° (10.47) 0.65° (5.67) 0.54° (2.63) 5.16° (4.5) 3.47° (9.43) 2.19° (4.64)	–	–	–	–	✓
Miezal et al. [15]	Validate sensor fusion/ algorithm	Xsens	EKF, WLS	Not described	Natural Point Optitrack system 13 cameras	Yes	Eight-shaped movements at varied speeds, smooth parts imitating reaching and steering in the	Shoulder Elbow Wrist Shoulder	1DOF 1DOF 1DOF 1DOF	– –	Chaintracker (real fast w/mag) 9.38° (5.79) 11.91° (6.27) 7.37° (4.60) Chaintracker	 – 	 – 	–	✓	–

Table 3 List of the selected 22 articles organised by first author and containing information related to the validation of wearable sensors for the measurement of joint angle in upper limb when compared to a three-dimensional motion analysis system *(Continued)*

First Author	Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	Degrees of Freedom	Movements	Mean error (SD)	RMSE	Correlation coefficients	Calibration		
														System	Static	Dynamic
							case of real-slow, and agile parts with quick starts and stops, as well as, parts reminding of sportive movements, such as boxing, in the case of real fast	Elbow Wrist	1DOF 1DOF		(real slow w/mag) 4.76° (2.24) 8.83° (4.64) 4.72° (2.61)	– –	–			
								Shoulder Elbow Wrist	1DOF 1DOF 1DOF	–	Optitracker (real fast w/mag) 1.88° (0.91) 2.22° (1.38) 2.28° (1.15)	– –	–			
								Shoulder Elbow Wrist	1DOF 1DOF 1DOF	–	Optitracker (real fast w/mag) 1.27° (0.81) 2.16° (1.35) 2.32° (1.37)	– –	–			
Lambretcht et al. [62]	Validate sensor fusion/ algorithm	Custom	DMP algorithm	S1: Sternum S2: Upper arm S3: Distal forearm S4: Hand	Optotrak	Yes	Reaching movements	Shoulder Elbow Wrist	3DOF 2DOF 2DOF	Azimuth Elev Int rot Flex Pro Flex/Ext Dev	–	4.9° 1.2° 2.9° 7.9° 1.5° 5.5° 2.6°	0.99 0.99 0.99 0.99 0.99 0.97 0.94	✓	–	–
Zhang et al. [34]	Validate sensor fusion/ algorithm	Xsens	UKF	S1: Sternum S2: Lateral side above the elbow S3: Lateral and flat side of the forearm near the wrist	BTS SMART-D optoelectronic tracking system	Yes	Move the upper limb arbitrarily.	Shoulder Elbow	3DOF 2DOF	Flex/ext Ab/ad Int/ext rot Flex/ext Pro/sup	Independent Estimation 0.070° (0.083) 0.023° (0.042) 0.061° (0.061) 0.052° (0.155) 0.321° (0.265)	 0.11° 0.04° 0.08° 0.16° 0.41°	 0.99 0.99 0.99 0.81 0.96	–	✓	–
								Shoulder Elbow	3DOF 2DOF	Flex/ext Ab/ad Int/ext rot Flex/ext Pro/sup	Constraints method 0.040° (0.039) 0.013° (0.018) 0.029° (0.032) 0.046° (0.100) 0.155° (0.143)	 0.05° 0.02° 0.04° 0.11° 0.21°	 0.99 0.99 0.99 0.88 0.96			
								Shoulder Elbow	3DOF 2DOF	Flex/ext Ab/ad Int/ext rot Flex/ext Pro/sup	Papers proposed method 0.028° (0.029) 0.007° (0.013) 0.035° (0.036) 0.054° (0.093) 0.168° (0.153)	 0.04° 0.01° 0.05° 0.10° 0.22°	 0.99 0.99 0.99 0.89 0.96			
Morrow et al. [42]	Validate protocol	Opal	–	Bilateral: S1: Lateral aspect upper arms S2: Forearms	Raptor 12 Digital Real-time Motion Capture System	No	Peg transfer task using straight laparoscopic surgical instruments.	Shoulder Elbow	1DOF 1DOF	Elevation Flexion	3.0° (2.1) 2.2° (1.6)	6.8° (2.7) 8.2° (2.8)	–	–	✓	✓
Callegas-Cuerro et al. [59]	Validate protocol	Invensense MPU-9150	KF	S1: External arm aligned with the humerus.	Qualisys Oqus 5	No	Flex/ext	Elbow	1DOF	Flex/ext	< 3.0° to < 5.0°	2.44%	–	–	✓	✓

Table 3 List of the selected 22 articles organised by first author and containing information related to the validation of wearable sensors for the measurement of joint angle in upper limb when compared to a three-dimensional motion analysis system *(Continued)*

First Author	Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	Degrees of Freedom	Movements	Mean error (SD)	RMSE	Correlation coefficients	Calibration		
														System	Static	Dynamic
				S2: Between the radial styloid and ulnar styloid, aligned with external part of the hand.												
Meng et al. [56]	Validate protocol	Shimmer	KF	Not described	Vicon Mocap System	No	(1) Raise shoulder. (2) Move shoulder right then left. (3) Clockwise axial rotation to its max, then rotate the upper arm counter clockwise. (4) Elbow extension move into flexion.	Shoulder Elbow	3DOF 2DOF	Flex/ext Ab/ad In/ext rot Flex/ext Pro/sup	0.50° (1.79) 0.18° (1.34) 0.16° (1.96) 1.86° (1.85) 1.22° (2.87)	1.85° 1.35° 1.96° 2.62° 3.12°	–	✓	–	–
Cifuentes et al. [81]	Validate protocol	Custom	–	S1: Arm S2: Forearm	Optical tracking system	No	Reaching and grasping from the rest position with the forearm on the table, at angle of approximately 90° with respect to the arm before reaching and grasping an object, and then returning it to starting position.	Elbow	1DOF	Flex/ext	No discrete data reported only figures of continuous data			–	–	–
Muller et al. [22]	Validate sensor fusion/ algorithm	Xsens	KF*	S1: Thorax. S2: Lateral side of the arm S3: Posterior side of the wrist	Vicon	No	(1) Flex/ext in a horizontal plane with the shoulder abducted 90° flex/ext in a sagittal plane while standing with the elbow close to the trunk. (2) Flex/ext in a sagittal plane with the spine bent forward 90° and the upper arm aligned horizontally and parallel to the	Elbow Elbow	2DOF 2DOF	Flex/ext Pro/sup Flex/ext Pro/sup	Proposed algorithm – Manual alignment –	 2.7° 3.8° 3.8° 8.7°	– –	✓	✓	–

Table 3 List of the selected 22 articles organised by first author and containing information related to the validation of wearable sensors for the measurement of joint angle in upper limb when compared to a three-dimensional motion analysis system *(Continued)*

First Author	Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	Degrees of Freedom	Movements	Mean error (SD)	RMSE	Correlation coefficients	Calibration		
														System	Static	Dynamic
							ground sup/pro with the elbow flexed 90°									
Bertomu-Motos et al. [55]	Validate sensor fusion/ algorithm	Shimmer	EKF	S1: Shoulder S2: Upper arm	Optitrack	No	The activity consisted of taking a box from the perimeter and placing it in the centre of the screen.	Shoulder	5DOF	Unclear	Without compensation Filter			–	–	–
											5.24° (3.38) 0.5° (1.6) 3.6° (2.1) 1.8° (1.0) 1.60° (0.6)	–	–			
								Shoulder	5DOF	Unclear	Compensation filter					
											1.69° (2.1) 1.1° (0.8) 5.9° (2.3) 2.6° (1.7) 0.9° (1.2)	–	–			
Karunarathne et al. [68]	Validate sensor fusion/ algorithm	BioKin WMS	KF*	S1: Near the elbow S2: Wrist	Vicon	No	Lifting a water bottle	Elbow	1DOF	Flex/ext	High-pass filte—gyroscope			–	–	–
											–	10.18°	–			
								Elbow	1DOF	Flex/ext	Low-pass filter—accelerations					
											–	18.30°	–			
								Elbow	1DOF	Flex/ext	Tradition complementary filter					
											–	10.30°	–			
								Elbow	1DOF	Flex/ext	Adaptive complementary filter					
											–	8.77°	–			
El-Gohary et al. [50]	Validate Sensor fusion/ algorithm	Opal	UKF	S1: Upper arm S2: Forearm	Vicon motion analysis system	No	Single movements: Shoulder flex/ext, ab/ad, Elbow flex/ext and forearm sup/pro.	Shoulder Elbow	2DOF 2DOF	Flex/ext Ab/ad Flex/ext Pro/sup	–	5.5° 4.4° 6.5° 0.95°	0.98 0.99 0.98 0.95	–	✓	
							Complex tasks: (1) touching nose and (2) reaching for door	Shoulder Elbow	1DOF 1DOF	–	9.8° 8.8°	6.5° 5.5°	0.94 0.95			
El-Gohary et al. [51]	Validate Sensor fusion/ algorithm	Opal	UKF	S1: Between the shoulder and elbow S2: Near the wrist	Eagle Analog System, Motion Analysis	No	Single movements at different speeds: Shoulder flex/ext, ab/ad, Elbow flex/ext, sup/pro	Shoulder Elbow	2DOF 2DOF	Flex/ext Ab/ad Flex/ext Pro/sup	Normal speed –	– –	0.97 0.94 0.92 0.96	–	–	–
								Shoulder Elbow	2DOF 2DOF	Flex/ext Ab/ad Flex/ext Pro/sup	Fast speed		0.94 0.91 0.89 0.93			
Perez et al. [39]	Validate sensor	Xsens	–	S1: Back S2: 18 cm from	BTS SMART-D optoelectronic	No	Single movements: Shoulder flex/ ext,	Shoulder Elbow	3DOF 2DOF	Flex/ext Ab/ad	13.4° 17.2°	–	0.99 0.71	✓	–	–

Table 3 List of the selected 22 articles organised by first author and containing information related to the validation of wearable sensors for the measurement of joint angle in upper limb when compared to a three-dimensional motion analysis system *(Continued)*

First Author	Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	Degrees of Freedom	Movements	Mean error (SD)	RMSE	Correlation coefficients	Calibration		
														System	Static	Dynamic
	fusion/ algorithm			acromion S3: 25 cm from epicondyle S4: 5.5 cm from distal radio-cubital joint.	tracking system		horizontal ab/ad, and internal rotation. Elbow flex, pro/sup and wrist flex/ext.	Wrist	1DOF	In rot Flex Pro/sup Flex/ext	60.4° 5.8° 24.1° 11.6°		0.99 0.98 0.96 0.98			
							Pouring water from a glass jar into a glass	Shoulder Elbow Wrist	3DOF 2DOF 1DOF	Flex/ext Ab/ad In rot Flex/ext Pro/sup Flex/ext	13.8° 7.4° 28.8° 18.6° 11.7° 26.8°	–	0.99 0.90 0.85 0.97 0.92 0.92			
Zhou et al. [37]	Validate sensor fusion/ algorithm	Xsens	KF	S1: Lateral aspect of upper arm between the lateral epicondyle and the acromion process (5 cm from the AP) S2: Wrist centre on the palmer aspect	CODA	No	Reaching, shrugging, forearm rotation	Elbow	2DOF	Flex/ext Rot	0.4° (2.34) 0.06° (4.82)	2.4° 4.8°	–	–	✓	–
Luinge et al. [41]	Validate sensor fusion/ algorithm	Xsens	KF	S1: Lateral upper arm near the elbow S2: Dorsal side of the forearm near the wrist.	Vicon	No	(1) Mimicking eating routines (pouring a glass eating soup, eating spaghetti, eating meat, drinking). (2) Mimicking morning routines (splashing water on face and drying it using a towel, applying deodorant, buttoning a blouse, combing hair, brushing teeth).	Elbow	2DOF	–	No discreet data reported			–	✓	✓
Peppoloni et al. [57]	Validate kinematic model	Shimmer	UKF	S1: Scapula beside the angulus acromialis S2: Lateral side of the upper arm above the elbow. S3: Lateral side of forearm a few centimetres far from the wrist.	Vicon	No	Single movements: Scapula elev/dep, ante-position/retro-position. Shoulder flex/ext, ab/ad, and int/ext rotation. Elbow flex/ext, pro/sup.	7DOF model						–	✓	✓
								Scapula Shoulder Elbow	2DOF 3DOF 2DOF	Elev/dep Prof/retr Flex/ext Ab/ad In/ext rot Flex/ext Pro/sup	–	6.19° 3.43° 8.19° 10.68° 8.79° 5.00° 9.61°	0.65 0.74 0.94 0.63 0.97 0.99 0.85			
								5DOF model								
								Shoulder Elbow	3DOF 2DOF	Flex/ext Ab/ad In/ext rot Flex/ext	–	7.03° 6.03° 4.95° 9.93°	0.95 0.87 0.99 0.98			

Table 3 List of the selected 22 articles organised by first author and containing information related to the validation of wearable sensors for the measurement of joint angle in upper limb when compared to a three-dimensional motion analysis system *(Continued)*

First Author	Aim of the study	Brand of Sensors	Sensor fusion algorithm	Placement of sensors	Comparison system	Used same segment tracking	Task(s)	Anatomical Segment(s)	Degrees of Freedom	Movements	Mean error (SD)	RMSE	Correlation coefficients	Calibration		
														System	Static	Dynamic
										Pro/sup		11.29°	0.85			
Robert-Lachaine et al. [25]	Validate calibration method	Xsens	KF	–	Optotrak	No	Single plane movements	–	–	–	No discrete data reported			–	–	–
Bouvier et al. [23]	Validate calibration method	Xsens	KF	S1: Sternum S2: Central third of upper arm laterally (or slightly posterior) S3: Dorso-distally on the forearm S4: Dorsum hand	Eagle 4 Optoelectric system	No	Move through 9 calibration trials for each joint.	Shoulder Elbow Wrist	3DOF 2DOF 2DOF	Flex/ext Ab/Ad Wheel Flex/ext Pro/sup Flex/ext Ab/sd	– – – – – – –	– – – 20.46° 14.76° 14.21° 13.9°	– – – 0.84 0.94 0.93 0.68	–	✓	✓

Abbreviations: RMSE root mean square error, *SD* standard deviation, *CMC* coefficient of multiple correlation, *KBF* Kalman-based filter, *KF* Kalman filter, *EKF* extended Kalman filter, *UKF* unscented Kalman filter, *WLS* weighted least squares, *Flex* flexion, *Ext* extension, *Pro* pronation, *Sup* supination, *Ab* abduction, *Ad* adduction, *Dev* deviation, *Rad* radial, *Uln* ulnar, *In* internal, *Ex* external, *Rot* rotation, *Elev* elevation, *Dep* depression, *DOF* degrees of freedom, *C* customised, *M* manufacture

*The information was obtained from the manufacturer procedure manual or other referenced papers

–Information was not reported and/or unclear in the study and/or unable to be obtained from the manufacturer manual

Table 4 Summary of the software customisation reported by the authors for validation studies that used the same segment tracking

First author	Sensor hardware	Software			
		Sensor fusion algorithm	Calibration	Anatomical segment definition	Kinematic calculation
Robert Lachaine et al. [24]	Commercial—Xsens MVN	Manufacturer	Manufacturer	Custom	Custom
Ligorio et al. [69]	Commercial—YEI Technology	Custom	Custom	Custom	Custom
Fantozzi et al. [45]	Commercial—ADPM Opal	Custom	Custom	Custom	Custom
Gil-Agudo et al. [30]	Commercial—Xsens MTx	Custom	Custom	Custom	Custom
Miezal et al. [15]	Commercial—Xsens	Did not report	Did not report	Custom	Custom
Lambretcht et al. [62]	Commercial—InvenSense MPU9150 chip	Custom	Custom	Custom	Custom
Zhang et al. [34]	Commercial—Xsens MTx	Custom	Manufacturer	Custom	Custom

Reliability

Adequate to excellent agreement was reported for 2DOF at the shoulder (ICC 0.68–0.81) and poor to moderate agreement for the 2DOF at the elbow (ICC 0.16–0.83). The wrist demonstrated the highest overall agreement with ICC values ranging from 0.65 to 0.89 for 2DOF [73].

Risk of Bias

The sample sizes of the included studies were mostly inadequate, with 30% including single participants (Table 1). Twenty-eight percent of the included studies were conference papers, providing limited information.

Discussion

This systematic review described the characteristics of wearable sensors that have been applied in research and clinical settings on the upper limb, the populations with whom they have been used with, and their established psychometric properties. The inclusion of 66 studies allowed for a comprehensive synthesis of information.

Similar to other systematic reviews on wearable sensors, commercial wearable sensors, as opposed to custom designed, were reported in most studies (83%) [17]. One benefit for users of commercial wearable sensors is the user-friendly nature of the associated manufacturer guidelines and processing software, including in-built fusion algorithms and joint calculation methods. However, the studies that utilised commercial hardware often customised aspects of the software (i.e. fusion algorithm, calibration method, anatomical segment definition, and the kinematic calculation). Therefore, the validity and reliability of an entirely commercial system (hardware and software) for use in the upper limb remains unknown. Customisation impacts the clinical utility of the wearable sensor systems, especially if there are no support personnel with appropriate knowledge and expertise.

Of the studies reviewed, there was no consensus on the procedures to follow for using wearable sensors on the upper limb. The placement of the wearable sensors varied and, in some cases, was poorly described. Manufacturer guidelines for placement of commercial wearable sensors were not referred to, which lead to apparent differences in placement for studies that utilised the same commercial brand. Multiple fusion algorithms were reported, with no clear outcome about which was best suited to a specific joint or movement. The level of customisation of fusion algorithms makes it difficult to compare between studies, and often, the specifics of the algorithm were not readily available, limiting replication. Similar inconsistencies and a lack of consensus were reported in other systematic reviews investigating use of wearable sensors [16, 87]. Without clear guidelines, measurement error can be introduced and/or exacerbated depending on the procedures followed.

The methods of calibration also varied between studies, with a static anatomical calibration the most commonly utilised method (typically adopting a neutral pose, standing with arms by the side and palms facing forward, as recommended by most manufacturers). Dynamic anatomical calibration was often customised to suit the needs of the study and the joint being measured. For example, dynamic anatomical calibration of the elbow varied from repetitions of flexion and extension at various speeds [59], to the rapid movement of the arm from 45° to neutral [42]. Details of the dynamic anatomical calibrations were omitted in some studies, limiting replication. More pertinent for the calculation of joint kinematics is anatomical calibration as compared to system calibration, with the type of calibration (i.e. static or dynamic) and movements of the dynamic anatomical calibration, having a significant impact on the accuracy of wearable sensors [69].

Of the 66 studies included in this review, almost half (45%) were validation studies with the remaining studies using wearable sensors as an outcome measure. Over one third (29%) were conference proceedings in the field of engineering, thus limiting the amount of information available. The median sample size was 7.6 participants per study; only one study was considered to have an adequate sample size for the validation of a measurement

tool as per the COSMIN guidelines [19]. The majority (78%) of the results were obtained from healthy adults, with clinical populations (12%) and those under the age of 18 (1.5%) not well represented. Research investigating the use of wearable sensors to measure lower limb kinematics has demonstrated a level of accuracy with clinical populations and children. Errors < 4° were reported for elderly individuals with hemiparesis [88] and RMSEs between 4.6 and 8.8° for children with spastic cerebral palsy [10]. There is potential for wearable sensors to be applied to the upper limb of these populations; however, more research is required to determine the optimal procedures prior to implementation in clinical practice.

The validity and reliability of wearable sensors when applied to the upper limb has not been clearly described to date. When compared to a robotic device, the commercial wearable sensors with customised software recorded errors below McGinley's [7] suggested 5.0° threshold. Less than 3.9° was reported for replica/simulated movements of the wrist in 3DOF [28, 46, 48, 56], < 3.1° for 2DOF at the elbow [46, 48, 56], and < 2.5° for 1DOF (flexion/extension) at the shoulder [48]. Shoulder internal and external rotation resulted in the largest error (3.0–9.7°) [48], and therefore, results for this movement should be interpreted with caution.

The next section will discuss 'in vivo' studies with 3DMA as a pseudo gold standard. Studies that made a direct comparison between the wearable sensors and 3DMA system (i.e. used the same segment tracking) demonstrated differences that exceeded the suggested 5.0° threshold, with up to 15.0° difference reported for the elbow. However, depending on the software specifications and level of customisation, a difference of < 0.11° (3DOF shoulder), < 0.41° (2DOF elbow), and < 2.6 (2DOF wrist) was achievable. The range in difference observed between the two systems is indicative that wearable sensors are still largely in a 'developmental phase' for the measurement of joint angle in the upper limb.

Consistent with prior findings, error values were unique to the joint and movement tasks being measured. Most of the tasks involved movements in multiple planes (i.e. reaching tasks), which resulted in more error compared to studies that assessed isolated movement in a single plane (i.e. flexion and extension). Measuring multiple planes of movement poses a further challenge to motion analysis and needs careful consideration when interpreting the results [89].

Limitations

Due to the heterogeneity in the reported studies, a meta-analysis was not appropriate given the variance in sample sizes, movement tasks, different procedures, and statistical analyses used. It was also not possible to apply a standard assessment of quality and bias due to the diversity of the studies. The inclusion of small samples (30% single participant) is a potential threat to validity, with single participant analysis insufficient to support robustness and generalisation of the evidence. The inclusion of conference papers (28%) meant that many papers provided limited detail on the proposed system and validation results. Small sample sizes and the inclusion of mostly healthy adults means the results of this review cannot be generalised to wider clinical populations. In addition, studies that utilised different segment tracking (i.e. 3DMA markers were not mounted on the wearable sensor) were not further analysed as it was not possible to delineate between the sources of error.

Conclusion

Wearable sensors have become smaller, more user-friendly, and increasingly accurate. The evidence presented suggests that wearable sensors have great potential to bridge the gap between laboratory-based systems and the goniometer for the measurement of upper limb joint angle during dynamic movement. A level of acceptable accuracy was demonstrated for the measurement of elbow and wrist flexion/extension when compared to a robotic device. Error was influenced by the fusion algorithm and method of joint calculation, which required customisation to achieve errors < 2.9° from known angles on a robotic device. Higher error margins were observed in vivo when compared to a 3DMA system, but < 5° was achievable with a high level of customisation. The additional level of customisation that was often required to achieve results with minimal error is particularly relevant to clinicians with limited technical support, and critically, when using a system 'off the shelf', the expected level of accuracy may not be comparable to the findings reported in this review.

With this technology rapidly evolving, future research should establish standardised protocol/guidelines, and subsequent reliability and validity for use in the upper limb, and in various clinical populations. Direct comparisons with the gold standard (i.e. same segment tracking) is needed to produce results that are most meaningful. We recommend and encourage the use of wearable sensors for the measurement of flexion/extension in the wrist and elbow; however, this should be combined with outcome measures that have demonstrated reliability and validity in the intended population.

Abbreviations

3DMA: Three-dimensional motion analysis; Ab: Abduction; Acc: Acceleration; Ad: Adduction; C: Customised; CMC: Coefficient of multiple correlations; Con: Conference paper; Dep: Depression; DOF: Degrees of freedom; DS: Double sided; EKF: Extended Kalman filter; Elev: Elevation; Ext rot: External rotation; Ext: Extension; Flex: Flexion; Full: Full text; Gyr: Gyroscope; ICC: Intra-class correlation coefficient; Int rot: Internal rotation; KBF: Kalman-based filter; KF: Kalman filter; M: Manufacturer; Mag: Magnetometer; PD: Parkinson's disease; Pro: Pronation; Rad dev: Radial deviation; RMSE: Root mean square error; ROM: Range of motion; SCI: Spinal cord injury; SD: Standard deviation; Sup: Supination; UKF: Unscented Kalman filter; Uln dev: Ulnar deviation

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Availability of Data and Materials
Data presented in this systematic review is available in the associated studies, and references are provided.

Authors' Contributions
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Authors' information
Not applicable

Ethics Approval and Consent to Participate
Ethical approval was not required for this systematic review.

Consent for Publication
Not applicable as this manuscript does not include any individual person's data.

Competing Interests
The authors Corrin Walmsley, Sian Williams, Tiffany Grisbrook, Catherine Elliott, Christine Imms, and Amity Campbell declare that they have no competing interests.

Publisher's Note

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A.2 Validation of custom wearable sensors to measure angle kinematics: A technical report

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ORIGINAL PAPER

Validation of custom wearable sensors to measure angle kinematics: A technical report

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Abstract
The objective of this study was to determine the accuracy of custom designed wearable sensors when compared to a robotic device to measure i) peak angles in a single plane (flexion/extension) and ii) the extent of error associated with speed of movement. Two experimental procedures were undertaken; i) one wearable sensor was mounted on the arm of a step motor that simulated wrist flexion/extension at the speed of 90°/s with the other wearable sensor static (flat surface); and ii) two wearable sensors were each mounted on a step motor which was programmed to move at two movement speeds 30°/s and 90°/s. When compared to pre-determined angles of the robotic device, the wearable sensors detected peak angles with mean error ranging from -0.95° to 0.11° when one wearable sensor was static and the other dynamic. When two wearable sensors were moving, movement at the higher speed (90°/s) had a mean error range of -2.63° to 0.54, and movement at the slower speed (30°/s) had a mean error range of -0.92° to 2.90°. The custom wearable sensors demonstrated the ability to measure peak angles comparable to the robotic device and demonstrated acceptable to reasonable error when tested at two movement speeds. The results warrant future *in vivo* testing.

Keywords Wearable sensors · Inertial movement units · Measurement · Angle

1 Introduction

Accurate measurement of range-of-motion (ROM) forms an important part of clinical assessment, with the information used to guide treatment plans, determine efficacy of treatment and monitor patients' progress [1]. Clinical measurement of active and passive ROM is typically completed using a universal goniometer [2]. Use of this instrument is reliant on the clinician's ability to accurately palpate bony landmarks and visually estimate the alignment of the axis and arms of the goniometer to the joint being measured. It remains the most versatile, reliable and widely used instrument for the

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measurement of ROM in clinical practice irrespective of measurement errors up to 15° [3] reported in literature. For static and single plane movements, the universal goniometer provides quantified insight into the ROM at a joint. However, for active movement, use of the goniometer is very difficult, and not always possible in some populations; particularly those who are unable to reliably respond to instructions to movement, for example young children or those with cognitive impairments.

Three-dimensional motion analysis (3DMA) systems provide alternative methods to measure active ROM in multiple planes of movement and are considered a pseudo gold standard, with measurement errors up to 0.5 mm, and angular errors less than 5° [4]. Although accurate, these systems are largely unused by clinicians because they are expensive, require expertise to operate along with dedicated laboratory space and equipment [5].

Wearable sensors have potential to overcome these limitations. Lightweight, portable and relatively low in cost in comparison to 3DMA systems, wearable sensors are emerging as favourable instruments for quantifying joint angle and position in the upper limb [6–8]. Wearable sensors typically contain a miniaturised accelerometer, gyroscope and magnetometer [9], data from which are integrated using sophisticated sensor fusion algorithms to determine the three-dimensional orientation of each wearable sensor with respect to its global coordinate system [10]. When used to quantify joint angle in the upper limb, wearable sensors have demonstrated an acceptable level of accuracy in adult populations [11].

In this paper, small, custom-designed, wearable sensors were utilised. The wearable sensors were developed collaboratively by a multidisciplinary team, and are novel in their small size (22 × 24 × 18 mm) and light weight casing. The small size of the wearable sensors is a necessary characteristic as we intend to use them with young children with a brain injury. In a systematic review of the literature, commercial wireless wearable sensors ranged in size (length, width and height) from 34.5 × 57.8 × 14.5 mm to 58 × 58 × 22 mm, with size varying depending on their intended application [11]. Various commercial wearable sensors were piloted on the hand and forearm of infants less than two years of age prior to the development of the custom wearable sensors used in this study. It was observed that the larger wearable sensors either i) did not fit on the dorsal surface of a small hand; ii) restricted wrist ROM, particularly in wrist extension when the hand and forearm wearable sensors came into contact; and iii) the weight of some wearable sensors impacted the child's normal spontaneous use of the hand.

Given the vulnerability of the population of interest (i.e. children), it was not reasonable to use the wearable sensors prior to accuracy being established due to potential inherent insurmountable measurement error associated with the use of the custom wearable sensors, and thus inconveniencing children and families. Determining the accuracy of the wearable sensors on a rigid static device or robotic device prior to use with human participants is common [12–17]. Therefore, the aim of this study was to compare the small custom designed wearable sensors to known angles of a robotic device and determine the true error of the wearable sensors when measuring peak angles, prior to *in vivo* testing.

2 Methods

2.1 Instruments

Two custom wearable sensors containing an inertial measurement unit (IMU) with the dimensions of 22 × 24× 18 mm were used. Each contained a tri-axial accelerometer, tri-axial gyroscope and a tri-axial magnetometer. Further details on the engineering specifications of each unit are published elsewhere [18]. The acceleration and angular velocity of the movement was sampled at 100 Hz and transmitted from the wearable sensors to a personal computer (PC) using radio frequency (RF) at the rate of 100 Hz. The magnetometer was not used in the calculation of angles due to likelihood of interference with the environment [19]; however, it was used to assist with the calibration of the wearable sensors [18]. The receiver has an approximate communication range of 10 m. A custom developed software program was used to collect, store and process the data.

Two step motors (28BYJ-48) were used to simulate movement of the wrist joint, specifically wrist joint flexion and extension. The step motors were programmed to perform synchronized circular movements.

2.2 Experimental set up

Data were collected using the wearable sensors for 1 degree of freedom (DOF) (flexion/extension) in two separate experiments. The wearable sensors were calibrated on a flat surface (i.e table) prior to collecting data. Double sided tape was used to attach the wearable sensors to the devices.

2.2.1 Experiment one

The objective of this experiment was to determine the accuracy of the angular measurements recorded by the wearable sensors compared with the robotic device in a condition whereby one sensor was static and the other

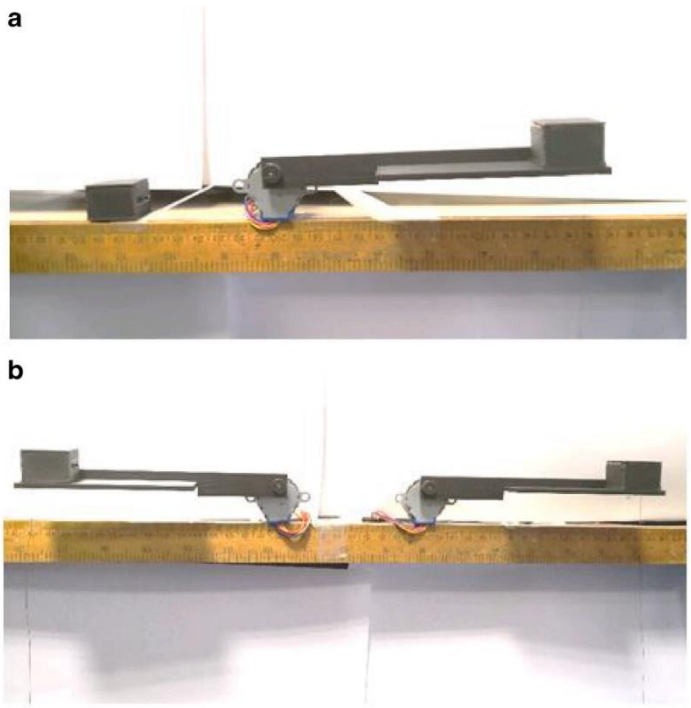

Fig. 1 Set up of wearable sensors for **a**) experiment one and **b**) experiment two

was moving. The wearable sensors were set up with a step motor, as shown in Fig. 1a, with one wearable sensor static on the table and the other placed on the step motor arm that moved to simulate flexion and extension. The step motor started at neutral (0°) and was programmed to move in approximately 15° increments returning to 0° between each increment (i.e., 0, 15, 0, 30, 0, 45, 0, 60, 0, 75). This was repeated for five trials at the movement speed of 90°/s.

2.2.2 Experiment two

The objective of this experiment was to determine the accuracy of measurement using the wearable sensors when both sensors are moving, and whether this accuracy is influenced by speed of movement. The wearable sensors were mounted on the arm of each step motor, as shown in Fig. 1b. The starting angle of each step motor was set to neutral (0°) and programmed to move in 30° increments returning to 0° between each increment (i.e., 0, 30, 0, 60, 0, 90, 0, 120, 0, 150°). Exact robot angles are outlined in Table 2. This was repeated for five trials at two movement speeds: 30°/s and 90°/s.

2.3 Data processing

Raw data from the wearable sensors were exported into an Excel spreadsheet and analysed in MATLAB (R2014b) using the sensor fusion algorithms and filtering techniques outlined in [18].

2.4 Statistical analysis

The mean and standard deviation (SD) of the peak angles were manually determined in Excel. To help guide the clinical interpretation of the measurement error, the following parameters were considered: <2.0° error was considered acceptable, between 2.0 and 5.0° was regarded as reasonable but requires consideration when interpreting the data, and > 5.0° of error should be interpreted with caution [20].

3 Results

3.1 Experiment one

The mean error between the robot and wearable sensor when detecting peak angle ranged from -0.95° (± 0.34) to 0.11°(±0.56) (Table 1).

Table 1 Experiment one: The mean error between the robot and wearable sensors to detect peak angles at 90°/s movement speed

Target robot angle (°)	Robot angle (°)	WS angle (°)					Mean WS angle (°)	Mean error (Robot – WS) (± SD) (°)
		Trial 1	Trial 2	Trial 3	Trial 4	Trial 5		
15	15.24	14.41	14.64	15.52	15.58	15.49	15.13	0.11 (± 0.56)
30	29.16	30.10	31.55	26.67	28.65	29.80	29.35	−0.19 (± 1.82)
45	44.08	45.06	44.54	45.48	45.11	44.96	45.03	−0.95 (± 0.34)
60	60.00	60.64	60.02	60.96	61.61	60.90	60.82	−0.83 (± 0.58)
75	76.14	76.82	76.53	76.77	77.14	76.44	76.74	−0.60 (± 0.27)

WS Wearable sensor, *SD* Standard deviation

3.2 Experiment two

The mean error between the robot and the wearable sensors ranged from -0.92° (±0.94) to 2.90° (±6.47) when the movement speed was set at 30°/s and ranged from -2.63° (±0.96) to 0.54 (±1.24) at a movement speed of 90 °/s (Table 2).

4 Discussion

The purpose of this study was to determine the error in the measurement of angles associated with custom designed wearable sensors when compared to a robotic device. The comparison of wearable sensor output to known angles from a robotic device provides a measure of 'true error,' and is commonly undertaken in studies as the first step towards the validation of wearable sensors [12–17].

In experiment one, an acceptable mean error (range: -0.95° to 0.11°) was demonstrated when one wearable sensor was static and the other dynamic. The largest mean error (-0.95°) was observed for the 44.08° angle measurement. The mean error associated with smaller angle measurements of 15.25° and 29.16° (range: -0.19 to 0.11) was less than the mean error associated with larger angle measurements of 60° and 76.14°. The error, however, was not constant. Similar results have been achieved when comparing wearable sensors to a pan and tilt unit that simulated wrist flexion, with mean error between 0.06° (±9.20) [21] and 1.8° (±6.0) [12]. This type of movement task can be likened to measuring passive wrist range of motion, whereby the forearm wearable sensor is static, and the hand wearable sensor is dynamic. This is a common clinical assessment completed by therapists using visual estimation or a goniometer [22]. Given the demonstrated potential accuracy, further *in vivo* research is required to determine the agreement between the wearable sensors and the goniometer - the tool typically used clinically.

Whether or not speed of movement influences the accuracy of wearable sensors on the upper limb is debatable. One study that utilised wearable sensors to measure wrist flexion/extension and twist on a robotic device demonstrated a slight increase in error from the slow (root mean square (RMS) error range: 1.1° - 1.8°) to the fast movement speed (RMS error range: 1.8° - 3.4°) [16]. However, Zhou and Hu [23] found that when wearable sensors were used to determine wrist

Table 2 Experiment two: The mean error between the robot and wearable sensors at two movement speeds

Movement speed (°/s)	Target robot angle (°)	Robot angle (°)	WS angle (°)					Mean WS angle (°)	Mean error (Robot – WS) (± SD) (°)
			Trial 1	Trial 2	Trial 3	Trial 4	Trial 5		
30	30	30.48	29.74	31.02	16.05	30.22	30.90	27.58	2.90 (±6.47)
	60	59.96	60.08	59.46	58.54	60.93	61.81	60.16	−0.20 (±1.27)
	90	88.74	89.55	90.19	90.95	89.02	88.58	89.66	−0.92 (±0.94)
	120	119.53	119.39	119.28	117.06	119.41	119.35	118.90	0.63 (±1.03)
	150	150.20	150.05	148.66	150.50	150.61	150.25	150.01	0.19 (±0.79)
90	30	30.48	31.14	29.24	31.26	28.38	29.65	29.94	0.54 (±1.24)
	60	59.96	61.84	60.20	59.19	58.97	59.84	60.00	−0.04 (±1.13)
	90	88.74	92.32	92.26	91.24	91.06	89.98	91.37	−2.63 (±0.96)
	120	119.53	122.45	121.26	121.55	120.84	121.46	121.51	−1.98 (±0.59)
	150	150.20	152.96	152.24	151.94	152.32	152.45	152.38	−2.18 (±0.37)

WS Wearable sensor, *SD* Standard deviation

position on human participants; no significant change in error was associated with speed variations. The current study also found that the speed of movement (i.e. slow and fast) did not significantly effect measurement error. Rather, variability in the magnitude and direction of the error was observed across the different measurement angles, with no systematic or constant error apparent. The custom wearable sensors also had a slight tendency to over-estimate the angle, reflected by the negative sign (−).

The largest mean error reported for the slow movement speed (30°/s) was 2.90° (± 6.47) at the 30.48° angle. The increase in error observed at this angle was due to a drop in communication between one of the wearable sensors and the receiver device for approximately 1 second. The mean error is reduced when the outlier is removed (0.01° ± 0.60). For the fast movement speed (90°/s) the largest mean error reported was -2.63° (±0.96) at the 88.74° angle.

Overall, the custom wearable sensors demonstrated similar error across both experimental conditions irrespective of whether one or two wearable sensors were moving, and error did not appear to be significantly influenced by movement speed. Therefore, we anticipate that the custom wearable sensors could be used with confidence to measure flexion/extension of the wrist at slow and controlled movement speeds, and further *in vivo* testing is now required. Data collected for populations whose speed may be faster and more sporadic (i.e. young children) needs to be interpreted with knowledge that increased speed of movement may be associated with an increase in error. Analysis of error associated with use of the custom wearable sensors *in vivo* with children of typical development and children with a brain injury will provide further evidence of this accuracy and is currently underway.

5 Limitations

The robotic devices used in this study were limited to single plane movement (i.e. flexion/extension); the error associated with movement in multiple planes of movement is likely to be greater than that demonstrated in this study but requires further investigation.

6 Conclusion

The custom wearable sensors utilised in this study have demonstrated an acceptable level of error to measure peak angles (1DOF: flexion/extension) when compared to known angles from a robotic device, with mean error ranging from -2.63° to 2.90° across both experiments. Further to this, they also demonstrate acceptable to reasonable error at both a fast and slow movement speed. The results are positive and warrant further investigation of the accuracy of the wearable sensors when used in vivo for single and multiplane movement.

Acknowledgements This research was completed with support from the Australian Government Research Training Program Scholarship and Perth Children's Hospital Foundation. A grant was awarded from the Australian Catholic University to fund the development of the wearable sensors.

Compliance with ethical standards

Disclosure of potential conflicts of interest Author CE holds a position at Perth Children's Hospital, and CI is employed by the Australian Catholic University. The authors declare that neither the Australian Catholic University nor the Perth Children's Hospital Foundation had a role in the conduct of the research or the reporting or interpretation of results.

Ethical approval Ethical approval was not required.

Informed consent This study did not include human participants and therefore informed consent is not applicable.

Conflict of interest The authors declare that they have no conflict of interest.

Abbreviations *3DMA,* Three-Dimensional Motion Analysis; *WS,* Wearable sensor; *SD,* Standard deviation; *RMS error,* Root mean square error; *DOF,* Degree of freedom

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Appendix B Published Conference Abstracts

B.1 Measuring upper limb range of moton using wearable sensors: A systematic review

Presented at the Australasian Academy of Cerebral Palsy and Developmental Medicine. AACPDM 66th Annual Meeting. 2018, Auckland, New Zealand

C WALMSLEY[1], S WILLIAMS[2], T GRISBROOK[2], C ELLIOTT[3], C IMMS[4], A CAMPBELL[2]

[1]School of Occupational Therapy & Social Work, Curtin University, Perth, Australia; [2]School of Physiotherapy & Exercise Science, Curtin University, Perth, Australia; [3]Department of Paediatric Rehabilitation, Princess Margaret Hospital, Perth, Australia; [4]Faculty of Health Science, School of Allied Health, Australian Catholic University, Melbourne, Australia

Background and Objectives: Accurate and reliable measurement of joint range of motion (ROM) in the upper limbs of children with cerebral palsy (CP) provides valuable clinical information, with such information used to guide treatment plans, determine the efficacy of such treatment and monitor progress over time. Wearable sensors are portable measurement tools that are becoming increasing popular for the assessment of active movement. However, with many brands emerging on the market, each with variations in hardware and protocols, evidence to inform selection and application is needed. Therefore, the objective of this systematic review was to identify: (i) the wearable sensors that have been reported in the literature for measuring ROM in the upper limbs, (ii) the established psychometrics of reported measures and (iii) which wearable sensors have been used to measure upper limb ROM in children with CP and/or other movement disorders.

Study Design: Systematic Review (Prospero registration: CRD42017059935).

Methods: Searches were completed in MEDLINE, EMBASE, CINAHL, Web of Science, SPORTDiscus, IEEE and Scopus. Included studies were reviewed, and data extracted independently by two reviewers. A narrative synthesis of the findings was undertaken.

Results: Of 1759 records identified through database searching, 50 met the inclusion criteria and were included in the review. Of these, 17 reported on the validation of the wearable sensors against a motion analysis system and seven reported on the validation against a non-human reference (i.e. robotic device). One study reported on reliability outcomes and 25 reported use of wearable sensors as an outcome measure. Various commercially available brands (n=11) and custom designed (n=6) wearable sensors were reported, each with variations in their placement on the upper limb, calibration methods and data fusion techniques which influenced the accuracy of the wearable sensor. The mean error (in degrees) between the wearable sensors and a 'gold standard' motion analysis system ranged from 0.02 (± 0.04) to 9.38 (± 5.79) for the shoulder, 0.04 (± 0.10) to 11.91 (± 6.27) for the elbow, and 2.19 (± 4.64) to 7.37 (± 4.60) for the wrist. None of the studies included a population of children with movement disorders.

Conclusions: Wearable sensors have the potential to be used as an alternative to three-dimensional motion analysis system to measure upper limb joint ROM during active movement. Additional research needs to explore the use and accuracy of the wearable sensors for the clinical application to children with CP.

B.2 Passive range of motion – is it useful? Understanding the relationship between passive and functional range of motion at the wrist in children with cerebral palsy

Presented at the European Academy of Childhood Disability (EACD) 2018, Paris, France

E FERNANDO[1], C WALMSLEY[1], C WILD[1], T GRISBROOK[1], S WILLIAMS[1,2]
[1]Curtin University, Perth, Australia; [2]University of Auckland, Auckland, New Zealand

Introduction: While measurement of passive wrist range of motion (ROM) using a goniometer is used to evaluate the effectiveness of interventions in children with cerebral palsy (CP), it may not reflect the ROM used during functional tasks. This study aimed to (1) describe the relationship between functional and peak-passive wrist ROM, and (2) compare functional and passive wrist ROM of children with CP to typically developing (TD) peers.

Patients and Methods: Thirteen children with CP (Manual Ability Classifications System levels I–IV; 8y 4mo±2y 4mo) and 14 TD children (9y 9mo±2y 11mo) had measurements of passive wrist ROM (goniometry), and functional wrist ROM (three-dimensional motion analysis) during upper limb tasks taken. Peak-passive ROM was compared to functional ROM (paired *t*-tests), and values between groups were cross-compared (independent *t*-tests).

Results: Children with CP had significantly smaller peak-passive and functional ROM compared to TD children ($p<0.001$). Children with CP used more of their passive wrist extension ROM to complete functional tasks (86±48%, TD: 51±9%). Typically developing children completed the tasks wholly in extension, using −10±7% of their passive flexion ROM (CP: 30±25%). There was no correlation between passive and functional wrist ROM in either group ($r= 0.535$ to 0.367; $p>0.05$).

Conclusion: Findings raise the question of the suitability of passive ROM measurement as a clinical indicator of upper limb function. In addition to measuring peak-passive ROM, clinicians should consider the amount of functional ROM needed to complete specific tasks, and aim to incorporate goal-orientated

Appendix C Ethical Approval

C.1 Curtin University – Ethical Approval

MEMORANDUM

Curtin University

To:	Dr Sian Williams School of Physiotherapy and Exercise Science
CC:	Miss Corrin Walmsley
From:	Dr Catherine Gangell, Manager, Research Integrity
Subject	Ethics approval Approval number: RDHS-11-16
Date:	18-Jan-16

Office of Research and Development
Human Research Ethics Office

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

Thank you for your application submitted to the Human Research Ethics Office for the project: 6535

An investigation into the feasibility of using three dimensional motion analysis and portable inertial motion units to measure active and passive upper limb range of motion in children

Your application has been approved through the low risk ethics approvals process at Curtin University.

Please note the following conditions of approval:

1. Approval is granted for a period of four years from **18-Jan-16** to **18-Jan-20**
2. Research must be conducted as stated in the approved protocol.
3. Any amendments to the approved protocol must be approved by the Ethics Office.
4. An annual progress report must be submitted to the Ethics Office annually, on the anniversary of approval.
5. All adverse events must be reported to the Ethics Office.
6. A completion report must be submitted to the Ethics Office on completion of the project.
7. Data must be stored in accordance with WAUSDA and Curtin University policy.
8. The Ethics Office may conduct a randomly identified audit of a proportion of research projects approved by the HREC.

Should you have any queries about the consideration of your project please contact the Ethics Support Officer for your faculty, or the Ethics Office at hrec@curtin.edu.au or on 9266 2784. All human research ethics forms and guidelines are available on the ethics website.

Yours sincerely

[redacted]

Dr Catherine Gangell
Manager, Research Integrity

C.2 Child and Adolescent Health Service – Ethical Approval

Government of **Western Australia**
Department of **Health**
Child and Adolescent Health Service
Research Governance Office

Our Ref: 2014061EP

Professor Christine Imms
Level 2 Daniel Mannix Bldg
Australian Catholic University
17 Young Street
Fitzroy VIC 3067

Dear Professor Imms

HREC REF **2014061EP**
STUDY TITLE **iWHOTrial:A Multicentre Randomised Controlled Trial of Rigid Wrist and Orthoses for Young Children with CereorarPalsy.**

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

Princess Margaret Hospital for Children - CAHS

This authorisation is based on the approval from PMH HREC and the review from the Research Governance Office. This authorisation is valid subject to the ongoing approval from the HREC.

This authorisation is based on the ethical approval from the 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 being withdrawn.

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

Y[redacted]

Dr Mark Salmon
Executive Director
Medical Services

27/11/2014

]

C.3 Child and Adolescent Health Service – Extension Approval

Government of **Western Australia**
Child and Adolescent Health Service

Our Ref: 2014061EP

From: CAHS, Ethics <pmhethics@health.wa.gov.au>

To: christine.imms@acu.edu.au

cc: Catherine.Elliott@health.wa.gov.au; Catherine.Elliott@health.wa.gov.au

Subject: 2014061EP - EXTENSION OF TRIAL APPROVAL

Dear Professor Imms

HUMAN RESEARCH ETHICS COMMITTEE (HREC)

HREC Ref	**2014061EP**
Study Expiry Date	**24/10/2018**
Study Title	**iWHOTrial:A Multicentre Randomised Controlled Trial of Rigid Wrist hand Orthoses for Young Children with Cerebral Palsy**

The Children and Adolescent Health Service (CAHS) HREC has recommended approval of the extension application of this study. This recommendation has been ratified and confirmed by the Child and Adolescent Health Service.

It should be noted that all other aspects of the approval remain unchanged, in particular in relation to the progress reports required, as in National Statement S5.5 & S5.7.1, and regarding any further amendments to the protocols.

Please do not hesitate to contact me if you have any queries in regards to this study. Please quote the above study number 2014061EP on all correspondence associated with this study.

Yours sincerely

Dr Catherine Choong
Deputy Chair, CAHS HREC
10/10/2017

C.4 Curtin University – Reciprocal Ethical Approval

MEMORANDUM

Curtin University

To:	Catherine Elliott Occupational Therapy and Social Work
CC:	
From	Professor Peter O'Leary, Chair HREC
Subject	Reciprocal ethics approval Approval number: HR223/2015
Date	08-Dec-15

Office of Research and Development
Human Research Ethics Office

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

Thank you for your application submitted to the Human Research Ethics Office for the project: 6231

iWHOTrial: A Multicentre Randomisted Controlled Trial of Rigid Wrist and Orthoses for Young Children with CereorarPalsy

Your application has been approved through Curtin University Human Research Ethics Committee (HREC) through a reciprocal approval process with the lead HREC.

The lead HREC for this project has been identified as PMH Human Research Ethics Committee

Approval number from the lead HREC is noted as: 2014061EP

Please note the following conditions of approval:

1. Approval is granted from **08-Dec-15** to **21-Aug-17**
2. Research must be conducted as stated in the approved protocol.
3. Any amendments to the approved protocol must be approved by the Ethics Office.
4. An annual progress report must be submitted to the Ethics Office annually, on the anniversary of approval.
5. All adverse events must be reported to the Ethics Office.
6. A completion report must be submitted to the Ethics Office on completion of the project.
7. Data must be stored in accordance with WAUSDA and Curtin University policy.
8. The Ethics Office may conduct a randomly identified audit of a proportion of research projects approved by the HREC.

Should you have any queries about the consideration of your project please contact the Ethics Support Officer for your [redacted] Office at hrec@curtin.edu.au or on 9266 2784. All human research ethics [redacted] are available on the ethics website.

Yours sincerely

[redacted]

Professor Pete[redacted]
Chair, Human Research Ethics Committee

Appendix D Parent and Participant Information and Consent Forms

D.1 Curtin University – Parent and Guardian Information Sheet

Government of Western Australia
Department of Health

Curtin University

Parent and Guardian Information Sheet (0 – 4 years)

The feasibility of using sensors to measure arm and hand movement in young children.

Sensors are a new technology that can measure the amount of movement your child has at the wrist. As they are new, it is important that we ensure the results we get from them are accurate. To know this, the sensors need to be compared to the most accurate method of measuring movement which is three dimensional motion analysis (3DMA).

As a parent of a child between the ages of 6 months and 4 years, you and your child are invited to take part in this study which compares the use of sensors to 3DMA. If you chose to be involved in this study, it will require yourself and your child to attend Curtin University on one single occasion.

About the sensors:

- There are two sensors (Figure 1) that will be applied using hypoallergenic double-sided tape.
- The tape may leave a slight red mark on your child's arm. This should disappear within 30 minutes.
- The sensors are wireless and send information about your child's movement to the computer.

Figure 1: Lego sensors

About three dimensional motion analysis:

- 16 small markers will be used and placed on your child's arm using hypoallergenic double-sided tape.
- Multiple video cameras pick up on the movement of the markers.
- Computer software analyses the movement.

Figure 2: Placement of sensors and 3DMA markers

Things to know:

- Your child will be required to wear a singlet so that we can place some markers on the shoulder
- As the sensors and markers are small, we encourage that if your child takes a pacifier to bring it with you to prevent them from mouthing the equipment.
- The session will be completed within one hour.
- The placement of the markers may take some time, we encourage you bring a toy or something your child likes to help distract them.
- Change table and toilet facilities are close by in the next building.
- You are welcome to watch the assessment.

Government of Western Australia
Department of Health

Curtin University

What to expect:

- Two sensors will be placed on your child's arm (on the forearm and hand). The therapist will place these by feeling lightly for specific locations on the arm and use a measuring tape to determine the distance.
- The therapist will gently move your child's wrist upwards and downwards, and then use a tool called a goniometer to measure the angle of movement.
- 16 circle markers will then be placed on your child's arm in addition to the two sensors. The therapist will place these by feeling lightly for specific locations on your child's hand and arm.
- Your child will then be seated in a high chair and a short play session will be run by the therapist. The play session will be video recorded.
- The two sensors and reflective markers will be removed from your child's arm and hand.

Figure 3: Play session

Figure 4: Goniometer with sensors

Benefits:

While there are no direct benefits for your child, the information gained from this study will help the research team understand movement patterns of typically developing children which can then be compared to other childhood populations.

Possible risks or side effects:

It is possible that your child's skin may appear red after the sensors and markers have been removed from their arm. This should subside after the session and should not have any long term effects.

Confidentiality:

You and your child will be allocated the same participant ID which allows all of the data collected to remain confidential, meaning names and other identifiable information will not be used. The data will be stored on a secured hard drive at Curtin University and Princess Margaret Hospital. The hard copy of the questionnaire responses will be stored in a locked filing cabinet at Princess Margaret Hospital.

D.2 Curtin University – Parent and Guardian Consent Form

For all queries, please contact:
Corrin Walmsley
Occupational Therapist, PhD Candidate

Phone: 93802126
Email: corrin.walmsley@health.wa.gov.au

Curtin University

Government of Western Australia
Department of Health

Parent/Guardian Consent Form

Title	**The feasibility of using sensors to measure arm and hand movements in young children**
Principle Investigator	Sian Williams
Location	Curtin University

Declaration by Parent/Guardian

I have read the Parent/Guardian Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I understand that my participation in this study will involve myself (the parent) completing a short questionnaire.

I understand video records will be taken of my child and will be viewed by the research team.

I understand that my child's de-identified data may be accessed for future ethically approved studies.

I understand the entire session may take up to an hour of my and my child's time.

I understand that the information collected will be kept confidential and will only be accessed by the researcher and supervisors.

I understand my and my child's participation in this study is completely voluntary and I have the right to withdraw myself and my child at any time without penalty or need for reason.

I agree for myself (the parent) and my child to participate in this research project.

Name of Child (please print) _____

Name of Parent/Guardian (please print) _____

Signature of Parent/Guardian _____ Date _____

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number RDHS-11-16). Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au.

Participant Consent Form_V1_12/01/16

D.3 ACU – Parent and Guardian Sensor Information Supplement

Government of Western Australia
Department of Health
Child and Adolescent Health Service

ACU
AUSTRALIAN CATHOLIC UNIVERSITY

Parent and Guardian Sensor Information Supplement

Using sensors to measure arm and hand movement

Sensors are a new technology that can measure the amount of movement your child has at the wrist and elbow. As they are new, it is important that we ensure the results we get from them are accurate. To know this, the sensors need to be compared to the most accurate way of measuring movement which is three dimensional motion analysis (3DMA). As part of the iWHOTrial you are invited to attend Curtin University on **one** single occasion. By comparing the sensors to 3DMA we are one step closer to making movement analysis accessible to in the hospital setting.

Sensors:

- There are three sensors (Figure 1) that will be applied using hypoallergenic double sided tape on your child's arm.
- The tape may leave a slight red mark on your child's arm. This should disappear within 30 minutes.
- The sensors are wireless and send information about your child's arm movements to the computer.

Figure 1: Lego sensors

Three dimensional motion analysis:

- 18 small reflective markers will be placed on your child's arm and hand using hypoallergenic double sided tape (Figure 2).
- Multiple video cameras pick up on the movement of the markers.
- Computer software analyses the movement.

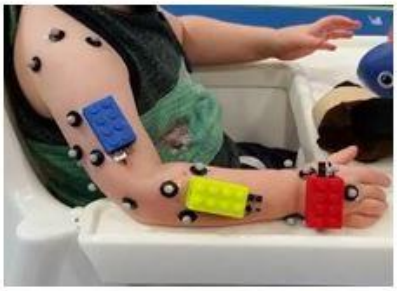

Figure 2: Placement of sensors and 3DMA markers

Things to know:

- Your child will be required to wear a singlet.
- The markers and sensors are designed small so that they will all fit on your child's arm and hand, we therefore encourage if your child takes a pacifier to bring it with you to prevent them from mouthing the equipment.
- The placement of the markers may take some time, we encourage you bring a toy or something the child likes to distract them during this time.

Curtin University

- Change table and toilet facilities are close by located in the next building.
- The session will be completed within one hour.
- You are welcome to watch the assessment.

Procedure:

- Three sensors will be placed on your child's arm at three locations, on the hand, forearm and upper arm. The therapist will place these by feeling lightly for specific locations on the arm and use a measuring tape to determine the distance.
- The therapist will gently move your child's wrist upwards and downwards, and then use a tool called a goniometer to measure the angle of movement. This will happen three times.
- Reflective markers will then be placed on your child's arm in addition to the three sensors. The therapist will place these by feeling lightly for specific locations on your child's hand and arm.
- Your child will then be seated in a high chair and a short play session will be run by the therapist.
- The three sensors and reflective markers will be removed from your child's arm and hand.
- We ask that you then complete a short form about how you feel the session was for your child. You will also receive a phone call which will ask if, and how long for, your child's skin appeared red after the session.

Figure 3: Play session

D.4 ACU – Parent and Guardian Consent Form

Government of Western Australia
Department of Health
Child and Adolescent Health Service

ACU
AUSTRALIAN CATHOLIC UNIVERSITY

Parent/Guardian Consent Form

Title	*iWHOTrial*: A multicentre randomised controlled trial of rigid wrist hand orthoses for young children with cerebral palsy
Short Title	*iWHOTrial*: Infant Wrist Hand Orthoses Trial
Protocol Number	Version 4, 11/09/14
Project Sponsor	Australian Catholic University
Coordinating Principal Investigator/ Principal Investigator	**Principal Investigator:** Professor Christine Imms, Australian Catholic University **Site-specific coordinator:** Professor Catherine Elliott, Princess Margaret Hospital
Project Coordinator	Dr Melinda Randall, Australian Catholic University
Location	Princess Margaret Hospital

Declaration by Parent/Guardian

I have read the Parent/Guardian Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my child's doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Princess Margaret Hospital concerning my child's diagnosis and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to my child participating in this research project as described and understand that I am free to withdraw them at any time during the research project without affecting their future health care.

I understand that, if my child is already wearing a night time orthosis and is randomised to the control group, my child will be required to stop wearing the existing orthosis for the 3 year study period.

I understand videorecords will be taken of my child and will be viewed by the research team

I understand that my child's de-identified data may be accessed for future ethically approved studies.

I understand that, if I decide to discontinue my child's participation in this study a request may be made for him/her to attend follow-up visits to allow collection of information regarding his/her arm and hand movements. Alternatively, a member of the research team may request my permission to obtain access to my child's medical records for collection of follow-up information for the purposes of research and analysis.

I understand that I will be given a signed copy of this document to keep.

Government of Western Australia
Department of Health
Child and Adolescent Health Service

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Name of Child (please print) _____

Name of Parent/Guardian (please print) _____

Signature of Parent/Guardian _____ Date _____

Name of Witness* to
Parent/Guardian's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the parent/guardian has understood that explanation.

Name of
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Appendix E Play Session Protocol

INTRODUCTION

BACKGROUND

Voluntary activation of the extensor muscles is often difficult for children with cerebral palsy (CP) due to a myriad of secondary musculoskeletal changes that occur in addition to spasticity and muscle weakness. As a result, children with CP may have reduced range of motion (ROM) at the wrist joint. Reductions in passive wrist extension can occur within the first few years of life, and clinically reductions in active wrist extension can ensue from an early age. However, quantifiable and objective measurement of maximal active wrist extension has its challenges in young children with CP. Irrespective of the measurement tools used to measure active ROM, there was a need to develop a play session using carefully selected toys to provoke the movement of interest in young children with CP.

PURPOSE

The main purpose of this protocol is to provide guidance to facilitate a uni-manual play session using a careful selection of toys, to provoke maximal active wrist extension. Secondary to this, the aim is to provoke uni-manual maximum active elbow extension. The selection of toys, set up and administration of the play session are crucial to observe the movements of interest.

SET UP OF THE PLAY SESSION

The play session should be playful and ensure the child is comfortable and happy. It is best to complete the play session when the child is most alert and awake. Encourage the parent to bring any snacks for the child.

SEATING

A highchair with a tray table is recommended for children who can sit upright or for children from around the age of 6 months. External support such as padding, a towel or a pillow can be used to ensure the child is stable when sitting independently. Older children from around the age of 2 years may prefer to sit independently on a chair at a table with their hips and knees approximately at 90 degrees. Sitting on the parents or caregivers lap should be the last option. When this is needed, encourage the parent or caregiver to support the child's hips and not to interfere with movement of the upper limb.

Regardless of the type of seating, ensure the infant is as upright as possible and symmetrical with their arms free to play. Ensure the straps are fastened securely and the tray table is secure and stable.

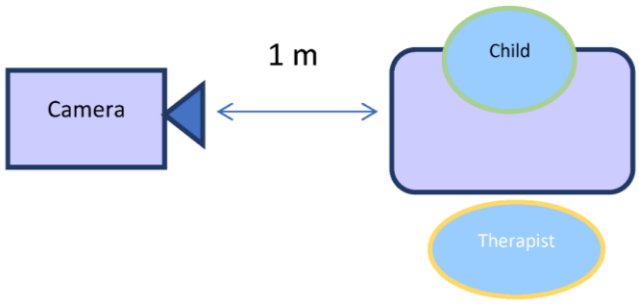
CLOTHING

A sleeveless top is preferable to avoid restriction of movement, and to allow for the placement of the measurement devices (e.g. wearable sensors) on the arm with ease and to observe arm and hand movements. If a long sleeve top is worn, roll the sleeves up as much as possible.

CAMERA

One camera on a tripod is required to capture the play in a standardised manner. The camera height should be at the level of activity and should be set up to capture the child, with minimal foreground/background in view.

Camera	Plane	Distance
1	Sagittal	1 meter from tested arm



POSITION OF THE PLAY FACILITATOR

The play facilitator/therapist should be seated or kneeling directly in front of the child, rather than be posed at one side.

POSITION OF THE PARENTS/CARETAKER

The parent should be situated wherever the child is most comfortable. Inform the parents of the camera lay out to ensure they do not block the cameras view of the child.

POSITION OF THE TOYS

The toys are best kept out of the child's view, ideally underneath the highchair or table. A set of unrelated toys should be available to give to the chid before and after the session to ensure the specific play toys remain new for the play session.

FILMING

Start by filming a piece of paper that outlines the child's initials, date of recording (dd/mm/yy) and arm being assessed (left or right), for approximately 10 seconds.

Example:

A.G

DOB: 05/06/2018

DOA: 23/04/19

ARM: R

SELECTION OF TOYS

Play facilitators are required to self-assemble a toy kit which consists of four toys that can be used with children from 6 months to 5 years of age with varying grasping, reaching and manipulation abilities. Toys similar to the following are recommended; maracas, beads, Velcro ball and magnet board.

TIMEFRAME

The entire session should be completed within a 10-minute timeframe. Each toy should be presented to the child for up to 2 minutes. During the two minutes, the toy should be presented to the child in a number of different ways in attempt to elicit the movements of interest (the position of the toys will be discussed further in detail below).

REQUIREMENTS OF THE PLAY

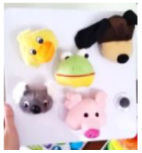
- The toys should be presented one by one for no more than 2 minutes each toy.
- If the child does not wish to play with a toy, the therapist should move on and introduce the next toy. The toy should be taken away from the child if they lose interest, or if they are wanting to play with the toy for an extended time.
- Demonstrate the desired use of the toy to the child to encourage imitation. If required, the parent can model the play.
- Present the toy in a playful manner.
- If the child does not spontaneously initiate movement towards the toy, provide physical prompts in the form of tapping or stroking the top of the hand.
- Gentle restriction of the un-assessed hand may be required to promote uni-manual play.

PLACEMENT OF THE TOYS

The placement of the toys in relation to the child is crucial to elicit the movements of interest (maximal wrist and elbow extension):

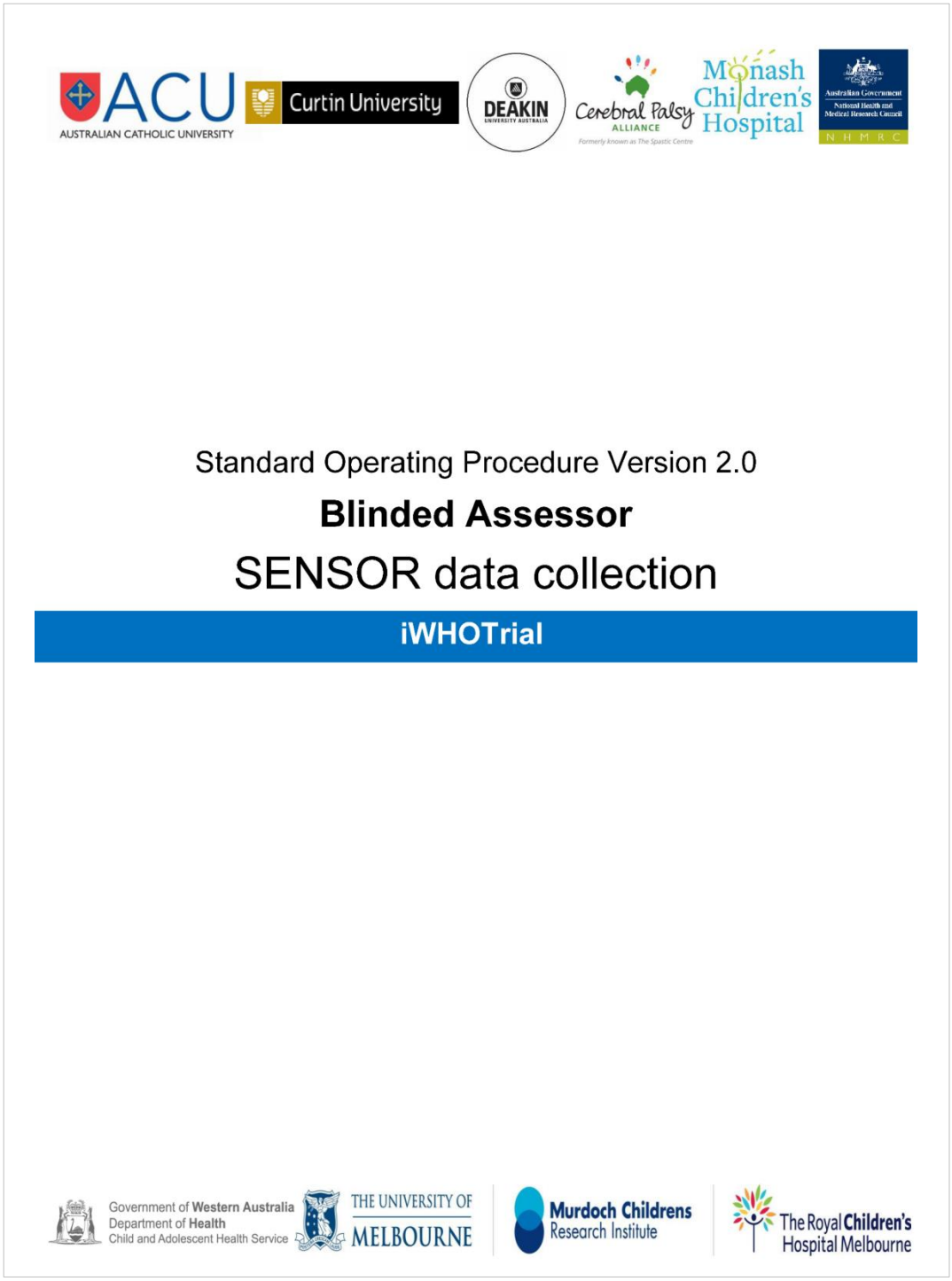
- The *height* of the toy and the *distance* at which the toy is placed away from the infant will determine the amount of active wrist extension, and elbow extension needed for the infant to play with the toy.
- Presenting the toys on the *side* of the assessed hand will encourage the infant to use this hand to explore the toy
- Some toys should be held at shoulder height to encourage reaching and wrist extension.

PLAY PROTOCOL

Beaded string (8mm diameter, 1 m length)		
	Hold the beads vertically at arm's length from child and to the side of assessed hand. Alternate the height of the beads (i.e. head height, shoulder height and closer to the table) and encourage the child to reach and grasp for the beads. Place the beads on the table and encourage the child to pick them up and place them in the play facilitator's hand. After the child has explored the beads, take them away and re-present them to the child again at a different height or distance away from the child.	Elbow flex/ext Wrist flex/ext
Baby maracas		
	Demonstrate shaking maraca in one hand. Hold the maracas at an arm's length from child and to the side of assessed hand. Encourage the child to reach and grasp for the maraca. Alternative the height of the maraca and place the maracas on the table to encourage child to pick the maraca up.	Wrist flex/ext Elbow flex/ext
Magnet Animal Board		
	Demonstrate how to take the animal off the magnet board and place it back on. Hold the board vertically in front of the infant at arm's length and at shoulder height. Encourage child to reach towards the board, if possible, touch the animals or pull the animals off the board, and place them back on.	Wrist ext Elbow flex/ext
Frog Velcro set		
	Demonstrate taking the ball on and off the frog. Hold the frog in front of the child at arm's length and shoulder height. Encourage the child to reach and touch the ball, and if possible, take the ball off. If the Velcro is too strong for the child to pull the ball off, ensure it is adjusted to only slightly be attached to the Velcro to enable the child to easily grasp and take the ball off. Also encourage the child to place the ball back on the frog.	Elbow flex/ext Wrist ext

Appendix F Standard Operating Procedures

F.1 Blinded assessor – Wearable sensor data collection



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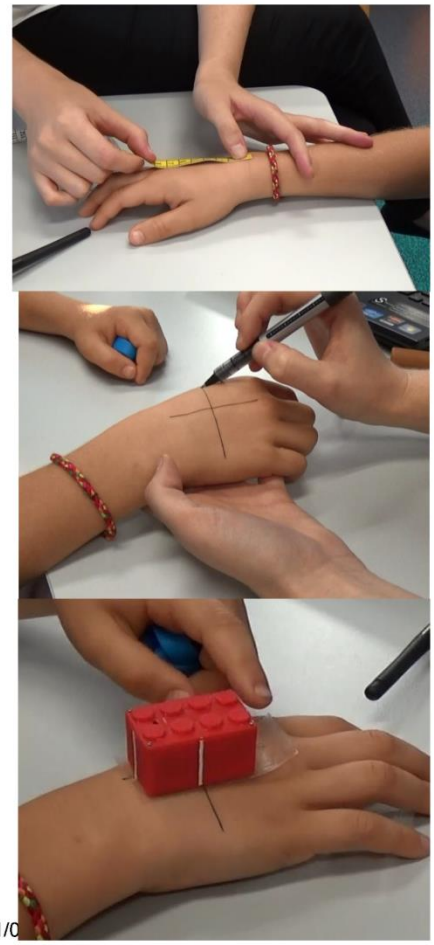
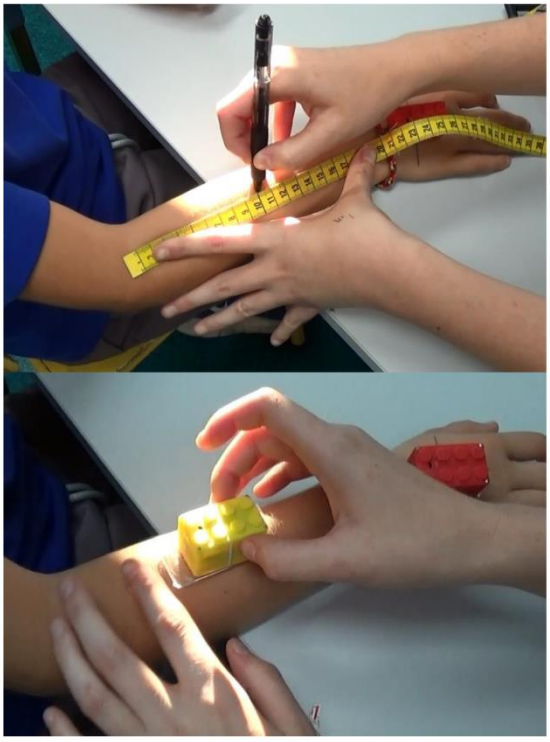
1.0 PLACEMENT OF THE SENSORS

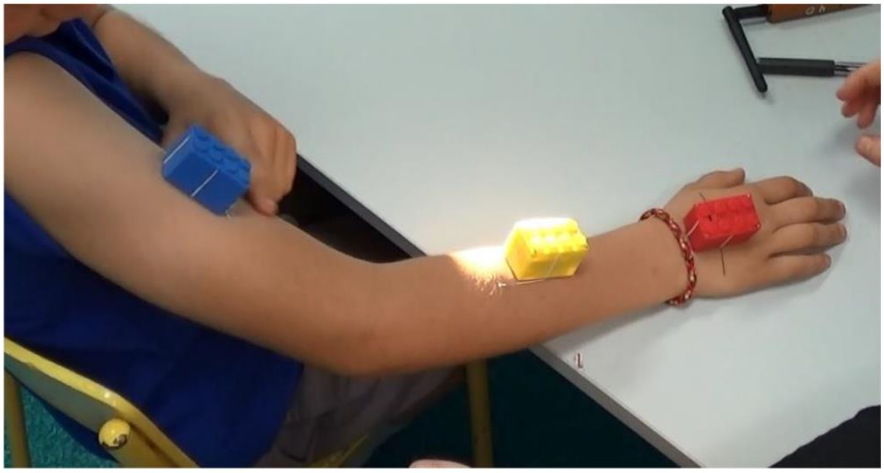
Code	Colour	Area	Description
Sensor 1	Red	Hand	Dorsal surface of hand. With subjects' fingers in flexion, therapist places wrist into passive, end of range extension and places sensor adjacent to dorsal wrist crease, perpendicular to line of 3rd metacarpal. Place sensor with switch facing distally.



Code	Colour	Area	Description
Sensor 2	Yellow	Forearm	Dorsal surface of forearm. Place centre of sensor at half the measured distance from the crease of the elbow and wrist, parallel to long bones of forearm and perpendicular to Sensor 1. Place sensor with switch facing distally.



Code	Colour	Area	Description
Sensor 3	Blue	Upper arm	Lateral surface of upper arm. Place centre of sensor at half the measured distance from the crease of the elbow and acromion process. Place sensor with switch facing towards the thumb.



2.0 PROTOCOL FOR SEMI STRUCTURED PLAY SESSION

The entire session should be completed within a 10 minute timeframe. The play session is semi-structured meaning the toys are pre-determined but there is no pre-determined order in which the toys are presented to the infant. However, it is important to remember that the aim of the session is to present the toys in a way that elicits the movements of interest, with particular focus on active wrist extension.

The play session will focus on uni-manual play. The purpose of this play session is to look at the infant's capacity to use their assessed hand to the best of their ability to handle a selection of toys. This may require restraint of the infant's non-assessed hand. The examiner or parent can gently manually restrain the hand while the examiner simultaneously catches the infant's interest with the activity they want the infant to do. Suggestions of toys to use are outlined in a table on the following page. This play session should run for three minutes. For an infant with unilateral involvement one uni-manual play session should be carried out with the sensors on their affected side. For a child with bilateral involvement, the play session should be repeated twice, one for the left arm with the sensors on and the second for the right arm with the sensors on.

	Uni-manual play
Unilateral involvement	1 x 3 mins
Bilateral involvement	2 x 3 mins

Examiners are required to self-assemble a toy kit which 4 toys. It is important that there are a range of toys suitable for infants 6 months to 3 years of age, who have varying grasping, reaching and manipulation abilities. In order to provide all infants with the same opportunity to demonstrate the movements of interest, all 4 toys within each set need to be presented to the infant one by one within three minute time frame. The examiner may demonstrate the use of the toy to encourage imitation and if the infant is distressed, encourage the parent to model the play. If the infant does not wish to play with a toy, the therapist should move on and introduce another toy.

The placement of the toys in relation to the infant is crucial to elicit the movements of interest (wrist and elbow flexion/extension):

- The *height* of the toy and the *distance* at which the toy is placed away from the infant will determine the amount of active wrist extension, and elbow flexion/extension needed for the infant to play with the toy.
- Presenting the toys on the *side* of the assessed hand will encourage the infant to use this hand to explore the toy
- If necessary, assist the infant to *hold* the toy by placing it in their hand and then encourage movement of their arm/hand.
- Some toys should be held in the air at shoulder height to encourage reaching and wrist extension.
- Placing the toys on the tray table may encourage wrist flexion when *picking* the toys up.

It is important that the therapist has the above factors in mind when conducting the play sessions.

The session should be relaxed and playful and it is important to ensure the infant is comfortable and happy. Consideration may need to be given to the time of day when the infant is most alert and awake. Therapists may wish to encourage parents to bring snacks and a pacifier for infant.

Before filming, allow time for the infant to adjust to the new room and people. Therapist may wish to have an additional toy for infant to play with as a distraction while placing SENSORS on the infant prior to filming.

3.0 TOYS FOR SEMI STRUCTURED PLAY SESSION

Beaded string (8mm diameter, 1 m length)		
	a) Examiner demonstrate picking beads up from table using one hand b) Examiner holds beads vertically at arm's length from infant to the side of included hand. Encourage infant to reach for beads and grasp them. c) After the infant has played with them for a while, take the beads away and place them on the table close to the infant. Move the beads again to gain infants interest and encourage infant to pick them up.	Elbow flex/ext Wrist flex/ext
Baby maracas		
	a) Examiner to demonstrate shaking maraca in one hand. b) Place the maracas on the table at arm's length and to the side of the involved hand to encourage infant to reach and pick the maraca up.	Wrist flex/ext Elbow flex/ext
Magnet Animal Board		
	a) Examiner to demonstrate pulling one animal head off the magnet board. b) Examiner holds the board vertically in front of the infant at arm's length and shoulder height. Encourage infant to reach towards the board, if possible touch the animals or pull the animals off the board.	Wrist ext Elbow flex/ext
Frog Velcro set		
	a) Examiner to demonstrate pulling the ball on and off the frog. b) Examiner holds the frog in front of the infant at arm's length and shoulder height. Encourage the infant to reach and touch the ball, and if possible to pull the ball off.	Elbow flex/ext Wrist ext

F.2 Reasearch assistant – Wearable sensor data collection

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1. PURPOSE

The purpose of this Standing Operating Procedure (SOP) is to outline the procedure for using the Sensors on infants 6 months to 4 years of age as part of the iWHOTrial.

2. PACKAGE CHECKLIST

Please ensure the following items are in the package that you received. All items are essential to the smooth running of this study. If you did not receive something on the list please contact your state study coordinator who will then contact the WA team.



a) Set of 4 lego SENSORS (red, yellow, blue and white) ☐

b) 2 x chargers for the SENSORS ☐

c) 1 x receiver dongle ☐

The following items will be accessible via drop box

d) Software and drivers

e) Standard Operating Procedure Booklet (this booklet)

f) Software demonstration video

3. ADMINISTRATION RIGHTS

To install the software and drivers to the laptop you will need to gain administration rights. You will not be able to make changes to the computer (download and install software) without these rights. To gain administration rights, contact IT department.

iWHOTrial_RA_v2 01/07/15

SOFTWARE INSTALLATION

iWHOTrial_RA_v2 01/07/15

4. HOW TO INSTALL SOFTWARE

a) You would have received a USB in the SENSOR kit. Insert the USB into the PC.

b) Open the USB file

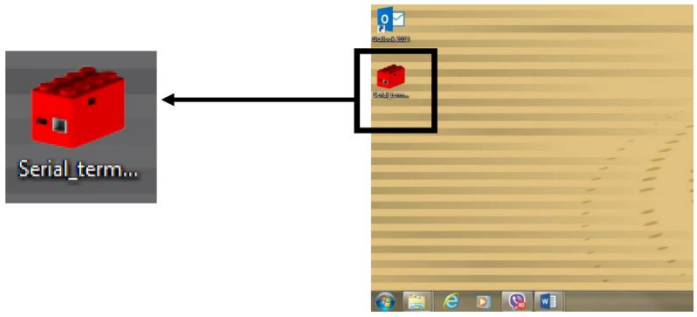
c) You will see a file named: Serial_terminal_upperlimbstudy.exe.

d) Right click and select Copy

e) Return to the PC desktop

f) Right click and select Paste

g) The Software thumbnail should now appear on your PC desktop.

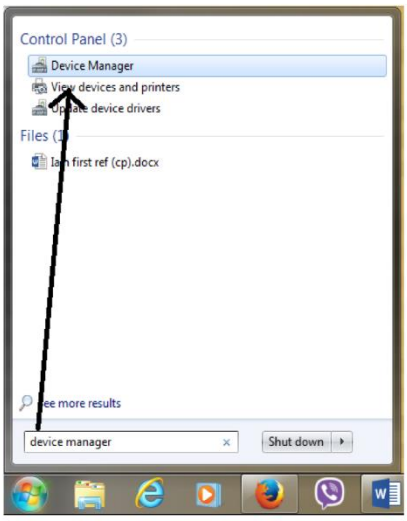


DRIVER INSTALLATION

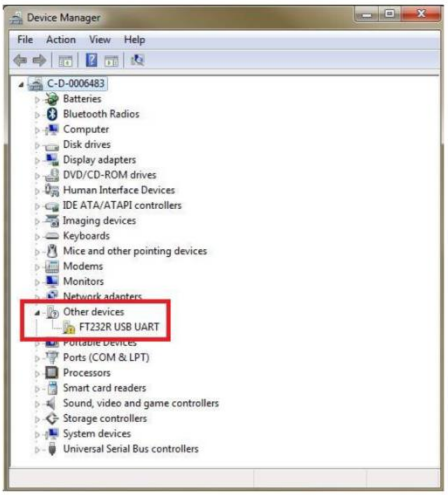
5. INSTALLING DRIVERS

a) Insert USB receiver dongle and USB stick into PC

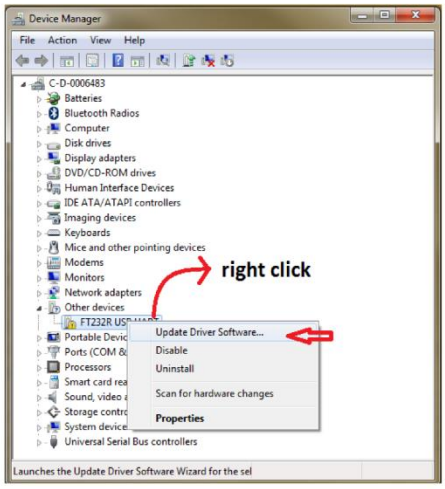
b) Open the device manager (Press the start menu > type 'Device manager' in the search field). Double click '**Device Manager**'



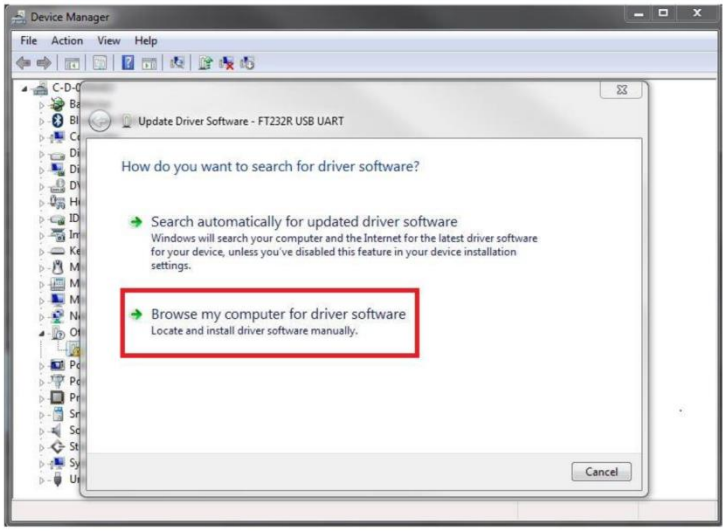
c) When the 'Device manager' file is open, look for 'Other Devices'. Under 'Other Devices' should be a file named **FT23R USB UART**



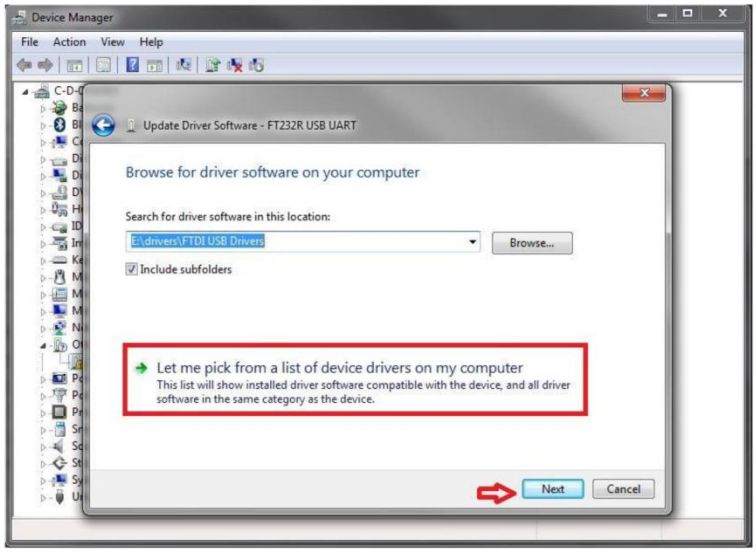
d) Right click on **FT23R USB UART** and select 'Update Driver Software'



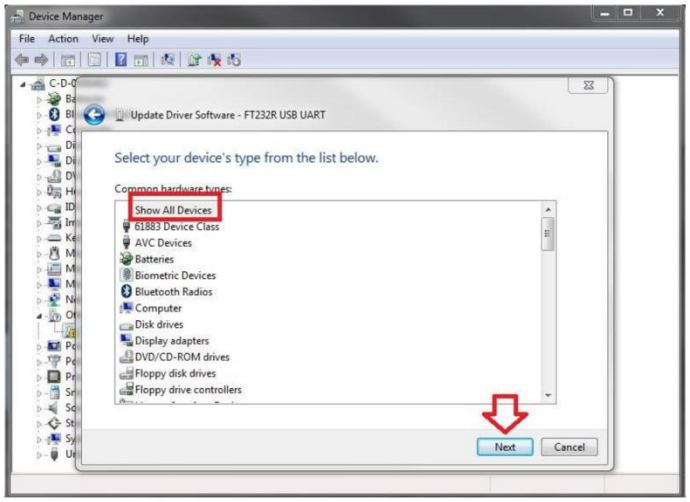
e) Select 'Browse my computer for driver software'



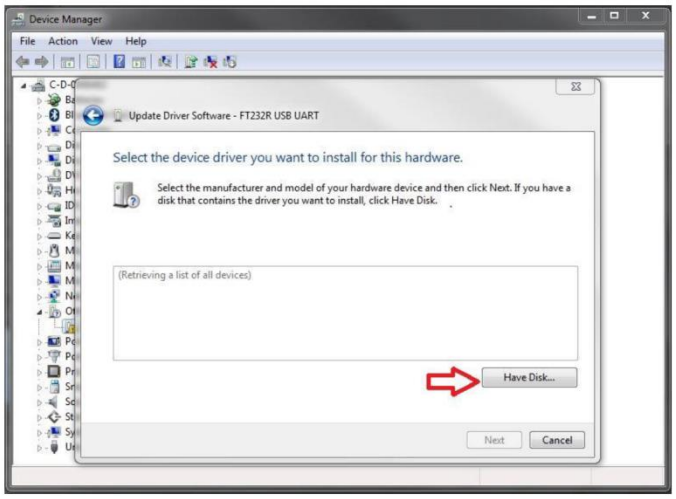
f) Select 'Let me pick from a list of device drivers on my computer' and click 'Next'



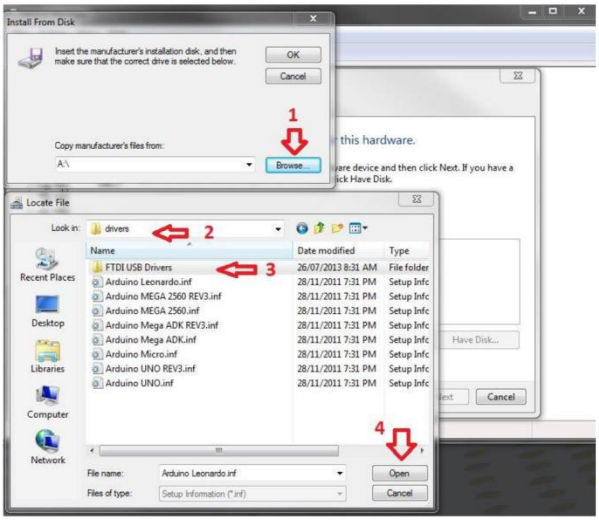
g) Select 'Show all devices' and click next



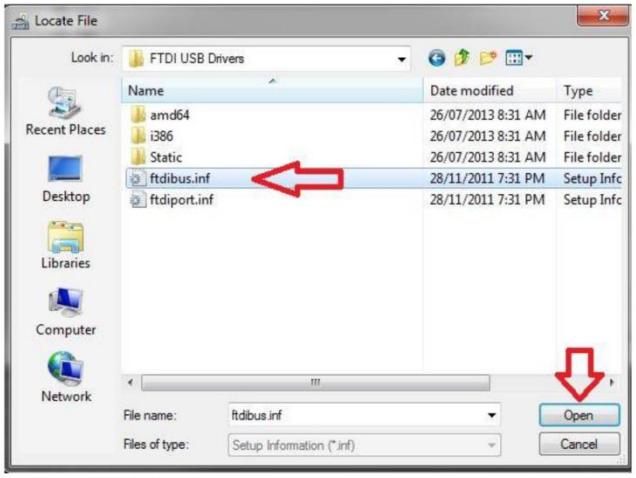
h) Select 'Have disk'



i) Select 'Browse'. When you select browse a separate window will open asking you to locate a file. From this window, you want to open a file on the USB. If it has not automatically appeared, press 'My Computer' and open the USB. Select a file named 'Drivers'. Double click 'FTDI USB Drivers' file. Select 'FTDI bus' Click 'Open' and then 'OK'

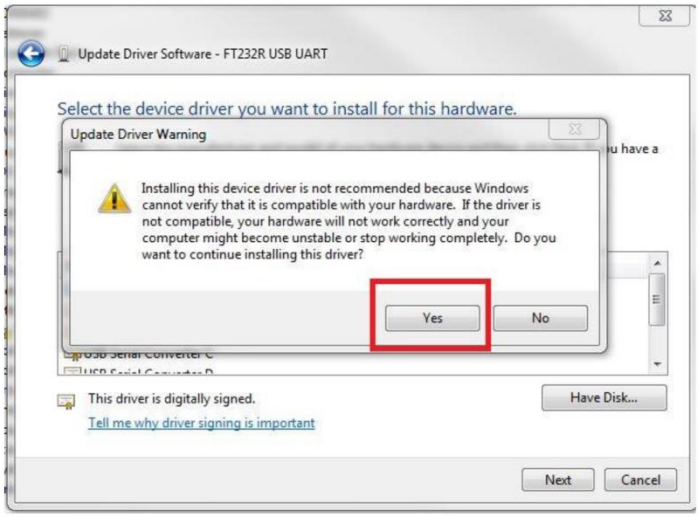


j) Select 'ftdiBUS' and then click 'Open'

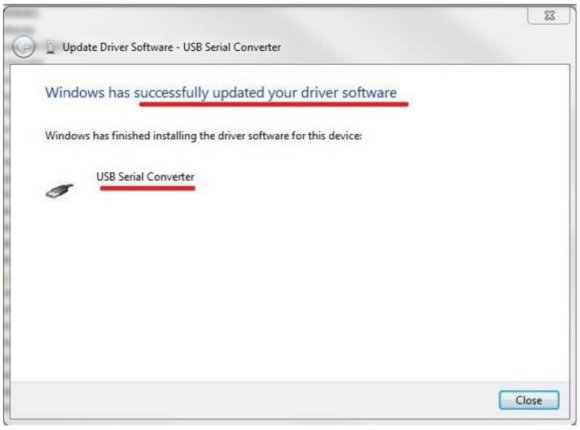


k) Select 'USB Serial Converter' and click 'Next'

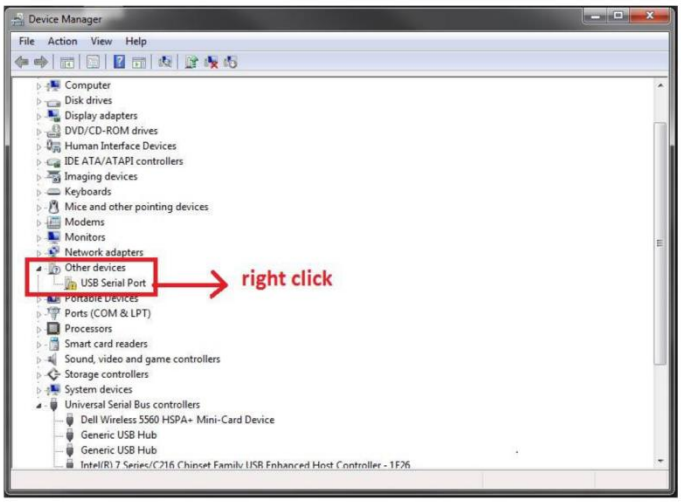
l) An 'Update Driver Warning' will appear. Click 'Yes'



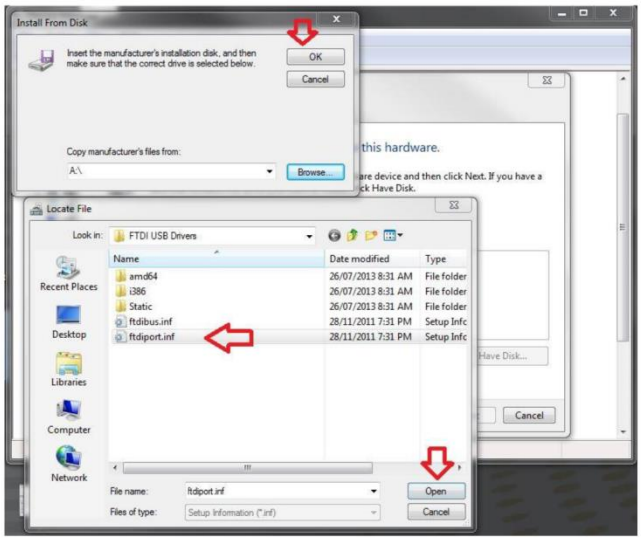
m) The driver should now be installing. Please ensure you wait until you see that the software has successfully updated



n) You now need to follow steps d to h to intstall an additional driver. Go back to the device manager, USB serial port and follow steps d to h

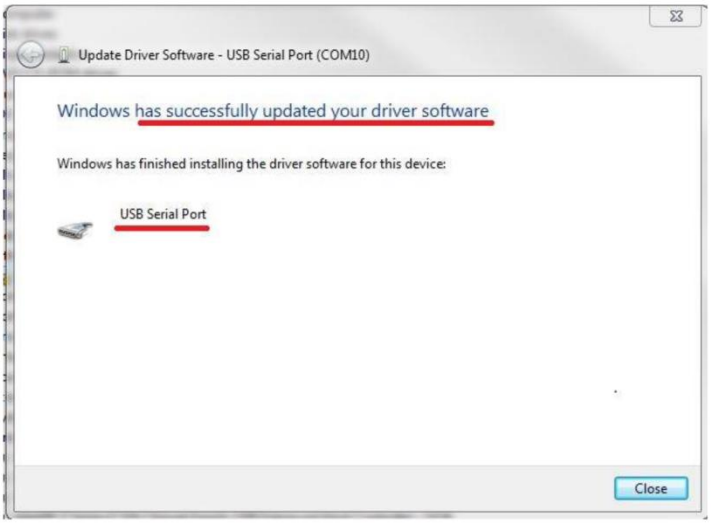


o) Select 'Browse'. When you select browse a separate window will open asking you to locate a file. From this window, you want to open a file on the USB. If it has not automatically appeared, press 'My Computer' and open the USB. Select a file named 'Drivers'. Double click 'FTDI USB Drivers' file. Select 'FTDI PORT' Click 'Open' and then 'OK'



p) Scroll to the bottom of the window and select 'USB Serial Port' and click 'Next'

q) The driver should now be installing. Please ensure you wait until you see that the software has successfully updated



***Please note: You will only have to install the software and drivers once to the laptop, providing you will use the same lap throughout the trial. In event that you will be using more than one laptop, the software and drivers can be installed onto multiple laptops.**

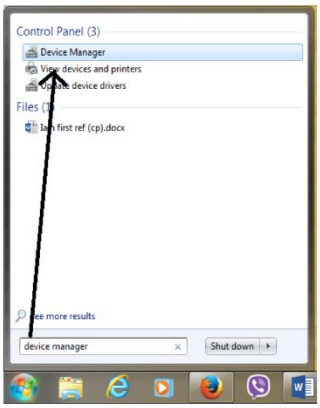
COMMUNICATION (COM) PORT

6. HOW TO SELECT COM PORT

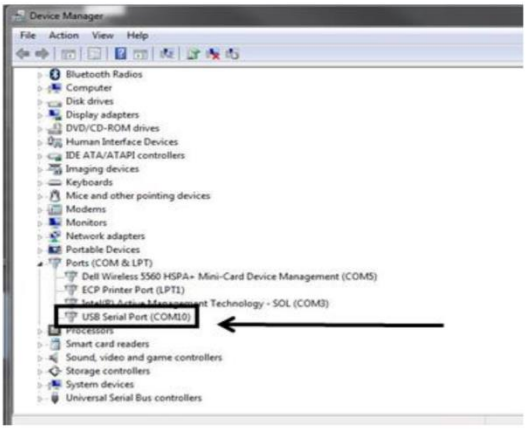
The software requires you to find the correct communication (COM) port. The COM port is where the reciver dongle is inserted into the USB port.

To find the number of the COM port follow these steps:

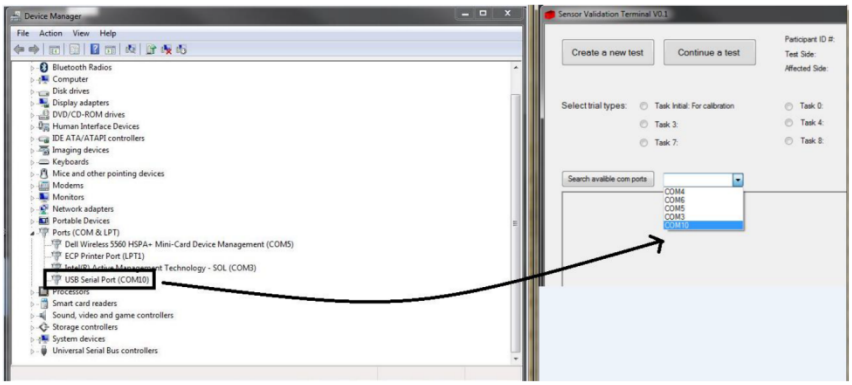
a) Open the device manager (Press the start menu > type 'Device manager' in the search field). Double click 'Device Manager'



b) When the 'Device manager' file is open, scroll the list until you find 'Ports'. Look for USB Serial Port. Ensure you write down the code located next to USB Serial Port , to avoid having to search for the port each time.



c) Go back to the software window. Press '**Search available com ports'.** In the drop down box located next to the 'Search available com ports' button , select the code that corresponds with the code from the **USB Serial Port**



If you insert the receiver dongle into the same USB port each time – the COM port number will remain the same. If you insert the receiver dongle into a different USB port you will have to follow the same procedure to determine the correct number.

***Please note: It may be useful to colour coordinate the receiver dongle with the USB port to save having to find the COM port number each time.**

HOW TO USE THE SENSORS

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7. HOW TO OPERATE THE SENSORS

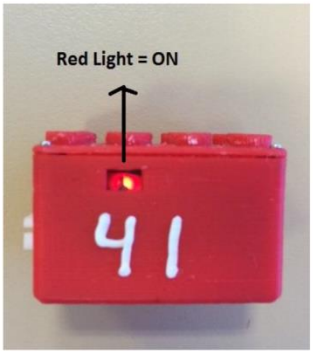
The SENSORS have been developed specifically for this study. Each SENSOR is an inertial motion unit (IMU) which is an electronic device that measures rotation and acceleration by using a combination of accelerometers, gyroscopes and magnetometers.

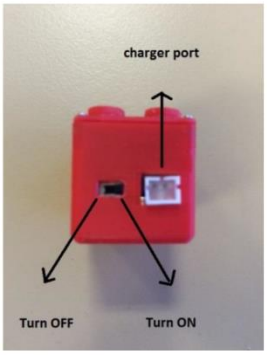
7.1 TURNING ON/OFF

Each SENSOR has an ON/OFF switch.

TURN ON The SENSOR is on when the switch is nearest to the charger port. A dim red light should be visible on each SENSOR when they are turned on.

TURN OFF The SENSOR is off when the switch is furthest away from the charger port. There will be **no** dim red light visible when the SENSOR is off.



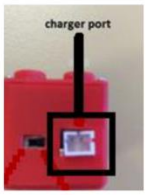


7.2 CHARGING THE SENSORS

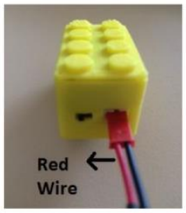
Ensure all SENSORS are charged before starting the session. Once fully charged, the battery has approximately 15 hours of use. It will take approximately 20 minutes per SENSOR to recharge to full battery after one participant.

To charge the SENSORS follow these steps:

a) The charger should be inserted into the white charger port located on each SENSOR. Please ensure you push this completely in the charger port until the red light disappears from the USB end of the charger.

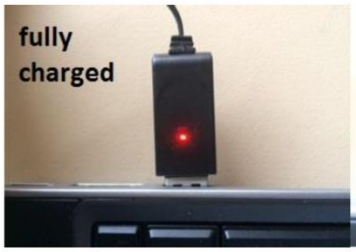


b) Ensure the red wire of the charger is closest to the ON/OFF switch.



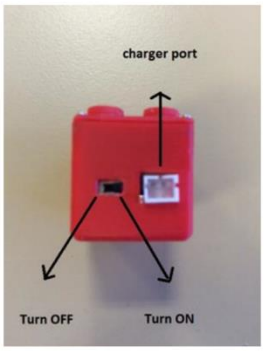
c) Insert the USB end of the charger into the USB port on the PC. (Ensure the charger is inserted into the SENSOR before inserting the USB end into the PC)

d) A red LED light will show when the SENSORS are fully charged. The red LED light should **not** show when the sensor is being charged



7.3 HOW TO RE-SET THE SENSORS

Reset the SENSORS by flicking the switch from ON > OFF > ON.



7.4 CALIBRATING THE SENSORS

The SENSORS need to be calibrated each time before they are placed on the infant. This should be completed just prior to the infant's arrival so that they are ready to be used when the infant arrives.

a) Turn SENSORS ON

b) Place the SENSORS on a flat surface

c) Select 'Calibration' on the software

d) Press 'search available com ports' and select correct com port

e) Press 'Start'. Check that all SENSORS are sending data by ensuring that they are flashing on the software (**Note: it will also flash offline/online – this is normal**). Allow the SENSORS to send data for approximately 60 seconds.

If the SENSORS are not flashing this means they are not sending data. If this happens you will need to press 'Stop', 'Clear without saving' and reset both the SENSOR and receiver dongle.

d) Press stop and then SAVE

e) The SENSORS are now ready to be used with the infant.

HOW TO USE THE RECIEVER

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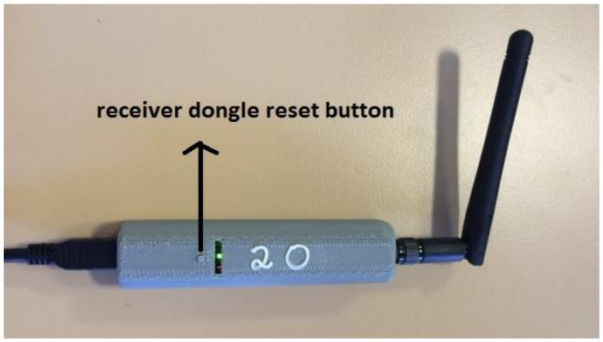
8. RECIEVER

Reset the receiver dongle by pressing the reset button. The receiver dongle needs to be pressed immediately before pressing start on the software, and this needs to occur before each individual movement trial. I.e. You will need to press the receiver dongle before pressing start on the software every time.

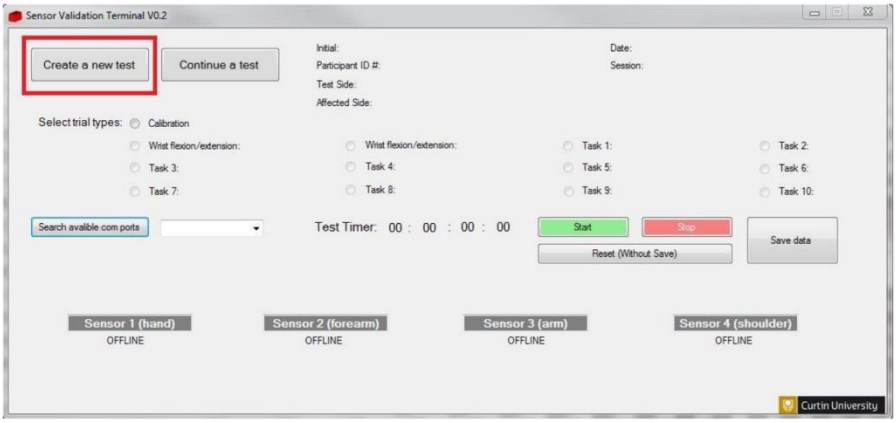


STARTING A TEST

9. STARTING A TEST

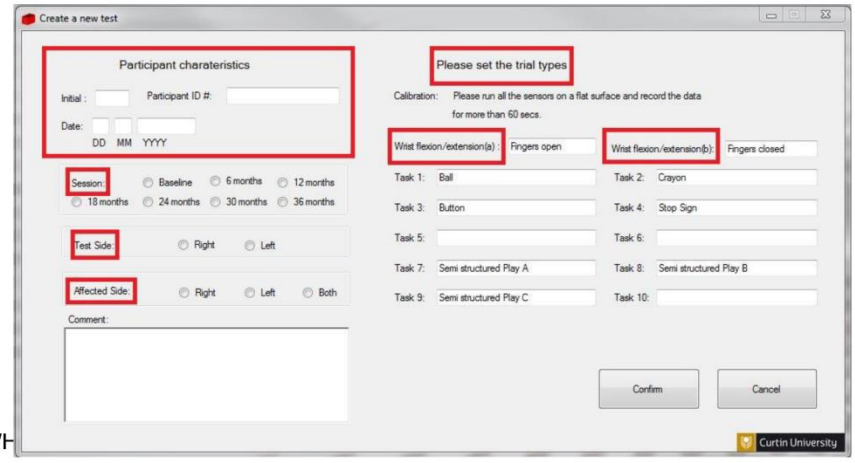
a) Open the software by double clicking on the thumbnail on your desktop

b) Press '**create a new test**'



c) A window will appear. It will ask you to fill out the infants details

You will need to fill out these details every time you see a new infant, and each time the infant attends an appointment (A new task needs to be created for each infant at baseline, 6, 12, 24 etc). If the infant has both hands included in the study you will need to create a new test for each of the included arms (R and L)



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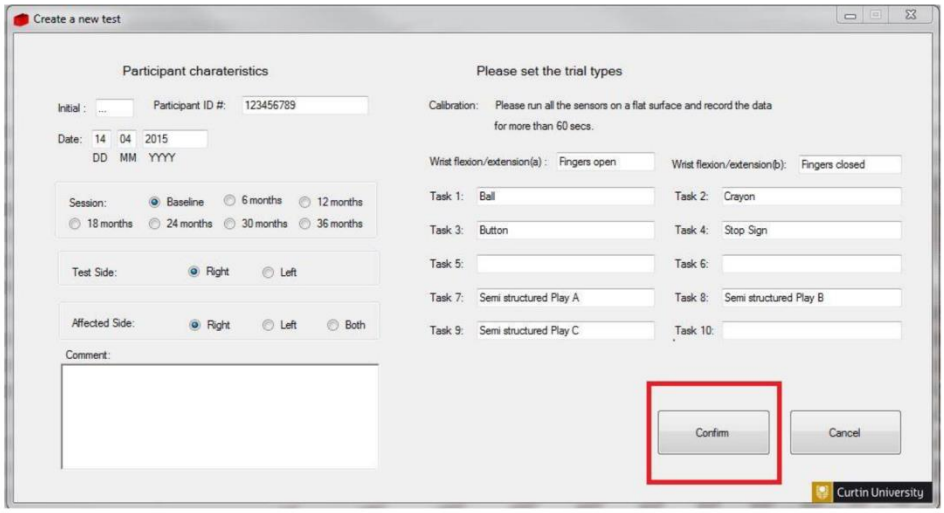
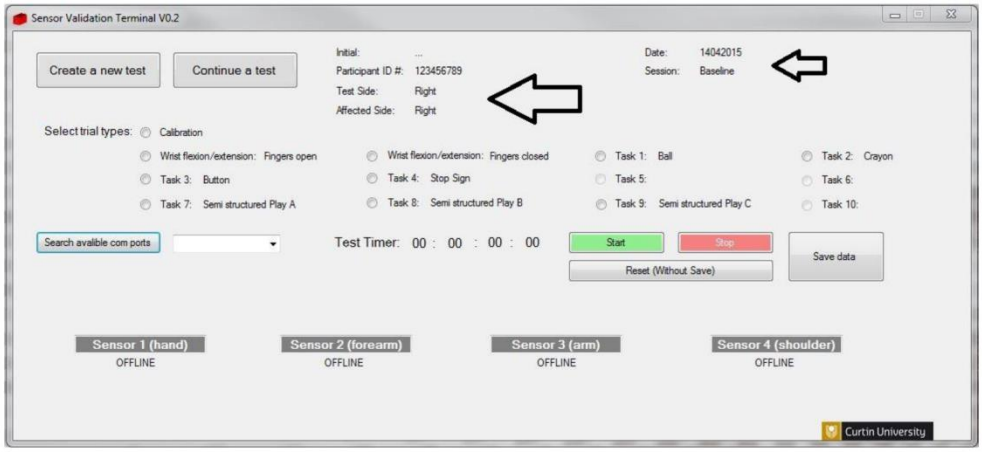
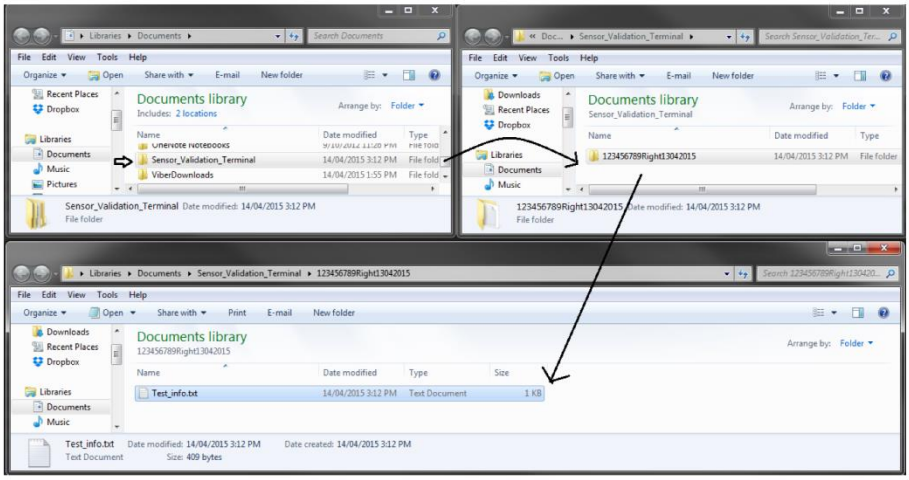
d) Press **'confirm'**



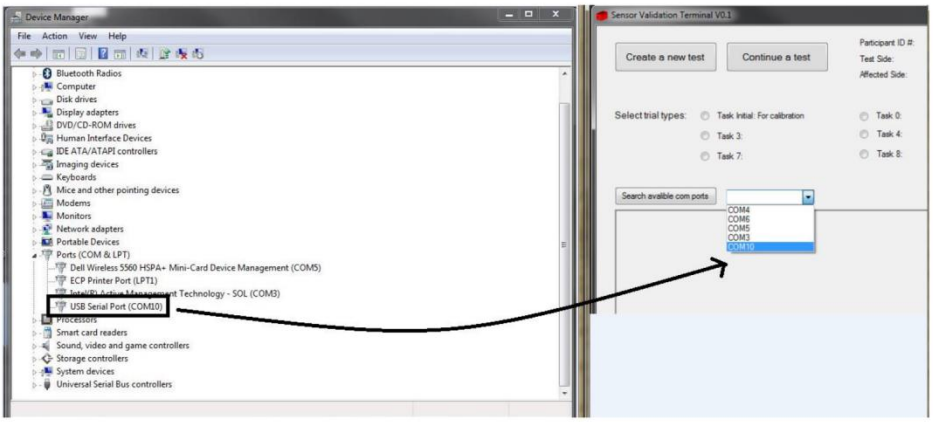
e) The infant's details should now be visible in the main window of the software.



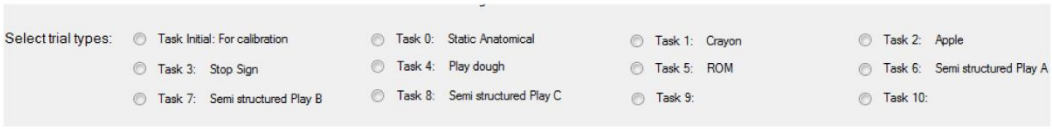
f) If for some reason you are seeing the infant twice in one day, you do NOT need to refill their details in. Instead, you can recall the infants saved information by pressing: '**Continue a Test'.** Choose the file from: Documents > Sensor_Validation_Terminal > Patient File > Test_info.txt
***Please note: The 'Patient File' will be saved with infants unique study ID, test side (ie: Right or Left) and the time point (ie: baseline, 6 months)**



g) The main window of the software requires you to select an appropriate COM port number.

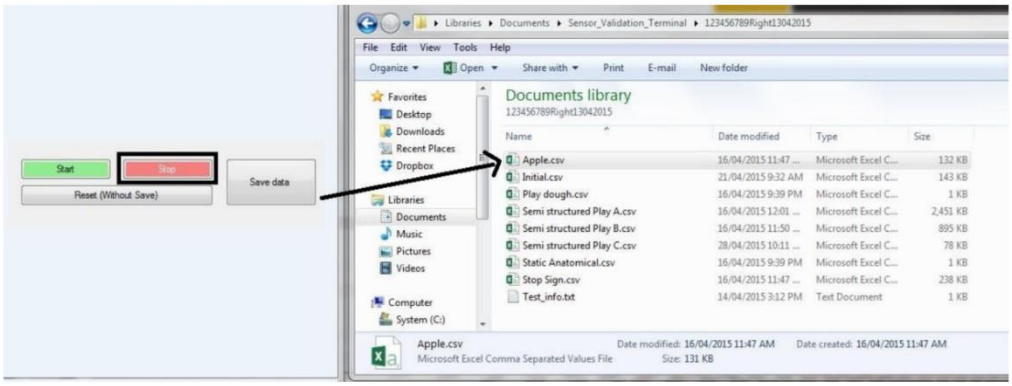


h) Choose the appropriate task.
***Please note: It is important that you choose the correct task name as this cannot be modified later.**

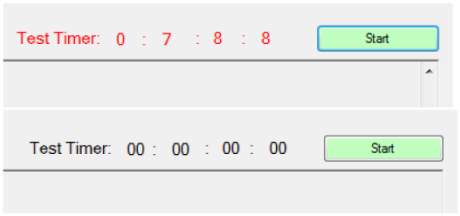


i) Press the reciever dongle and then immediately Press 'Start' on the software. Once you have pressed start it is important to check that all the SENSORS are sending data. To do this, make sure all three SENSORS on the software are flashing. If they are not flashing, press 'Stop' and 'Reset (without save). Turn the SENSORS ON/OFF and press the reciever dongle. Once this has been done, you can re-start the trial again. ***Please note: you will not be using the white SENSOR at this point in time, it will therefore not flash on the software.**

j) When you have finished the trial. Press 'Stop' then 'Save'.
The data will be saved as a .CSV file in the infants file and will be saved as the task name: Example: SemistructredPlayA.csv. After pressing 'Save' you should see a pop up window stating 'Data saved'.



k) The software has a stop watch built into the system. The stop watch starts as soon as you press the 'Start' button. The play session should last for 3 minutes (If you exceed 5 minutes the stop watch will turn red)



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FILE SAVING SYSTEM

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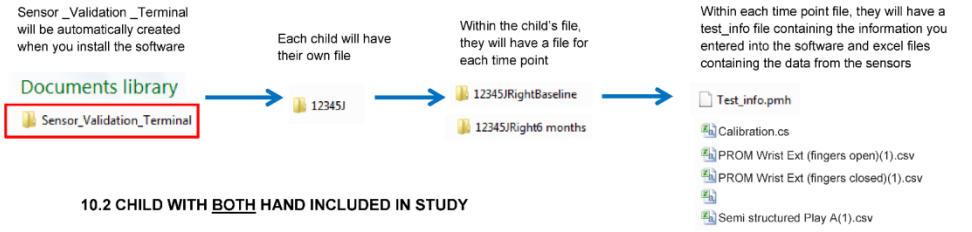
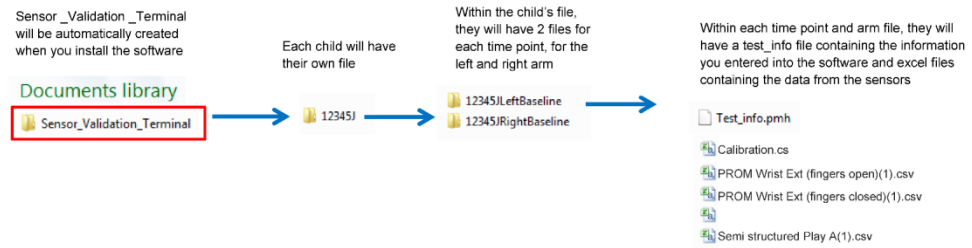
10. FILE SYSTEM

10.1 CHILD WITH ONE HAND INCLUDED IN STUDY



10.2 CHILD WITH BOTH HAND INCLUDED IN STUDY



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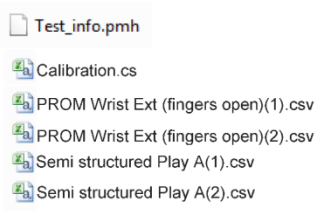
10.3 SAVING MULTIPLE TRIALS

If you repeat a trial, the excel file will automatically save the file with a number in the order in which it was completed. For example:



SOFTWARE CRASHES

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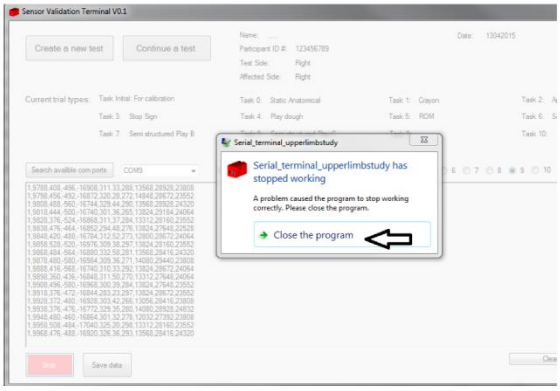
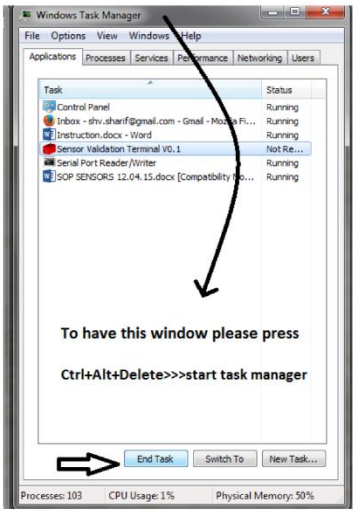
11. WHAT TO DO IF THE SOFTWARE CRASHES

If the software crashes you need to close and re-open the software following the steps below:

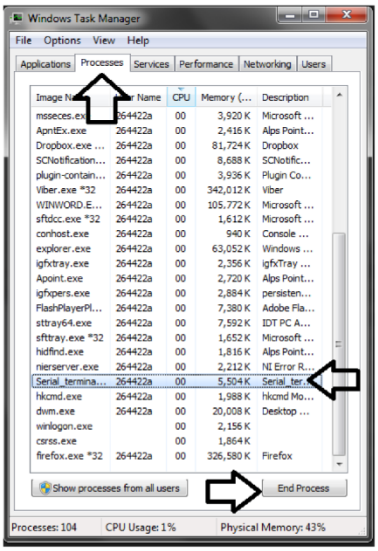
a) Select 'Close the program'



b) Open Windows Task Manager by pressing Ctrl + Alt + Delete at the same time on the keyboard. Select 'Sensor Validation Terminal V0.1' and then press 'End Task'.



c) Select ‘Processes’ then click on ‘Serial_Terminal’ and press ‘End Process’



11.1 HOW TO RECOVER A FILE

In event that the software crashes before you have saved, it is possible to recover the data captured up until the software crashed. The software automatically saves a recovery file located at:

Documents > Sensor_Validation_Terminal > ‘Recovery File’.

To recover the lost data, right click on the recovery file and select ‘Copy’. Double click on the correct infants file, right click and select ‘Paste’. You should then rename the file according to the task/movement you completed.

***Please note: The recovery file re-writes itself after each trial. If you do not follow the above steps immediately after the software has crashed and go on to continue to use the SENSORS for another trial, the previous data will not be available.**

11.2 SOFTWARE FEEDBACK FORM

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This software is newly developed and is the first version of the software to be used. The team who developed the software at Curtin University in Perth would appreciate a 'Software Feedback Form' to be completed if the software crashes or if you have feedback. This form will help improve the software so it is as user friendly as possible for use within the clinical setting. The Software Feedback Form can be found in Appendix C. Please send the form to your states study coordinator who will pass it on to the engineering team in Perth.

SET UP FOR PLAY SESSION

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12.1 SEATING

The seating depends on the infant's capability to sit. If the infant can maintain an upright sitting posture use a high chair with tray table similar to the one pictured below. If the infant has difficulties with postural control consider using alternative seating such as a baby bouncer. If the infant appears distressed, encourage the parent or caregiver to sit close-by. As a last resort, the infant may sit on the parent or caregivers lap. In which case, a table, adjusted to the appropriate height will be needed to carry out the play session.

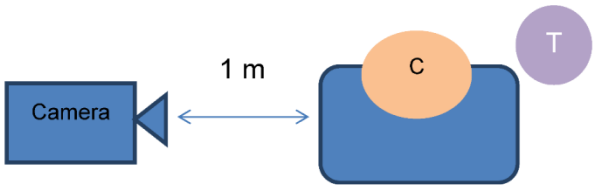
Regardless of the type of seating, the therapist should always ensure the infant is as upright as possible and symmetrical with their arms free to play. Ensure the straps are fastened securely and the tray table is secure and stable.

***Please specify the type of seating used on the data collection form.**

12.2 CAMERA

The play session is recorded in a standardised manner using two cameras. Please use a tape measure to determine the correct distance to position cameras.

Camera	Plane	Distance
1	Sagittal	1 meter from un-tested arm



The camera height should be set flush with the level of activity on the high chair tray table. Camera should also be set up to capture the infant, with minimal foreground/background in view. The parent should be close by, situated wherever the child is most comfortable. Inform the parents of the camera lay out to ensure they do not block the cameras view of the child.

*** Please note: If the infant has both arms included in the study, the play session will need to be repeated twice, one for each arm. The sagittal camera will need to be re-positioned to the other side of the infant after the first session to capture the other arm.**

12.3 FILMING

Start the session by filming a piece of paper showing the infant's initials, unique study code, date of recording (dd/mm/yy) and arm being assessed (left or right). Ensure the piece of paper is filmed for approximately 10 seconds.

Example:

INTIALS: A.G

STUDY CODE: 12345j

DATE OF RECORDING: 23/04/15

ARM: R

12.4 CLOTHING

Prior to the session, please request that the parents place infant in a sleeveless top. A sleeveless top is preferable to make it possible to place the SENSORS on the arm with ease and to observe arm and hand movements. If the child is wearing a long sleeve top ask the parents if it is ok for the infant to take their top off or roll the sleeves of the top up the arm as much as possible.

STEP BY STEP GUIDE TO DATA COLLECTION

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Prior to infants arrival	
1	Ensure all equipment is in the room • High chair • Toys • Double sided tape • Scissors • 3 x sensors and receiver • Lap top • Camera • Pen • Tape measure
2	Ensure camera is set up on tripod to specified distance (1 x camera, sagittal, 1 meter from un-tested arm)
3	Ensure laptop has software and drivers installed and SENSORS are charged ready to use
4	Insert receiver dongle into USB port
5	Open software. a. Select 'Create new test' b. Enter infants information c. 'Save' file
6	Have both the software and child's file open on the laptop (split screen)
7	Calibrate sensors. a. Turn sensors on b. Place sensors on a flat surface c. Select 'Calibration' on software d. Select COM port e. Press receiver immediately before pressing 'Start' on the software f. 'Start' g. Allow this to run for 60 seconds h. 'Stop' i. 'Save data' j. Ensure data have saved in child's file k. Turn off sensors
8	Place one side of the double sided tape on sensors (keep paper on other side)
Infant has arrived	
9	Allow child to sit with parent while placing the sensors on the child's arm.
10	BA place SENSORS on infants included arm in the study. (If both arms are included in the study the play session will need to be repeated with the SENSORS on the other arm)
11	Place child in high chair and ensure straps are secure

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12	Turn camera ON
13	Film a piece of paper showing the infants unique study code, date of recording (dd/mm/yyyy) and date of birth of the child (dd/mm/yyyy) for approximately 10 seconds. *see camera protocol*
14	BA to turn the SENSORS ON
15	Trial 1: a. Select 'PROM wrist ext (fingers flexed)' b. Select COM port c. Press receiver dongle immediately before pressing 'Start' on the software d. Press 'Start' e. BA to start trial with infant f. Make sure all 3 SENSORS are flashing on software (online/offline) g. Press 'Stop' h. Press 'Save data' i. Ensure data has saved in child's file
16	Trial 2: a. Select 'PROM wrist ext (fingers open)' b. Select COM port c. Press receiver dongle immediately before pressing 'Start' on the software d. Press 'Start' e. BA to start trial with infant f. Make sure all 3 SENSORS are flashing on software (online/offline) g. Press 'Stop' h. Press 'Save data' i. Ensure data have saved in child's file
18	Trial 3: a. Select 'Semi structured Play A' b. Select COM port c. Press receiver dongle immediately before pressing 'Start' on the software d. Press 'Start' e. BA to start trial with infant f. Make sure all 3 SENSORS are flashing on software (online/offline) g. Press 'Stop' h. Press 'Save data' i. Ensure data have saved in child's file
19	BA turn SENSORS OFF
20	BA remove SENSORS from infant
21	Turn camera OFF

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FAQ'S

1. **How do you clean the sensors?**

   You may use regular wipes to clean the sensor cases. It is not recommended that you open the case and make any direct contact with the electronic board.

2. **Do the sensors have to be turned on or off to charge?**

   For safety reasons, you should turn the sensor off while it is being charged

3. **For calibration do the sensors have to be in line with each other and in the order in which they are placed on the arm (ie: red, yellow, blue)?**

   You do not need to place the sensors in a line or in order during the calibration. Just make sure the sensors are on a flat surface.

4. **Do you have to calibrate the sensors before each child or just once at the beginning of the day?**

   You need to calibrate the sensors before seeing each child. The calibration trial should last 60 seconds and needs to be saved in the child's file. If the software crashes, you do not need to re-calibrate the sensors.

5. **When should I press the receiver dongle?**

   The receiver dongle needs to be pressed immediately before pressing start on the software. The sensors continually send data to the receiver so pressing the receive dongle ensures the data that is captured starts from the beginning.

Appendix G Copyright Permissions

309785 Permission request for WHO copyrighted material

Inbox ×

permissions <permissions@who.int> Fri, Jan 31, 11:04 PM

to me

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