School of Public Health

ORAL HYGIENE IN THE CONTROL OF OCCLUSAL CARIES IN NEWLY ERUPTED FIRST PERMANENT MOLARS

by

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ABSTRACT – Caries of the pits and fissures of permanent teeth continues to be a problem for children. Newly erupted permanent molars are particularly at risk. Oral hygiene measures have been shown to be able to reduce the incidence of caries. The aim of this study was to compare the caries preventive effects of a professional tooth cleaning and oral health education programme (test) with a standard preventive programme (comparison), comprising selective fissure sealing and application of topical fluorides on newly erupted first permanent molars. School Dental Service clinics of the Health Department of Western Australia, in Perth, were assigned to test (4) or comparison (4) clinics. Schoolchildren, mean age 6.3 ± 0.3 (s) yr with, sound, newly erupted first permanent molars were included in the study (n= 404; 207 test; 197 control).

Children were examined after twelve and twenty-four months by an examiner who was 'blind' to the test or control status of the children. After twelve months, 186 test and 163 control children were examined, and after twenty-four months, 179 test and 156 control children were examined. Three hundred and twenty children were examined in both years. After twenty-four months, 32 children in test and 31 children in control developed caries of the first permanent molars, the estimated risk ratio was 0.90 (95% CI 0.58, 1.41); and children in the test group had an average DFT score of 0.30 ± 0.75 compared with 0.30 ± 0.70 DFT in the control group (t-test, p = 0.96). The results suggest that, after two years, there was no statistically significant difference between the caries preventive effects of a professional tooth cleaning and oral health education programme and a programme based on selective fissure sealing and application of topical fluorides.

Baseline deciduous caries experience, presence of hypomineralised first permanent molars and frequency of toothbrushing were statistically significant factors in predicting molar caries. Using baseline deciduous caries experience as

a screening criterion to predict permanent molar caries, sensitivity of 0.67 and specificity 0.61 were obtained at a cutpoint of 1 dmfs. Sensitivity and specificity values were maximised at 0.72 by using a combined baseline dmfs and hypomineralisation as screening criteria. Cost-effectiveness analysis indicated an incremental cost-effectiveness ratio of $40/child/year. The test programme was more costly and produced similar outcomes and does not warrant adoption on economic grounds.

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CHAPTER 1

INTRODUCTION

A high proportion of the total caries experience among children is due to caries of the pits and fissures. It has been estimated that 90 per cent of the total caries burden in the 5–17-year-old schoolchildren in the United States is composed of pit and fissure caries (Stamm 1991). Occlusal surfaces of permanent teeth represent approximately 12.5 per cent of the total permanent tooth surfaces at risk of caries in 12–14-year-old children and yet account for nearly 50 per cent of permanent tooth caries experience (Ripa 1975). Recent data from the United States on caries experience among 5–17 years-old indicate little change in the distribution of surface specific caries, occlusal surfaces of permanent teeth remain the surfaces most commonly affected by caries, accounting for 56% of the total surface specific caries experience among this age group (Kaste *et al.* 1996). While the use of topical and systemic fluorides has dramatically reduced the overall prevalence of caries, reductions have occurred preferentially on smooth surfaces and pits and fissures have benefited least (Ripa 1980).

Permanent molar teeth appear to be at greatest risk of becoming carious (Eklund and Ismail 1986; Ruiken *et al.* 1986; Vehkalahti *et al.* 1991). Ruiken *et al.* (1986) reported that in a sample of 12-year-old children with low caries prevalence, permanent molars contributed 96 per cent of the total DMFS and 93 per cent of the total DMFS was due to lesions in the occlusal pits and fissures (excluding incipient lesions). Recent data from South Australia indicated that, among 5–15 year-old children enrolled with the South Australian School Dental Service, approximately 80–95% of the permanent tooth caries were in the pits and fissures and the majority were in the first permanent molars (Slade *et al.* 1996a). Caries of the pits and fissures is likely to be a continuing oral health problem in the future for children.

Studies conducted before the use of fluorides became widespread indicate a high risk of caries of the first permanent molars (Carlos and Gittelsohn 1965; Lewis and Hargreaves 1975). One study reported that 80 per cent of erupted first permanent molars had experienced decay by the age of seven years, and 40 per cent of the caries was of the occlusal surfaces (Lewis and Hargreaves 1975). More recent studies have reported a lower, constant, and sustained risk of caries of the first permanent molars (Bohannan et al. 1984; Chestnutt et al. 1996; Li et al. 1993; Ripa et al. 1988; Stahl and Katz 1993). Bohannan et al. (1984) reported that approximately 35 per cent of first permanent molars had experienced dental caries by the age of eight years in fluoridated communities. Vehkalahti et al. (1991) found 31 per cent of first permanent molars that were erupted at age seven had experienced caries by the age of eight and the caries rates were higher during the first two years after eruption than later years. Ripa et al. (1988) and Chestnutt et al. (1996) found a constant risk of caries on occlusal surfaces of first permanent molars, even up to ten years after eruption. Chestnutt et al. (1996) observed among Scottish 12-year-olds who participated in a toothpaste trial that over two-thirds of the occlusal surfaces of the first permanent molars had experienced decay and, over a three-year period, 40% of occlusal surfaces of first permanent molars that were sound at baseline became decayed.

The local environment of the tooth appears to be important for the initiation and progression of caries, and local accumulation of plaque is essential for this process to occur (Holmen et al. 1987b; von der Fehr et al. 1970). Pit and fissure caries is initiated on the enamel surface at the entrance to pits and fissures, sites that are relatively protected from occlusal functional forces and plaque control measures (Thylstrup and Fejerskov 1994). Plaque accumulation is greatest on the occlusal surfaces of molar teeth from commencement of eruption until the establishment of full functional occlusion, and hence, the period from

eruption till functional occlusion may pose the time of greatest risk for caries initiation in the pits and fissures (Carvalho *et al.* 1989; Fukada *et al.* 1982). It is likely that oral hygiene measures, especially during the high risk period, play a central role in the control of pit and fissure caries. The literature relating to the role of oral hygiene in dental caries is critically reviewed in Chapter 2.

Many methods have been tried to control caries of the pits and fissures (Meurman and Thylstrup 1994). Pit and fissure sealants have been shown to be effective in preventing pit and fissure caries (Ripa 1993). The effectiveness of a sealant is dependent on the extent to which the material is retained within the pits and fissures (Mertz–Fairhurst 1984). Sealants on partly erupted teeth are poorly retained due to difficulties in maintaining a dry field during placement (Dennison *et al.* 1990), and thus may be least effective during the period of greatest risk of caries. Furthermore, the cost-effectiveness of using pit and fissure sealants has not been fully established (Mitchell and Murray 1989) and published reports on economic evaluation of fissure sealants suffer from methodological deficiencies which render their findings unsuitable for policy makers (Lewis and Morgan 1994). Varnishes containing fluoride or chlorhexidine have also been tested for the control of occlusal caries (Bratthall *et al.* 1995; Petersson 1993). Although studies have shown these methods to have caries preventive effects, their cost-effectiveness has not been evaluated.

The School Dental Service (SDS) of the Health Department of Western Australia has responsibility for provision of oral health services to the schoolchildren of Western Australia (Appendix A) and has an obligation to be cost-effective and efficient. The SDS uses fluoride applications and fissure sealing of selected teeth (using a glass-ionomer cement) to control pit and fissure caries in the permanent molars. These preventive procedures require special materials and, in the case of fissure sealing, skilled personnel to perform the tasks. Alternative, less

resource intensive preventive procedures that can achieve better or similar outcomes are therefore desirable.

In Nexö, Denmark, in recent years, a strategy based on intensive plaque control in newly erupted first permanent molars has been reported to prevent effectively much early post-eruptive caries in these teeth (Carvalho *et al.* 1991; Carvalho *et al.* 1992). Although the strategy has been cited increasingly as an alternative form of caries prevention (Meurman and Thylstrup 1994), its scientific basis is dubious. The clinical trial of the strategy lacked a concurrent control group, the number of participants was small and just one clinician was involved. These issues call for a wider testing of the procedure before widespread implementation can be recommended.

AIM

The aims of this study were:

1. To compare, within a functioning school dental service, the effectiveness of a programme of professional toothcleaning and dental health education with the standard preventive procedures, including the use of topical fluorides and fissure sealants, to prevent pit and fissure caries.
2. To compare the cost-effectiveness of the two methods of controlling occlusal caries in newly erupted first permanent molars.

OBJECTIVES

1. To develop a programme of professional tooth-cleaning and chair-side dental health education.
2. To measure the incidence of occlusal pit and fissure caries in the first permanent molars of study participants.
3. To record the distribution of caries and plaque on the occlusal surfaces of first permanent molars of study participants.

4. To measure the incidence of caries in the deciduous canine and molar teeth of study participants.

5. To record the time and cost of materials required to provide the preventive treatments.

6. To assess and compare the cost-effectiveness of the two preventive procedures.

HYPOTHESIS

The primary hypothesis tested in this study was that the level of oral hygiene and caries prevention that can be achieved by the test programme (comprising professional tooth-cleaning and dental health education) was equivalent to the level of oral hygiene and caries prevention that can be achieved by the methods currently used in the SDS. A secondary hypothesis was that the two methods are also equally cost-effective.

BENEFITS OF THE STUDY

A number of benefits are likely to accrue from the study:

— Measurement of the cost-effectiveness of different methods of caries prevention will permit more efficient utilisation of limited resources.

— If shown to be equally effective, simple low cost methods of caries prevention requiring minimal training of personnel and equipment would provide advantages over traditional methods of caries prevention.

— Development of low cost, non-operative techniques of occlusal caries prevention will have implications for the current methods of controlling occlusal caries and the transfer of low cost technology will have positive benefits, particularly for less economically developed countries.

LIMITATIONS OF THE STUDY

- The study was a field trial without random allocation of participants to test or control groups. Clinics were systematically allocated to test or control groups to obtain approximately equal number of participants in the test and control groups.

- Due to the organisational requirements of the SDS, study participants were provided with care by a number of different clinicians, and calibration of these clinicians was not undertaken. This was not thought to be serious drawback because the study was a pragmatic field trial and the "real-life" organisational requirements were seen as a necessary part of the trial.

- Teeth that were filled were assumed to have been filled as a result of caries and were recorded as having carious experience. Variability among clinicians in their diagnosis and treatment prescriptions has been demonstrated (Bader et al. 1993; Kay et al. 1992; Lussi 1991; Riordan et al. 1991; Wenzel et al. 1994), and it is possible that a filled tooth may not have been carious. In this study, no attempt was made to calibrate the clinicians in their diagnosis and treatment prescriptions.

- No attempt was made to validate the reported brushing frequency and type of toothpaste used.

- The study assumes that the prevention of occlusal caries is inherently worthwhile, and no attempt was made to elicit utility values of unrestored/restored occlusal surfaces.

- The method of visual and tactile inspection was used for caries diagnosis. No attempt was made to validate the diagnosis. Validation would have required the extraction of the tooth for an histological examination; a procedure which

would be unethical and more than likely would have been refused by the participants.

- Participants were 6-year-old children enrolled with the SDS, and the findings may not be able to be generalised to other 6-year-old children.

- Study participants were not a representative sample of 6-year-old children enrolled with the SDS.

THESIS OUTLINE

Chapter 2 critically reviews the literature examining the relationship between oral hygiene and dental caries. Although the relationship between oral hygiene and dental caries has been a continuing topic of debate for many years, the literature review focused on the period 1950s onwards when epidemiological study methods were becoming more established and the use of statistical tests to examine relationships was becoming more common. The review identified the main types of study design used to examine the hygiene/dental caries relationship and highlighted the strength and weaknesses of the various types of study. The review also assessed the studies that examined the cost-effectiveness of caries preventive programmes.

Chapter 3 describes the methodology adopted in the present study. The chapter provides details on how reliability and validity was addressed and a description of the materials used in the trial. The perspective taken for the cost-effectiveness analysis and the measurement of costs and effects are also detailed. The types of statistical test used to examine the relationships in the present study are also presented.

Chapter 4 details the results obtained from the study, initially after the first twelve months and then the results after twenty-four months. The details of the

cost-effectiveness analysis, after twelve and twenty-four months, are also presented. The discussion of the findings is presented in Chapter 5, which concludes with recommendations for future research.

CHAPTER 2
REVIEW OF LITERATURE

The debate about the relationship between cleanliness of teeth and dental caries has continued for many years. The ancient Greeks observed dental caries associated with local accumulation of food which stagnated, putrified and produced local damage around the teeth (Newbrun 1977). The genesis of the link between caries 'and acid producing oral bacteria (chemo-parasitic theory) has been attributed to W.D. Miller who, through his work at the University of Berlin, demonstrated the ability of oral microorganisms to produce acids and decalcify tooth structures (Newbrun 1977). The role of bacterial plaque in the carious process is today well established (Newman 1986). Since it was coined, controversy has raged around the statement, attributed to (Williams 1927), that "a clean tooth never decays" .

A debate was held at a dental society meeting in New York, in 1934, in which six well-known dentists participated, to try to resolve the issue. The topic for the debate was, "That a clean tooth does not decay and that mouth cleanliness affords the best known protection against dental caries" (Hyatt *et al.* 1934). The editorial in that issue of *The Dental Cosmos* concluded that both sides of the debate won, indicating that the matter could not be resolved (Anthony 1934). Hine, in his review of the methods available for the control of dental caries, concluded that it is less likely that clean teeth will decay, but the near impossibility of achieving perfectly clean teeth "makes mechanical cleansing of teeth of limited value in dental caries control" (Hine 1948). Also, the validity of the statement 'a clean tooth never decays' has been questioned due to a lack of convincing evidence (Bibby 1966).

Review articles on the relationship between oral hygiene and dental caries have been published (Andlaw 1978; Bellini *et al.* 1981; Sutcliffe 1989; Town 1979). The findings on the effects of self performed plaque control measures such as toothbrushing and flossing on caries have been inconsistent. Some authors have reported a lower level of dental caries with good oral hygiene (Addy *et al.* 1986; Ainamo and Parviainen 1989; Ashley and Wilson 1977; Bay and Ainamo 1974; Mansbridge 1960; Øgaard *et al.* 1994; Wright *et al.* 1979), while others reported no association (Ainamo and Parviainen 1979; Etty *et al.* 1994; Granath *et al.* 1979; McHugh *et al.* 1964; Parviainen *et al.* 1977; Richardson *et al.* 1977); some even reported increased levels of caries with good oral hygiene levels (Miller and Hobson 1961; Trubman 1963). Studies that have examined the relationship between oral hygiene and caries fall predominantly into one of two types—cross-sectional and longitudinal studies.

Cross-sectional studies relate the presence or absence of a disease or condition to the presence or absence of putative causal factors at one point in time in a population selected without regard to exposure or disease status (Rothman 1986). Longitudinal studies usually involve ascertainment of the presence of a disease or an exposure at a point in time which is then related to prior exposures or subsequent development of diseases at some other point in time. Longitudinal studies may be observational or involve an intervention, and the time relationship may be retrospective or prospective. Such studies are more valid for studying the causal factors involved in the occurrence of a disease. The following review of the literature is conducted in chronological order by year of publication and will deal initially with cross-sectional studies, summarised in Table 3 (page 31–32).

CROSS-SECTIONAL STUDIES OF ORAL HYGIENE AND CARIES

In a study of 5103 public school children aged 5–15 years in New Jersey, USA, a higher proportion of children with 'dirty teeth' had active caries (87%) compared with children who had 'clean teeth' (68%) (Brucker 1943). There were sex and race differences in the proportion of children who had active caries. Non-white children with dirty teeth were less likely to have active caries (71%) compared with white children with dirty teeth (89%) and more white girls with dirty teeth had caries (95%) than non-white girls with dirty teeth (55%). Also, a higher proportion of children who reported brushing their teeth daily were without active caries (29%) compared with children who reported never brushing their teeth (14%). This early study used ill-defined criteria of oral hygiene and did not differentiate caries activity among different age groups nor tooth groups. Older children will have more teeth thus be more at risk of caries than younger children. Also, socio-economic factors were not controlled in the study.

Another study in Portland, Oregon, found no association between toothbrushing frequency and caries experience of the deciduous teeth of children (n=279) aged 1–6 years (Savara and Suher 1955). The children were a sample from a survey of 650 children examined for dental caries experience whose parents consented to an interview. The study had a high non-response rate which could have affected the findings. McCauley and Frazier (1957), however, found an association between higher levels of caries experience and poorer oral hygiene levels among their sample (n=2498) of 6, 8 and 10 year-old children in Baltimore, USA (McCauley and Frazier 1957). White children were sampled from schools randomly selected after stratifying by socioeconomic level (three schools from each socioeconomic level). Oral hygiene was determined by estimating the amount of plaque on the six anterior maxillary teeth. Children with the best oral hygiene score had a mean DMFT (D—decayed, M—missing, F—filled permanent teeth, lower case letters for deciduous teeth) score of 2.4

and those with the worst score had a mean DMFT score of 4.4. Although the study did not report any tests to determine if the differences were statistically significant, this seems likely in view of the large number of children.

In examining 426 children aged 12–14 years, and classified by oral hygiene level (good, fair, neglected), those with good oral hygiene had a lower level of permanent tooth caries experience (mean DMFT=9.58) compared with neglected oral hygiene (mean DMFT=11.47), and the difference was statistically significant, $p<0.01$ (Mansbridge 1960). The difference in caries experience between children with fair oral hygiene (mean DMFT=10.18) and neglected oral hygiene was also statistically significant, $p<0.05$. However, the differences were statistically significant only for the incisors and premolars; the difference in molar caries experience was not statistically significant. The criteria defining oral hygiene status were not reported. The author also reported on the toothbrushing frequency of the children. There was a close relationship between reported toothbrushing and oral hygiene level; more frequent brushers had better oral hygiene. However, the study did not report on the relationship between toothbrushing frequency and dental caries experience.

Bias was a major problem with the early studies because the methods used to determine oral hygiene were crude and relied on poorly defined criteria for classifying individuals. Statistical tests of significance between the different oral hygiene groups were also not widely used in oral health epidemiology before the 1970s and only crude comparisons were done.

A modified form of the Oral Hygiene Index (OHI) (Greene and Vermillion 1960) was used as a measure of the state of oral hygiene in the oral examination of 2905 thirteen-year-old Scottish children in Dundee (McHugh et al. 1964). The authors of this study did not find any statistically significant correlation

between oral hygiene levels and caries experience. The OHI used by McHugh *et al.* is a complex composite index with clearly defined criteria for classifying individuals based on their OHI score (see appendix B). The use of an index with clearly defined criteria meant that studies using the same index could now be compared.

Among preschool children, toothbrushing frequency appears to be inversely related to the prevalence of dental caries. An oral health survey of preschool children aged 12–60 months in London, England, found that those who did not brush their teeth daily were more likely to be free of dental caries experience (84%) than those reporting more frequent brushing (53% for 3 times/day brushers), $p<0.001$ (Winter *et al.* 1971). The study also found that frequent brushers were more likely to be free of incisor tooth caries than non-brushers, $p<0.05$ and the earlier the age at which toothbrushing commenced, the lower the caries experience of the child. The authors speculated that no association existed in young children between caries occurrence and toothbrushing because toothbrushing does not influence caries in the pits, fissures and approximal areas whereas toothbrushing does affect the more accessible surfaces, such as the labial surfaces of the incisors. It is also possible that some parents provided socially acceptable answers to the question on toothbrushing frequency, thus biasing the difference towards the null result.

A case-control approach was adopted by researchers in the United States where a number of prognostic variables in two groups were compared; one group was defined as caries-active (five or more carious teeth) and the other as caries-free (Duany *et al.* 1972). Forty-six caries-free and 40 caries-active children, aged 12–14 years were compared. All were students from a junior high school in Miami, USA. The authors used two measures of oral hygiene; one was the extent of erythrosine disclosed plaque covering the four maxillary incisors and the other

was the simplified OHI (OHI-S) (Greene and Vermillion 1964). The OHI-S is scored similarly to the OHI except that only the buccal surface of an upper molar tooth and lingual surface of a lower molar on each side of the arch and the labial surface of an upper and a lower incisor tooth are scored for the presence of debris and calculus. The authors found statistically significant differences in the extent of plaque and OHI scores between caries-active and caries-free groups, $p<0.01$.

A study of 9–13 years-old children in New York State (n=384), used frequency of toothbrushing as a measure of oral hygiene and found a statistically significant inverse relationship between reported toothbrushing frequency and caries experience (Berenie *et al*. 1973). Caries experience was expressed as the number of permanent tooth surfaces or teeth with caries experience (decayed, missing or filled) as a proportion of the total number of permanent tooth surfaces or teeth present or extracted due to caries. This expression controlled for the varying number of tooth units at risk of caries due to age.

The differences between different brushing groups were only significant for caries experience measured as DMFS (D—decayed, F—filled, M—missing permanent surfaces) and not as DMFT, and only between once a day brushers (n=143; DMFS proportion=0.10) and the categories of twice a day brushers (n=142; DMFS proportion=0.08) and more than twice a day brushers (n=50; DMFS proportion=0.06). The authors noted that more than 75% of the children in their sample brushed with a fluoride toothpaste and speculated that the differences may have been due more to frequent contact with fluoride than the actual toothbrushing. A follow-up report presented the extent of correlation between the level of oral hygiene (OHI-S) and caries experience among the same group of children (Ripa 1974). A weak direct correlation between oral hygiene

and dental caries experience was found; the correlation coefficient between OHI-S and DMFS was 0.24 and the correlation between OHI-S and DMFT was 0.17.

When the same children (n=290) in the survey by Berenie *et al.* (1973) were re-examined and questioned two and a half years later, a statistically significant difference in caries experience was found between children, now aged 12–15 years, who reported brushing at least twice a day (n=151; DMFS proportion=0.10) and those who brushed once a day or less (n=139; DMFS proportion=0.15; *p*< 0.01) (Leske *et al.* 1976). The authors speculated that the difference in caries experience between the groups was due to the difference in frequency of exposure to fluoride dentifrices.

A study in Copenhagen, Denmark, examined 293 seven-year-old children, selected through stratified random sampling (Bay and Ainamo 1974). Children with fewer than five decayed, filled or missing surfaces of combined permanent and deciduous teeth were classified as caries inactive group (n=89) and children with more than 22 DMF(dmf) surfaces were classified as caries active group (n=56). When oral hygiene was determined through the use of a modified plaque index (PLQ index) (Quigley and Hein 1962) the differences in plaque and gingivitis levels between the caries active and caries inactive groups were statistically significant. Lower levels of plaque and lower levels of gingivitis were found in the caries inactive group. The authors concluded however, that the differences were of no clinical significance. They also reported no difference between the groups with respect to social status, frequency of toothbrushing, dental knowledge or consumption of sweets. The latter findings should be treated with caution because the information was obtained by interviewing 7-year-old children and their response to the questions may be more a result of the desire to provide socially desirable or 'expected' answers rather than factual reporting.

In an attempt to control for confounding by dietary variables (sucrose consumption), a stratified analysis was used in a cross-sectional study of 6-year-old children (n=85) in Sweden (Granath *et al.* 1976). Caries experience of deciduous molars and canines was compared between groups with different dietary levels (between-meal sucrose consumption) and toothbrushing habits. Caries was assessed clinically as well as radiographically and caries experience on buccal and lingual surfaces was considered separately from caries experience of approximal surfaces; caries on the occlusal surfaces was not measured because of difficulty in diagnosing incipient lesions.

For all levels of the dietary variable, children who had adult assistance during daily toothbrushing had lower df scores for buccal and lingual surfaces compared with children who brushed daily without assistance; the percentage difference range was 15%–49%. The percentage differences for approximal surfaces were not as large; the difference ranged from 7% more decay to 5% and 31% less decay among children assisted with brushing. The difference in the slope of the regression line of diet on dental caries between children assisted with toothbrushing and children not assisted was not statistically significant, although the difference in the slope was nearly significant for buccal and lingual surface caries. The finding overall was of no statistically significant differences between the groups. This finding however should be treated with caution due to the small numbers in each of the strata. Also, the strata within the dietary variable were not mutually exclusive and may have diluted the observed differences. Possible confounding by social class was not considered. It is likely that higher social class groups would be more aware of good oral hygiene practices and assist their children with toothbrushing and perform other health related actions.

The statistical treatment of the data in the study by Granath *et al.* (1976) was quite complex for its time and involved stratified analyses and multiple group comparisons, a precursor to analysis of variance.

A study was conducted among 4-year-old children (n=515) in Sweden in order to further clarify the relationship between caries experience and oral hygiene, dietary variables and fluoride exposure (Granath *et al.* 1978). Assessment of caries, dietary and oral hygiene factors were the same as in the previous study and details of fluoride exposure were obtained from parents of the children (Granath *et al.* 1976). Stratified analyses revealed statistically significant relationships between all three variables on approximal caries experience, but only the dietary variable was statistically significant for buccal and lingual caries. Data were subjected to complex statistical manipulations and included multiple group comparisons. As in the previous study, a limitation of this study was the small number of subjects in some of the strata, thus reducing the power of the study to detect important clinical differences as statistically significant.

A cross-sectional study of adolescents (n=365; age range 13–15 years) from Finnish communities with low fluoride (0.2 mg/L), medium fluoride (1 mg/L) and high fluoride (2.5–5 mg/L) levels in the drinking water showed poor correlation between an index used to measure oral hygiene (Visible Plaque Index) (Ainamo and Bay 1975) and caries experience, but found a strong inverse relationship between fluoride level in the water and caries experience (Parviainen *et al.* 1977). The children from all three communities were reported as being of equivalent socioeconomic standing.

In a follow-up report, low levels of visible plaque and gingival bleeding were associated with reported increased tooth brushing frequency but caries experience was similar between groups with different brushing frequencies (Ainamo

and Parviainen 1979). A further follow-up report of adolescents (n=352) from the same three areas showed a statistically significant difference in caries experience between the infrequent and frequent brushers from the low fluoride area (Ainamo and Parviainen 1989). There was no statistically significant difference in caries experience between the different brushing groups in the optimum and high fluoride areas. The authors concluded that frequent toothbrushing may be an effective method of caries prevention if a fluoride toothpaste is used.

A Canadian study of two groups of children, mean ages 7 (n=234) and 13 years (n=223), also failed to demonstrate any statistically significant relationship between oral hygiene (Oral Hygiene Index) and caries experience (DMFS) (Richardson *et al.* 1977). The correlation coefficients were 0.10 and -0.07 for 7- and 13-year-old children, respectively. Statistical analysis using step-wise regression with oral hygiene and dietary variables as independent predictors also failed to find any significant relationship between oral hygiene and dental caries experience.

A large scale study of preschool children sought associations between the caries experience of 1453 3- and 4-year-old children in Edinburgh, Scotland with oral hygiene variables (Sutcliffe 1977). Oral hygiene levels were determined through the use of the Debris Index of OHI-S, adapted for deciduous dentition. Caries experience was measured by dmft and dmfs indices. Caries experience of children with good oral hygiene (debris index $\leq$ 0.5; n=259) was compared with the caries experience of children with poor oral hygiene (debris index $\geq$ 1.5; n=236). For both dmfs and dmft, the differences between groups were statistically significant at each age group, Table 1.

This study also included social indicators as an explanatory variable for caries experience, and stratified analysis indicated an independent effect of social

factors on caries after controlling for oral hygiene levels. Children in 'deprived' areas tended to have higher caries experience regardless of their oral hygiene level and the difference in caries experience (dmft) among children with good oral hygiene from 'deprived' (n=119; dmft=2.0) and 'non-deprived' (n=140; dmft=1.3) areas was statistically significant, p <0.05.

Table 1   Relation between oral hygiene and caries experience among 3- and 4-year-old children in Scotland

Subjects	Good oral hygiene		Poor oral hygiene		
	Numbers	Mean (s)	Numbers	Mean (s)	p value
dmft					
3-year-olds	113	1.15 (0.20)	86	2.76 (0.38)	< 0.001
4-year-olds	146	2.00 (0.26)	150	4.09 (0.34)	< 0.001
dmfs					
3-year-olds	113	1.5 (0.33)	86	3.92 (0.75)	< 0.01
4-year-olds	146	4.14 (0.75)	150	7.22 (0.74)	< 0.01

From Sutcliffe (1977)

A study in Finland of children aged 5, 9 and 13 years (n=564) in rural areas with low fluoride concentration in the water supply found higher risk of caries prevalence with increasing levels of plaque accumulation among all ages for all the tooth groups examined (Kleemola-Kujala 1978). Oral hygiene was assessed through the use of the Plaque Index (Silness and Löe 1964), and caries prevalence was the proportion of all surfaces examined that were decayed and/or filled. For analysis, plaque levels were grouped into three categories and crude risk ratios calculated comparing category one (PlI 0–0.9) with category two (PlI 1–1.9) and category three (PlI 2–3). The risk ratio was greater than one (indicating increased risk of caries) for all tooth groups and all age groups with increasing levels of plaque. The risk ratios were higher in tooth groups that were relatively more accessible to oral hygiene measures, such as incisors and canines, and was lowest for first permanent molars, where pit and fissure caries predominates. However, the author did not report the confidence intervals for

the risk ratio and therefore an assessment of the significance of the findings was not possible. The author cautioned that some confounding of the crude risk ratios by the use of dietary sucrose may have occurred.

In a follow-up report, the relationship between dental caries and oral hygiene (Plaque Index), with sugar consumption controlled, among children (n=543; age 5, 9 & 13 years) from low-fluoride areas (0.10–0.46 mg/L) was examined (Kleemola–Kujala and Räsänen 1982). A statistically significantly higher prevalence of decayed tooth surfaces among children with poor oral hygiene was found, $p<0.05$. Oral hygiene and caries prevalence were assessed as in the previous study (Kleemola-Kujala 1978). The risk of caries increased with increasing levels of plaque for all tooth groups, and all ages and all the tooth groups combined at all levels of sugar consumption. The authors also found that the effect of oral hygiene on dental caries was modified by the amount of sugar consumed by the children; when oral hygiene level was poor, even a low level of sugar consumption led to a higher risk of caries.

In a study of French-Canadian adolescents (n=159) aged 12–16 in Quebec City, data on dietary habits, presence of dental plaque on buccal and lingual surfaces of erupted teeth, dental hygiene habits and personal and family characteristics were related to caries experience (DMFT) (Lachapelle-Harvey and Sévigny 1985). Caries experience was assessed clinically and radiographically. Step-wise multiple regression analyses showed that plaque level was a statistically significant factor in explaining caries experience, $p< 0.001$; zero order correlation coefficient was 0.35. The regression model, which included plaque index, chocolate consumption between meals, sex, mother's education, amount of cakes with icing consumed at meal times and the amount of chewing gum eaten between meals, was able to explain 29% of the variation in caries experience.

A study of 5-year-old children (n=715) in Johannesburg, stratified participants according to the amount of sucrose consumed daily (3 levels), frequency of sugar consumption (3 levels) and level of oral hygiene (2 levels) (Cleaton-Jones *et al*. 1984). The caries experience of stratified groups for all the teeth and incisors and canines were then compared. Oral hygiene was determined by using the Debris Index of the OHI-S and children were grouped into 'no plaque' if the DI-S=0 and 'plaque' when the DI-S was 0.17–3, which gave a sample of 384 children. When all the tooth groups were included there was a consistent trend of increasing caries experience with poorer oral hygiene levels for all levels of sugar consumption and frequency of intake, but not all the differences were statistically significant. The effects of oral hygiene on caries was stronger and more consistent than the other two dietary factors.

A study in South Wales of a cohort of children (n=798) aged initially 11–12 years and re-examined at 15–16 years also found strong, statistically significant, direct relationships between oral hygiene (Plaque Index) and dental caries experience (DMFT, DMFS, DFS), between sugar consumption and dental caries experience, and an inverse relationship between frequency of toothbrushing and dental caries experience (Dummer *et al*. 1990b). Although the study was longitudinal in nature, the data were treated as though coming from two point prevalence surveys. The association between outcome (caries experience) and independent factors (oral hygiene, sugar consumption) was based on those variables measured at the same time. An earlier report of this study also found low but statistically significant correlations between oral hygiene and indices of caries experience (Addy *et al*. 1986).

The study by Dummer *et al*. (1990b) used multiple regression techniques and analysis of covariance with the number of erupted teeth and tooth surfaces as covariates, and the number of erupted teeth, amount of money spent on sweets,

frequency of toothbrushing, mean plaque scores, social class and frequency of dental visits as independent variables to predict dental caries experience. The relative importance of the variables depended on which index of caries experience was used; toothbrushing was statistically significant in the 15–16-year-olds for all the indices, but not among the 11–12-year-olds for the DMFT and DFS. Plaque score was statistically significant for both age groups for all caries experience indices. Caries experience was lower among children who brushed their teeth at least twice a day compared with children who brushed less than once a day, and among children who had a plaque score less than 2 compared with those who had a plaque score greater than 3. However, the authors were cautious in drawing any conclusions about the relationship between oral hygiene and caries experience, and attributed the differences to a dose response effect to fluoride exposure from toothbrushing.

A large cross-sectional survey of children aged 4–5 years (n=2728), conducted in South Africa in 1984 and using correlational analyses, reported that oral hygiene (DI-S) was a statistically significant factor for caries experience (dmfs) (Granath et al. 1991). Separate regression analyses of the four groups of children (rural black, urban black, urban Indian and urban white) found the debris index to be significantly associated with caries experience after controlling for other potential etiologic factors. The partial R^2 for the DI-S indicates that the variable explained only 2–4% of the variation in the total regression model.

A cross-sectional study of 5-year-old children (n=525) of different ethnic groups in the Netherlands found the age at which toothbrushing commenced for the child and the frequency of toothbrushing were related to caries experience (dmfs) (Verrips et al. 1992). A two stage sampling procedure was used in the study to obtain sufficient numbers of the minor ethnic groups in Amsterdam. All

the risk factors and risk indicators were coded as nominal variables and mean dmfs values calculated for each category of each variable. Bivariate analyses showed higher caries experience for children who commenced toothbrushing at a later age, for children who brushed less than once a day and for children who were irregular brushers. Multiple regression was used to control for the effect of individual factors and found that children who started brushing at 3 and 4 years of age had higher caries experience compared with children who started brushing at 1 year. The regression model was able to explain 15% of the variation in caries experience. The possibility of bias towards the null result, by parents providing socially desirable responses to the questions on health care behaviour was noted by the authors.

As part of a large study aimed at promoting preventive health behaviours among families, 1018 three-year-old children in Finland were examined for caries (Paunio *et al.* 1993). Potential risk factors in relation to dental caries were studied. Parents of participating children also completed a questionnaire on various health promoting behaviours; once when the children were 1.5 years old (852 responses) and again at 3 years of age (731 responses). Oral hygiene was determined on the basis of presence or absence of visible plaque on teeth (good=no visible plaque, poor=visible plaque). Caries was determined at two levels; at one level, the proportion of children with healthy teeth, proportion of children with enamel caries, and proportion of children with dentinal caries was calculated. At the second level the mean number of decayed teeth and tooth surfaces was calculated. Polytomous logistic regression was used to account for multi-category response variables. The model found significantly higher risk of caries among children who brushed irregularly compared with daily brushers (OR=1.9) and higher risk of decay among children with poor oral hygiene (OR=6.4). However, in the final step-wise model only the consumption of night

juice and poor oral hygiene were statistically significant factors for caries risk (OR=6.8 and OR=4.7, respectively).

One hundred and fifty-three children (3–5-year-old) from randomly selected preschools in Saskatoon, Canada, were examined for their caries experience (Koroluk *et al*. 1994). Oral hygiene was determined using the Plaque Index (Silness and Löe 1964). Caries was recorded at the level of decayed and/or filled teeth and surfaces. Correlation analyses revealed statistically significant correlations between plaque levels and both indices of caries experience.

In a survey of children participating in a dental programme in the Netherlands, children aged 5, 8 and 11 years (n=2301) were examined for their caries experience (Kalsbeek and Verrips 1994). Independent risk factors were related to caries experience using linear regression and logistic regression. In order to reduce the number of independent variables, oral hygiene variables comprising of use of fluoride tablets and fluoride toothpaste, frequency of toothbrushing by the child and frequency of toothbrushing by the parent were each given a score and then summed; higher score values indicated more favourable habits. For both types of regression, higher hygiene scores were associated with lower caries experience but because of the combination of the oral hygiene variables, independent contribution of each factor cannot be determined. The mother's education level and ethnic group was used to control for confounding by socioeconomic status.

A multistage randomised sample of French adolescents (14–15-year-olds) was used to assess the factors affecting caries experience (Tubert-Jeannin *et al*. 1994). Analysis was based on the data from 269 children out of 300 who responded to a questionnaire survey as well as receiving an oral examination. Known risk factors (diet, fluoride and oral hygiene) as well as related risk

indicators (sex, age, social class) were measured; caries experience was measured as DMFS. Bivariate analyses were used initially to assess significant factors, and all statistically significant factors were then used in the multiple regression analysis. Of the oral hygiene variables, toothbrushing frequency was found not to be statistically significant. Gingival bleeding at the time of toothbrushing was a statistically significant predictor of caries experience; those who bled on brushing were more likely to have higher caries experience.

More recent cross-sectional surveys also indicate a statistically significant relationship between caries and oral hygiene variables (Aleksejuniene *et al.* 1996; Mathieson *et al.* 1996). The study by Aleksejuniene *et al.* (1996) surveyed 1801 Lithuanian children aged 7, 12 and 15 years. Oral hygiene was determined by OHI-S and caries experience recorded as DMFT. Correlation analyses indicated a low, but statistically significant correlation between oral hygiene and caries experience for all age groups (r=0.11 for 12-year-olds; r=0.19 for 7- and 15-year-olds). A multiple classification analysis of all independent variables that were statistically significant in bivariate analyses showed an independent, statistically significant effect of oral hygiene on caries experience for the 12-and 15-year-olds, but not for 7-year-olds. The total model, which included fluoride content of the water, sex and oral hygiene, was able to explain 16% of the variation in caries experience of the 12-year-olds and 17% of the variation in caries experience of 15-year-olds. Omission of social status as an independent predictor of caries experience was notable.

A recent study in Norway that examined the relationship between oral hygiene and dental caries among 14-year-old adolescents (n=267) found statistically significant differences in decayed surfaces as well as total caries experience of approximal surfaces between children with 'poor' and 'good' oral hygiene (Mathieson *et al.* 1996). Children were categorised into 'poor' and 'good' oral

hygiene groups based on their Gingival Bleeding Index (GBI) score (Ainamo and Bay 1975). GBI is defined as the number of gingival sites that bled within 10 seconds of being probed with a blunt probe divided by the total number of gingival sites examined. Children with GBI less than the group mean were categorised as 'good' and the other children were categorised as 'poor' oral hygiene. Approximal caries was assessed clinically and from standardised bite-wing radiographs and recorded as DMFS.

Bivariate analyses found statistically significant effects of oral hygiene and frequency of sweets consumption; children with poor oral hygiene (DS=4.5; FS=1.4) and children who consumed sweets daily (DMFS=8.7) had higher levels of caries compared with children with good oral hygiene (DS=2.2; FS=0.2) and children who consumed sweets only once per week (DMFS=5.7). However, multiple linear regression analysis found oral hygiene to be the only variable that was statistically significantly associated with caries experience and the model was able to explain 31% of the variation in caries experience. Although the study controlled for fluoride supplementation, social factors were not included in the model.

Not all studies have been confined to children. Dale (1969), in his study of 730 Australian soldiers aged between 19 and 29 years, found lower numbers of decayed teeth and surfaces among those reporting more frequent toothbrushing; those who did not brush their teeth at all had, on average, 6.7 decayed teeth compared with 4.3 decayed teeth among once-a-day brushers, 3.0 decayed teeth for twice-a-day and 1.6 decayed teeth for three or more times a day brushers (Dale 1969). The differences were statistically significant, $p<0.001$. The study also measured oral hygiene levels using OHI and showed that more frequent brushers had statistically significantly better oral hygiene, $p<0.001$. However,

the study did not relate oral hygiene status with caries experience nor with the presence of decayed teeth and surfaces.

A study in Finland of 212 adult males (mean age, 33.2 years), using the proportion of decayed tooth surfaces among all surfaces at risk as the measure of dental caries prevalence, found lower caries prevalence among a group of adults who brushed their teeth daily compared with those who brushed sporadically (Rajala *et al.* 1980). A stratified analysis using a multivariate confounder summarizing score to control for confounding by age, number of teeth present, education, income, sucrose consumption, previous fluoride exposure and use of dental services found a statistically significant difference in caries prevalence between the toothbrushing groups, $p<0.01$.

A study of adults attending for care at a university dental school in Louisville, Kentucky, found a statistically significant relationship ($p<0.001$)between plaque accumulation and the presence of decayed teeth and marginal statistical significance ($p=0.05$) between plaque and caries experience (Kennon *et al.* 1979). Plaque was scored according to the Patient Hygiene Performance (PHP) index (Podshadley and Haley 1968) and caries was recorded as DMFT and the proportion of teeth that were carious among all the teeth present, expressed as a percentage. Regression analysis was used to examine the relationship between plaque and caries and showed that as plaque scores increased, the percentage of carious teeth increased in a linear fashion ($p<0.001$, $R^2=0.47$, calculated from the reported analysis of variance table), whereas caries experience (DMFT) increased initially for the lower plaque scores and levelled off at the higher scores, $p=0.05$.

In Norway, another study of adults compared the dental caries experience (DMFS and DS) of a group with good oral hygiene with the caries experience of a

group with poorer oral hygiene from a sample of 35-year-olds in 1973 (n=116), and in 1984 (n=144) (Bjertness *et al.* 1986). Oral hygiene was determined by using the OHI-S and categorised into three levels; OHI-S score 0–0.99, 1–1.99 and 2 or more. In both years, caries experience of adults with good oral hygiene was lower than the caries experience of adults with poorer oral hygiene, $p<0.05$. A follow-up report examined the relationship between oral hygiene and untreated caries among the sample from 1984 (n=142) (Bjertness 1991). The Multiple Classification Analysis (a multiple regression analysis that allows inclusion of categorical independent variables) indicated oral hygiene status to be the most important predictor of untreated carious surfaces, even after controlling for frequency of exposure to fluoride (toothbrushing), sex, education, frequency of dental visits, and past dental treatment. The model was able to explain 15% of the total variation in the number of carious lesions.

A stratified, randomly sampled study of Swedish adults aged 20 years or older (n=920) examined the relationship between mutans streptococci, oral hygiene and dental caries (Salonen *et al.* 1990). Oral hygiene was determined by the Plaque Index and caries was determined clinically as well as radiographically. Bivariate analyses found statistically significant differences in the mean number of carious tooth surfaces between various Plaque Index groups, Table 2.

Table 2   Mean number of decayed surfaces in relation to Plaque Index among adults in Sweden

	Plaque Index					
	0–0.5	0.6–1.0	1.1–1.5	1.6–2.0	2.1–3.0	ANOVA
Mean DS	2.7	3.4	4.7	5.1	4.5	$p<0.001$

From Salonen *et al.* (1990)

Multiple linear regression analysis showed a statistically significant association between both mutans streptococci and plaque levels with the number of decayed surfaces. The model explained 34% of the variation in decayed surfaces.

However, on the evidence of observed differences in caries after stratifying for plaque and mutans levels, the authors concluded that the relationship between caries and mutans streptococci was stronger than the relationship between caries and plaque.

A recent cross-sectional survey of adults (n=196; age 30–39 years) in Porto, Portugal, used bivariate and multivariate analyses to examine the relationship between caries and independent factors (Eriksen *et al.* 1996). The independent factors were grouped under four main areas: 'Environment', 'Behaviour', 'Human biology' and 'Health care organization'. Oral hygiene factors were grouped under 'Behaviour' and included OHI-S scores and toothbrushing frequency. Caries was registered clinically and radiographically. Bivariate analyses indicated statistically significant effects of both oral hygiene factors. The good oral hygiene group (OHI-S $\leq$ 3) had lower mean carious surfaces (DS=9.5) compared with the poorer oral hygiene group (OHI-S > 3; DS=16.7), $p<0.001$. Frequent brushers (brushed > once/day) had lower mean carious lesions (DS=11.9) compared with infrequent brushers (brushed $\leq$ once/day; DS=22.0), $p<0.01$. Multiple classification analysis showed that both OHI-S and toothbrushing frequency had independent, statistically significant effects on caries after other independent factors have been controlled. The complete model was able to explain 27% of the variation in carious surfaces.

Some cross-sectional studies showed an inverse relationship between oral hygiene and caries experience; good levels of oral hygiene were associated with higher levels of caries experience (Miller 1961; Miller and Hobson 1961; Trubman 1963). Miller (1961), used a combination of reported toothbrushing frequency and clinical presence of debris on teeth to classify 12-year-old children (n=736) in Manchester, England, into regular, irregular and no oral cleanliness groups. When the DMFT of the different oral cleanliness groups was compared,

the regular cleanliness group had a statistically significantly higher DMFT (5.8) compared with the irregular (5.0) and no cleanliness (5.0) groups, $p<0.05$. In a separate report, Miller and Hobson (1961) also found similar findings on caries experience of the same group of children stratified by sex and occlusion (Miller and Hobson 1961). The authors also reported (though did not explain in detail) a similar finding among a group of 4–6-year-old children who were receiving professional cleaning of teeth, once every two months for two years by dental hygienists. Children receiving professional cleaning had higher dmft levels (n=97; dmft=5.61) compared with children who did not receive professional cleaning (n=128; dmft=4.52). The difference was statistically significant, $p<0.05$.

The study by Trubman (1963) of 397 white children aged between 12 and 14 years in Jackson, Mississippi, found a negative, but not statistically significant correlation between oral hygiene (OHI) and caries experience (DMFS). The correlation coefficient was -0.07($p>0.05$). However, a direct, statistically significant correlation between oral hygiene and decayed tooth surfaces was found — correlation coefficient = 0.21, $p<0.01$.

The findings from cross-sectional studies on the relationship between oral hygiene and dental caries are inconsistent. The studies differ in the methods used and in the indices used for oral hygiene and dental caries experience, Table 3. Statistical treatment of the data also varied from study to study. Furthermore, cross-sectional studies have inherent limitations which make them unsuitable for studying causal relationships.

Table 3   Cross–sectional studies of oral hygiene and dental caries

Reference	Sample Size	Age (years)	Outcome Indicator	Oral Hygiene Indicator	Type of [*] association	Statistical tests
Brucker (1943)	5103	5–15	Decayed prevalence	subjective	Positive	none
Savara & Suher (1955)	279	1–6	deft	brushing frequency	Positive	correlation
McCauley & Frazier (1957)	2520	6,8, 10	DMFT	subjective	Positive	none
Mansbridge (1960)	426	12–14	DMFT	Subjective	Positive	t-test
Miller & Hobson (1961)	737	12	DMFT	Toothbrushing	Negative	not stated
Trubman (1963)	397	12–14	DMFS/DS	OHI	Mixed	correlation
McHugh et al. (1964)	2905	13	DMFT	OHI (modified)	None	correlation
Dale (1969)	730	17–29	DMFT/DS	Toothbrushing	Mixed	not stated
Winter et al. (1971)	602	1–4	% with def	Toothbrushing	Mixed	not stated
Duany et al. (1972)	86	12–14	DT	OHI, dental plaque	Positive	t-test
Berenie et al. (1973)	384	9–13	DMFT/S	Toothbrushing	Positive	t-test
Ripa (1974)	384	9–13	DMFT/S	OHI–S	Positive	correlation
Bay & Ainamo (1974)	293	7	DMFS/dmfs	Plaque Index	Positive	t-test
Granath et al. (1976)	88	6	defs	Toothbrushing	None	t-test, regression
Leske et al. (1976)	290	12–15	DMFT/S	Toothbrushing	Positive	t-test
Parviainen et al. (1977)	365	13–15	DFS	Plaque Index	None	correlation
Richardson et al. (1977)	457	7 & 13	DMFS	OHI-S	None	correlation
Sutcliffe (1977)	495	3 & 4	dmft	OHI (modified)	Positive	t-test
Granath et al. (1978)	515	4	defs	Toothbrushing	Positive	Wilcoxon's

[*] Positive= less decay with improved oral hygiene; mixed= positive with some indices and no relation or negative with others; none= no statistically significant relationship with oral hygiene

Contd.

Table 3 Continued

Reference	Sample size	Age	Outcome Indicator	Oral hygiene indicator	Type of* association	Statistical tests
Kleemola-Kujala (1978)	564	5, 9, 13	DFS/dfs	Plaque Index	Positive	risk ratios
Kennon et al. (1979)	611	Unknown	DMFT decay prev	PHP	Mixed	regression
Ainamo & Parviainen (1979)	365	13–15	DFS	Toothbrushing	None	not stated
Rajala et al. (1980)	212	mean=33	Decayed Prevalence	Toothbrushing	Positive	Maentel-Haenzel
Kleemola–Kujala & Räsänen (1982)	543 (?534)	5, 9, 13	Decayed Prevalence	Plaque Index	Positive	Maentel-Haenzel
Cleaton-Jones et al. (1984)	715	5	dmft	Debris Index	Positive	median test
Lachapelle-Harvey & Sévigny (1985)	159	12–16	DMFT	Plaque Index	Positive	regression
Addy et al. (1986)	1015	11–12	DMFT/S	Plaque Index	Positive	correlation
Bjertness et al. (1986)	260	35	DMFS/DFS	OHI	Positive	ANOVA
Ainamo & Parviainen (1989)	717	13–15	DFS	Toothbrushing	Mixed	t-test
Dummer et al. (1990b)	798	15–16	DMFT/S DFS	Plaque score, toothbrushing	Positive	regression ANCOVA
Salonen et al. (1990)	920	≥20	DS	Plaque Index	Positive	ANOVA regression
Bjertness (1991)	142	35	DS	OHI	Positive	regression
Granath et al. (1991)	2728	4–5	dmfs	Debris Index	Positive	correlation regression
Verrips et al. l(1992)	525	5	dmfs	Toothbrushing	Positive	regression
Paunio et al. (1993)	1018	3	ds/dt	Visible plaque	Positive	logistic regression
Koroluk et al. (1994)	153	3–5	dft/dfs	Plaque Index	Positive	correlation
Kalsbeek & Verrips (1994)	2301	5, 8, 11	DMFS/dmfs	combined	Positive	regression
Tubert-Jeannin et al. (1994)	269	14–15	DMFS	Bleeding gingivae	Positive	Kruskal-Wallis
Aleksejuniene et al. (1996)	1801	7, 12, 15	DMFT	OHI-S	Positive	correlation
Mathieson et al. (1996)	267	14	DMFS & approximal	GBI	Positive	t-test regression

* Positive= less decay with improved oral hygiene; mixed= positive with some indices and no relation or negative with others; none= no statistically significant relationship with oral hygiene

LIMITATIONS OF CROSS-SECTIONAL STUDIES

Cross-sectional studies are poorly suited to examine causal relationships because the classification of subjects with respect to exposure factors and disease outcome is made at one point in time. No account is taken of the time dimension in the causation of disease (Elwood 1988). In studying the relationship between oral hygiene and dental caries, the lifetime cumulation of dental caries is related to the current oral hygiene status. This does not make any "allowance for a time interval between exposure and disease onset that corresponds to a meaningful induction period" (Rothman 1986). In the context of dental caries, an allowance for a meaningful induction time is important because the disease process is slow, especially in permanent teeth, taking 12-36 months to develop to the cavity stage.

The foregoing review of cross-sectional studies indicates that the relationship between oral hygiene and dental caries is not clear. Most of the studies found a tendency to increased caries experience with poor oral hygiene status (irrespective of the index used) even when the differences did not achieve statistical significance (see Table 3). The differences in findings among the studies may be due to the variations (different oral hygiene and dental caries indicators) and deficiencies in methods (failure to control for confounding factors), rather than due to a lack of a clear relation between oral hygiene and dental caries. Few of the studies included SES as a predictor variable, yet social class, however measured, expresses a package of lifestyle attributes that affect the occurrence of caries.

Direct comparison of the findings among the studies reviewed is not possible because of the different disease and oral hygiene indicators that are used, Table 3. A number of studies used the DMF (for permanent teeth) and dmf (for deciduous teeth) measures of teeth as well as surfaces as outcome indicators.

The index is a combination of three separate indicators D—decayed, M—missing and F—filled permanent teeth (DMFT), or surfaces (DMFS). Where the M (missing) component is included, the DMF index can give an invalid estimate of caries experience if teeth missing for reasons other than caries are included, such as having been extracted for orthodontic treatment.

Also, care has to be taken in interpreting the DMF index when there is a wide age range of children and an imbalanced sex distribution of participants in the study because of the different numbers of permanent teeth that have erupted at different ages (Berenie *et al.* 1973). That is, children of different ages will have different number of teeth at risk of developing caries. In this respect sex can also confound the index because girls, in general, tend to mature dentally earlier than boys and will present with more teeth at risk of dental caries. However, the problem can be overcome by estimating the occurrence of caries in relation to time at risk (Hujoel *et al.* 1991)

Berenie *et al.* (1973) used the number of permanent teeth and surfaces that were decayed, missing and filled as a proportion of the total number of permanent teeth and surfaces that were present in the mouth or had been extracted, to control for the variation in the number of permanent teeth that were present. Parviainen *et al.* (1977) used the decayed and filled permanent tooth surfaces as the outcome indicator in order to eliminate the bias caused by the M component of the DMF index.

Caution also has to be exercised in the interpretation of the F component of the DMF index. It has been shown that there is great variation among dentists in their treatment prescriptions (Kay *et al.* 1992; Nuttall *et al.* 1993) and the effects of such variation on the DMF index is not fully known. To control for the effects of treatment, some studies used only the decayed teeth or surfaces as an

indicator of caries experience, Table 3. Dale (1969) found no statistically significant relationship between oral hygiene and caries experience when the DMF index was used ($p>0.05$), but found a statistically significant difference when oral hygiene was related to decayed teeth and surfaces, $p<0.001$. This form of control for treatment effect would only be of practical use in communities that have poor access to dental care and dental caries remains untreated.

The DMF index is cumulative and irreversible. This means that the index usually increases with age, whereas oral hygiene indicators, which are usually reversible, can change and improve with age. Thus, the use of the DMF index can lead to seemingly incongruous observations where individuals with good oral hygiene show a higher caries experience than individuals with poor oral hygiene.

The studies also varied in their use of the oral hygiene indicators, Table 3. Some studies used undefined criteria in the assessment of oral hygiene status which severely restricts the extent to which such studies can be compared with others (Mansbridge 1960). This was more problematical with studies before Greene and Vermillion introduced their Oral Hygiene Index (Greene and Vermillion 1960; Greene and Vermillion 1964), and studies conducted after the mid-1960s generally used clearly defined criteria to assess oral hygiene.

The use of self-reported frequency of toothbrushing as an indicator of oral hygiene also has problems due to the likely over-reporting of this practice because of the social desirability of the measure. Misclassification of less frequent brushers into more frequent brushing group will result in a reduced chance of detecting any difference between the different brushing groups. The misclassification may be differential or non-differential. Non-differential misclassification is most likely because individuals are more likely to over-report

toothbrushing frequency, which is seen as being socially desirable. Regardless of the type of misclassification, it introduces a bias towards the null hypothesis and the possibility of its presence needs to be assessed when a finding of no statistically significant effect has been made (Rothman 1986). A number of studies which used toothbrushing as an indicator of oral hygiene and found no statistically significant difference in caries experience among the different brushing groups did not indicate whether the possibility of misclassification had been investigated (Ainamo and Parviainen 1979; Ainamo and Parviainen 1989; Berenie *et al.* 1973; Dale 1969; Miller and Hobson 1961).

Toothbrushing frequency as an indicator of oral hygiene status is an indirect method of assessing oral hygiene and is therefore subject to errors. The presence of intervening factors such as fluoride, and the efficiency of toothbrushing, are ignored. Leske *et al.* (1976) and Ainamo and Parviainen (1989) attributed the lower caries experience observed in their sample groups to frequent exposure to fluoride rather than to mechanical effects of frequent toothbrushing, although these authors did not measure fluoride exposure. Bay and Ainamo (1974) also observed that the low caries risk children were more likely to have had parental supervision when toothbrushing (possibly resulting in actual brushing of teeth and more efficient brushing). The effects of toothbrushing are also confounded by other health related behaviours, such as restricting sugar consumption and seeking regular dental care.

Studies that used oral hygiene indices such as the Oral Hygiene Index and the Plaque Index also showed conflicting results, Table 3. Oral hygiene indices have been designed to assess the relationship between plaque and gingival and periodontal status and their use to relate dental caries experience with oral hygiene may not be appropriate (Bellini *et al.* 1981). Richardson *et al.* (1977) noted that one possible explanation for the observed lack of correlation between

oral hygiene and dental caries in their study may have been the way in which oral hygiene was measured. The oral hygiene indices measure the presence of plaque on smooth surfaces of teeth, yet most dental caries occurs on interproximal surfaces, where plaque is difficult to measure; or in pits and fissures, where plaque is not measured at all (Bellini *et al.* 1981).

The Oral Hygiene Index was also developed to fill the need for an index to use in large population studies. It was intended to be easy to use and suitable for quick examination of large numbers. The index may not be sensitive enough to be used to demonstrate differences in caries between different levels of the index among individuals. For this reason, its use in epidemiological studies in recent times has declined (Burt and Eklund 1992).

A few studies used an index of gingival bleeding (GI, GBI) to assess oral hygiene status (Berenie *et al.* 1973; Parviainen *et al.* 1977). This measure may provide a more accurate assessment of oral hygiene compared with indices that measure the presence of plaque. Bleeding gingivae are an indication that plaque has been present long enough to have brought about early inflammatory changes and possibly early carious changes (von der Fehr *et al.* 1970). However, not all the studies that used the index examined the relationship between the index and dental caries experience (Berenie *et al.* 1973). Parviainen *et al.* (1977) found a direct, statistically significant correlation between GBI and caries prevalence among girls in a low fluoride area ($p<0.001$), and among boys in a high fluoride area ($p<0.001$), but further follow-up studies did not report on the relationship between GBI and caries prevalence (Ainamo and Parviainen 1979; Ainamo and Parviainen 1989).

Most of the studies reported the relationship between oral hygiene and total caries experience. A few studies reported on oral hygiene and caries experience

of specific groups of teeth and very few studies examined the relationship between oral hygiene and surface specific caries. Mansbridge (1960) reported that the difference in caries experience of the molar teeth between the good oral hygiene group and the neglected oral hygiene group was not statistically significant. Sutcliffe (1977) found statistically significant differences in caries experience among 3- and 4-year-olds in all the tooth groups between good and poor oral hygiene groups. Kleemola-Kujala & Räsänen (1982), using estimates of attributable risk of caries from increased plaque accumulation, showed that permanent molars would benefit less than other permanent teeth by improving oral hygiene.

In examining surface-specific caries experience, Sutcliffe (1977) reported on caries experience and oral hygiene among 3-and 4-year-old children in Scotland. He found statistically significant differences in caries experience of occlusal and approximal surfaces between good and poor oral hygiene groups. There was no difference in caries experience of buccal and lingual surfaces between the groups. Similarly, Beal et al. (1979) found differences in caries experience among specific tooth surfaces between different oral hygiene groups. It is likely that oral hygiene factors have differential effects on different tooth surfaces and studies should endeavour to analyse the effects of oral hygiene on specific tooth surfaces rather than use the mean differences in carious surfaces for the entire dentition.

Some of the studies used more than one index to measure oral hygiene. Bay and Ainamo (1974) used the plaque index and toothbrushing frequency to examine the relationship between oral hygiene and dental caries. Children were grouped into a low or a high caries risk group. No difference in brushing frequency was found between the two caries risk groups. Although, the difference in plaque levels between the low (DMFS+dmfs $\leq$ 4) and high (DMFS+dmfs > 22) caries

experience groups was found to be statistically significant, it was considered not to be of any clinical significance. Such inconsistent findings with the use of different indices add to the difficulties in interpreting the reported results.

Statistical analyses undertaken also varied among the studies. Early studies lacked statistical sophistication and most used bivariate analyses. Later studies used multivariate analyses which allowed for simultaneous control of confounding factors. This fact may explain the apparent lack of a statistically significant association between oral hygiene and dental caries among early studies while the findings from more recent studies generally indicate an association between lower caries experience and good oral hygiene levels. A major limitation of cross-sectional studies is that they are only able to determine an association between two or more variables at a point in time, and cannot therefore establish causal relationships. Cross-sectional studies that examine the relationship between dental caries and oral hygiene relate accumulated caries experience to reported oral hygiene at one time only and any association found cannot be used to attribute causality. Well controlled, randomised clinical trials are required to demonstrate the causal effects of therapy.

LONGITUDINAL STUDIES

Longitudinal studies that examined the relationship between oral hygiene and dental caries can be subdivided into those that used self-performed oral hygiene measures and those that used a combination of oral hygiene measures including professional cleaning of teeth. There are also variations among longitudinal studies in the methods used to examine the relationship between oral hygiene and dental caries, Table 4. Some studies obtained data retrospectively from clinical trials (Ashley and Wilson 1977; Beal et al. 1979; Chesters et al. 1992; Øgaard et al. 1994; Sutcliffe 1973; Tucker et al. 1976) while others obtained

their data prospectively (Carvalho *et al.* 1992; Etty *et al.* 1994; Stecksén–Blicks and Gustafsson 1986).

Table 4   Longitudinal studies on oral hygiene and dental caries

Reference	Study group	Age (years)	Duration (years)	Outcome indicators	Oral Hygiene Indicators	Data type	Type of association[*]
Sutcliffe (1973)	398	11–12	3	DMFT	Own index	Prospective	Positive
Tucker *et al.* (1976)	740	11–12	3	DMFT/S	Oral Debris Index	Prospective	Positive
Ashley & Wilson (1977)	51	11–12	3	DFS	Dry weight plaque	Prospective	Positive
Beal *et al.* (1979)	305	11–12	3	DMFS	Own index	Prospective	Positive
Woltgens *et al.* (1984)	137	2–14	6 mo	caries initiation progression regression stabilisation	OHI-S	Prospective	Mixed
Stecksén–Blicks & Gustafson (1986)	171	8 & 13	1	dmfs/DMFS	GBI	Prospective	Positive
Dummer *et al.* (1990a)	798	11–12	4	caries initiation	Toothbrushing Plaque Index	Prospective	Positive
Neilson & Pitts (1991)	2854	13	2	caries progression regression stabilisation	OHI-S	Prospective	Positive
Sundin *et al.* (1992)	69	15	3	approximal caries	Gingivitis	Prospective	Positive
Chesters *et al.* (1992)	2182	mean=12.5	3	DMFS	Toothbrushing	Prospective	Positive
Etty *et al.* (1994)	460	4–16	2	Caries initiation progression regression	PHP Index	Prospective	No relation
Alaluusua & Malmivirta (1994)	92	19 months	18 months	dt/dfs	Plaque on incisors	Prospective	Positive
Wendt *et al.* (1994)	632	1	2	Caries prevalence	Plaque on incisors	Prospective	Positive
Øgaard *et al.* (1994)	165	15	1	Approximal caries	Non-bleeding papillae	Retrospective	Positive
Roeters *et al.* (1995)	193	2	3	dmfs	Plaque Index	Prospective	Positive
Chestnutt *et al.* (1995)	4294	mean=12.5	3	recurrent caries	Brushing frequency	Prospective	Positive

[*] positive= less decay with improved oral hygiene; mixed= positive with some indices and no relation with others; no relation= no statistically significant relationship with oral hygiene indices

Self performed oral hygiene measures (Observational Studies)

Sutcliffe (1973) related the three-year caries increment (DMFT) among children (n=398; aged 11–12 years) with their level of oral hygiene at their annual clinical examinations. Oral hygiene was determined by the amount of plaque detected on the labial surfaces of the permanent incisor and canine teeth of both jaws. Children who had clean teeth (i.e. no plaque detected when the side of a sickle probe was moved over the tooth surface) at baseline and at each of the three annual examinations were classified 'good oral hygiene' (n=42). Children who had plaque at each examination were classified 'poor oral hygiene' (n=107) and those who had plaque on some visits and were plaque free at other times were grouped under 'fair oral hygiene' (n=249).

Table 5   Caries increments among 11–12-years-old boys and girls in Yorkshire for different oral hygiene levels for all teeth and selected tooth groups

Tooth groups	Boys			Girls		
	Good OH n=8	Poor OH n=78	percent difference	Good OH n=34	Poor OH n=29	percent difference
DMFT	3.00	3.47	13.5	4.21	4.52	6.9
Molars	1.63	1.42	-14.8	2.06	1.28	-60.9
Premolars	1.13	1.33	15.0	1.71	2.17	21.2
Incisor/ canines	0.25	0.71	64.8	0.44	1.07	58.9

From Sutcliffe (1973)

Analyses, comparing the 'good' with the 'poor' groups, stratified by sex were presented because of differences in oral hygiene level between girls and boys. Good oral hygiene groups had lower caries increments compared with the poorer oral hygiene groups, but the difference of 0.5 teeth for boys and 0.3 teeth for girls was not statistically significant, Table 5. The largest caries increment was observed in the molar teeth of girls with good oral hygiene and the largest difference in caries increment between the good and poor oral hygiene groups was also observed in the molar teeth of girls. The small number of boys in the

good oral hygiene category (n=8) means that the conclusions from this study must be treated with caution.

The correlation between the amount of plaque present in the mouth and caries increment has been examined (Ashley and Wilson 1977). Plaque was collected from schoolboys in London, England (n=51; aged 11–12 years) every six months from the buccal, lingual, mesial and distal surfaces of teeth from one randomly chosen side of the mouth. The caries increment over three years was related to the amount of plaque collected for each year and the mean of all the years. All correlations between the mean dry weight of plaque and the three-year caries increment (DFS) were positive, but only the correlation between the first year plaque and DFS was statistically significant (correlation coefficient=0.33; $p < 0.05$). The extent of the correlations and their statistical significance did not alter when pit and fissure caries was excluded to control for the possible bias introduced by not collecting plaque from pits and fissures. The analysis, however, was based only on the 35 individuals who were present for all the examinations. As no information on 'drop-outs' was reported, the likelihood of bias from the loss could not be determined.

Data from a three-year clinical trial that tested the caries preventive effects of a fluoride-containing toothpaste were used to examine the relationship between oral hygiene and caries increment (Tucker et al. 1976). Schoolchildren (n=740, mean age 11 years) in Bristol, England (F⁻ level 0.07–0.14 mg/L) were stratified according to sex, tooth eruption pattern and past caries experience and then randomly assigned to matched test and control groups. Oral hygiene level was determined by the mean amount of oral debris present [Debris Index (DI) of OHI] and caries increment was expressed through the DMFT, DMFS and DFS indices at each of the three annual examinations. Among the group that used a non-fluoride toothpaste, children with good oral hygiene (DI≤0.8; n=184) had a

statistically significantly lower caries increment compared with children with poor oral hygiene (DI>0.8; n=192). Children with good oral hygiene had a mean caries increment of 4.25 DMFT and the poor oral hygiene group had 4.96 DMFT, $p<0.05$, (Table 6).

Table 6   Mean caries increment (DMFT) among 11-year-old girls and boys and all the children between different oral hygiene groups for both fluoride and placebo toothpaste in England

Toothpaste type	Girls			Boys			All		
	Good OH	Poor OH	Percent difference	Good OH	Poor OH	Percent difference	Good OH	Poor OH	Percent difference
Fluoride	3.68 (102)	4.00 (69)	8.0	3.27 (64)	3.94 (129)	17	3.52 (166)	3.96 (198)	11.1*
Placebo	4.37 (110)	4.96 (61)	11.9	4.08 (74)	4.96 (131)	17.7	4.25 (184)	4.96 (192)	14.3*

From Tucker et al. (1976). Numbers of children are in brackets; *= p<0.05

Tucker et al. (1976) also found lower caries increment among children who reported more frequent brushing, regardless of the type of toothpaste used (fluoride-containing or fluoride-free). The difference in caries increment of 0.65 DMFT between children who reported brushing at least twice a day (n=187; DMFT=4.29) compared with those who brushed less often (n=189; DMFT=4.94) was statistically significant among the children who used a non-fluoride toothpaste, $p < 0.05$.

Holloway and Teagle (1976) reported, as an abstract, their findings on the association between oral hygiene and dental caries assessed as part of a three-year clinical trial (Holloway and Teagle 1976). Adolescents with good oral hygiene (n=63) had about one DMFS less than children with poor oral hygiene (n=52) and the difference was not statistically significant.

Data from another three-year clinical trial in England that tested the caries preventive effects of a fluoride toothpaste showed better gingival health and

lower caries increments among children who had consistently clean teeth during the trial (Beal *et al.* 1979). Children (aged between 11 and 12) who had a good standard of oral hygiene at baseline and at each of the three annual clinical examinations were classified as having 'clean' teeth (n=110) and those who never had good oral hygiene were classified as 'not clean' (n=195). Lower caries increments were observed in children with 'clean' teeth, regardless of whether or not they used a fluoride-containing toothpaste, but those who used a fluoride toothpaste obtained additional caries preventive benefits. Children with 'clean' teeth in the non-fluoride toothpaste group (n=59) had a mean DMFS increment of 7.59 and the 'not clean' children (n=101) had a DMFS increment of 10.29; the difference was statistically significant, $p<0.05$. The 'clean' (n=51)and 'not clean' (n=94) children in the fluoride toothpaste group had a mean DMFS increment of 5.41 and 7.70 respectively, and again the difference was statistically significant, $p<0.05$.

Beal *et al.* (1979) also examined the surface specific caries increment among the non-fluoride group and found a statistically significant difference of 46.7% in the buccal and palatal surface caries increment between the 'clean' and 'not clean' groups, $p<0.05$. Differences of 30% for approximal and 7% for occlusal surfaces were not statistically significant. Oral hygiene measures had the greatest effect on the more easily cleaned buccal and palatal aspects of teeth while the more difficult to clean occlusal and approximal surfaces were less affected. The study did not control for socio-economic factors.

A study in The Netherlands examined caries initiation, progression, stabilisation and regression in relation to salivary factors and oral hygiene (Wöltgens *et al.* 1984). Children (n=137) aged 2–14 years who attended a university paedodontic department were enrolled as participants. The correlation between oral hygiene (modified OHI–S) and carious changes

(measured clinically and radiographically) that occurred during six months were determined. Oral hygiene levels were positively correlated with caries initiation, progression and remineralisation (r=0.39, r=0.18, r=0.03, respectively), but the correlation was statistically significant only for caries initiation, $p < 0.001$.

In another longitudinal study, the dental health of 8-year-old (n=83) and 13-year-old (n=88) children from a low fluoride area (0.3 mg/L) of Sweden was monitored for twelve months (Stecksén–Blicks and Gustafsson 1986). Children with lower caries increments (dmfs/DMFS $\leq$ 2) had fewer gingival bleeding sites (an indicator of the level of oral hygiene) compared with children who had caries increments of 3 or more surfaces. The difference in Gingival Bleeding Index (GBI) between the low caries increment and high caries increment groups among the 8-year-old and 13-year-old was statistically significant, $p < 0.05$ and $p < 0.01$, respectively. In the discriminant analysis, 77% of 8-year-olds and 70% of 13-year-olds were correctly grouped into high and low risk groups using dietary and bacteriological variables. When the GBI, toothbrushing frequency, use of fluoride toothpaste and fluoride rinsing were added to the discriminant analysis, additionally 4% of 8-year-old and 11% of 13-year-old children were correctly classified into high and low caries increment groups. The GBI was also found to be the most discriminating of the additional variables.

The effects of oral hygiene and other factors on caries incidence among specific tooth surfaces were examined in a study of 11–12-year-old children in Wales (Dummer et al. 1990a). Children (n=798) were examined at baseline and after four years. Oral hygiene was scored as frequency of toothbrushing and Plaque Index and caries initiation was recorded for pits and fissures of posterior teeth, approximal surfaces of posterior and anterior teeth, and buccal and lingual smooth surfaces of all the teeth. Caries was assessed clinically and radiographically.

Bivariate analysis using ANOVA found statistically significant effects of baseline plaque score on caries initiation in pits and fissures ($p<0.001$) and approximal surfaces of posterior ($p<0.01$) and anterior teeth ($p<0.001$); low plaque scores were associated with low caries scores. Plaque score at follow-up examination and toothbrushing frequency at baseline examination were statistically significant for caries initiation on approximal surfaces of posterior and anterior teeth; low plaque scores and frequent brushers had lower caries scores. Multiple linear regression found baseline plaque score was a statistically significant predictor of caries initiation on all surfaces except buccal and lingual smooth surfaces, after controlling for other independent factors (money spent on sweets, toothbrushing frequency, frequency of dental visits, social class and sex). However, the regression models only explained 4–6 percent of the variation in caries initiation.

A Scottish study monitored the behaviour of free smooth surface lesions among children (n=2854; mean age 13.3 years) who participated in a toothpaste clinical trial (Neilson and Pitts 1991). The progress of free smooth surface lesions detected at baseline examination was monitored over two years of the trial and the behaviour of the lesions was then related to a number of clinical factors. Oral hygiene was determined by OHI and the children grouped into good, fair and poor oral hygiene groups based on a mean score calculated from values obtained at each of the four annual examinations for the toothpaste trial. Caries was scored according to the criteria developed during the first year of the trial. When the behaviour of carious lesions was compared among the different oral hygiene groups, a higher proportion of children in the poor oral hygiene group had lesions that had progressed or had teeth extracted ($p<0.001$) and a lower proportion of poor oral hygiene children had static lesions, $p<0.02$.

A Swedish study examined the incidence of caries on approximal surfaces of posterior teeth among 15-year-old adolescents (n=69) over a three-year period (Sundin *et al.* 1992). Oral hygiene was scored as the mean number of bleeding gingival sites recorded at baseline and after three years. Caries incidence was expressed as the proportion of sound surfaces at baseline that became carious, determined radiographically after three years. Simple correlation analyses found oral hygiene was of marginal importance in caries incidence (r=0.221, *p*=0.069). When children were grouped into 'favourable' and 'unfavourable' fractions of the independent factors, a high, statistically significant correlation between sweets consumption and caries incidence was found for children in the poor oral hygiene fraction (r=0.511, *p*=0.002). The value of the correlation coefficient increased when other independent factors were also included.

Data collected as part of a three-year clinical trial that involved 2182 children (mean age 12.5 yrs) in Scotland were used to examine the relationship between oral hygiene behaviour and dental caries (Chesters *et al.* 1992). Frequency of toothbrushing, self-reported at each of the three annual examinations, was used as an indicator of oral hygiene status. A statistically significant difference in caries experience and increment was found between adolescents who reported brushing at least twice a day with a fluoride toothpaste (base DMFS=8.96; DMFS increment=5.38) and those who reported brushing once a day or less (base DMFS=10.57; DMFS increment=6.95: *p*<0.001). The difference in caries increment was still significant after controlling for sex and baseline caries experience. However, possible influences of socio-economic factors were not included in the analysis. The study did not measure oral hygiene status directly, therefore, it is possible that the observed relationship between brushing frequency and caries increment in this study was a consequence of fluoride exposure.

In a follow-up report of the above study, a lower proportion of adolescents with recurrent caries was found among those who reported, at their last clinical examination, brushing at least twice a day compared with those who reported brushing once a day or less (Chestnutt *et al.* 1995). The difference was statistically significant, $p < 0.01$.

Recent studies have also examined the effects of oral hygiene on initiation, regression, stabilisation and progression of carious lesions (Etty *et al.* 1994; Øgaard *et al.* 1994). Etty *et al.* (1994) investigated the effects of oral hygiene on early enamel caries among 548 children aged 4–16 years in The Netherlands. The children were examined six monthly for two years and oral hygiene was determined at each visit using a modified PHP Index (Podshadley and Haley 1968). Regression analysis demonstrated no clear relationship between oral hygiene and caries initiation, regression or progression. The linear regression found static carious lesions were more common in fissures of children with poorer oral hygiene, $p < 0.05$.

The children in the study by Etty *et al.*(1994) were subjected to intensive fluoride therapy which included the use of fluoride toothpaste three times daily, fluoride tablet supplementation (1 mg daily), twice a year professional cleaning of teeth with a fluoride-containing paste, topical fluoride applications (twice a year) and most had weekly fluoride rinsings at school. So, it is possible that such intensive fluorotherapy could have masked the effects, if any, of oral hygiene on incipient enamel caries. The study also reported inter-examiner reliability, expressed as kappa (range 0.57–0.81); the low value is consistent with moderate strength of agreement and the high value with good agreement (Landis and Koch 1977). A moderate level of inter-examiner agreement may not be sufficient in a study which is attempting to measure early carious changes.

Øgaard et al. (1994) found a statistically significant relationship between oral

hygiene status and approximal caries among 15-year-old Norwegian children

(n=165). Oral hygiene was determined by the number of non-bleeding papillae

(NBP) of premolar and molar teeth after a wooden toothpick was inserted

interdentally. Children were classified into good oral hygiene group if their NBP

was at least the same as the mean NBP, and poor oral hygiene if their NBP was

less than the mean NBP. Caries was assessed from bitewing radiographs at age

14 and 15 years (caries data at age 14 were obtained from past clinical records).

There were statistically significant differences between the two groups with

respect to caries initiation and progression; the poor oral hygiene group had

more new and progressing carious lesions.

Observational studies on infants and preschool children have also contributed

towards an understanding of the relationship between oral hygiene and dental

caries (Alaluusua and Malmivirta 1994; Roeters et al. 1995; Wendt et al. 1994).

Alaluusua and Malmivirta (1994) monitored the development of caries among

19-month-old infants (n=92) over a one and one-half year period, in Finland. Of

the four predictor variables recorded at baseline, the use of nursing bottle and

the presence of visible plaque on the labial surfaces of maxillary incisors were

strongly associated with caries development. At 36-months of age, children

without plaque had 0.1 dt and dfs compared with children with plaque, who had

2.8 dt and 5.1 dfs, $p<0.001$. As a screening criterion, the presence of plaque at 19

months achieved sensitivity of 0.83 and specificity of 0.92.

Wendt et al.(1994) monitored the development of caries among infants, initially

1-year-old over a two-year period. Six hundred and twenty-nine children were

examined at baseline and a randomly selected subgroup of 298 children was

examined at two years of age and 593 children were examined at three years of

age. Oral hygiene was assessed by the presence or absence of visible plaque on

the labial surfaces of maxillary incisors. The chi-square test was used to compare the proportion of children with caries among groups with plaque and without plaque. A higher proportion of children with plaque at both one and two years of age had caries by age three ($p<0.001$) and a higher proportion of children with plaque at age one had caries by age two, $p<0.001$.

Roeters *et al.* (1995), in the Netherlands, monitored two-year-old children (n=193) over three years for caries development. Oral hygiene (modified Plaque Index and Gingival Index) and caries were assessed 6-monthly. Spearman rank correlations between oral hygiene and dental caries were low (r $\leq$ 0.21), but statistically significant, $p<0.05$. This study, although longitudinal in design, did not indicate which time periods for oral hygiene were correlated with which time period for caries. If the oral hygiene variable of a time period was correlated with the caries data of the same time period then it should be more properly viewed as a cross-sectional study and the correlation should be viewed more appropriately as an association rather than causal.

The findings of longitudinal observational studies on the relationship between oral hygiene and caries have also produced inconsistent findings. The majority of studies showed small, weak, positive associations between good oral hygiene and lower risk of caries. All the studies have methodological limitations.

LIMITATIONS OF LONGITUDINAL STUDIES

A major limitation of longitudinal studies relates to establishing a relationship between a fairly long disease process (dental caries, measured on an irreversible scale) with a transient putative causative factor measured at a single point in time (oral hygiene, measured on an reversible scale). The problem is particularly acute when oral hygiene indices which measure the presence of plaque (e.g. OHI, Plaque Index) are used because the presence of plaque may be transitory

and may not be a true indicator of the usual, customary oral hygiene status. To overcome the problem, most studies used the mean oral hygiene status from a number of clinical examinations carried out at 6-12-month intervals, and some performed the clinical examinations without giving prior warning to the children in the hope of getting a more valid estimate of prevailing oral hygiene levels.

Direct comparisons between the studies covered in this review are difficult, because of the different caries and oral hygiene indices that are used, Table 4. The decayed, missing and filled teeth/surfaces measure is an irreversible index and thus an insensitive outcome indicator of the reversible and relatively rapid changes that can occur with oral hygiene. Recent studies have included early (reversible) stages of caries to assess the effects of oral hygiene on caries (Etty *et al.* 1994; Øgaard *et al.* 1994). The use of more sensitive diagnostic thresholds may be indicated in populations with low caries prevalence in order to detect relatively weak effects. Their use has been limited until recently due to the concern with measurement errors. However, Pitts and Fyffe (1988) showed no loss in intra-examiner reliability when more sensitive caries diagnostic thresholds were used in a population with low caries prevalence.

The findings on the effects of tooth brushing and oral hygiene on caries increment are not clear. There appears to be an additive relationship between brushing frequency and use of fluoride-containing toothpastes (Beal *et al.* 1979; Chesters *et al.* 1992; König 1993; Rølla *et al.* 1991; Thylstrup 1990). The effectiveness of toothbrushing with non-fluoride toothpastes appears to be limited to approximal and buccal/lingual surfaces (Beal *et al.* 1979; Horowitz *et al.* 1977a; Horowitz *et al.* 1980). The use of toothbrushing frequency as an indicator of oral hygiene in an environment in which fluoridated toothpastes are widely used may no longer be useful in determining the effects of oral hygiene

on dental caries, with the possible exception of its use as an indicator of frequency of exposure to fluoride.

Ainamo and Parviainen (1989) concluded that tooth brushing can be an effective caries preventive measure provided that brushing is carried out at least once a day with fluoride-containing dentifrices. An indication of the dose-response effect of exposure to fluoride contributing to the relationship observed with toothbrushing frequency and caries was demonstrated by a study that tested the effectiveness of dentifrices with two different concentrations of fluoride (Moorhead *et al*. 1991). The study found that more frequent brushers had lower caries increments compared with less frequent brushers for both types of toothpastes. It was also observed that more frequent brushers using the lower fluoride concentration toothpaste had similar caries increment compared with less frequent brushers who used the more concentrated fluoride toothpaste.

An earlier review on the relationship between oral hygiene and dental caries concluded that self performed preventive measures such as tooth brushing are relatively ineffective in preventing caries on the inaccessible occlusal and approximal surfaces, these preventive measures can control caries on the more accessible lingual and buccal surfaces and they can improve gingival health (Bellini *et al*. 1981).

Sutcliffe (1989) has indicated that the only way to determine the existence of a direct relationship between oral cleanliness and dental caries is through the means of clinical trials in which the provision of restorative care is controlled, and the effects of other strong preventive agents, such as fluoride, are absent. The last requirement may not be able to be achieved in developed countries where exposure to fluoride in one form or another is almost universal (Downer

1991), nor would it be ethically acceptable to withhold fluoride, a proven efficacious therapeutic agent.

The establishment of a direct causal relationship between oral hygiene and dental caries is strengthened by the fact that most studies, using different methods, have found a weak, direct relationship between lower risk of caries and good oral hygiene levels. However, it is expected that intervention studies with random assignment of groups will provide a more definitive answer to the question on the relationship between oral hygiene and dental caries.

Caries risk assessment studies

A different approach to assessing the relation between oral hygiene and dental caries is that of using oral hygiene as a predictor of dental caries in caries risk models. A number of investigators have used this method (Grytten *et al*. 1988; Klock *et al*. 1989; Russell *et al*. 1991; Schröder and Granath 1983), but the findings are inconsistent; some found oral hygiene to be a predictor of dental caries (Demers *et al*. 1992; Russell *et al*. 1991; Schröder and Granath 1983), while others found no predictive value of oral hygiene (Grytten *et al*. 1988; Klock *et al*. 1989).

Schröder and Granath (1983) found in their study of 3-year-old children (n=143) that oral hygiene was a predictive variable for caries experience. A combined oral hygiene (gingival status) and diet (frequency of sugar consumption) variable was used to determine the most discriminating border where both sensitivity (0.89) and specificity (0.70) were at their maxima. Variations in oral hygiene levels had a more marked effect on caries than variations in dietary levels. The oral hygiene information was obtained at the same time as the scoring of caries and so the study should be viewed as cross-sectional rather than longitudinal.

This limits the conclusions that can be drawn on the predictive ability of oral hygiene for dental caries.

Further studies by the above group using a longitudinal design among 1 1/2-year-old children (Schröder *et al.* 1994) and 5-year-old children (Sullivan and Schröder 1989) failed to obtain high sensitivity and specificity with the oral hygiene variable alone or in combination with other factors as caries predictors. Russell *et al.* (1991) used data from a toothpaste trial to assess predictive ability of a number of independent factors. Oral hygiene variable (Debris Index) was found to be correlated to both one-and two-year caries increment. The oral hygiene variable, however, was no longer statistically significant in multivariate step-wise regression model.

Demers *et al.* (1992) found in their study of 5-year-old Canadian children (n=302) that oral hygiene (Debris Index) was a predictor of caries development over a twelve-month period; children with poorer oral hygiene developed more caries. Chi square (p=0.017) and logistic regression (OR=3.1) analyses found oral hygiene to be a statistically significant predictor of caries development, and oral hygiene combined with past caries experience achieved sensitivity of 0.81 and specificity of 0.73.

Klock *et al.* (1989) examined the ability of a number of factors to predict caries development and progression over a twelve-month period among 14-year-old children (n=100) in Sweden. The correlation between oral hygiene (Visible Plaque Index) and the twelve-month development and progression of dental caries in approximal surfaces of posterior teeth was found not to be statistically significant.

A major limitation of caries risk assessment studies is the reduction of the caries outcome into an all or none dichotomy or a selected arbitrary cut-off point defining high-risk and low-risk. This means that not all the available information is entered into the prediction model. The effects of model selection on the predictive ability of independent factors have been highlighted (Beck *et al.* 1992). Many studies also failed to consider the predictive ability of independent factors on specific tooth surfaces, and given that caries in children is now predominantly pit and fissure caries, surface specific prediction models will become increasingly important. The findings from risk assessment studies point to a relatively weak effect of oral hygiene on caries development.

INTERVENTION STUDIES (*Self-performed oral hygiene measures*)

Intervention studies that attempt to examine the effects of oral hygiene measures have also produced mixed results, Table 7. Nine hundred and forty-six university students participated in a two-year trial aimed at assessing the effects of toothbrushing on caries incidence (Fosdick 1950). The experimental group (n=523, mean age 22.7 years) was advised to brush their teeth within ten minutes of eating, using a non-medicated toothpaste, and when brushing was not practical, to rinse their mouths thoroughly with water. The control group (n=423, mean age 23.5 years) was advised to continue with usual oral hygiene procedures. Caries increment was determined clinically and radiographically. At the end of two years, 702 participants remained in the study (429 test and 273 control). The caries increment was lower in the test group; the difference between the groups was statistically significant at both one and two years, $p < 0.001$. This early study suffered a high drop-out rate, especially in the control group and no details of the assessment of the effect of this was reported. Group assignment details were not reported. The conclusions drawn from the findings must therefore be treated with caution.

Table 7   Studies on controlling caries with self-performed oral hygiene procedures

Reference	Sample size Test	Control	Age (yrs)	Duration (yrs)	OH Indicator	Procedures Test	Control	Caries increment Test	Control	Percent difference	Statistical tests
Fosdick (1950)	523	423	22-23	2	Not stated	Brush after meals	Usual routine	1.49	2.53	41	Not stated
Hewat et al. (1950)	41	40	18-20	1	Not stated	Brush after meals	Usual routine	3.92	2.29	-7	Not stated
Kerr & Kesel (1951)	171	251	10-11	2	Not stated	Brush daily at school	Usual routine	7.9	8.4	6	Not stated
Hewat et al. (1952)	78	76	17-20	1	Not stated	Brush after meals	Usual routine	3.64	3.82	5	Not significant
Koch and Lindhe (1970)	56	46	9-11	1	Plaque Index	Brush daily at school		8.32	8.98	7	Not significant
Clark et al. (1973)	112	145	11	19 mths	PHP Index	Brush daily at school	Usual routine	0.31	0.91	66	Not tested
Mckee et al. (1977)	89	64	10-12	3	Not stated	Brush and floss daily at school	Usual routine	10 yo=6.1 11 yo=7.1 12 yo=5.6	13.7 4.3 12.4	10 yo -65 11 yo -65 12 yo -55	Not tested
Silverstein et al. (1977)	227 combined		12	29 mths	PHP index	Brush and floss daily at school	Usual routine	Not reported			Not significant
Spears et al. (1978)	97	261	4-14	21 mths	Not stated	Brush and floss daily at school	Not reported	0.92	0.93	1	Not significant
Horowitz et al. (1980)	111	168	10-13	3	PHP Index	Brush and floss daily at school	Usual routine	4.27	4.89	13	Not significant
Fogels et al. (1982)	109	109	7-11	1	None	brush at school	Usual routine	0.39	2.34	83	p<0.001

Two studies in New Zealand tested the effects of oral hygiene procedures on caries increment among student dental nurses (Hewat *et al.* 1950; Hewat *et al.* 1952). In the first study, test group participants (n=41) were advised to brush their teeth each time after eating or to rinse their mouths with water if brushing was not possible (Hewat *et al.* 1950). The control group (n=40) was not given any instructions regarding oral hygiene procedures. After one year, a higher caries increment was observed among the test group (3.9% of surfaces at risk became carious) compared with the control group (2.3% of surfaces at risk became carious). In the second study, the same protocol for test and control groups was adopted (Hewat *et al.* 1952). After twelve months, more new caries was observed among the control group (n=76; Δ DS=3.82) compared with the test group (n=78; Δ DS=3.64), the largest difference between the groups was on buccal and lingual surfaces; however, the differences were not statistically significant.

A study among children who brushed their teeth under supervision at school was conducted in two cities in Illinois, USA (Kerr and Kesel 1951). The two test groups (n=179 and n=144; aged 10–11 years) toothbrushed twice a day at school using an ammoniated dentifrice. A positive control group (n=160) toothbrushed twice a day with a neutral dentifrice and the true control group (n=301) did not toothbrush at school. Group assignment details were not reported. Caries increment was determined clinically and radiographically and scored as the mean number of teeth becoming carious as a proportion of the total number of teeth at risk. After two years, more caries was observed among children who did not brush at school. There was 9% less caries in the positive control group compared with the true control group.

Caries and plaque reducing effects of a school oral health education programme among sixth grade schoolchildren were examined in Cleveland, Ohio (Clark *et al.* 1974). Test and control groups were matched for school, SES and race (age of

the participants was not reported). Test group children were provided with oral health lessons at school and participated in demonstrations of plaque control techniques. Oral hygiene was assessed at baseline and at eight-and fourteen-months, using the PHP index. The original aim of the study was to test the effects of an education programme on plaque levels, and information on caries increments was not collected at the time of oral hygiene assessments. Caries data were obtained from routine annual screening of the children by the Ohio State Health Department, conducted using a tongue depressor and a flashlight. After nineteen months, more caries was observed to have occurred in the control group (n=145; ΔDMFT =0.91) compared with the test group (n=112; ΔDMFT =0.31). The authors reported that the caries reduction among the test group was significant, but the difference in caries increment between the test and control group was not statistically tested.

The early intervention studies had methodological limitations which weakened the findings of the study. The protocol used to assign participants to the test and control groups was often not reported (Fosdick 1950; Hewat *et al.* 1950; Kerr and Kesel 1951). The examination criteria used to determine caries increment were also inadequately explained and whether or not the examiner was blind to the group status of the participants was seldom reported. The statistical treatment of the data was, in most cases, inadequate and no tests were performed (Hewat *et al.* 1950; Kerr and Kesel 1951) or, if statistical tests were used, the details were inadequately reported (Clark *et al.* 1974; Hewat *et al.* 1952). Almost no information on participant drop-out and loss to follow-up was provided. Thus, the findings from early studies should be interpreted with caution.

In a well controlled randomised study, Koch and Lindhe (1970) reported on their findings among children (n=299; aged 9–11 years) in Sweden (Koch and Lindhe 1970). The children were randomly allocated into five groups; two test, two

positive control and one true control. One test group (n=57) performed daily supervised brushing with a fluoridated toothpaste, the positive control (n=56) brushed daily with a placebo. The second test and positive control groups were used to test the effects of fluoride rinsing. The true control did not perform any of the procedures. Caries increment was measured as the number of new decayed surfaces (Δ DS).

After three years, both the test brushing group (Δ DS=4.40) and the positive control brushing group (Δ DS=8.32) had lower caries increment compared with the true control group (Δ DS=8.98). The differences between the test group and the two control groups were statistically significant. Oral hygiene was measured by the Gingival Index and Plaque Index and indicated improved levels of oral hygiene among both brushing groups compared with the true control group, but no difference between the test group and the positive control group. The authors concluded that daily supervised toothbrushing has beneficial effects on the health of the gingivae but is of little value in preventing caries. Although this was a well designed study, the authors did not report on drop-out, nor did they report on whether the examinations were done 'blind'.

The effects of a dental health programme based on self-performed plaque control was examined in a study in Tacoma, Washington (McKee *et al.* 1977). Children aged 10–12 years attending a public school, rated as being representative of schools in the district, were enrolled as test participants (n=219). Students from other schools matched on a number of criteria were enrolled as controls (n=306). Children in the test group were instructed in correct brushing and flossing techniques and carried out the procedures daily at school. After four years, oral hygiene levels (PHP index) and caries increment (DMFS) between test and control groups were compared. Oral hygiene in the test group improved during the first twelve months of the study but, by the end of the study, had returned to

baseline levels and was not different from the levels of the control group. There was also no difference in caries increment between test and control groups. However, the findings of this study need to be treated with caution due to high drop-out: 59% in test group and 79% in control group.

Silverstein *et al.* (1977) reported in an abstract on a randomised study that examined the effects of supervised self-performed oral hygiene procedures among seventh-grade school children in California, USA (Silverstein *et al.* 1977). After twenty-nine months, 59% of the original participants (n=227) were examined and their oral hygiene (PHP index) and caries increment (DMFS) scored. The test group had lower PHP scores compared with the control group, but there was no statistically significant difference in caries increment.

A 21-month field trial in California, USA also reported indifferent results to attempts at controlling caries through supervised plaque control (Spears *et al.* 1978). Test group children from one school (n=97) brushed, with a non-fluoride toothpaste, and flossed daily at school under supervision and the children in the control group from a different school (n=261) did not brush or floss at school. The difference in caries increment between the test group (0.92 DMFT and 1.55 DMFS) and the control group (0.93 DMFT and 1.18 DMFS), after adjustment for age differences between groups, was not statistically significant. The study did not report how the children were assigned to test or control groups and the adjustment procedure for age difference between test and control group was not explained adequately. The study also failed to report on drop-out, sex composition and socio-economic status of the participants.

As part of a demonstration project, the effects of supervised plaque control measures on caries increments were examined in Connecticut, USA (Horowitz *et al.* 1977a; Horowitz *et al.* 1980). Children aged 10–13 years from one school in

Connecticut (n=481) were randomly assigned to a treatment or a control group after stratifying for school grade and sex. The treatment group received intensive oral hygiene instructions and carried out supervised daily plaque removal through brushing (non-fluoride toothpaste) and flossing at school. The control group did not receive any oral hygiene instructions nor did they participate in supervised plaque removal at school. Loss of subjects and being absent at annual examinations (n=202) during the trial resulted in a statistically significant difference in baseline caries experience of the remaining children in the treatment (n=111) and control (n=168) groups, and an adjusted (standardised) data analysis was conducted to correct the imbalance. Statistically significant improvements in oral hygiene and gingival health were observed in the treatment group. While the treatment group caries increment (DMFS=4.27) was lower than that of the control group (DMFS=4.89), the difference was almost totally accounted for by the difference in approximal caries and was not statistically significant.

A study in the Boston area of the United States compared caries increment among a group of children (n=109, aged 7–10 years) who were participants, as controls, in a clinical trial and used a non-fluoride toothpaste in daily supervised brushing programme at school with caries increment among a matched group of children who continued with usual oral care routine at home (Fogels *et al.* 1982). The children were matched for age, school, DFS and surfaces at risk. After twelve months, the caries increment among the children who were brushing at school (DFS=0.39) was significantly lower than among children who brushed at home (DFS=2.34), $p<0.001$. However, the findings of this study should be interpreted with caution because no mention is made in the report about matching for two other possible confounders, sex and socioeconomic status. Also, the study did not explain if the study groups were concurrent groups and did not report on the oral hygiene levels of the groups.

COMBINED ORAL HYGIENE MEASURES

A combination of oral hygiene measures including professionally performed plaque control measures appears to be more successful than self-performed plaque control in controlling caries increment, Table 9. The studies by Axelsson and Lindhe in Karlstad, Sweden, demonstrated the caries preventive efficacy of their system of professional tooth cleaning (Axelsson and Lindhe 1974; Axelsson and Lindhe 1977; Lindhe and Axelsson 1973; Lindhe *et al.* 1975). In a four-year study, children in the test group (n=116, ages 7–8, 10–11 and 13–14 years) had their teeth cleaned by a trained auxiliary, once a fortnight during school term time for the first two years, using dental floss in interproximal areas, and with a fluoride-containing abrasive paste on other surfaces. The children were also provided with oral hygiene instructions. In the third year, children were seen for professional cleaning once every 4–8 weeks, and in the fourth year, children were seen every two months. The control group (n=100) continued with supervised brushing with a fluoride solution once a month. The differences in caries increment between test and control groups for children seen at all the four years were statistically significant, Table 8.

Table 8   Mean caries increment (DFS) for test and control groups for each year and all the years in a Swedish professional cleaning trial

	First year	Second year	Third year	Fourth year	All years
Test (n=85)	0.07	0.15	0.25	0.29	0.76
Control (n=78)	3.24	2.78	2.92	3.18	12.13
Percent difference	98	95	91	91	94

From Axelsson and Lindhe (1977)

At the end of four years, 85-test and 78-controls completed the study. The caries preventive effects were equally pronounced on occlusal/approximal surfaces as well as on buccal/lingual surfaces. The caries preventive effects were

maintained, but at a slightly reduced level, when the intervals between cleanings were increased.

In a one-year study that attempted to replicate the Karlstad study (n=216, aged 10–12 years), statistically significant differences between the test and control groups in approximal caries (0.6 DS *vs* 1.3 DS; $p<0.001$) and the overall caries increment (3.4 DS *vs* 4.5 DS; $p<0.01$) were obtained and greater treatment effects were observed in children with high caries experience (Badersten *et al.* 1975). Each child in the experimental group received professional cleaning once a month. Treatment was carried out with a non-fluoride paste and the children rinsed for one minute with a 0.2% fluoride solution at the end of the cleaning session. Children in the control group continued with supervised toothbrushing with 0.2% fluoride solution once every six weeks. No statistically significant differences in occlusal, buccal or lingual surface caries increments between test and control groups were found.

The failure to replicate the results of Axelsson and Lindhe (1974) was attributed to the reduced frequency of professional cleaning sessions. Furthermore, the caries preventive effects obtained after the time interval between cleanings was increased by Lindhe *et al.* (1975) could have been influenced by the two earlier years of intensive oral health education. Also, the frequent professional cleaning sessions may have had their effect through the more frequent exposure of teeth to fluoride rather than the mechanical cleaning procedures.

Table 9   Studies on professional cleaning in caries control

Reference	Sample size		Age (years)	Duration (years)	Prophy frequency	Prophy paste	Oral hygiene Indicator	Caries increment		Percent difference	Statistical tests
	Test	Control						Test	Control		
Axelsson & Lindhe (1977)	Grp1=39 Grp2=33 Grp4=13	Grp1=37 Grp2=26 Grp3=15	7-8 10-11 13-14	4	Fortnightly first 2 years then at longer intervals	F-	Plaque Index	1st yr=0.07 2nd yr=0.19 3rd yr=0.25 4th yr=0.29 all yrs=0.76	1st yr=3.24 2nd yr=2.78 3rd yr=2.92 4th yr=3.18 all yrs=12.13	98 93 91 91 94	Mann-Whitney $p < 0.001$
Badersten et al. (1975)	113	113	10-12	1	Monthly	non-F-	Gingivitis	3.4	4.5	24	t-test, $p < 0.01$
Poulsen et al. (1976)	37	33	7	1	Fortnightly	non-F-	Plaque Index	0.43	1.42	70	ANOVA, $p > 0.05$
Ripa et al. (1976)	151	139	9-13	2	Twice yearly	both	OHI	12.5	13.5	7	t-test, $p > 0.05$
Agerbæk et al. (1977)	30	32	8	1	Once every 3 weeks	non-F-	Plaque Index	1.4	2.09	33	ANOVA, $p > 0.05$
Vestergaard et al. (1978)	68	73	5-13	2	Fortnightly	F-	Not assessed	1.44	1.75	18	ANCOVA, $p > 0.05$
Hamp et al. (1979)	137	140	10-11	3	Once every 3 weeks	F-	Plaque Index	6.3	12.8	51	t-test, $p < 0.001$
Kjaerheim et al. (1980)	154	139	7, 10, & 13	2	Fortnightly	F-	Plaque Index	7 yo=0.22 10 yo=0.29 13 yo=1.32	7 yo=0.51 10 yo=1.32 13 yo=2.96	57 78 54	Not tested
Craig et al. (1981)	48	41	11-12	21 mths	Fortnightly	non-F-	PHP Index	2.6	2.9	10	GLM, $p > 0.05$

Continued

Table 9 Continued

Reference	Sample size Test	Sample size Control	Age (yrs)	Duration	Prophy frequency	Prophy paste	Oral hygiene indicator	Caries increment Test	Caries increment Control	Percent difference	Statistical tests
Ashley & Sainsbury (1981)	119	102	11–14	3	Fortnightly	non-F⁻	Plaque weight	4.83	4.34	-11	Not stated, p>0.05
Axelsson & Lindhe (1981)	310	146	≤35 yo=174, 36–50=172, >50=110	6	once every 2 mths first 2 years then once every 3 mths	F⁻	Plaque Index	≤35yo=0.2, 36–50=0.2, >50=0.3	≤35yo=14.9, 36–50=15.1, >50=11.9	99, 99, 97	Not tested, but large differences between groups
Zickert et al. (1982)	171	89	13–14	2	Monthly & 3-monthly	F⁻	Plaque Index	3.2–4.2	7	54–40	ANOVA, p<0.01 and p<0.05
Hamp & Johansson (1982)	Grp A=29, Grp B=32, Grp C=25	20	16	3	1st year every 3rd week; then longer intervals	F⁻	Plaque Index	Grp A=1.0, Grp B=1.2, Grp C=2.0	3.3	70, 64, 39	ANOVA, p<0.01
Gisselsson et al. (1983)	19	20	10–11	2	Fortnightly for 10 weeks then every 2–4 weeks	Not stated	Gingival status	1.4	4.3	67	Chi-square, p<0.01
King et al. (1985)	206	137	11–12	3	Fortnightly	F⁻	Plaque Index	2.7	3.4	21	t-test, p>0.05
Klimek et al. (1985)	104	117	12–13	2	9 sessions/yr + F⁻ varnish twice/year	non-F⁻	Plaque Index	2.71	5.02	46	Mann-Whitney, p level not stated
Kerebel et al. (1985)	98	100	7–8	3	Daily brushing at school + prophy & topical F⁻ 5 times/yr	Not stated	Plaque index	1.72	4.3	60	ANCOVA, p<0.01

Further follow-up studies by the Karlstad group to separate out the effects of fluoride showed that the use of fluoride prophylactic paste had no additional caries preventive effects compared with thorough mechanical cleaning (Axelsson and Lindhe 1975; Axelsson et al. 1976).

In another Swedish study, the effects of professional cleaning and oral health education among high caries risk children were tested (Klock and Krasse 1978). Children in both the high and low risk groups who received professional cleaning had statistically significantly lower caries increments compared with the controls (children who did not receive professional cleaning) in each year of the two-year study. However, newly erupted occlusal surfaces of the test group children were fissure sealed and the results did not present the findings for specific tooth surfaces; thus, the independent effects of the oral hygiene measures could not be determined.

The findings of the Karlstad group have frequently not been replicated by other researchers (Agerbæk et al. 1977; Ashley and Sainsbury 1981; Craig et al. 1981; King et al. 1985; Poulsen et al. 1976; Vestergaard et al. 1978). Some have found little or no statistical difference between the test and control groups when professional cleaning was performed with a fluoride-free paste.

Poulsen et al. (1976) tested the Karlstad method of caries prevention among 7-year-old children (n=78) in Denmark. Test group children received professional tooth cleaning once a fortnight with a fluoride-free paste. Both groups continued with fortnightly rinsing with a fluoride solution. After twelve months, 37 test and 33 control children were examined. There was a reduction in permanent tooth caries increment of 70% in the experimental group after twelve months (test Δ DMFS=0.43, control Δ DMFS=1.42). This difference was not statistically significant. When a two-way ANOVA was used to control for the presence or

absence of initial caries, the difference in caries increment was statistically significant, $p<0.05$. A follow-up report of the results after two years found a non statistically significant 33% reduction in caries increment among the test group participants (Agerbæk *et al.* 1977). However, the number of participants was small, 30 test and 32 control, which limited the power of the study.

The study by Ashley and Sainsbury (1981) on 11-year-old school girls (n=261) found no statistically significant difference in caries increment between the test and control groups after three years when fluoride-free cleaning paste was used, although the test group had a slightly higher caries increment. The test group received fortnightly professional cleaning at school and the control group was given oral health education consisting of plaque disclosure and toothbrushing during 3 group sessions. After three years, the test group (n=119) had a DMFS increment of 4.97 and the control group (n=102) had a DMFS increment of 4.34; the difference was not statistically significant. The authors noted that about 50% of the caries increment in both groups was in the pits and fissures.

Craig *et al.* (1981) tested the Karlstad programme in real-life conditions in a New Zealand public school dental service. Children aged 11–12 years were randomly assigned to one control and two test groups. The control group (n=55) received normal School Dental Service care; one test group (grp1, n=55) received fortnightly professional cleaning with a fluoride-free toothpaste and the second test group (grp2, n=54) received a fortnightly professional cleaning and then rinsed for two minutes with a sodium fluoride solution. After twenty-one months, 138 children (41 control, 97 test) completed the study and both test groups had lower caries increment (grp1 Δ DFS=2.6; grp2 Δ DFS=1.8) compared with the control group (Δ DFS=2.9), but only the difference between the fluoride rinse group and the control group was statistically significant. There was also no

statistically significant difference in oral hygiene levels (PHP index) between the groups at baseline nor at the end of the study period.

A pragmatic field-trial among community health clinics near London, England failed to find any statistically significant caries preventive effects of a professional plaque control programme (King *et al.* 1985). Children were randomly allocated into two test and one control group. Of the 511 children (aged 11–12 years; 347 test, 164 control) who commenced the study, 69% (test=206, control=137) completed the three-year study. One test group received professional cleaning of teeth once every two weeks with a fluoride paste, the other test group received the same cleaning routine and additional oral hygiene instruction; the control group did not receive any special instructions or treatment. There were statistically significant improvements in oral cleanliness (modified Plaque Index) and gingival health (modified Gingival Index) of the test group, but the difference in caries increment between the test (Δ DMFS=2.7) and control groups (Δ DMFS=3.4) was not statistically significant.

Another field trial of the Karlstad method of caries prevention conducted with more than 2000 children over three years in Sweden reported a reduced caries increment in the test group compared with the control group (Hamp *et al.* 1978). Children from one school district formed the test group while children from another school district acted as the control. The study reported on the findings from a reference group of 10–11-year-olds (137 test, 140 control) who completed the 3-year study. Test group children received professional cleaning with a fluoride paste once every three weeks, and during the second and third years of the study, rinsed with a fluoride solution after cleaning. Control group children continued to participate in an established fortnightly fluoride rinsing programme. Caries reduction of 51% was achieved after three years (test DFS=6.3; control DFS=12.8). The difference in caries increment between the

groups was statistically significant for all the years except the first year, and although the authors did not statistically test the three-year caries increment, the increment was of such magnitude that the difference was likely to be statistically significant. The greatest reduction in caries occurred on approximal surfaces and occlusal surfaces derived the least benefit.

The Karlstad programme of caries prevention was also tested in Norway among children aged 7,10 and 13 years (Kjærheim *et al.* 1980). Children were randomly assigned to test or control group. The test group (n=170) received professional cleaning once a fortnight with a fluoride paste and flossing and brushing instructions. The control group (n=179) brushed with a fluoride solution once a month. Only smooth surface caries was assessed because of routine fissure sealing. After two years, 139 test and 154 control children were examined; a statistically significantly higher proportion of test group children had no caries increment and test group children, on average, had a 64% lower caries increment (test Δ DFS=0.58; control Δ DFS=1.61). The test group children also achieved statistically significant improvements in the level of oral hygiene (VPI) and gingival condition (GBI).

The caries preventive effects of professional tooth cleaning performed bi-annually was tested among school children in New York, USA (Ripa *et al.* 1976). Test group children (n=192, mean age=10.2 years) had their teeth cleaned professionally every six months and the control group (n=192, mean age 11.6 years) did not receive any professional cleaning. After two years, 151 test and 139 control children had completed the study and the oral hygiene levels (OHI-S), gingival health (modified GI) and caries increment (DMFS) were not significantly different between the groups. The use of fluoride-free or fluoride cleaning paste had no statistically significant effect on caries increment.

Another study in Sweden examined the effects of extended intervals between cleanings and addition of fluoride to the professional cleaning programme (Zickert *et al.* 1982). Children (13–14-year-old) were grouped into two main groups (professional cleaning once a month, n=145 *vs* cleaning once every three months, n=145) with three subgroups in each (group A rinsed after cleaning with a sodium fluoride solution and used sodium fluoride toothpaste at home; group B rinsed with MFP solution after cleaning and used MFP toothpaste at home; and group C rinsed with distilled water and used a non-fluoride toothpaste at home). After two years, 128 children in the once a month group (grpA=39, grpB=44, grpC=45) and 132 children in the once every three months group (grpA=44, grpB=44, grpC=44) completed the study. Professional cleaning was performed using a fluoride-free paste. Caries was determined clinically and radiographically.

There were statistically significantly fewer decayed surfaces among the fluoride groups compared with the non-fluoride group (once a month grpA ΔDS=3.2, grpB ΔDS=3.2, grpC ΔDS=5.4; once every three months grpA ΔDS=3.8, grpB ΔDS=4.2, grpC ΔDS=7.0), but no significant differences between once a month cleaning and once every three months cleaning. There was also no statistically significant difference in caries increments between the two fluoride groups. The differences were only significant for approximal caries, there was no significant inter-group difference concerning occlusal and buccal/lingual caries. The use of a fluoride agent during the cleaning session appears to have additional caries preventive effects. After two years, there were also statistically significant improvements in oral hygiene (Plaque Index) and gingival health (Gingival Index) among both groups.

The effects of the professional cleaning programme on children with differing risks to caries were also tested (Gisselsson *et al.* 1983). Children (10–11 year-

olds) were stratified into three risk groups based on their caries experience and gingival status and allocated into test (Grp1, n=8; Grp2, n=5; Grp3, n=6) and control (Grp1, n=8; Grp2, n=6; Grp3, n=6) groups. The test group children were subjected to individual professional cleaning once a fortnight for ten weeks, then at 2–4-week intervals. Control group children rinsed once-a-week with 0.2% NaF solution. Both the test and control groups also continued with the weekly fluoride rinsings. After two years, the test group (Grp1–Grp3) had a lower caries increment (DFS=1.4) compared with the control group (Grp1–Grp3) (DFS=4.3). More children in the test than the control group had no caries increment and the difference was statistically significant, $p<0.01$.

The professional cleaning programmes also appear to have preventive effects among older adolescents (Hamp and Johansson 1982) as well as adults (Axelsson and Lindhe 1981; Axelsson *et al.* 1991). In a three-year study, Hamp and Johansson (1982) had 16-year-old adolescents in the test group (n=110) undergo professional tooth-cleaning once every three weeks for the first year of the study. In the second year, the test group was further subdivided into three groups (GrpA, n=38; GrpB, n=38 and GrpC, n=34). Group A had professional cleaning once a month; group B had professional cleaning twice a year; and group C had no professional cleaning. In the third year, groups A and B had professional cleaning twice a year and group C had no professional cleaning. The control group (GrpD, n=25) had no professional cleaning for all three years. There were no statistically significant differences in caries experience between the groups after one year. In the second year, the control group had a higher caries increment (ΔDFS=2.0) compared with the three test groups (GrpA ΔDFS=0.2; GrpB ΔDFS=0.6; Grp C ΔDFS=0.9; $p<0.001$). Eighty-six test and 20 control participants completed the three-year study. During the third year, there was higher caries increment among group C (ΔDFS=1.3) and the control group (ΔDFS=1.4) compared with group A (ΔDFS=0.9) and group B (ΔDFS=0.6)

but the differences were not statistically significant. For the entire two years, the control group developed statistically significantly more caries than group A and group B.

The effects on caries increment of the Karlstad programme among adults were as dramatic as the apparent effects on children (Axelsson and Lindhe 1981). Adults in the test group were stratified into three age groups and for the first two years of the study received professional toothcleaning and instructions on oral hygiene techniques once every two months. The same clinical procedures were repeated once every three months for the next four years of the study. The test group had better oral hygiene and almost no caries increment over the six years of the study and the differences between the groups were statistically significant.

A recent clinical study examined the effects of professional cleaning which mimicked cleaning levels achievable under normal conditions and found that such measures had clearly caries preventive effects (Holmen *et al.* 1988). The children (n=14) had homologous pairs of premolar teeth which were due to be extracted for orthodontic reasons. Both premolars were banded to provide protected areas where plaque could accumulate. One tooth of each pair was debanded weekly and cleaned professionally. Seven teeth were cleaned with a non-fluoride pumice paste on a rubber cup while the remaining seven teeth were cleaned by rubbing the area with a water moistened cotton pellet. The bands were recemented after the teeth were cleaned. After five weeks, the teeth were extracted and examined macroscopically and under polarized light and scanning electron microscope. Teeth subjected to mechanical cleaning were without signs of caries while non-treated teeth showed marked signs of caries.

Separate effects of self-performed flossing (Granath *et al.* 1979) as well as flossing by professionals (Wright *et al.* 1979) on caries increments have also been examined. Granath *et al.* (1979) used 12–13-year-old children (n=140) who received training in the flossing techniques and who performed the procedure daily on one randomly selected side of the mouth under supervision at school. After two years, caries was determined clinically and radiographically. Analyses of data after stratifying for diet and oral hygiene variables failed to detect any statistically significant effects of flossing.

Wright *et al.* (1979) used trained assistants who flossed the teeth of children in their study. Two successive cohorts of children were enrolled in the study (mean age=5.8 years; n=66 and n=52). One randomly assigned side of the mouth of each child was flossed daily for the duration of the school terms (eight months) for two years. At the conclusion of the study period, control side had higher caries increment (14.4% of surfaces at risk at baseline became carious) compared with the test side (6.7%) and the difference was statistically significant.

A study which tested the caries preventive effects of professional flossing with a chlorhexidine gel four times/year also found some caries preventive effects of flossing with a placebo (Gisselsson *et al.* 1988). The study of 12-year-old children in Sweden used three groups; a test group (n=72) that flossed with chlorhexidine gel, a positive control group (n=77) that flossed with a placebo gel and a true control group (71) that did not floss. More children in the positive control group (32%) were caries free after three years compared with the true control group (18%). The difference was statistically significant. The positive control group had a lower caries increment ($\Delta DFS=4.3$) compared with the true control group ($\Delta DFS=5.25$), but this was not tested statistically.

A three-year study, similar in design to the above, was also conducted among initially 4-year-old children (Gisselsson *et al.* 1994). The study found a slightly higher proportion of children who were caries free in the placebo gel group (30.4%) compared with the true control (28.6%) and a slightly lower increment of decayed teeth among the placebo gel group (Δds=1.85) compared with the true control group (Δds=2.12). However, the differences were not statistically significant.

Studies using professional cleaning regimes with and without fluoride-containing paste, in combination with supervised or unsupervised tooth brushing and topical fluoride treatments, have frequently been shown to be effective in reducing caries increment. Again, the greatest benefit was on the approximal surfaces (Kerebel *et al.* 1985; Klimek *et al.* 1985). However, in studies in which a combination of preventive agents and/or regimes are used, the effects of individual factors on the carious outcome are not easily measured. For example, Klimek *et al.* (1985) used a combination of professional cleaning, topical fluoride varnish application and provision of fluoride toothpastes to test participants in their preventive programme. This makes it difficult to measure the effect of individual factors on the outcome of the study. Large scale community trials involving oral hygiene procedures have also shown caries reducing effects (Marthaler 1972a; Marthaler 1972b), and in these studies the contribution by oral hygiene measures in reducing caries increments cannot be separated from the effects of other factors, such as dietary modifications and use of fluorides.

There has been little recent longitudinal research on the effects of oral hygiene measures on caries increments, and even fewer studies on the effects of oral hygiene on occlusal caries. Most studies have concentrated on the effects of fluoride in its various forms and the use of fissure sealants to prevent caries of

the pits and fissures (König 1993; Petersson 1993; Ripa 1993). Further, the perceived high cost–benefit ratio obtained with professional cleaning programmes inhibited their widespread application in public health systems, and it has been recommended that their use be limited to high caries risk individuals (Agerbæk *et al.* 1977; Badersten *et al.* 1975; Kjærheim *et al.* 1980; Poulsen *et al.* 1976).

A recent study that used professional cleaning procedures in combination with oral health education suggested that the treatment programme was able to control caries on the occlusal surfaces of newly erupting molars (Carvalho *et al.* 1991; Carvalho *et al.* 1992). The study used intensive patient education, individual professional cleaning and oral health education and individually determined recall intervals to control occlusal caries. The children in the test group (n=56) were subjected to individually tailored professional cleaning and oral health education and the children and their parents were instructed on the appropriate toothbrushing methods (all used fluoridated dentifrice). The children were then placed on recall intervals determined by a simple two point scoring system summed across four criteria, Table 10. The recall intervals ranged from one month for a score of 8, to six months for a score of 4.

After three years, children in the treatment group had fewer sealed and filled teeth and had made fewer recall visits than a historical 'control group' (n=58). Regression of active carious lesions was also observed in majority of occlusal sites. However, the generalisability of the study was limited due to the small number of participants in the study and the lack of a concurrent control group (historical controls were used). The authors of the study interpreted their findings to mean that a professional plaque control programme combined with health education can effectively control occlusal caries in newly erupting per-manent molars, but the study design does not warrant such a conclusion. Also, it

is likely that the more frequent recall visits of the children could have affected the provision of preventive and restorative care, especially when the researchers ('blinded' status was not reported) were providing care to the children.

Table 10   Criteria for assessment of recall intervals

	Score value	
	1	2
Cooperation of the parents	Good	Poor
Active lesions within the dentition	No	Yes
Stage of eruption of permanent first molars	Full occlusion	Partly erupted
Status of occlusal surfaces of first permanent molars	Caries free or arrested lesion	Active lesion

COST-EFFECTIVENESS STUDIES

Cost-effectiveness analysis is a term which is related to, but quite different from, cost-benefit analysis (Weinstein and Stason 1977). The key distinction is that in cost-benefit analysis all the costs and benefits are measured with the same economic metric (usually money), whereas in cost-effectiveness analysis benefits do not need to be measured in these terms. Cost-effectiveness is used to compare the costs of competing programmes to achieve a stated outcome, for example, to reduce the number of individuals experiencing occlusal caries through the use of sealants versus fluoride varnish applications. The method is useful in assisting with decision-making, but does not replace the role of the decision-maker in arriving at a decision (Warner 1989).

Most of the studies that have looked at strategies available for controlling occlusal caries have concentrated on the use of pit and fissure sealants since the technique was introduced in the mid-1960s (Cueto and Buonocore 1967), and the effectiveness of this method was demonstrated in the 1970s (Bonjanini et al. 1976; Going et al. 1976a; Going et al. 1976b; Horowitz et al. 1977b). Since then, few comparative studies have been done to test the effectiveness of alternative

preventive agents in controlling occlusal pit and fissure caries, most have compared different types of sealant materials rather than test alternative methods of prevention (Arrow and Riordan 1995; Forss *et al.* 1992; Forss *et al.* 1994; McLean and Wilson 1974; Mejàre and Mjör 1990; Ripa 1993; Williams *et al.* 1996).

Although fissure sealants have been shown to be effective, the cost-effectiveness of the method has not been appropriately tested (Mitchell and Murray 1989). For example, Lennon *et al.* (1984) reported a cost-effectiveness analysis, based on a pragmatic field trial, which compared the success of a fissure sealant programme with a restorative care programme in maintaining the four first permanent molars with good prognosis (at most two surfaces affected by caries) until 10 years of age. The study found the sealant programme to be less cost-effective than the restorative programme. However, that study, and others which sought to examine the cost-effectiveness of sealants has been criticised for using inappropriate methodology (Lewis and Morgan 1994). Using the evaluation framework of Drummond *et al.* (1987), Lewis and Morgan (1994) found that most studies misclassified the type of study, used inappropriate endpoints and procedures for comparison, and were incompletely analysed.

A study which compared the cost-effectiveness ratios of four dental preventive programmes (community water fluoridation, school water fluoridation, weekly school-based fluoride mouth rinses and a school-based fissure sealant programme) using a hypothetical population of schoolchildren concluded that community water fluoridation was the most cost-effective and school-based sealants the least (Niessen and Douglass 1984). Recently, studies have compared the caries preventive effects of alternative methods of pit and fissure caries control in field settings (Bratthall *et al.* 1995; Songpaisan *et al.* 1995), and one study compared the effectiveness of a topical varnish with fissure sealants

(Bravo *et al.* 1996). Although the field studies had an implicit aim of testing the cost-effectiveness of alternative methods (the studies were conducted in developing countries using non-dental personnel and used technically simple procedures which can be applied by non-dental personnel), none of the studies conducted a formal cost-effectiveness analysis.

Early studies that used professional cleaning to control caries reported that although the procedure was effective, it was costly, the cost-benefit ratio of the procedure was not good enough to warrant its widespread adoption and that its use should be restricted to 'at risk' children only (Badersten *et al.* 1975). Kjærheim *et al.* (1980) concluded that the cost of the professional cleaning programme was high and even if the procedure reduced restorative costs, the total cost of the programme was likely to be similar to the conventional programme among a group with low caries activity. Gisselsson *et al.* (1983) reported that the professional cleaning programme used in their study was expensive and its use as a long term preventive measure could not be economically justified. However, the early studies did not conduct formal cost-benefit or cost-effectiveness analyses and their conclusions on the relative cost-effectiveness of the programmes must be treated cautiously.

The developers of the 'Karlstad' method of caries prevention conducted a cost analysis of the preventive programme in the early 1970s and reported that the cost of treating established caries in the control group was about 20 times more than treating caries in the test group (Lindhe *et al.* 1975). However, the analysis cannot be considered a true cost-effectiveness analysis but a cost analysis because only the cost of treating established caries between the two programmes was compared; the cost of implementing the preventive programme was not included.

A more detailed cost-effectiveness and cost-benefit analysis comparing a professional cleaning programme with a standard preventive programme of a school dental service was conducted in Sweden (Klock 1980). The costs and effects were estimated over two years. The author found that although the test preventive programme (comprising professional cleaning, dental health education, application of fluorides and pit and fissure sealants) was more effective, it was also more expensive. When benefits were valued at the amount of money saved due to the number of carious lesions prevented, a cost-benefit ratio of 3.7 was obtained and an average cost-effectiveness ratio was 186 Swedish Crowns per person per year to save one tooth surface (about A$35). In calculating the cost-effectiveness ratio the author presented incremental effectiveness but average costs for the programme and the findings from this study therefore should be treated with caution.

A criticism of this form of cost-benefit analysis is that a restored tooth is considered to have the same value as a sound unrestored tooth. To overcome the difficulties of accounting for intangible benefits and valuing sound versus restored teeth, some authors have recommended using cost-effectiveness analyses (Horowitz and Heifetz 1979). Some authors have also explored the use of a quality adjusted indicator of tooth health to use in comparative analyses of treatment/preventive programmes (Birch 1986; Forbes and Donaldson 1987; Fyffe and Kay 1992). The development and application of these methods in dentistry is in its infancy and further research is required before such techniques can be fully employed in comparative studies.

The early studies were also conducted at a time when caries prevalence and caries incidence was high, and caries experience was universal. The current disease pattern is quite different. Caries rates are lower and many children have no caries experience (Vehkalahti et al. 1991),and technological

improvements have meant that delivery of preventive care can be performed much more cheaply and programmes which at one time were not considered cost-effective may now be so, particularly if preventive care is provided selectively. The efficiency of any preventive programme is context specific and has to be evaluated in the context of the prevailing conditions (Birch *et al.* 1996). For example, a recent study among children in the SDS found low caries increments on occlusal surfaces and questioned the efficiency of fissure sealing all newly erupted molars (Arrow and Riordan 1995).

SUMMARY CONCLUSIONS FROM LITERATURE REVIEW

Studies have shown that it is possible to arrest completely the development of clinically visible carious lesions through simple mechanical cleaning of teeth (Holmen *et al.* 1988). Complete removal of accumulated plaque does not appear to be necessary to stop the development of clinically visible carious lesions; mechanical disturbance, which alters the local environment, as can be achieved through self-performed toothbrushing, appears to be sufficient (Årtun and Thylstrup 1989; Carvalho *et al.* 1989; Holmen *et al.* 1988; Holmen *et al.* 1987a; Holmen *et al.* 1987b). However, the effects were observed predominantly on smooth surfaces and the preventive effects of mechanical cleaning on pit and fissure surfaces have not been fully examined. The efficacy and cost-effectiveness of simple non-operative measures to control occlusal caries require further investigation and development (Meurman and Thylstrup 1994).

The literature review has indicated an unclear association between oral hygiene and dental caries. The findings from cross-sectional studies should be treated with caution because of the limitations of the study design. Longitudinal studies (observation and intervention) showed conflicting findings, although the majority suggest an association between caries and oral hygiene. A general conclusion can be made that there is probably a weak association between oral

hygiene and dental caries. The literature review also indicated a potential for using oral hygiene measures to control pit and fissure caries. The review also identified the need to establish the cost-effectiveness of any new procedures using an appropriate analytical framework. Many of the studies did not incorporate a cost-effectiveness or cost-benefit analysis, and studies that included a cost-benefit analysis had poor economic designs that measured the benefits and outcomes inappropriately.

The aims of this study, therefore, were to compare the effectiveness of two methods of controlling occlusal caries in a field setting and to use the results of the study to conduct a cost-effectiveness analysis using an appropriate economic framework. The following chapter details the methods and materials used in the conduct of this study.

CHAPTER 3

MATERIALS AND METHODS

The study was a pragmatic field trial conducted within an administrative area of the SDS. The methods of pragmatic field trials are suitable for answering the question of the efficacy of new treatments under real-life conditions and in assisting with public health decision-making (Lennon *et al.* 1980; Lennon *et al.* 1984). The major differences between pragmatic trials and explanatory trials have been highlighted (O'Mullane 1976; Schwartz and Lellouch 1967). Explanatory trials test one or more effects of an agent or procedure under strictly controlled (artificial) conditions in order to determine whether an agent has an effect; the aim is to develop an *understanding*. Pragmatic trials are conducted under real-life conditions with the aim of making a *decision*. Pragmatic trials are also seen as better suited for economic evaluations because the findings reflect what is achievable in conditions that are likely to prevail in practice rather than under the restrictive conditions of a controlled trial. Hence, pragmatic trials are considered to have stronger external validity than controlled trials (Drummond and Jefferson 1996).

The clinical outcomes of interest in this pragmatic study are:

1. The incidence of occlusal caries on sound, newly erupted first permanent molars.

2. The distribution of caries and plaque on the occlusal surfaces of the test and control participants.

3. The increment of caries in the deciduous canine and molar teeth.

ETHICAL REVIEW

Ethical approval for the study was given by the Director, Health Statistics and Epidemiology Branch of the Health Department of Western Australia and Curtin University's Human Research Ethics Committee. The Director, Dental Services of the Health Department of WA gave permission for the study to be conducted within the School Dental Service.

PARTICIPANTS

Sample Size— The size of the study group is influenced by the incidence of pit and fissure caries in the first permanent molars and the anticipated treatment effect. Based on a recent finding that 10% of permanent teeth had caries experience (likely to be pit and fissure caries on the first permanent molars only) among 7-year-old schoolchildren in Western Australia (Riordan 1993), and an expected reduction in caries experience of 75% with the test programme (Carvalho *et al.* 1992, observed an 88% reduction), the required study group was estimated to be 322 (α=0.05; β=0.10) (Friedman *et al.* 1985). Allowing for loss to follow-up and drop-out, an initial study group of about 400 was estimated to be required.

Children who were in the first year of primary school in 1994 (age of entry is at least 5 years) and were eligible to attend the eight clinics within one metropolitan administrative area of the SDS were screened for inclusion in the study. Only children enrolled with the SDS and who had sound, newly erupting and/or erupted first permanent molar teeth were included (unenrolled eligible children were offered enrolment with the SDS). The parents/guardians of eligible children were issued with an information leaflet explaining the trial and requesting their child's participation (Appendix C1 and C2). Over one thousand children were screened and 533 were eligible to participate. Four hundred and four children were examined at baseline and included in the study (participation

rate=76%). Non-participation of 127 children was due to non-consent and two children were unable to be examined due to a lack of co-operation by the child. At the twelve-month review, three children were found to have received treatments on their first permanent molars before the trial commenced and were excluded from the analysis of caries incidence.

A group randomization procedure was used. Clinics were assigned to a test or a control group based on the expected number of eligible children so that there were approximately equal numbers of children in each group. Clinics rather than children were assigned to test or control groups to minimise variations in treatment prescriptions by clinicians and to minimise 'leakage' of oral hygiene advice and information provided to the parents of children in the trial (spillover effects). If a clinician were providing care to both the test and control children, it would be possible that the clinician's implementation of the test programme would be influenced by the same clinician's implementation of the control programme. Group randomization is a means of overcoming the possibility of 'contamination' (Buck and Donner 1982). Study participants were not a representative sample of children enrolled with the SDS. The comparability of characteristics (deciduous tooth caries experience and SES classification) between study participants and other children enrolled with the SDS was tested.

Staff at the clinics maintained a register of participants in the study. During the course of the study, clinicians recorded in the register details of treatment provided to the test teeth and details of any children that moved locations. Treatment details were also recorded in each participant's clinical record card. The clinical records were labelled to facilitate follow-up of these children. A central register of the study children was kept by the investigator and updated when a change in the status of a child was reported, such as transferred to

another clinic, or required operative treatment in the first permanent molars, or if a parent wished to change any aspect of the participant's treatment.

EXAMINATIONS

Participants were examined by the investigator at the commencement of the study and by a different examiner, who had been calibrated to the investigator, at twelve and twenty-four months. The second examiner was blind to the test/control status of the participants. The examinations were carried out using a mirror and a probe, no radiographs were taken as part of the trial. The probe was used only to remove debris and plaque, and minimal pressure was applied to suspect cavities. The teeth were dried with compressed air and examined under standard dental lighting in the clinic the child normally attended. The information obtained from the examinations was recorded on a trial record sheet (Appendix D).

At baseline examination, caries experience of deciduous canines and molars and the clinical status, extent of eruption and distribution of plaque on the first permanent molars were recorded. Other variables recorded included sex, date of birth, school attended, participant's residential address, frequency of toothbrushing and brand of toothpaste used (as reported by the parent who brought the child to the examination, to enable assessment of fluoride exposure). At the twelve-and twenty-four-month examinations, treatments received, the time taken to provide preventive treatments to the first permanent molars, presence or absence of dental fluorosis and the presence or absence of any hypomineralised teeth were also recorded on the trial record sheet.

The variable 'hypomineralised teeth' was included after the trial commenced because as the trial progressed, it became apparent that some children had hypomineralised teeth and to exclude these children would have reduced the

number of participants. The condition is also a potential confounder for caries incidence. Furthermore, the pragmatic study design meant that these teeth would still need to be managed in clinical practice and hence could not be excluded. The diagnosis of hypomineralisation was made clinically and used the criteria for differential diagnosis of fluoride and nonfluoride enamel opacities described by (Russell 1961), and was recorded only as present or absent, the extent and severity of hypomineralisation was not recorded.

Residential address and post code were used to group children into various census collector districts (CDs). Grouping of children was achieved through a geo-coding process using a geographical information system software (Map-Info, Version 3, Map-Info Corp. New York) at Curtin University. Collector districts are the smallest administrative units (approximately 200 households) on which census information is released by the Australian Bureau of Statistics. Children were classified into socio-economic levels according to their CD based on a classification produced by the Australian Bureau of Statistics for the 1991 Census (Socio-Economic Indicators for Areas, SEIFA) (Australian Bureau of Statistics 1993).

The socio-economic indices were derived from principal component analysis of variables known to be associated with measures of socio-economic status. The SEIFA database contains five socio-economic indicators: 1. Urban Index of Relative Socio-economic Advantage; 2. Rural Index of Relative Socio-economic Advantage; 3. Index of Relative Socio-economic Disadvantage; 4. Index of Economic Resources; 5. Index of Education and Occupation. In this study, the index of Relative Socio-Economic Disadvantage was used. This is a general socio-economic index that summarises the variables related to economic resources of households, education and occupation. The index is standardised to the distribution of households in Australia with a mean of 1000 and standard

deviation 100. A higher index number indicates an area with a relatively higher level of economic resources, education and occupations.

The socio-economic indicator used in this study is an ecological variable; it is an attribute which is assigned to an individual, but the attribute is an aggregated characteristic of individuals within a CD and is not an attribute of individuals in the study. Therefore, the indicator should be viewed as a relatively crude measure of socio-economic status with a potential for misclassification of individuals and should be interpreted with caution. However, area level socio-economic indicators derived from census information have been shown to correlate well with individually derived measures and have an advantage of being more easily obtained (Krieger 1991; Krieger 1992).

The clinical examinations were conducted at the dental clinic the child normally attended. At the clinical examination, the occlusal surfaces of the first permanent molars of each participant were stained with a plaque disclosing solution (Erythrosin) applied with a cotton wool pledget. Plaque distribution in the grooves and fossae was marked in green ink on the occlusal morphology drawing of the first permanent molars on the trial record sheet, as used by Carvalho et al. (1989) (Appendix D) and was expressed as the mean number of plaque covered sites per erupted tooth per child. The teeth were then cleaned with a water/pumice slurry on a rotating bristle brush, dried with compressed air and examined using a mirror and probe. Caries of the first permanent molars was assessed according to the criteria of Carvalho et al. (1989):

(0) Normal enamel translucency (sound tooth surface).

(1) Opaque enamel with dull-whitish surface (active lesion).

(2) Shiny appearance of opaque area with different degrees of brownish discolouration (arrested lesion).

(3) Dull-whitish enamel with localised surface destruction (active lesion with cavitation).

The twelve- and twenty-four-month examinations were carried out in a similar manner. When there was uncertainty about the filled or sealed status of a test tooth, clinical records were consulted to ascertain the true status. Checking of the clinical records was done without the examiner being made aware of the test or control status of the participant.

Caries increment was recorded using the DMF index (dmf for deciduous teeth); D is the number of decayed permanent teeth, surfaces or sites, M is the number of missing permanent teeth, surfaces or sites due to caries and F is the number of filled permanent teeth, surfaces or sites. In this study, DMF first permanent molar teeth and sites were used because the occlusal surface was already included as the surface of primary interest. Caries on the first permanent molars commonly begins in one of three fossae (mesial, central or distal fossa) and a fully erupted molar can be considered to have three occlusal sites at risk of decay (the upper first permanent molar has an additional site on the palatal surface). Thus a child with four fully erupted first permanent molars can be considered to have 14 sites at risk of caries.

VALIDITY AND RELIABILITY

The issue of the validity of caries diagnosis was not directly assessed in this study. This was not felt to be a major limitation in this study. The clinical examinations were carried out by two experienced clinicians who were calibrated with each other in the examination criteria. The visual and tactile method of caries diagnosis has high specificity and low sensitivity (Angmar–Månsson and ten Bosch 1993). It is the most widely used method of caries diagnosis in clinical practice and epidemiological studies (World Health

Organization 1987) and it is considered to be an appropriate method for studies that test community effectiveness of a preventive agents, and where disease prevalence is low and disease progression is slow (Downer 1989; Palmer *et al.* 1984). A recent study also found a high correlation between the external macroscopic appearance of occlusal caries and histologic findings of dentine reaction (Ekstrand *et al.* 1995). Also, in a community trial like the present study, it would be unethical to establish validity through the histological examination of sectioned extracted teeth. Although it is recognised that advances are being made in non-invasive methods of occlusal caries diagnosis, particularly electrical resistance measurements, the methods should be viewed as being experimental and their wide-scale application in epidemiological studies requires further development (Angmar–Månsson and ten Bosch 1993; Le and Verdonschot 1994; Ricketts *et al.* 1996). Dental radiographs were not used in this study for similar ethical reasons.

Reliability of clinical examinations was established through calibration of the examiners. The level of intra- and inter-rater reliability was expressed using the kappa coefficient (Fleiss *et al.* 1979). Kappa coefficient is an indicator of agreement which corrects for chance agreement between examiners, or consistency of judgements by the same examiner on more than one occasion, when the judgements are classified into categories (Hunt 1986; Nuttall and Paul 1985). Kappa can take values between minus 1 (perfect disagreement), 0 (chance agreement) and 1 (perfect agreement); kappa values between 0.61 and 0.80 indicate 'substantial' reliability and values greater than 0.81 indicate almost 'perfect agreement' (Landis and Koch 1977). Confidence intervals for kappa were also calculated (Altman 1991)

A related issue to reliability is the occurrence of *reversals* in longitudinal studies. A reversal is a change of diagnosis which is unrelated to the carious

process that occurs after sufficient time has elapsed for real changes to have taken place; a tooth diagnosed as carious at baseline is diagnosed as sound at a subsequent examination (negative reversal) or a tooth is diagnosed as sound (in error) at baseline and is diagnosed as carious at a subsequent examination (positive reversal). Burt and Eklund (1992; pp74–75) recommended that net results of longitudinal studies should be analysed without adjustment for reversals because the negative reversals and positive reversals should be assumed to balance out, provided the examiner is consistent in his/her diagnosis (Burt and Eklund 1992). Other authors have advocated adjustments for reversals due to examiner misclassification in instances where reversals were more than 10% of the total caries increment (Beck *et al.* 1995). In this study data were analysed without adjustment for reversals because adjustment for reversals imply knowledge of all reversals, negative as well as positive, but only the negative reversals would be known and adjustment would then introduce its own bias into the results.

CALIBRATION OF EXAMINERS

Calibration of examiners was undertaken over five half-day sessions one month before the trial participants were examined for their twelve-month review, and over two half-day sessions one month before their twenty-four-month review. Children from one clinic who were the same age as study participants, but not in the study, were selected for the calibration exercise. The examiner who was being calibrated was provided with written criteria for the diagnosis of caries prior to the start of the calibration session. Each child was examined in turn by the two examiners. Caries was diagnosed in the deciduous teeth using WHO (World Health Organization 1987) diagnostic criteria. The criteria of Carvalho *et al.* (1989) were used to diagnose caries in the first permanent molars. The findings of the examiners were compared after each examination and, where there were disagreements on diagnosis, a discussion was held until agreement was reached.

At baseline, thirty-six of the participants were re-examined within two weeks to assess intra-rater reliability. The findings from twenty-seven children at twelve-month and ten children at twenty-four-month calibration sessions were used to assess inter-rater reliability. Twenty-seven children at twelve-month and 35 children at twenty-four-month review were examined twice within three weeks by the examiner to determine intra-rater reliability.

PROCEDURES

Clinical procedures were performed by school dental therapists. In Western Australia, school dental therapists are dental auxiliaries trained to provide a limited range of clinical services to school children. For twenty children from one clinic, the test procedures were carried out by a dentist because of administrative difficulties encountered in implementing the study. Clinicians who cared for the test group participants were provided with written materials (Appendix E) and participated in a one and a half hour presentation about the trial and the procedures to be followed. When a change of personnel occurred, the new clinician was provided with the written materials and verbally instructed about the trial procedures. Dental therapists at the control clinics were advised to provide care to the trial participants at their clinics in the usual manner.

TREATMENT PROTOCOLS

Control Group– After baseline examination, children in the control group continued to receive standard preventive care of the SDS. The standard preventive care of the SDS included application of a topical fluoride paste (10%, stannous fluoride) to occlusal surfaces of newly erupted permanent molars[*] and fissure sealing with a glass-ionomer cement if the clinician judged the tooth to be at high risk of becoming carious. A tooth indicated for fissure sealing is not usually treated with topical fluoride prior to sealing. Criteria for risk

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[*] The SDS policy on application of topical fluorides was amended recently (November 1996) to include only high risk children. This occurred after the study was completed.

assessment are issued by the SDS to all clinicians and are based on published criteria (Blinkhorn and Geddes 1987). Details of treatment provided to participants were recorded in each participant's clinical record.

Test Group– After baseline examination, appointments were made for the test group participants for professional tooth cleaning and dental health education. At the clinical session, the parents/guardians of each child received information on the role of plaque in the initiation and progression of caries. Accumulated plaque on the occlusal surfaces of their child's permanent molars was demonstrated and how they could assist with the brushing of their child's teeth was explained. The technique of brushing the teeth with the toothbrush held bucco-lingually using small rotatory movements was demonstrated on models as well as in the child's mouth.

It was recommended that toothbrushing be done twice a day, once in the morning and once in the evening and parents were encouraged to assist with their child's toothbrushing at least on one of those occasions. Each child's teeth were then cleaned by the clinician using a fluoride-containing paste (0.15%, CaF_2)* on a rotating bristle brush. The details of treatment as well as the time taken for the procedure were recorded in the participant's clinical record card. Each child was recalled for another consultation after an interval based on the sum of scores obtained from the criteria shown in Table 11, and the recall interval for each summed score was determined from Table 12. A child was recalled at an interval of twelve months if there was no active carious lesions, all fully erupted first permanent molars were without active caries and the parents were supportive and co-operated with preventive efforts (overall score, 4). If a child presented with active carious lesions, partly erupted first permanent molars with signs of active caries and had parents who were not supportive of preventive efforts, then that child would be recalled at six months (overall score, 8).

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* Cleanic® Hawe–Neos Dental, Switzerland.

Children in both test and control groups were provided with necessary care during the trial.

Co-operation of the parents was assessed by each clinician based partly on the knowledge of the family from past encounters and partly from contact at each visit. No formal assessment of compliance with oral hygiene recommendations was made; anecdotal information from clinicians was obtained regarding parental involvement and compliance with the test programme. At recall appointments, test participants were examined clinically and the same chairside preventive procedures were carried out. Any other treatment that was required to maintain overall oral health was also provided.

Table 11   Criteria for assessment of recall intervals

	Score Value	
	1	2
Cooperation of the parents	Good	Poor
Active lesions within the dentition	No	Yes
Stage of eruption of permanent first molars	Full occlusion	Partly erupted
Status of occlusal surfaces of permanent first molars	Caries free or arrested lesion	Active lesion

Table 12   Recall intervals for score values

Score	Recall interval
8	6 months
7	7 months
6	8 months
5	9 months
4	12 months

COST-EFFECTIVENESS ASSESSMENT

Cost-effectiveness analysis was used in this study to determine the relative worth of the two alternatives to control pit and fissure caries. Cost-effectiveness analysis is a valuable tool used to assist decision-making. It requires the identification, measurement, and comparison of all significant costs and outcomes of alternatives available to address a given problem (Warner and Luce 1982).

Cost-effectiveness analysis was undertaken from the perspective of the School Dental Service and follows the basic principles outlined by Antczak-Bouckoms *et al.* (1989) for cost-effectiveness evaluation in dentistry. Effectiveness was measured by the number of individuals prevented from experiencing decay on the occlusal surfaces of their first permanent molars as a result of the preventive interventions.

No direct costs were incurred by the recipients of SDS care; the service was free at point of delivery. Programme costs were estimated using labour costs (the wage costs of clinicians and chairside assistants) and the cost of materials to perform the preventive procedures (fissure sealing, topical fluoride application, professional cleaning and dental education). Labour costs were estimated by converting the time taken to perform the preventive procedures (in minutes) and multiplying it by the wage rate. The amount of time an assistant was required during a procedure was estimated by direct questioning of the clinicians and chairside assistants. Time used to provide treatments as a measure of resource costs, where no direct market prices are available, has been used in a number of studies (Mackie and Lennon 1984; Parker *et al.* 1982; Woodward *et al.* 1995).

For the control group, the time taken to perform the preventive procedures was estimated by asking selected clinicians to record the time taken to carry out the procedures on a number of 'typical patients'. Clinicians were selected, based on years since graduation, to control for differing levels of proficiency in the performance of clinical tasks. The times recorded by all the clinicians were pooled and the mean value was taken to be the time required to perform each task. Each clinician in the test group recorded, in each patient's clinical record, the time taken (to the nearest five minute unit) to carry out the preventive procedures. A random sample was taken of test participants' clinical records and the mean time for performing the preventive procedures calculated.

Information on the cost of the materials was obtained from the Dental Services' Supply Division. The amount of materials used for each preventive procedure was estimated by direct measurement of a 'typical' amount used for each of the procedures. The 'typical' amount of material used was measured and weighed. Indirect costs to patients and their parents (travelling time, loss of wages, time away from school, pain and discomfort resulting from the procedures) and costs arising from overheads and capital (equipment, buildings, and land) were not included in the analysis (indirect costs, overheads and capital costs in this study were common to both groups). However, the number of visits required for preventive treatments per person per year was used as an estimate of additional costs borne by one group over the other in receiving care.

The cost of a preventive treatment was calculated for an individual tooth and the cost per tooth was multiplied by the average number of teeth per individual who received that treatment to arrive at an estimate of the cost per person. The costs were then calculated for a hypothetical cohort of one hundred individuals allocated to either test or control treatments. The cost of some materials was constant for the number of teeth treated and was treated as cost per individual;

for example, one brush would be used for cleaning one tooth or twenty teeth in an individual patient. Administrative tasks associated with the trial, such as arranging appointments, were assumed to be performed by the clinic assistant. Costs were deflated and discounted to 1994 dollar value using the Australia-wide price deflator for the health sector. Incremental cost-effectiveness ratios were calculated as

$$\frac{\text{cost of test - cost of control}}{\text{effectiveness of test - effectiveness of control}}$$

Incremental cost-effectiveness ratios are more useful in assisting the setting of priorities for allocating resources because the ratios demonstrate the additional costs per unit of benefit of switching from one treatment programme to another (Detsky and Naglie 1990).

Initial estimates of cost-effectiveness were based on average labour costs and average effectiveness data obtained from the trial and used a 5% discount rate. Sensitivity analysis was applied to test the sensitivity of findings to variations in the discount rate, estimated labour costs (more experienced versus less experienced clinicians) and the estimated risk difference. The discount rates used ranged from 3% to 10% and labour costs were varied for the wage cost of clinicians from the least to the most experienced clinician (dental therapists' and chairside assistants' salaries are based on seniority in the SDS). The range of risk differences were the upper and lower limits of the 95% confidence interval.

A decision tree was used to assign probabilities and assist in the cost-effectiveness analysis (Petitti 1994). The probability values from the clinical trial were used to assign probabilities at the chance nodes. There are nine possible outcomes to a cost-effectiveness analysis and these can be tabulated as shown in Table 13 (Birch and Gafni 1994). These outcomes were used to interpret the findings from the cost-effectiveness analysis. The analytical

outcomes in cells 4, 7 and 8 clearly favour the adoption of the test programme because more health benefits are produced at the same or reduced costs and cells 2, 3 and 6 indicate that the test programme should not be adopted because less health benefits are produced for the same or increased cost. Cell 5 is equivalent to the existing programme and thus would not warrant adoption (on an economic basis). Cell 1 and 9 are toss-up situations where more (less) health benefits are produced at increased (less) costs.

Table 13   Possible outcomes of a cost-effectiveness analysis

<u>Costs</u>	<u>Benefits</u>		
	Increased	Same	Reduced
Increased	1	2	3
Same	4	5	6
Reduced	7	8	9

DATA ANALYSIS

The cumulative incidence of children with first permanent molar caries in the test and control groups was presented as a contingency table as shown in Table 14.

Table 14 Notation for a contingency table for caries incidence (counts of individuals)

Caries	Test	Control	Total
Cases	a	b	M_1
Non-cases	c	d	M2
Total	N_1	N_0	T

From the table, point estimates of risk ratio and risk difference were calculated using the crude data, and because the data relates to counts of individuals

rather than person-time, the risk ratio was estimated by using the following (Rothman 1986);

$$\hat{RR} = \frac{a/N_1}{b/N_0}$$ [eq. 1]

and the approximate confidence interval was estimated by,

$$\exp\left\{Ln\left(\hat{RR}\right) \pm Z \cdot SD\left[Ln\left(\hat{RR}\right)\right]\right\}$$ [eq. 2]

where the standard deviation of the logarithmically transformed risk ratio was estimated by,

$$SD\left[Ln\left(\hat{RR}\right)\right] = \sqrt{\frac{c}{aN_1} + \frac{d}{bN_0}}$$

The risk difference was estimated by,

$$\hat{RD} = \frac{a}{N_1} - \frac{b}{N_0}$$ [eq. 3]

and the approximate confidence interval was estimated by,

$$\hat{RD} \pm Z \cdot SD\left(\hat{RD}\right)$$ [eq. 4]

where the standard deviation of the risk difference was estimated by,

$$SD\left(\hat{RD}\right) = \sqrt{\frac{a(N_1 - a)}{N_1^3} + \frac{b(N_0 - b)}{N_0^3}}$$

From the above formulae other useful epidemiological measures were also calculated. An estimate of the proportion of the disease among the exposed that is related to the exposure (attributable proportion) was calculated by,

$$1 - \frac{1}{\hat{RR}}$$

However, when exposure to the test agent is protective, the risk ratio is less than one and the risk difference is negative and the attributable proportion is undefined, but an analogous measure, the prevented fraction can be calculated by,

$$1 - \hat{RR}$$

which is interpreted as "the proportion of the potential cases (in the absence of exposure) that was prevented by exposure" (Rothman 1986). The negative risk difference was replaced with a positive quantity called 'attributable benefit' for calculating cost-effectiveness ratios (Elwood 1988).

Data were also analysed using 'Stata Statistical Software: Release 5' (Stata Corporation, Texas) statistical package on a personal computer. Tests of statistical significance were set at the 0.05 alpha level and associated 95% confidence intervals were calculated. Bivariate analysis was used to test for differences between the groups, the t-test was used for mean values and the chi-square was used for categorical variables (Fisher's exact test used with small cell numbers) and tests of proportion. Multiple linear regression was used for multivariate analysis when the outcome variable was continuous, such as the number of teeth experiencing caries (DMFT, DMFS and dmfs were treated as continuous discrete variables). For an outcome Y with a number of independent variables the regression equation took the form;

$$Y = a_0 + a_1 X_1 + a_2 X_2 + a_3 X_3 + ...$$

where X_1, X_2, and X_3 ... are the independent variables. The inferences that can be drawn from the coefficient of a predictor variable are conditional on the remaining independent variables in the model. Thus the model is able to control for the effects of the other independent variables and is useful in controlling confounding (Afifi and Clark 1990). The method of backward elimination was used during the model building. All the baseline independent variables and first order interaction terms were entered into the regression model. Categorical variables were entered as dummy variables. The variable with the highest p value was removed first from the model and the process repeated until all the remaining variables were statistically significant at $p < 0.05$ level.

The regression model is built on the assumption that the difference between fitted and observed values (residuals) is normally distributed with a mean of zero and a constant variance. The assumption of the linear model was tested by plotting the fitted values against the residuals. When the assumptions were not fulfilled data transformations to normalise the data and stabilise the variance were examined (Salas-Wadge 1994), however these were not feasible.

It has been argued that the use of multiple regression models for dental caries data is not entirely appropriate because the data violate certain assumptions inherent in the regression model (Salas-Wadge 1994). The assumptions of normality of the dependent variable and the homogeneity of variance (homoscedasticity) of the residual errors (the difference between observed and predicted values) are not usually fulfilled by dental caries data (Salas-Wadge 1994). The dependent variable (carious teeth) is skewed to the right with many individuals having no permanent tooth caries.

An alternative to multiple linear regression is to use a transformed linear model with the outcome variable dichotomised. The caries outcome variable was dichotomised as individuals who had any permanent tooth caries experience or no permanent tooth caries experience, to enable the use of a transformed linear model. If Y is the proportion of individuals with caries experience then 1–Y is the proportion without caries experience and,

$$\frac{Y}{1-Y}$$

is the odds of a person experiencing caries. By taking the logarithm of the odds of Y (logit) the outcome variable can be modelled as a linear equation,

$$\ln\left[\frac{Y}{1-Y}\right] = a_0 + a_1 X_1 + a_2 X_2 + \ldots$$

where X_1, X_2 ......are the independent variables and a_1, a_2...... are the coefficients. The equation may be written in logistic form as,

$$Y = \frac{1}{1 + e^{-\left(a_0 + a_1 X_1 + a_2 X_2\right)}}$$

If the independent variable is binary and is coded "0" for unexposed (control) and "1" for exposed (test), then the antilogarithm of the coefficient is interpretable as the odds ratio of the outcome, given the exposure. When the independent variable is ordinal or continuous, the antilogarithm of the coefficient is interpretable as the incremental odds ratio for a change in one unit of that variable (Afifi and Clark 1990). Backward elimination procedure was used in the model building. The statistic obtained by multiplying the ratio of the log likelihood of the model without the variable to the log likelihood of the model with the variable by -2 was used to assess the value of the variable to the model (Hosmer and Lemeshow 1989). The statistic follows a chi-square distribution with 1 degree of freedom and if $p \geq 0.05$ the variable was removed from the model. If the k levels of a categorical variable were entered into the logistic model as 'dummy' variables then the variable will contribute k-1 degrees of freedom to the likelihood ratio test. The fit of the data to the logistic model was examined by using summary measures of fit (Hosmer and Lemeshow 1989; StataCorp 1997).

The outcome for each first permanent molar was also categorised into a molar with caries experience or a sound molar. Standard logistic regression models were unable to be used in this instance because of the lack of independence between the four first permanent molars within an individual. Logistic regression using generalized estimating equations was used to control for the lack of independence between the four first permanent molars within an individual (StataCorp 1997). An exchangeable correlation model which assumes a constant correlation between the units was specified. A limitation of the logistic model is that the disease outcome is reduced to a binary variable, resulting in loss of information.

It has been argued that measures of dental disease (dental caries) should more closely reflect standard epidemiological measures of disease occurrence (Hujoel *et al.* 1991). It has also been argued that, dental disease data may be more closely approximated by a Poisson random variable, where a count is taken of occurrence of events over time, rather than by a normally distributed variable. By using Poisson regression models, a more appropriate model of incidence data can be generated which takes into account the time at which the teeth are at risk of dental caries (Hujoel *et al.* 1994). For the Poisson regression the unit of analysis in the present study was the individual and the rate of molar teeth experiencing caries over time within an individual (measured in months) as a function of the independent variables was estimated by the Poisson regression model. The Poisson regressions are usually of the form:

$$\log(y_{ij}) = \log(T_{ij}) + \alpha + \Sigma(\beta_s X_{ijs})$$

Where y_{ij} is the caries incidence rate for person i with j tooth and T is the time at risk (exposure time) for person i with j tooth; α is the intercept and β_σ is the coefficient of the independent variables X for s variables within individual i with j tooth. Exponentiating the coefficients provides an estimate of the rate ratio (Hujoel *et al.* 1994). The fit of the data to the model was determined by chi-square goodness-of-fit. The present study also tested the effects of the independent variables on first permanent molar caries by using Poisson regression with generalized estimating equations to model the rate of caries experience over time, controlling for the correlation within an individual over time (StataCorp 1997). Models with robust estimates of standard errors were also tested (DeRouen *et al.* 1991).

At the commencement of the study, participants were, on average, six years old. At least one first permanent molar tooth had erupted in most of the children. The time at risk for a tooth was estimated by assuming that teeth already erupted at baseline had erupted six months prior to the examination. Teeth that

erupted between the review examinations were assumed to have erupted mid-
way during the period, and, in the case of teeth that were restored for caries or
recorded as being carious, the carious lesion was assumed to have progressed to
cavitation at the mid-way point.

Factors that were statistically significant in the logistic regression models were
then used to determine their utility as screening criteria to predict occurrence of
occlusal pit and fissure caries in the first permanent molars (DMFT $\geq$ 1) of an
individual. Results of screening tests can be presented as a 2x2 table as shown
in Table 15. Cell a is the number of individuals who were positive for the
screening criterion and who got the disease/condition (true positives); b is the
number of individuals who were positive for the screening criterion but did not
get the disease or condition (false positives); c is the number of individuals who
were negative for the screening criterion but got the disease or condition (false
negatives); and d is the number of individuals who were negative for the
screening criterion and did not get the disease or condition (true negatives)
(Sackett *et al.* 1991).

Table 15   Outcomes for a screening test

	Disease occurrence Yes	No	
Test +ve	a	b	a+b
Test -ve	c	d	c+d
	a+c	b+d	N

From the table, measures of the performance of the screening criterion were
calculated. The proportion

$$\frac{a}{a+c},$$

is the proportion of individuals who got the disease and screened positive for the

test, and is termed *sensitivity*.

The proportion

$$\frac{d}{b+d},$$

is the proportion of individuals who did not get the disease and screened

negative for the test, and is termed *specificity*.

The proportion

$$\frac{a}{a+b},$$

is the proportion of individuals who screened positive and got the disease, and is

termed *positive predictive value* (PPV). This value is affected by the prevalence

of the condition; as prevalence declines the positive predictive value decreases.

The proportion

$$\frac{d}{c+d},$$

is the proportion of individuals who screened negative and did not get the

disease, and is termed *negative predictive value* (NPV). This value increases as

prevalence declines.

When the predictor variable was measured on a continuous scale, various levels

were tested as cut-points to determine the optimum screening level. The use of

several cut-points produces several sensitivity and specificity values. These

values were plotted to better visualise the effect on sensitivity and specificity of

the various cut-points. The plots were used to assist in determining the

optimum screening criterion for the desired sensitivity and specificity. An ideal

screening test would have a criterion that achieves a sensitivity and specificity

of one.

A comparison of the predictive power of a number of different variables was

performed by examining the plots of the sensitivity and specificity values for

different cut-points used as a screening criterion. A plot was made of the test's sensitivity and 1–specificity (ROC curve). The area under the ROC curve was used to compare the screening tests; the screening test with the largest area under the ROC curve is considered a better screening test because a higher proportion of individuals are correctly classified compared with a screening test with a smaller area under the curve. ROC curves have been used in dental research by a number of investigators to compare caries prediction models (Helfenstein and Steiner 1994; Steiner *et al.* 1992; ter Pelkwijk *et al.* 1990).

CHAPTER 4
RESULTS

Baseline information

Of the five hundred and thirty-three children eligible to participate in the trial, the parents of 404 gave permission for their child to participate (76% participation). Baseline deciduous tooth caries experience and SES classification of children in the study and all other children enrolled with the SDS were compared using the t-test. There was no statistically significant difference in deciduous tooth caries experience between study participants (dmft= 1.50 ± 2.17) and children enrolled with the SDS (dmft= 1.37 ± 2.42), t = 0.95, 1540 df, p=0.34. The SES level among study participants (953) was lower than the State average (999).

The baseline information for the participants in the test and control groups is shown in Table 16. Statistical tests (t-test for mean values and chi-square test or Fisher's exact test for categorical values) were used to assess the differences between the test and control groups. The groups were very similar with respect to age, caries experience of deciduous teeth (dmfs), the number of occlusal sites at risk of developing caries, toothbrushing frequency and the use of fluoride toothpaste. Ninety-one percent of test group children and 83% of the control group reported brushing their teeth at least once a day. The use of fluoride toothpaste was almost universal; only 1% of children in both the test and control group reporting the use of other types of toothpastes. The test group had more boys than girls and the children were from higher socio-economic areas.

Table 16   Baseline variable values in test and control participants

Variable	Test (n=207)	Control (n=197)	P value
Age (mean ± s)*	75.8 ± 3.5 mo	76.1 ± 3.9 mo	0.33
Sex (N)	girls = 90 boys = 117	girls = 110 boys = 87	0.01
dmfs (mean ± s)	2.4 ± 3.9	2.4 ± 4.31	0.99
Toothbrushing frequency	irregular = 14 once a day = 82 ≥ twice a day=106 unknown=5	irregular = 24 once a day = 79 ≥ twice a day = 85 unknown = 9	0.12
Use of fluoride toothpaste	yes = 196 no = 3 unknown = 8	yes = 185 no = 2 unknown = 10	0.78
SES (mean ± s)	971.6 ± 90.9	933.7 ± 115.1	<0.001
Risk sites (mean ± s)	8.2 ± 3.8	8.6 ± 3.7	0.24

* the age of one test participant is not known

There were no statistically significant differences in sex, socio-economic status or deciduous tooth caries experience between participants and non-participants, Table 17.

Table 17   Comparison of sex, socio-economic status and dmfs between participants and non-participants

	Participants	Non-participants*	P value
Sex	Male = 204 Female = 200	Male = 65 Female = 64	0.98
SES (mean ± s)	956.2 ± 57.5	961.8 ± 56.6	0.33
dmfs (mean ± s)	2.4	1.8	0.12

*Baseline information of non-participants was obtained from information recorded in their clinical records at their last clinical examination

INTER-AND INTRA-RATER RELIABILITY

The findings from the baseline examination of thirty-six children, examined within two weeks, were used to determine intra-rater reliability of the examiner, and the data are shown in Table 18. The kappa values obtained for sound, filled and decayed deciduous tooth surface categories were 0.90, 0.95 and 0.77, respectively, and the overall kappa was 0.89 (95% CI 0.83—0.95). These values indicated excellent intra-rater reliability (Landis and Koch 1977). The information obtained from children examined during the last two sessions of the calibration phase of the study was used to determine inter-rater reliability. The data for calculating inter-rater reliability are shown in Tables 19 and 20. Overall, kappa of 0.89 (95% CI 0.81—0.97) for deciduous tooth status and 0.66 (95% CI 0.50—0.82) for permanent tooth status was obtained. In calculating kappa for the first permanent molars, the criteria of Carvalho *et al.* (1992) were re-coded; codes 0 and 2 (sound surface and surface with arrested lesion) were categorised as sound, code 1 (active lesion without cavitation) as initial caries and code 3 (active lesion with cavitation) as caries.

Table 18   Baseline examination data for intra-rater reliability

		1st Examination			
	Categories	Sound	Filled	Carious	Total
	Sound	361	1	8	370
2nd Examination	Filled	1	39	1	41
	Carious	1	1	19	21
	Total	363	41	28	432

Table 19   First permanent molar data for inter-rater reliability at twelve months

		Examiner 1				
	Categories	Sound	Sealed	I/caries	Carious	Total
	Sound	76		1	1	78
Examiner 2	Sealed		7			7
	Initial caries	7		5	1	13
	Carious	3		1	4	8
	Total	86	7	7	6	106

Table 20   Deciduous tooth data for inter-rater reliability at twelve months

		Examiner 1			
	Categories	Sound	Filled	Carious	Total
	Sound	162		1	163
Examiner 2	Filled	1	33		34
	Carious	7		13	20
	Total	170	33	14	217

Twenty-seven children were randomly selected and examined twice within three weeks during the twelve-month review by the second examiner to assess intra-rater reliability. The raw data for the estimation of kappa are shown in Tables 21 and 22. Kappa values of 0.90 (95% CI 0.81—0.99) for deciduous teeth status and 0.69 (95% CI 0.53—0.85) for permanent teeth status were obtained. The kappa values are consistent with excellent reliability of diagnosis for deciduous teeth and substantial reliability of diagnosis for permanent molars (Landis and Koch 1977).

Table 21　　　　　First permanent molar data for intra-rater reliability at twelve months

		1st examination				
	Categories	Sound	Sealed	Initial caries	Carious	Total
	Sound	77	1	5	1	84
2nd examination	Sealed	1	9			10
	Initial caries	2		5		7
	Carious	2		1	4	7
	Total	82	10	11	5	108

Table 22　　　　　Deciduous tooth data for intra-rater reliability at twelve months

		1st examination			
	Categories	Sound	Filled	Carious	Total
	Sound	190			190
2nd examination	Filled		19		19
	Carious	3	1	3	7
	Total	193	20	3	216

Calibration of the examiner in the examination criteria was conducted one month prior to the twenty-four-month clinical examinations. The data from ten children examined at the twenty-four-month calibration session were used to determine the inter-rater reliability. Details for the combined permanent and deciduous teeth are shown in Table 23. A kappa value of 0.89 (95% CI 0.81—0.97) was achieved, indicating excellent reliability.

TABLE 23　　　　　Data for inter-rater reliability at twenty-four months

		Examiner 1						
	Categories	Sound	Sealed	Filled	Initial caries	Carious	Missing	Total
	Sound	121	2	1		1		125
	Sealed		7		1			8
Examiner 2	Filled			22		1		23
	Initial caries							
	Carious			1		1		2
	Missing						2	2
	Total	121	9	24	1	3	2	160

The examiner also re-examined 35 children within three weeks at the twenty-four-month review to assess intra-rater reliability. The data for calculating kappa are shown in Tables 24 and 25. A kappa value of 0.87 (95% CI 0.76—0.98) for permanent teeth was obtained. The kappa value for deciduous teeth was 0.97 (95% CI 0.94—1.00). The kappa values indicate excellent intra-rater reliability.

Table 24   Twenty-four-month data for intra-rater reliability (permanent teeth)

		1st examination					
	Categories	Sound	Sealed	Filled	Initial caries	Carious	Total
	Sound	114			1	2	117
	Sealed		9				9
2nd examination	Filled			4			4
	Initial caries	1				1	2
	Carious	1				7	8
	Total	116	9	4	1	10	140

Table 25   Twenty-four-month data for intra-rater reliability (deciduous teeth)

		1st examination				
		Sound	Filled	Carious	Absent	Total
	Sound	340	1	1		342
	Filled	1	52	1		54
2nd examination	Carious			6		6
	Absent				18	18
	Total	341	53	8	18	420

TWELVE-MONTH FOLLOW-UP

After twelve months, 186 test and 163 control children were examined. The majority of the children that could not be examined were unavailable because of the family leaving the area while others failed to keep their scheduled appointments. A comparison of the baseline variables between test and control children examined at twelve months is shown in Table 26. Almost all the children used a fluoride toothpaste and there was no statistically significant

difference between the two groups of children examined at twelve months. At the twelve-month review, the difference in socio-economic level between the test and control group was still statistically significant ($t= -3.44$, 347 df, $p < 0.001$). The groups were now more comparable for sex.

Table 26 Comparison of baseline variables between test-and control-group children examined at twelve months

Variable	Test	Control	P value
Age (mean ± s)	75.8 ± 3.5 mo	76.2 ± 3.9 mo	0.29
Sex (N)	girls = 83 boys = 103	girls = 86 boys = 77	0.13
dmfs (mean ± s)	2.3 ± 3.7	2.5 ± 4.5	0.58
Toothbrushing frequency	irregular = 12 once a day = 75 ≥ twice a day = 106 unknown = 5	irregular = 15 once a day = 69 ≥ twice a day = 72 unknown = 7	0.51
Use of fluoride toothpaste	yes = 176 no = 3 unknown = 7	yes = 155 no = 0 unknown = 8	0.25*
SES (mean ± s)	976.7 ± 85.3	939.8 ± 114.3	<0.001
Risk sites (mean ± s)	8.1 ± 3.8	8.6 ± 3.6	0.18

* Fisher's exact test with 'unknown' toothpaste category excluded

Tables 27 and 28 show the baseline characteristics of the test and control group children who were examined at twelve months and those who were lost to follow-up at twelve months. In the test group, children from higher socio-economic areas were more likely to have been examined at twelve months compared with children from lower socio-economic areas ($t= -2.42$, 205 df, $p<0.05$).

Table 27   Comparison of baseline variables for test-group children examined at twelve months and who were lost to follow-up

Variable	Examined	Not examined	P value
Age (mean± s)	75.8 ± 3.5 mo	75.4 ± 3.8 mo	0.63
Sex (N)	girls = 83 boys = 103	girls = 7 boys = 14	0.32
dmfs (mean ± s)	2.3 ± 3.7	3.2 ± 5.7	0.32
Toothbrushing frequency	irregular = 12 once a day = 75 ≥ twice a day = 94 unknown = 5	irregular = 2 once a day = 7 ≥ twice a day = 12 unknown = 0	0.53[*]
Use of fluoride toothpaste	yes = 176 no = 3 unknown = 7	yes = 20 no = 0 unknown = 1	0.59[‡]
SES (mean ± s)	976.7 ± 85.3	926.7 ± 124.3	< 0.05
Risk sites (mean ± s)	8.1 ± 3.8	9.4 ± 3.0	0.13

[*] Excludes irregular and unknown categories due to small numbers in the cells.
[‡] Excludes the no-fluoride category due to the small numbers in the cells (Fisher's exact test).

Eighty-seven percent of children in the control group who were examined at twelve months reported brushing their teeth at least once a day compared with 68% of children who were not seen at twelve months (χ^2=8.4, 2 df, p=0.02). The control group children who were examined at twelve months were from higher socio-economic areas compared with control children not examined, but the difference was not statistically significant. Children who were irregular brushers were more likely to have been lost to follow-up at twelve months.

Table 28   Comparison of baseline variables for control-group children examined at twelve months and who were lost to follow-up

Variable	Examined	Not examined	P value
Age (mean ± s)	76.2 ± 3.9 mo	75.6 ± 3.7 mo	0.41
Sex (N)	girls = 86 boys = 77	girls = 24 boys = 10	0.06
dmfs (mean ± s)	2.5 ± 4.5	1.6 ± 3.0	0.26
Toothbrushing frequency	irregular = 15 once a day = 69 ≥twice a day = 72 unknown = 7	irregular = 9 once a day = 10 ≥ twice a day = 13 unknown = 2	0.02‡
Use of fluoride toothpaste	yes = 155 no = 0 unknown = 8	yes = 30 no = 2 unknown = 2	0.67*
SES (mean ± s)	939.8 ± 114.3	904.5 ± 116.0	0.10
Risk sites (mean ±s)	8.6 ± 3.6	8.8 ± 4.1	0.79

‡Excludes unknown category due to small numbers.
*Fisher's exact test, excludes no fluoride category.

Study outcomes

The primary clinical outcome measures of interest in this trial were the difference in cumulative caries incidence (caries with cavitation), caries incidence rate and caries increment on the occlusal surfaces of the first permanent molars between test and control. Other outcomes of interest were the change in distribution of plaque on the first permanent molars and the deciduous tooth caries increment. The cost-effectiveness of the two programmes in preventing occlusal caries in the first permanent molars was also estimated.

This pragmatic trial was aimed at comparing the caries preventive effects of an oral hygiene based preventive programme (professional tooth cleaning) with an operative based programme (fissure sealing), and it was conducted in a functioning school dental service where individual clinicians provided care based on their clinical judgements. Hence, a number of children in the test group

received fissure sealants on their first permanent molars in addition to the professional cleaning and education. The numbers of children and the type of treatment received by each child examined at twelve months are shown in Table 29. Thirty-seven percent of children in the control group received fissure sealants compared with 6% in the test group (χ^2=51.7, 1 df, p<0.001).

Table 29   Preventive treatment received by test and control groups at twelve months

Treatment received	Test (n=186)	Control (n=163)
No specific treatment	•	88
Topical fluoride	•	15
Fissure sealants	•	60
Prophylaxis	175	•
Prophy + fissure seals	11	•

Twelve-month caries incidence and increment

Table 30 shows the outcome data for the twelve-month follow-up examinations. Three children (two test, one control) were excluded from the analysis of first permanent molar caries because they had received treatment (fillings and preventive care) on the first permanent molars prior to study commencement.

Table 30   Twelve-month carious outcome

Caries	Test	Control
Cases	34	35
Non-cases	150	127
Total	184	162

Using the described equations (eqs 1–4, page 98), the risk ratio and the associated 95% confidence interval were estimated as follows;

$$\hat{RR} = \frac{34/184}{35/162} = 0.86$$

and the approximate 95% confidence interval is

$$\exp[-0.156 \pm 1.96(0.215)] = 0.56, 1.30$$

The risk difference and the 95% confidence interval were estimated as

$$\hat{RD} = \frac{34}{184} - \frac{35}{162} = -0.03, \text{ 95\% CI= -0.12, 0.05}$$

The prevented fraction was 0.14 and because the exposure is preventive the risk difference can be considered as 'attributable benefit' and becomes 0.03, 95% CI -0.05, 0.12 (Elwood 1988).

There were no permanent teeth missing due to caries and the DMF index in this study is made up of DF teeth or sites only. A comparison of the mean number of first permanent molar teeth and molar sites that became carious and the deciduous tooth caries increment in an individual among the groups is shown at Table 31.

Table 31 Twelve month caries increment (DF teeth, DF sites and dmfs) between test and control group

Caries increment	Test (mean ± s)	Control (mean ± s)	P value (t-test)	Confidence intervals (95%)
DF teeth	0.26 ± 0.62	0.29 ± 0.64	0.67	-0.10 — 0.16
DF sites	0.28 ± 0.69	0.36 ± 0.90	0.34	-0.09 — 0.25
dmfs	0.83 ± 1.83	0.52 ± 1.34	0.07	-0.02 — 0.66

The test group children experienced a greater deciduous tooth caries increment and a lower first permanent molar caries increments. However, the difference between the two groups in permanent molar tooth or molar site caries increment, and deciduous tooth caries increment was not statistically significant. The caries outcome data are skewed and although the t-test assumes that the compared means are normally distributed, the test is a robust test of significance for data which depart from normality, provided sample sizes are

large (Worthington 1984). Frequency distributions of caries incidence data among test and control groups are shown in Table 32. The majority of children did not experience any caries on the first permanent molars and most of the other children had caries on one tooth only.

Table 32   Frequency distribution of molar caries among test and control at twelve months

Carious teeth (n)	Test	Control
0	150	127
1	24	26
2	6	7
3	4	1
4	0	1

Twelve-month plaque distribution

Differences in the distribution of plaque on the occlusal surfaces at baseline and at twelve months between the two groups were also tested statistically, Table 33. Sites with plaque on all erupted first permanent molars were summed and mean values for erupted molars per person were compared between the two groups. There was no statistically significant difference in plaque level between the groups at baseline nor at the twelve-month review. There was a tendency for there to be more plaque on the teeth of test group children at baseline, but this was reversed at twelve months. There was a statistically significant improvement in the level of plaque on the teeth of both groups at twelve months compared with their scores at baseline (paired t-test, $p < 0.001$).

Table 33 Plaque levels between groups at baseline and at twelve months, and plaque levels of all the children at baseline and twelve months

	Test (mean ± s)	Control (mean ± s)	P value (t-test)
Baseline plaque	6.68 ±1.84	6.63 ± 2.04	0.79
12-month plaque	5.74 ± 1.83	5.79 ± 2.04	0.82
	Baseline plaque	**12-month plaque**	
All children	6.66 ± 1.94	5.76 ± 1.93	< 0.001

Multivariate analyses

Multiple linear regression

Multiple linear regression was used to examine the effects of independent variables (baseline variables and hypomineralisation) on the mean number of first permanent molars experiencing new caries (DF teeth and DF sites) within the twelve months. Deciduous tooth caries experience and the presence of hypomineralised teeth were statistically significant predictors of caries experience, Table 34 and Table 35. The test or control status of the child was not statistically significant. The regression models explained 13 and 14 percent of the variation in caries experience of molar teeth and molar sites, respectively.

Table 34 Regression of first permanent molar teeth with caries (DFT) on baseline dmfs and hypomineralisation at twelve months

Variable	B coefficient	Std Error	t-value	P value
dmfs	0.03	0.01	4.40	< 0.001
Hypomineralisation absent = 0 present = 1	0.54	0.10	5.65	< 0.001
constant	0.13			

$$R^2 = 0.13$$

Table 35   Regression of carious first permanent molar teeth sites on baseline dmfs and hypomineralisation at twelve months

Variable	β coefficient	Std Error	t-value	p value
dmfs	0.04	0.01	4.44	< 0.001
Hypomineralisation absent = 0 present = 1	0.74	0.12	6.15	< 0.001
constant	0.12			

$$R^2 = 0.14$$

The appropriateness of the linear model for the caries outcome of the first permanent molars was visually examined by plots of the residuals against fitted values and by more formal statistical tests (StataCorp 1997). The plots and statistical tests indicated that the assumptions (normality of the outcome variable and homogeneity of variance) of the linear model were not met by the caries outcome data. Although transformations of data have been suggested as a method of normalising the outcome data and stabilising the variance, transformations were not possible in this study because the modal value of the distribution was zero (Afifi and Clark 1990).

Logistic regression

Logistic regression was used to overcome the limitations of the linear regression and the caries outcome on the first permanent molars was dichotomised into 'no caries experience' DMFT=0 and 'any caries experience' DMFT ≥ 1. All baseline variables and first order interaction terms, including test or control status, were included initially in the model. Backward elimination procedure was used and the change in the log likelihood (likelihood ratio test) of the model was used to decide whether to include or omit candidate variables, Table 36. The summary statistics indicated a good fit of the data to the logistic model, Pearson χ^2=30.07, df = 25, p=0.22; Hosmer-Lemeshow χ^2 =3.75, df=5, p=0.59.

Table 36   Logistic regression on individuals with caries experience, (DFT=0 or DFT≥1) at twelve months

Variable	Odds Ratios	P value	OR 95% CI
dmfs	1.10	0.001	1.04–1.17
Hypomineralisation absent = 0 present = 1	3.80	<0.001	1.90–7.60

The logistic model found that children with higher baseline deciduous tooth caries experience had a higher risk of first permanent molar caries. There was a 10% increased risk of molar caries experience for each additional deciduous surface affected by caries. Having hypomineralised teeth placed a child at approximately four times the risk of first permanent molar caries compared with children without hypomineralisation. Test or control status had no statistically significant effect on the caries risk of first permanent molars.

Poisson regression

Although logistic regression overcame the limitations of the linear model, reducing the outcome to a dichotomy results in a loss of information. The frequency distribution of caries occurrence indicated that the majority of children did not experience caries and because caries data were a count of the number of teeth experiencing caries within the twelve months the fit of the data to a Poisson distribution was examined. The results of the Poisson regression are shown in Table 37. The data fitted the Poisson model well and indicated that baseline deciduous caries experience, the presence of hypomineralised permanent molars and reported frequency of toothbrushing ('twice-a-day' compared with 'irregular') were statistically significant risk factors for permanent molar caries occurrence. Test or control status was not a statistically significant risk factor.

Table 37   Poisson regression of twelve-month DFT on hypomineralisation, toothbrushing frequency and baseline dmfs

Variable	Rate ratio	Standard error	P value	RR 95% CI
dmfs	1.07	0.17	<0.001	1.04–1.11
Hypomineralisation absent=0				
present=1	3.53	0.77	<0.001	2.29–5.43
Toothbrushing irregular=0				
once a day=1	0.64	0.21	0.18	0.33–1.22
twice a day=2	0.50	0.17	0.04	0.26–0.98
unknown=3	1.42	0.61	0.41	0.61–3.31

Goodness of fit chi square=270.3, df 340, p=0.998

The variable 'frequency of toothbrushing' was further collapsed into two categories; categories 0 and 3 were combined and categories 1 and 2 were combined. The rate ratio for brushing at least once a day compared with irregular and unknown brushing frequency was 0.50, p=0.005, 95%CI 0.31–0.81. The rate ratios for hypomineralisation and baseline dmfs were altered marginally in the collapsed model and remained statistically significant.

COST EFFECTIVENESS ANALYSIS (TWELVE MONTHS)

Cost-effectiveness analysis was conducted using the guidelines of Antczak-Bouckoms et al. (1989) and Petitti (1994). A decision tree was constructed (Figure 1, page 125) to demonstrate the pathways for a hypothetical cohort (one hundred children) allocated to either a test or a control programme. The probability values were derived from the trial. The professional cleaning-oral hygiene programme 'saved' three more individuals from experiencing caries on their first permanent molars after twelve months compared with standard preventive care. The numbers of teeth that received a particular preventive treatment in the test and control groups are shown in Table 38.

Table 38   Number of teeth in test and control groups and type of preventive treatments received by each tooth at twelve months

Treatments	Test group (n[*])	Control group (n[*])
Fissure sealants	27 (11)	203 (60)
Topical fluorides		59 (15)
Professional cleaning	All erupted teeth (186)	0

* Number of individuals

Table 39 presents the costs for test and control groups; labour costs for clinicians and clinic assistants were based on the mean of the minimum and maximum salary as at July 1994.

Table 39   Costs for preventive procedures for test and control groups at twelve months

Factors	Unit costs ($)	Cost per child per procedure ($)
Labour		
Dental Therapists	Mean=$0.27/min	Test sealants = 2.03 Control sealants = 2.75 Test cleaning = 1.35 Control topical fluoride = 1.35
Dental Clinic Assistants	Mean=$0.19/min	Test sealants = 1.43 Control sealants = 1.94 Administration= 0.29
Fissure sealing materials		
Glass-ionomer cement	$50/12g pack ≈ 160 sealants	Test 2.5 sealants/child = 0.78 Control 3.4 sealants/child = 1.06
Bristle brushes	$57/144 brushes	1/child = 0.40
Hydrogen peroxide	$0.58/100ml	4ml/child = 0.02
Cotton wool rolls	$11.30/1000 rolls	2–4 rolls ≈ 0.02–0.05
Dry guards	$26.55/200 guards	1–2 guards ≈ 0.13–0.27
Pumice powder	$6/500g	1–2g ≈ 0.01
Cleaning materials		
Prophylaxis paste	$9/100g jar	Test ≈ 1.35 g/child = 0.12
Bristle brushes	$57/144	1/child = 0.40

The estimated time for fissure sealing was three minutes per tooth, and for professional cleaning was five minutes per child. Clinicians reported that chair-side assistance was required for the duration of the fissure sealing procedure

but was not required for the professional cleaning procedures (information was obtained by direct questioning of participating clinicians). Administrative time required for each child was estimated to be 1.5 minutes. The materials cost for topical fluoride administration was less then $0.01 per child and was therefore considered to be negligible. Costs of treatments for a child in either a test or a control group are shown in Table 40.

Table 40   Cost of treatment per child for test and control groups at twelve months

Treatments	Test	Control
Fissure sealants	$4.81	$6.49
Professional cleaning	$1.87	
Topical fluoride		$1.35
Administration	$0.29	$0.29

The mean cost of fissure sealing a test-group child is less because, on average, only 2.5 teeth per child were sealed (for those children who received fissure sealants) compared with 3.4 teeth sealed per child in the control group. The test group children also required more frequent visits for preventive care; on average, each test child made 1.8 visits in the twelve months compared with 1.2 visits per child for the control group (t = −10.24, df 346, $p<0.001$). Table 41 details the frequency distribution of the number of visits among the test and control groups. Most of the children in the test group made two visits while two thirds of the control group made, at most, one visit for preventive care in the twelve months.

Table 42 details the cost for a cohort of 100 children in the test and control groups. Approximately ten percent of the children were assumed to require a follow-up reminder for an appointment (this proportion was obtained by direct questioning of the clinical staff).

Table 41   Frequency distribution of number of visits among control and test groups at twelve months

Number of visits	Control N[a] (%)	Test N (%)
0	21 (13)	1 (0.5)
1	92 (56.8)	35 (19)
2	47 (29)	149 (80)
3	1 (0.6)	1 (0.5)
4	1 (0.6)	none

[a]one child attended for care elsewhere

Table 42   Cost of treatments for a cohort of 100 children in either the test or the control programme at twelve months

Treatments	Test	Control
Fissure sealants	$29	$240
Professional cleaning	$337	
Topical fluoride		$12
Administration	$56	$38
Total	**$422**	**$290**

The incremental cost-effectiveness ratio was;

$$\frac{\$422 - \$290}{81 \text{ persons} - 78 \text{ persons}} = \frac{132}{3} = \$44 / \text{person}$$

The cost of labour makes up, approximately, 75% of the total cost of treatments. Sensitivity analysis was conducted to test the stability of the findings to variations in labour costs and estimate of the risk difference, Table 43.

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Table 43   Costs and incremental cost-effectiveness ratios for different wage levels and risk differences at twelve months

Factors	Test ($)	Control ($)	Cost-effectiveness ratio ($/person)
Maximum wage	470	324	49
Minimum wage	374	253	40
Maximum risk difference & maximum wage	470	324	12
Maximum risk difference & average wage	422	290	11
Maximum risk difference & minimum wage	374	253	10

Figure 1   Decision tree for a cohort of 100 children allocated to either the test or the control programme (twelve months)
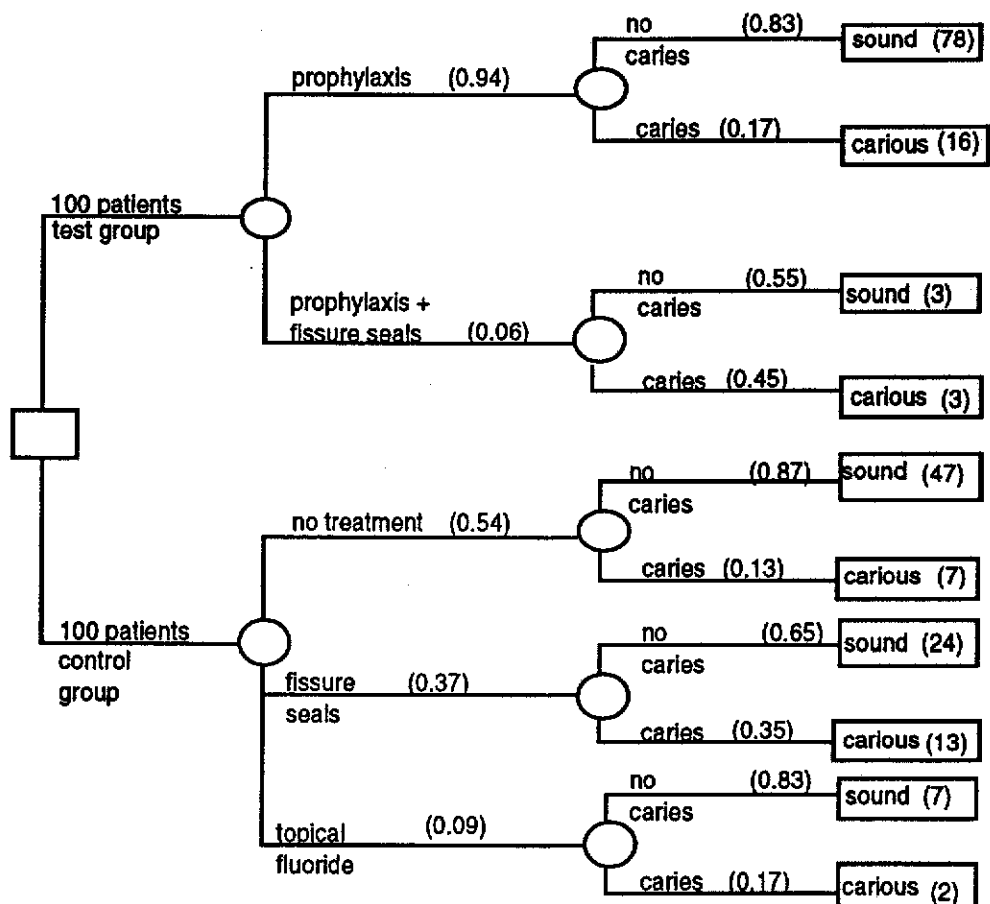
TWENTY-FOUR-MONTH FOLLOW-UP

After twenty-four months, 335 children were examined (156 control and 179 test; 83% follow-up). Of the 69 children lost to follow-up, 49 had moved from the region (19 test and 30 control), 16 failed to keep the examination appointment (eight test and eight control) and four had withdrawn from the study for various reasons (one test and three control). Twenty-nine children who were not seen at twenty-four months had been seen at the twelve-month review and 15 children who were not examined at twelve months were examined at twenty-four months, Table 44. Three hundred and twenty children were examined at both twelve- and twenty-four-month reviews. Analysis of variance found no statistically significant difference in baseline dmfs between the children examined and not examined at twelve and twenty-four months, $p=0.20$.

Table 44   Mean dmfs of children examined and not examined at twelve and twenty-four months

		Examined at 24 months	
		No	**Yes**
Examined at 12 months	**No**	2.63 ± 4.81 (n=40)	1.13 ± 2.13 (n=15)
	Yes	3.38 ± 5.14 (n=29)	2.31 ± 3.98 (n=320)

Baseline comparisons

Comparison of baseline variables between test and control group children examined at twenty-four months is shown in Table 45. The difference in SES level between test and control group children was still statistically significant; more children in the test group were from a higher SES classification. Almost everyone used a fluoride toothpaste. There were more girls than boys in the control group and more boys than girls in the test group; the difference in sex between the groups was not statistically significant, $p=0.10$.

Table 45 Comparison of baseline variables between test and control groups examined at twenty-four months

Variable	Test (n=179)	Control (n=156)	P value
Age (mean ± s)	75.8 ± 3.5 mo	76.2 ± 4.0 mo	0.31
Sex	girls=78 boys=101	girls=82 boys=74	0.10
dmfs (mean ± s)	2.2 ± 3.7	2.3 ± 4.2	0.80
Toothbrushing frequency	irregular=13 once a day=72 ≥twice a day=89 unknown=5	irregular=15 once a day=67 ≥twice a day=67 unknown=7	0.53
Use of fluoride toothpaste	yes=169 no=3 unknown=7	yes=147 no=1 unknown=8	0.68[*]
SES (mean ± s)	976.7 ± 86.0	942.7 ± 114.1	<0.01
Risk sites (mean ± s)	8.0 ± 3.8	8.5 ± 3.6	0.21

[*] Fisher's exact test used due to small cell numbers

A comparison of the baseline variables between children examined at twenty-four months and those not examined at twenty-four months among test group and control group is shown at Table 46 and Table 47, respectively. The test group children who were examined at twenty-four months were significantly more likely to be from relatively higher socio-economic areas and have more teeth erupted at the commencement of the study than control children. Among the control group children, none of the differences in baseline variables, except SES, were statistically significant between children examined and not examined; those examined at twenty-four months were from relatively higher socio-economic areas compared with those not examined. For both test and control, children who were examined at twenty-four months had lower baseline deciduous tooth caries experience than children not examined; the difference was not statistically significant. There were no statistically significant differences in baseline deciduous caries experience and the SES levels between

test and control children who were lost to follow-up (t-test; t = 0.74, 67 df,

p = 0.46 and t = 1.43, 67 df, p = 0.16, respectively).

Table 46   Comparison of baseline variables between test group children examined and not examined at twenty-four months

Variable	Examined	Not examined	P value
Age (mean ± s)	75.8 ± 3.5 mo	75.8 ± 3.7 mo	0.96
Sex	girls=78 boys= 101	girls=12 boys=16	0.94
dmfs (mean ± s)	2.4 ± 3.7	3.5 ± 5.1	0.12
Toothbrushing frequency	irregular=13 once a day=72 ≥twice a day=89 unknown=5	irregular=1 once a day=10 ≥twice a day=17 unknown=0	0.69*
Use of fluoride toothpaste	yes=169 no=3 unknown=7	yes=27 no=0 unknown=1	1.0‡
SES (mean ± s)	976.7 ± 86.0	939.1 ± 114.1	< 0.05
Risk sites (mean ± s)	8.0 ± 3.8	9.6 ± 3.2	0.03

* Fisher's exact test used due to small cell numbers; excludes unknown category
‡ Fisher's exact test; excludes 'no' category.

Table 47   Comparison of baseline variables between control group children examined and not examined at twenty-four months

Variable	Examined	Not examined	P value
Age (mean ± s)	76.2 ± 3.4	75.9 ± 3.4	0.66
Sex	girls=82 boys=174	girls=28 boys=13	0.07
dmfs (mean ± s)	2.3 ± 4.2	2.6 ± 4.9	0.72
Toothbrushing frequency	irregular=15 once a day=67 ≥twice a day=67 unknown=7	irregular=9 once a day=12 ≥twice a day=18 unknown=2	0.06
Use of fluoride toothpaste	yes=147 no=1 unknown=8	yes=38 no=1 unknown=2	1.00‡
SES (mean ± s)	942.7 ± 114.1	899.3 ± 113.6	< 0.05
Risk sites (mean ± s)	8.5 ± 3.6	9.2 ± 4.0	0.28

‡ Fisher's exact test; excludes 'no' fluoride category.

Twenty-four-month caries incidence and increment

The cumulative caries incidence for the children examined at twenty-four months is shown at Table 48. One control and two test children were excluded from the analysis of first permanent molar caries because they had received treatment on their first permanent molars prior to study commencement.

Table 48   Twenty-four-month carious outcome

Caries	Test	Control
Yes	32	31
No	145	124
Total	177	155

The cumulative incidence and the risk ratio and the risk difference and their associated confidence intervals were calculated using the previously described equations (eqs 1–4, page 98). The risk ratio and the 95% confidence interval were, 0.90, 0.58—1.41. The risk difference and its 95% confidence interval were, -0.02, -0.10—0.07, or if the risk difference was considered as attributable benefit, 0.02, -0.07—0.10.

Caries increments (DMF/dmf index) after twenty-four months between the two groups are detailed in Table 49. There were no statistically significant differences between the test and control groups in both permanent and deciduous caries increments. On average, each child in each group experienced one new carious deciduous tooth surface and one child in three experienced one carious lesion in the occlusal pits and fissures of a first permanent molar tooth. Most of the caries increment among the first permanent molars occurred during the first twelve months, by subtraction, 0.24 DFT and 0.26 DFS compared with 0.06 DFT and 0.10 DFS during the second twelve months.

Table 49   Comparison of caries increment between test and control group after twenty-four months and the second twelve months (between twelve and twenty-four months)

Caries Increment (mean ± s)	Test (mean ± s)	Control (mean ± s)	Confidence intervals (95%)	P value
DF teeth	0.30 ± 0.75	0.30 ± 0.70	-0.16 — 0.15	0.96
DF sites	0.36 ± 1.03	0.41 ± 1.04	-0.17 — 0.27	0.62
dmfs	0.94 ± 1.93	0.80 ± 1.79	-0.54—0.26	0.49
	Second 12 month caries increments			
	Test (n=169)	Control (n=148)	Confidence intervals (95%)	P value
DF teeth	0.06 ± 0.50	0.01 ± 0.54	-0.06–0.16	0.32
DF sites	0.10 ± 0.69	0.05 ± 0.65	-0.10–0.20	0.49

Twenty-four-month plaque distribution

Plaque levels at baseline and at twenty-four months for the children examined at twenty-four months among the test and control groups, and all the children combined are shown at Table 50. There were no statistically significant differences between the groups in plaque levels at baseline nor at twenty-four months. The plaque level at twenty-four months was lower than the plaque level at baseline for all the children and the difference was statistically significant (paired t-test, $t = 5.97$, 333 df, $p < 0.001$). The plaque level at twenty-four months was marginally less than at twelve months and the difference was not statistically significant (paired t-test, $t = -1.13$, 319 df, $p = 0.26$).

Table 50   Plaque levels between groups at baseline and twenty-four months and plaque levels for all the children at baseline and twenty-four months, and plaque levels for all the children examined at twelve and twenty-four months

	Test (mean ± s)	Control (mean ± s)	P value (t-test)
Baseline plaque	6.52 ± 2.12	6.61 ± 1.88	0.67
24-month plaque	5.67 ± 2.14	5.60 ± 2.01	0.76
	Baseline plaque	**24-month plaque**	**Paired t-test**
All children (n=334)	6.57 ± 2.01	5.65 ± 2.07	$p < 0.001$
	12-month plaque	**24-month plaque**	
All children (n=320)	5.74 ± 1.95	5.61 ± 2.08	0.26

Power calculations were conducted to determine the power of the study to detect the differences because statistical tests of differences in the means and proportions indicated no difference between the groups. For the mean DMFT the power of the study was 0.03, for DMF sites 0.06 and for the difference in proportions it was 0.05. The findings indicate relatively low power of the study to detect these small differences. The number of participants estimated as required to demonstrate the difference in proportions found in this study at alpha 0.05 and beta 0.80 was 6810 in each group.

Multivariate analyses

Multiple linear regression with backward elimination was used to assess the effects of the independent variables on the occurrence of caries on the first permanent molars, caries of the deciduous canines and molars, and the distribution of plaque on the first permanent molars. Table s 51 shows the results of the multiple linear regression of DMFT increment (no teeth were missing) on independent variables. The variables, hypomineralisation and baseline deciduous tooth caries experience were statistically significant predictors of first permanent molar caries. The regression model explained 29% of the variation in first permanent molar caries.

Table 51   Regression of DFT on deciduous tooth caries experience, hypomineralisation and brushing frequency

Variable	ß coefficient	Std Error	t-value	p value
Hypomineralisation absent=0				
present=1	0.88	0.10	9.04	<0.001
dmfs	0.04	0.01	4.11	<0.001
Brushing freq irregular=0				
once/day=1	-0.24	0.13	-1.91	0.06
twice/day=2	-0.32	0.13	-2.53	0.01
unknown=3	0.32	0.21	1.50	0.14
Constant	0.34			

$$R^2 = 0.29$$

Reported frequency of toothbrushing was of border-line statistical significance and was retained in the model. The brushing frequency of some children was unknown because their parents failed to attend the review appointment. Using a one-way ANOVA with Scheffé's test for multiple comparisons, twice-a-day brushers (n=154; DMFT = 0.18 ± 0.49) had fewer molar teeth with caries experience compared with irregular brushers (n=28; DMFT = 0.61 ± 0.88), $p<0.05$; and children whose brushing frequency was unknown (n=12; DMFT = 1.00 ± 1.48) had more affected molars compared with once-a-day (n=138; DMFT = 0.32 ± 0.78) and twice-a-day brushers, $p< 0.05$.

Because the variable hypomineralisation had such a strong influence on permanent molar caries, the proportions of children with hypomineralisation in the test and control groups were tested. There were more children with hypomineralisation in the control group (0.19) than in the test group (0.11), and the difference was statistically significant (χ^2= 4.96, 1 df, $p<0.05$). The influence the presence of hypomineralised first permanent molars had on preventive care decisions made by clinicians in the control group was also examined. After twenty-four months, of the thirty children affected by hypomineralised molars in the control group, twenty received fissure sealants (χ^2= 6.7, 1 df, $p=0.01$).

The result of the linear regression of first permanent molar caries sites on independent variables is shown in Table 52. The variables, hypomineralisation and baseline deciduous tooth caries experience were predictors of the number of permanent molar sites experiencing caries over two years. The regression model explained 23% of the variation in first permanent molar site caries. Toothbrushing was no longer a statistically significant factor in the regression model. One-way ANOVA found statistically significant differences in permanent molar site caries between once-a-day brushers (n=138; DMFS=0.43 ± 1.18) and children with unknown brushing frequency (n=12; DMFS = 1.33 ± 2.10), and

between twice-a-day brushers (n=154: DMFS = 0.23 ± 0.71) and children with

unknown brushing frequency, $p<0.05$.

Table 52	Regression of DFS on hypomineralisation and deciduous caries experience			

Variable	ß coefficient	Std Error	t-value	p value
Hypomineralisation absent=0 present=1	1.31	0.14	9.12	<0.001
dmfs	0.05	0.01	3.56	<0.001
Constant	0.10			

$$R^2=0.23$$

The result of the multiple logistic regression of individuals with first permanent

molar caries experience (DMFT=0 and DMFT>0) on independent variables is

presented in Table 53. Hypomineralisation and baseline deciduous tooth caries

experience were statistically significant risk factors for first permanent molar

caries occurrence. There was a 10% increased risk of molar caries for an

increase in one baseline dmfs, and nearly a 12-fold increased risk of molar caries

among children with hypomineralised molars.

Table 53	Logistic regression of individuals with permanent molar caries experience with baseline deciduous caries experience, hypomineralisation and brushing frequency

Variable	Odds Ratios	P value	OR 95% CI
dmfs	1.10	<0.01	1.03–1.18
Hypomineralisation absent = 0 present=1	11.73	<0.001	5.73–24.01
Brushing freq irregular=0 once/day=1	0.41	0.10	0.16–1.17
twice/day=2	0.31	0.03	0.11–0.87
unknown=3	1.15	0.95	0.21–5.31

Toothbrushing frequency was of border-line statistical significance; children who reported brushing at least twice-a-day were less likely to get permanent molar caries compared with children who brushed irregularly. The standard chi-square test of proportions found a statistically significant association between caries occurrence and toothbrushing frequency, Table 54. A trend towards decreasing caries experience with increasing brushing frequency was seen.

Table 54   Reported brushing frequency at baseline and caries incidence

	Caries		
Brushing frequency	Yes	No	Proportion Carious
Irregular	10	18	0.36
Once/day	28	110	0.20
Twice/day	21	133	0.14
Unknown	5	7	0.42

$\chi^2 = 11.97, 3df, p=0.007$

The logistic model for the first permanent molar with caries experience, using the generalized estimating equations (GEE) is shown in Table 55. The odds ratios were marginally higher for baseline deciduous caries experience compared with the model of individuals with molar caries experience. The risk of occlusal first permanent molar caries when the tooth is affected by hypomineralisation is nearly 14 times that of a non-affected tooth. Children who brushed at least twice a day were at a lower risk of experiencing occlusal caries on the first permanent molars.

The correlation between the first permanent molars was estimated to be 0.11. The effects of specifying an unstructured correlation model had minimal effects on parameter estimates and no logical pattern of correlation was observed. The correlation values ranged from 0.3 between upper molars to 0.0 between upper left molar and lower right molar.

Table 55   Logistic regression on first permanent molars using GEE

Variable	Odds Ratios	P value	OR 95% CI
dmfs	1.11	<0.001	1.06—1.16
Hypomineralisation absent = 0 present=1	13.75	<0.001	7.88—24.01
Brushing freq irregular=0			
once/day=1	0.58	0.16	0.27—1.24
twice/day=2	0.29	<0.01	0.13—0.66
unknown=3	1.61	0.40	0.53—4.90

The results of the Poisson regression are shown in Table 56. The model fitting procedure indicated that the data fitted the Poisson model. Children with hypomineralised first permanent molars had seven times the rate of caries of the first permanent molars compared with children without hypomineralised molars. Children who brushed their teeth at least once a day experienced lower rates of first permanent molar caries while there was a nine percent increased rate of first permanent molar caries for each increment of deciduous surface affected by caries.

Table 56   Poisson regression of DFT on baseline deciduous caries experience, hypomineralisation and brushing frequency at twenty-four months

Variable	Rate Ratios	Std. error	P value	RR 95% CI
dmfs	1.09	0.02	<0.001	1.06—1.13
Hypomineralisation absent = 0 present=1	7.16	1.46	<0.001	4.81—10.66
Brushing freq irregular=0				
once/day=1	0.51	0.15	0.02	0.29—0.90
twice/day=2	0.39	0.12	<0.01	0.21—0.73
unknown=3	1.72	0.65	0.15	0.82—3.60

Goodness-of-fit $\chi^2_{(326)}=284$; $p=0.95$

When the risk of first permanent molar caries was modelled over time using Poisson regression with GEE (controlling for lack of independence within an individual over time, exchangeable correlation) the parameter estimates of the variables were less than in the standard Poisson model, but still statistically significant, Table 57. The categories of *irregular* and *unknown* toothbrushing frequency were combined because of the small numbers in the *unknown* category and robust standard errors were estimated. The risk of permanent molar caries associated with hypomineralised molars is still high though is attenuated with time. The risk of caries associated with deciduous caries experience remained the same and the risk associated with toothbrushing frequency was marginally reduced. Specification of robust standard errors resulted in widened 95% confidence intervals for hypomineralisation and toothbrushing frequency. The exchangeable correlation between the two years was 0.45 and an unstructured correlation was 0.49.

Table 57   Poisson regression of DFT on baseline deciduous caries experience, hypomineralisation and brushing frequency over two years

Variable	Rate Ratios	Robust std. err	P value	RR 95% CI
dmfs	1.09	0.02	<0.001	1.05—1.12
Hypomineralisation absent = 0 present=1	6.01	1.40	<0.001	3.80—9.50
Brushing freq irreg/unkno=0 once/day=1	0.42	0.12	0.002	0.24—0.73
twice/day=2	0.33	0.11	0.001	0.17—0.63

The deciduous tooth caries increment was examined using multiple linear regression and the results are shown in Table 58. Previous deciduous tooth caries experience, the presence of hypomineralised first permanent molars and sex were significant predictors of deciduous tooth caries increment. An increase of five baseline deciduous tooth surfaces affected by caries increased by one the

number of deciduous tooth surfaces that decayed over two years, and girls

experienced more decay than boys. The presence of hypomineralised first

permanent molars was also associated with an increased number of deciduous

surfaces that decayed. The regression model was able to explain 17% of the

variation in deciduous tooth caries increment.

When the level of plaque was regressed on the baseline variables, none of the

recorded variables were statistically significantly associated with plaque

decrement.

Table 58

Regression of deciduous caries increment on baseline deciduous caries experience, hypomineralisation and sex at twenty-four months

Variable	ß coefficient	Std Error	t-value	p value
Hypomineralisation				
no=0				
yes=1	0.71	0.26	2.68	0.008
dmfs	0.17	0.02	7.28	<0.001
Sex				
male=0				
female=1	0.48	0.19	2.59	0.010
Constant	0.15			

$$R^2=0.17$$

Treatments received

Preventive treatments received by test and control group children on each first

permanent molar are shown in Table 59 and Table 60, respectively. Two

children in the test group did not receive any preventive treatments due to their

failure to keep their appointments, and in 15 test children at least one first

permanent molar was fissure sealed. Among the control group, at least one first

permanent molar was sealed in 61 children, 19 children received some form of

topical fluoride treatment and 76 children did not receive any specific preventive

treatment on their first permanent molars.

Table 59   Treatments received by tooth type (test group)

Treatments	Upper right	Upper left	Lower left	Lower right
None	2	2	2	2
Professional cleaning	164	162	164	163
Cleaning.+fissure seal	13	15	12	14

Table 60   Treatments received by tooth type (control group)

Treatments	Upper right	Upper left	Lower left	Lower right
None	79	77	76	81
Fluoride	19	19	19	18
Fissure sealants	58	60	61	57

Deciduous tooth caries experience among children who received fissure sealants and those who did not was compared using the t-test. Among the test group, there was no statistically significant difference between sealed (n=23;dmfs = 2.9 ± 4.4) and non-sealed (n=156; dmfs = 2.1 ± 3.6) children, p=0.33. Among the control group, the mean difference between sealed (n=71; dmfs = 3.6 ± 5.4) and non-sealed (n=85; dmfs = 1.2 ±2.3) children was statistically significant, p<0.001.

Screening for caries risk

The multivariate analysis indicated a close association between deciduous tooth caries experience and first permanent molar caries incidence, a finding which has been reported in studies elsewhere (Gray *et al.* 1991; Rise *et al.* 1979). This association has also been tested as a screening criterion to predict caries increment (Helfenstein and Steiner 1994; Rise *et al.* 1979; Steiner *et al.* 1992; ter Pelkwijk *et al.* 1990). The association between deciduous caries experience and first permanent molar caries experience (DFT≥1) is shown in Table 61.

Table 61   First permanent molar caries experience by baseline deciduous caries experience at twenty-four months

dmfs	Molar caries Yes	No	Total	Proportion carious
0	21	164	185	0.11
1	7	25	32	0.22
2	4	18	22	0.18
3	5	7	12	0.42
4	6	14	20	0.30
5	3	7	10	0.30
≥6	18	33	51	0.35
Total	64	268	332	0.19

Using the association between deciduous tooth caries experience and first permanent molar caries experience as a screening test for the occurrence of any molar caries, the following results were obtained for different cut-points, (Table 62):

Table 62   Sensitivity, specificity, and predictive values for the data in Table 61

Cut point	Sensitivity	Specificity	PPV	NPV
dmfs< 1	0.67	0.61	0.29	0.89
dmfs< 2	0.56	0.71	0.31	0.87
dmfs< 3	0.50	0.77	0.34	0.87
dmfs< 4	0.42	0.80	0.33	0.85
dmfs< 5	0.33	0.85	0.34	0.84
dmfs< 6	0.28	0.88	0.35	0.84
dmfs< 7	0.20	0.90	0.33	0.83

Setting the cut-point at one dmfs, sensitivity of 0.67 and specificity of 0.61 was obtained. When the cut-point was set at six or fewer dmfs, sensitivity of 0.20 and specificity of 0.90 was obtained. The positive predictive value (PPV) for all the cut-points was low; a maximum PPV of 0.35 was obtained at a cut-point of five or fewer baseline dmfs.

The area under the ROC curve was used to compare the predictive ability of
using baseline dmfs and hypomineralisation separately and combined to predict
any first permanent molar caries. ROC curves for dmfs, hypomineralisation, and
both dmfs and hypomineralisation combined are shown in Figures 2–4. The
diagonal line in the figures indicate prediction based on pure chance alone and
the area under the curve is 0.5. A combined prediction model performed better
than either variable individually. There was an increase in prediction of 19%
over dmfs alone and an increase of 14% over hypomineralisation alone. The cut-
points that can be used to achieve various sensitivities and specificities are
shown in Figure 5. Addition of further variables did not result in improved
prediction models.

Figure 2   Plot of sensitivity versus 1–specificity using baseline deciduous tooth caries
experience to predict molar caries occurrence

Area under ROC curve = 0.6599
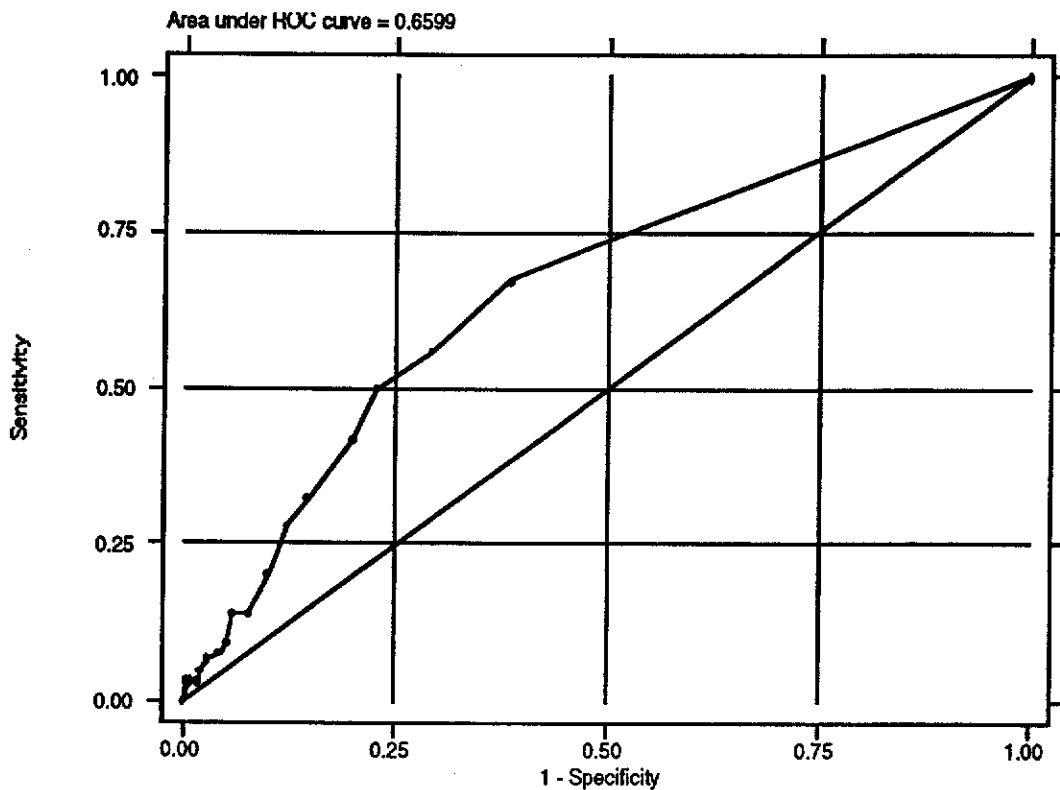
Figure 3   Plot of sensitivity versus 1–specificity using presence or absence of hypomineralisation to predict molar caries occurrence

Area under ROC curve = 0.6930
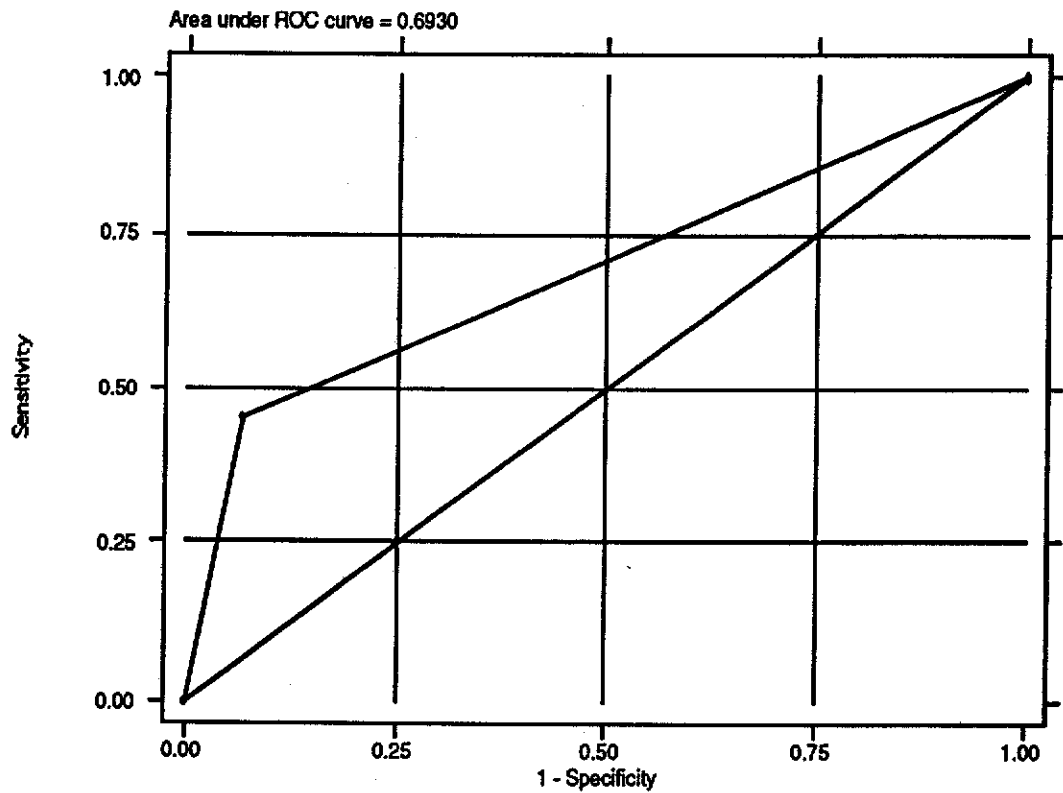
Figure 4   Plot of sensitivity versus 1–specificity using baseline deciduous tooth caries experience and hypomineralisation to predict molar caries occurrence

Area under ROC curve = 0.7872
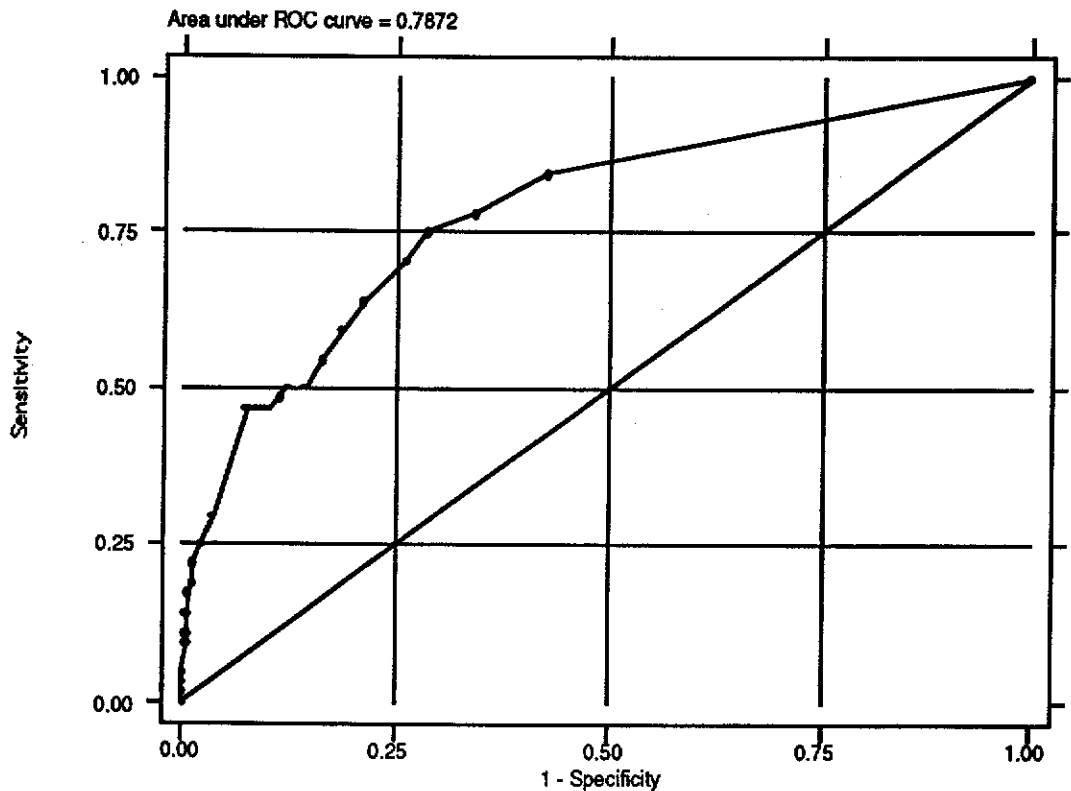
Figure 5   Sensitivity and specificity curves at various cut points for the combined dmfs and hypomineralisation
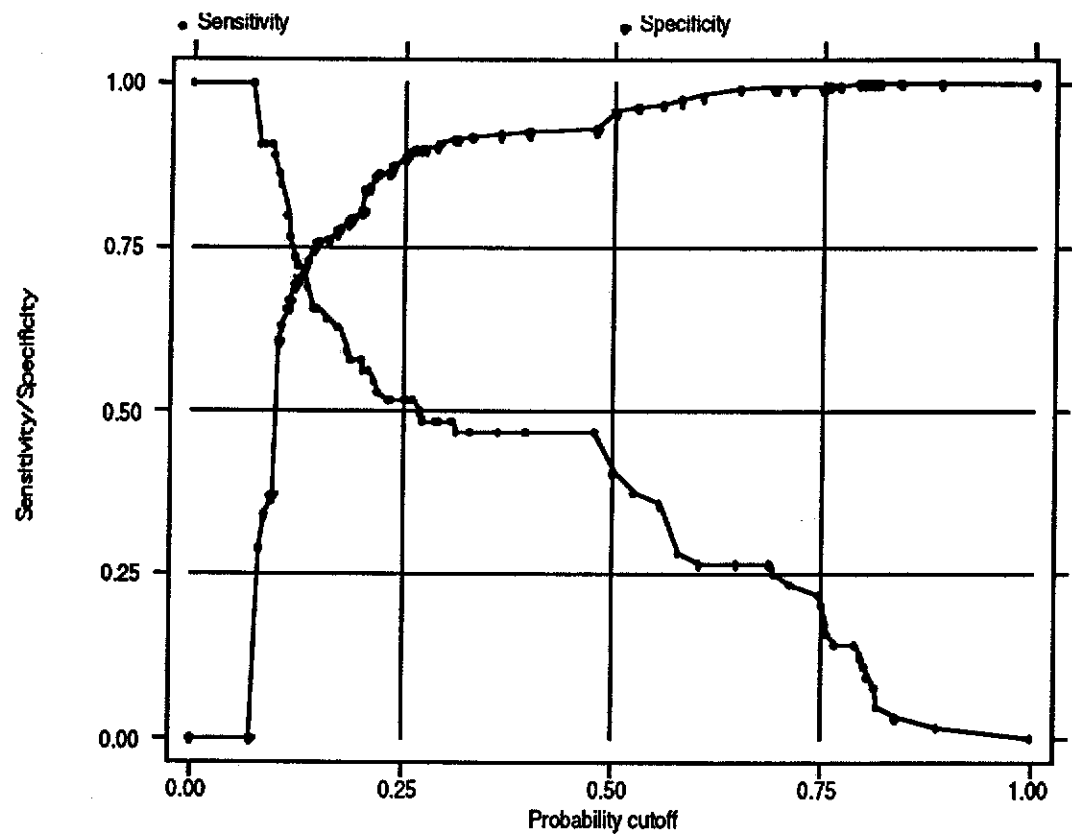
COST-EFFECTIVENESS ANALYSIS (TWENTY-FOUR MONTHS)

The cost-effectiveness analysis was based on data from 317 children who were examined at both the twelve- and the twenty-four-month reviews. A decision tree was constructed to map the probabilities and outcomes for a theoretical cohort of 100 children allocated to either the test or the control programme using the probability values derived from the clinical trial, Figure 6. Table 63 details the treatments received by the children of each group over the two years.

Table 63   Preventive treatments received by test and control children over two years

Treatments	1994/95		1995/96	
	Test (n=169)	Control (n=148)	Test (n=169)	Control (n=148)
No specific treatment		74		127
Topical fluoride		20		4
Fissure sealants		54		17
Professional cleaning	158		161	
Cleaning+ fissure seals	11		8	

The cumulative caries incidence for the children who were examined at both reviews is presented as a contingency table in Table 64.

Table 64   Caries outcome for test and control after twenty-four months for children examined at both reviews

Caries	Test	Control
Cases	30	32
Non-cases	139	116
Total	169	148

The risk ratio is 0.82, 95% CI 0.53 – 1.28. The risk difference is 0.04 and the 95% CI, -0.05 – 0.13.

Figure 6 Decision tree for a cohort of 100 children allocated to either the control or the test program

First Year
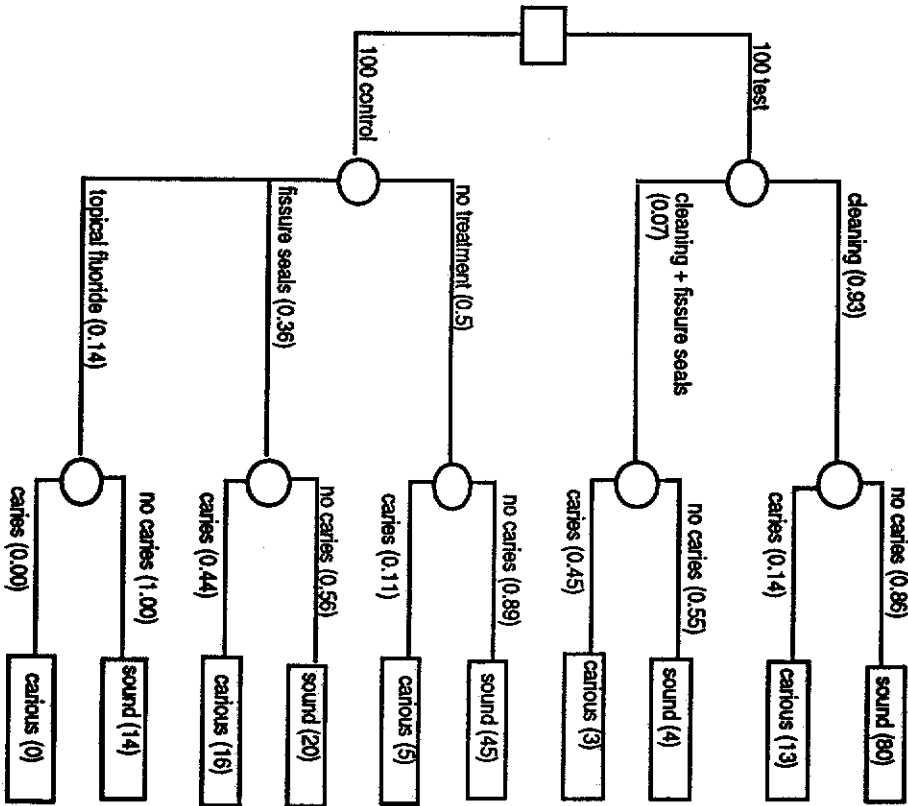
Second Year
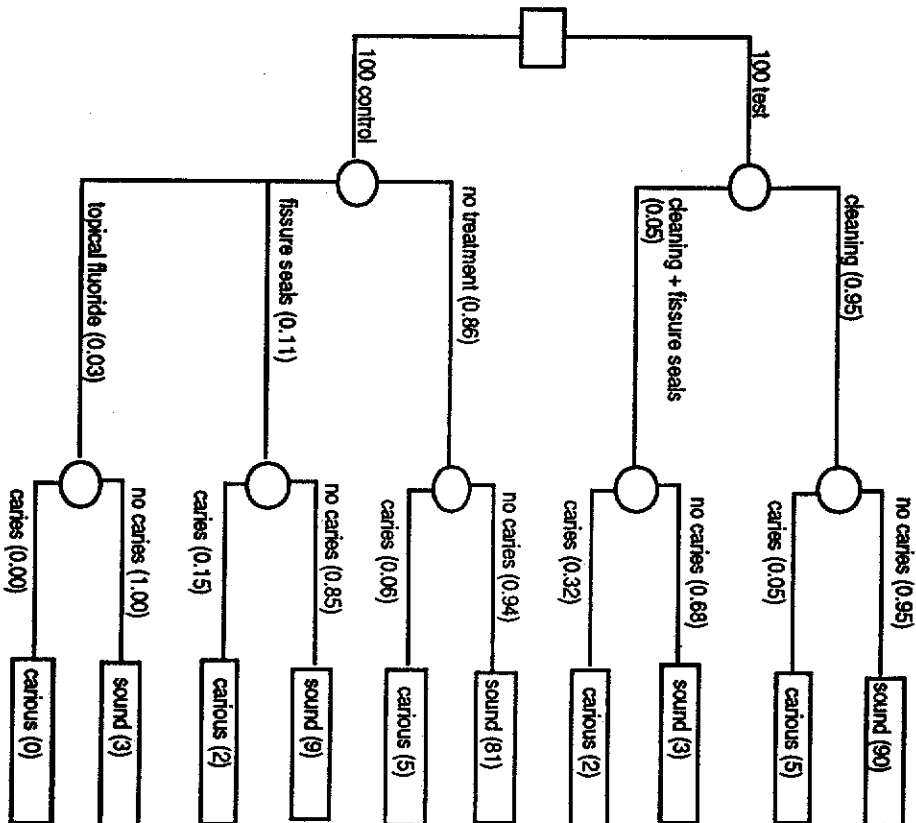
Although direct costs to the consumers of the service were not measured, the frequency of visits for treatments was used as an indicator of the costs borne by individuals receiving treatment. The frequency of visits for test and control children is shown in Table 65. During the first year, test group children had more visits than control children ($\chi^2 = 90.8$, 4 df, $p < 0.001$), and in the second year, the frequency of visits between the groups was similar ($\chi^2 = 2.1$, 4 df, $p = 0.72$).

Table 65   Frequency of visits for each year of the study

	1st 12 months		2nd 12 months	
Visits	Control	Test	Control	Test
0	19	1	20	26
1	85	31	99	109
2	44	138	25	30
3	0	1	4	4
4	1	0	0	2

The number of teeth receiving each type of preventive treatment is shown in Table 66. Children who were recorded as having experienced caries during the first year were included among the children receiving preventive treatments and in calculating the costs of preventive care during the second year, but were excluded when calculating the probabilities and caries outcomes for the second year.

During the first year, when the first permanent molars were erupting, 50% of the children in the control group received some specific preventive treatment on the first permanent molars, but during the second year only 14% of the control children were provided with specific preventive treatment on the first permanent molars.

Table 66   Number and types of treatments received by test and control participants for the first and second twelve months

Treatments	1st 12 months		2nd 12 months	
	Test (n*)	Control (n*)	Test (n*)	‡Control (n*)
Fissure sealants	28 (11)	173 (54)	20 (8)	48 (17)
Topical fluoride		55 (20)		12 (4)
Professional cleaning	(158)		(161)	
None	(2)	(75)	(2)	(127)

* The number of children are in brackets. ‡ One control attended for care elsewhere

Information on the unit cost of materials was obtained from Dental Services' Supply Division. The unit costs of all materials, except the cleaning paste, were the same for both years of the study. Labour costs were based on the wage costs as at July of each year and were marginally higher during the second year (2.3%–4.1%). The second year costs were deflated (0.964) and discounted (5%) to 1994. Table 67 details the costs for test and control groups during the second year of the study. Some material costs, for example bristle brushes, were the same regardless of the number of teeth treated per individual, while other material costs, for example fissure sealant materials, increased with increasing number of teeth treated.

Costs of treatments for a test or a control child are shown in Table 68. The cost of fissure sealing teeth in a test child is less than that of a control child because, on average, test children had fewer sealants placed per child (2.5 sealants/child in each year) compared with control children (3.2 sealants/child in the first year and 2.8 sealants/child in the second year).

Table 67   Costs for preventive procedures for test and control groups (2nd year, undiscounted and undeflated)

Factors	Unit costs ($)	Cost per child per procedure ($)
Labour Dental Therapists	Mean=$0.276/min.	Test sealants = 2.07 Control sealants = 2.32 Test cleaning = 1.38 Control topical fluoride = 1.38
Dental Clinic Assistants	Mean=$0.195/min.	Test sealants = 1.46 Control sealants = 1.64 Administration = 0.29
Fissure sealing materials Glass-ionomer cement	$50/12g pack ≈ 160 sealants	Test 2.5 sealants/child = 0.78 Control 2.8 sealants/child = 0.88
Bristle brushes	$57/144 brushes	1/child = 0.40
Hydrogen peroxide	$0.58/100ml	4ml/child = 0.02
Cotton wool rolls	$11.30/1000 rolls	2–4 rolls ≈ 0.02–0.05
Dry guards	$26.55/200 guards	2 guards ≈ 0.27
Pumice powder	$6/500g	1–2g ≈ 0.01
Cleaning materials		
Prophylaxis paste	$16/100g jar	Test ≈ 1.35 g/child = 0.22
Bristle brushes	$57/144	1/child = 0.40

Table 68   Cost of treatment per child provided with the treatment for test and control children (undiscounted, undeflated)

	1st Year		2nd Year	
Treatments	Test	Control	Test	Control
Fissure sealants	$4.97	$6.14	$5.04	$5.57
Professional cleaning	$1.87		$2.00	
Topical fluoride		$1.35		$1.38
Administration	$0.29	$0.29	$0.29	$0.29

The total cost for 100 children allocated either into a test or a control programme for the whole two years is detailed in Table 69. A discount rate of five percent and deflation factor 0.964 (obtained from the Australian Bureau of

Statistics, Consumer Price Index for the Health sector, a weighted average of eight capital cities) was applied.

Table 69   Two-year cost of treatments for a cohort of 100 children allocated to either the test or the control programme

Treatments	Test	Control
Fissure sealants	$58	$277
Professional cleaning	$542	
Topical fluoride		$23
Arrange appointments	$89	$69
Total	$689	$369

The incremental cost-effectiveness ratio was:

$$\frac{689-369}{82-78} = \frac{320}{4} = \$80 \text{ / child or } \$40 \text{ / child / year}$$

The sensitivity of the ratio to variations in labour costs was tested. When the wage rates of the clinicians and chairside assistants were set at the minimum of the salary scale the incremental cost-effectiveness ratio was:

$$\frac{615-328}{82-78} = \frac{285}{4} \approx \$72 \text{ or } \$36 \text{ / child / year}$$

and when the wage rates were at the maximum:

$$\frac{785-415}{82-78} = \frac{370}{4} \approx \$93 \text{ or } \$47 \text{ / child / year}$$

When the 95% confidence limits of the rate difference were used to test the sensitivity of the cost-effectiveness ratio, the lower limit has no meaning because it was negative. At the upper limit there were 13 children in the test group prevented from experiencing first permanent molar caries. The incremental cost-effectiveness ratios when the risk difference was at the upper limit of the 95% confidence interval, and the wage levels were at maximum, average, and minimum were, $14/child/year, $13/child/year and $11/child/year,

respectively. Varying the discount rates between 3–10% did not alter the findings appreciably. When average labour costs were used at 3% discount rate, the incremental cost-effectiveness ratio was approximately $40/child/year and when the discount rate was set at 10%, the cost-effectiveness ratio was approximately $38/child/year.

CHAPTER 5
DISCUSSION

AIMS OF THE STUDY AND SUITABILITY OF THE RESEARCH DESIGN

The aims of the present study were:

1. To test under field conditions the hypothesis that a suitably tailored professional cleaning programme with individualised dental health education and individualised recall intervals would prevent occlusal pit and fissure caries as effectively as the standard preventive programme in a functioning school dental service.

2. To compare the cost-effectiveness of the test programme with the standard programme by the development of a suitable effectiveness measure and a resource-based costing approach.

A pragmatic field trial design was chosen as being the most appropriate study design because it allows the assessment of what is achievable by a programme in a real-life situation (Schwartz and Lellouch 1967), thereby assisting in policy decision-making (Lennon et al. 1980). Furthermore, a cost-effectiveness analysis based on the findings of a pragmatic trial may have stronger external validity because it is based on actual community behaviour in a real-life setting and not on findings from artificially controlled conditions of a clinical trial (Drummond and Jefferson 1996). However, the limitation of this study design in controlling the standardisation of study protocol is recognised.

The children in the present study were not randomly sampled; they were a convenience sample from an administrative area of the School Dental Service of Western Australia (SDS). A comparison of deciduous tooth caries experience of study participants and other children enrolled with the SDS indicated that they had similar deciduous caries experiences. However, the study participants were

from lower socio-economic areas compared with the rest of the children in the SDS. This has the effect of increasing the power of the study because low SES groups exhibit greater susceptibility to dental caries and contribute more towards demonstrating differences (if any) in disease occurrence between the study groups (Burchell *et al.* 1991). It also has the potential to inflate any differences compared with what might have been observed in the population as a whole.

Study participants were 6-years-old, on average, at the commencement of the study and were enrolled with the SDS. In WA, over 90% of eligible schoolchildren are enrolled with the SDS (Riordan 1995), therefore the findings from this study can be reasonably applied to 6-year-old schoolchildren in fluoridated communities in Western Australia. However, the findings of this study may not be generalisable to populations elsewhere, especially to regions where organised school dental care and community water fluoridation are not available.

Validity and reliability issues

The issue of validity of caries diagnosis was not directly addressed in this study. Ethical and practical considerations, as outlined earlier, did not allow for validation through histological examination of sectioned extracted teeth. The method of caries diagnosis used in the present study (visual and tactile examination) has high specificity and low sensitivity (Angmar–Månsson and ten Bosch 1993). Low sensitivity of the visual and tactile method could have resulted in some carious lesions being overlooked, but, if the examiner held a reasonably consistent diagnostic standard then the extent of missed carious lesions should be similar for both groups and should have no effect on the comparison of effects between groups (this factor was controlled in the present study by 'blinding' the examiner). Low sensitivity of the diagnostic method could

have the effect of overstating the effectiveness of both preventive programmes. However, the visual and tactile method of caries diagnosis is the most widely used method of caries diagnosis in clinical practice and the findings by this method are more likely to be valid for clinical practice.

Examiner consistency was established by calibration of the examiners one month before the twelve-month examinations, Tables 18–25. Assessment of examiner reliability indicated 'excellent' inter- and intra-rater reliability of clinical diagnosis for deciduous tooth status (kappa was in the range 0.88–0.89) and 'substantial' inter- and intra-reliability of diagnosis for permanent molar status (kappa range 0.66–0.86) (Landis and Koch 1977). During calibration, it was noted that most disagreements were in the diagnosis of initial caries and it is likely that diagnostic reliability for the permanent molars would be higher if the category of initial caries were excluded (Palmer et al. 1984). This contrasts with the findings of Pitts and Fyffe (1988), who found minimal effects on reliability when the early stages of caries were included in the diagnosis. Because of poor reliability of diagnosis of initial caries, the category was excluded from analyses of the outcome. Also, during the course of the study, it was observed that the presence of initial caries had no influence on the clinicians' management of the preventive treatment of a tooth, and the exclusion of the initial caries category from the analysis was judged unlikely to have affected the study findings.

The number of participants lost to follow-up after two years was relatively small (17%). The majority were lost because of the family relocating to another region and were unable to be contacted for review, 16 failed to keep the review appointments and 4 children withdrew from the study for various reasons (the parents of one child were unable to supervise their child for toothbrushing, another preferred not to use fluoride agents and two attended for care from a

private practitioner). An assessment of the baseline deciduous caries experience of children lost to follow-up indicated a slightly higher caries experience, but the difference was not statistically significant, compared with children who were reviewed after twenty-four months.

More children were lost from the control group than the test group and children who were lost to follow-up were more likely to have lived in the lowest socio-economic areas. However, there were no statistically significant differences in baseline deciduous caries experience and the SES levels of children lost to follow-up from the control and the test groups. At the twelve-and twenty-four-month reviews more children who were lost to follow-up from the control group were irregular brushers. Given the finding in this study that irregular brushers were more likely to experience first permanent molar caries than children who brushed at least once-a-day, the children lost to follow-up could have biased the findings of this study towards the null hypothesis.

Oral hygiene and caries control

It has been a long held belief that a clean tooth does not decay, but scientific evidence to support mechanical cleaning of teeth as an effective means of caries prevention has been lacking (Addy 1986; Bellini *et al.* 1981). There have been reported exceptions, such as the Karlstad studies (Axelsson and Lindhe 1974; Lindhe and Axelsson 1973), but the fact that these studies have been difficult to replicate could indicate that special local factors were at work. Recently, interest in mechanical plaque control as a form of caries preventive technique was rekindled with reports from Denmark that pit and fissure caries of the first permanent molars were effectively prevented by these means (Carvalho *et al.* 1991; Carvalho *et al.* 1992), and studies from other European countries supporting an association between oral hygiene and dental caries

(Aleksejuniene *et al.* 1996; Ekstrand *et al.* 1997; Mathieson *et al.* 1996; Øgaard *et al.* 1994; Tubert-Jeannin *et al.* 1994).

The claim by Carvalho *et al.* (1992) of pit and fissure caries prevention by plaque control is of interest because these lesions dominate the total caries burden among children (Chestnutt *et al.* 1996; Li *et al.* 1993). Existing methods to control pit and fissure caries are relatively expensive, usually requiring skilled personnel and specialised equipment and materials. Therefore, an effective, low-cost, low-technology method of pit and fissure caries control would be valuable. However, the studies by Carvalho *et al.* (1991, 1992) had low numbers of participants, lacked a concurrent control group, and did not test the hypothesis they endorsed. The purpose of the present work was to test the hypothesis that individually tailored oral health instructions and frequent dental recall visits to monitor progress would be sufficient to prevent or reduce the occurrence of occlusal caries.

The present study found minimal differences in first permanent molar caries increment, deciduous tooth caries increment and plaque accumulation between the test and control groups, after twelve and twenty-four months, Tables 49-50. The study did not set out to test the efficacy of the professional cleaning and oral health education programme, but aimed to compare the effects of the test programme with an established programme within a functioning school dental service, thus a 'positive' control group rather than a non-intervention control group was used. Therefore, it is possible that lack of a statistically significant difference between the groups, in the absence of a true control group, may be an indication that both programmes were equally effective or equally ineffective.

The findings of the present study contrast with the findings of Carvalho *et al.* (1991, 1992), who found oral hygiene measures were more effective than fissure

sealing in preventing occlusal pit and fissure caries. However, the present study is not directly comparable with the study by Carvalho *et al.* (1992). This study was set in a functioning school dental service using a larger number of participants, a pragmatic field design and a concurrent comparison group. However, participants of both studies had the advantage of living in a community with optimally fluoridated water supply, and nearly all were using fluoride toothpastes.

The interval between recall visits for children in this study was relatively long (6–12 months) compared with the recall interval (1–6 months) in the study by Carvalho *et al.* (1992). The intervals between examinations for children enrolled with the SDS have been increasing gradually (mean interval 13 months in 1994) without any apparent adverse consequences on the children's oral health (Riordan 1995), and for the test procedure to be cost-effective, the intervals between recall visits needed to approach the recall interval of the control group. A follow-up period of twenty-four months is relatively short, although it is of sufficient duration for caries to develop and to enable an assessment of the effects of the two preventive programmes. The emphasis of the study also was to study the preventive effects on newly erupted molars.

Unlike the study by Carvalho *et al.* (1992), where the majority (69%) of children in the historical comparison group had received fissure sealants, members of the control group in the present study were provided with preventive care selectively and not all children received specific preventive care. All clinicians with the SDS were issued guidelines on determining the risk status of a child and the selection of a child for preventive care depended on a clinician's assessment of each child's risk status.

The findings of this study are consistent with other studies that found oral hygiene measures on their own have minimal effect in reducing the incidence of dental caries (Ashley and Sainsbury 1981; Craig *et al.* 1981; King *et al.* 1985). It has been suggested that the spectacular success of the Karlstad studies might be due to the unusually enthusiastic and motivated clinicians performing the cleaning and educational procedures (Koch *et al.* 1994). A similar effect may have been at work in the studies by Carvalho *et al.*(1991, 1992). Clinicians in the present study were not selected; they were the clinicians allocated to the dental clinics. There was no reason to believe that they were any more or less motivated or enthusiastic than other clinicians in the SDS.

The findings of this study suggest that both programmes had similar effects on the occurrence of occlusal pit and fissure caries in the first permanent molars. The estimated risk ratio (0.82; 95% CI 0.53—1.28) for children who were examined at both annual reviews indicated a protective effect of exposure to the test programme, but it was not statistically significant (95% confidence interval includes one). The risk difference (attributable benefit) also indicated protective effects of exposure to the test programme (0.03; 95% CI -0.06—0.11), but the 95% confidence interval includes zero, which means that there was no statistically significant difference in risk between test and control groups. The test group children also had fewer first permanent molars with caries, but the difference was not statistically significant. The difference was probably due to the higher proportion of children with hypomineralised teeth among the control group. When multivariate analysis was used, which controlled for other independent factors, the test or control status of a participant had no statistically significant influence on the occurrence of caries.

In the present study, the control group was provided with specific preventive treatments on a selective basis. Recent studies have shown a low prevalence and

incidence of permanent tooth caries among WA children (Arrow and Riordan 1995; Barnard 1993; Riordan 1993), and because of the low incidence of caries, the net gain from universal application of preventive measures will tend to be low and selective application of preventive agents to 'at risk' children only is justified. Also, the use of glass-ionomer cements as fissure sealants has been shown to be effective in preventing occlusal pit and fissure caries (Arrow and Riordan 1995; Williams *et al.* 1996). In this study, the operation of selective preventive care among control children and its absence among the test group children has the potential to inflate the cost of care provided to test group children.

The School Dental Service's guidelines for preventive treatment of newly erupting permanent molars recommends that fissure sealing is done selectively (based on assessed risk) and all newly erupted molars not fissure sealed should receive an application of topical fluoride. Previous caries experience is a factor to be considered in determining caries risk. An assessment of deciduous tooth caries experience among control children provided with specific preventive treatments indicated that children with any caries experience were more likely to receive preventive treatments (fissure sealants). Studies have shown a close association between previous caries experience and subsequent caries increments (Bader *et al.* 1986; Demers *et al.* 1990; Disney *et al.* 1992; Gray *et al.* 1991; Helfenstein and Steiner 1994; Raadal and Espelid 1992; Steiner *et al.* 1992), and the present study found that clinicians who treated the control group were using previous caries experience to determine risk status and to decide on a preventive treatment strategy.

After twelve months, bivariate analyses indicate that the effects of the test programme were similar to those of the control programme in controlling caries of the first permanent molars, caries of the deciduous teeth and the levels of

plaque accumulation. Multivariate analyses were used to test the effects of multiple independent factors on the occurrence of dental caries. Analyses of the twelve-month data indicated that, although the caries outcome data did not fully meet the assumptions of the multiple regression model, the results of the regression model and the multiple logistic model were in close agreement. This suggests that the linear regression model may be robust and assist in explaining the data.

After twelve months, multivariate analyses using multiple linear regression and multiple logistic regression found past deciduous tooth caries experience and the presence of hypomineralised first permanent molars to be statistically significant predictors of occlusal caries in the first permanent molars. When the data were fitted using Poisson regression, reported toothbrushing frequency (irregular brushing) was found to be an additional statistically significant risk factor for caries. After twenty-four months, using Poisson regression, past deciduous tooth caries experience, presence of hypomineralised molars and reported frequency of toothbrushing were found to be statistically significant predictors of occlusal caries in the first permanent molars, Table 56. These same variables were also statistically significant risk factors for the occurrence of molar occlusal caries in the longitudinal model, Table 57.

Multiple linear regression produced a model with past deciduous tooth caries experience, presence of hypomineralised first permanent molars and reported frequency of toothbrushing as statistically significant predictors of first permanent molar caries after twenty-four months, Table 51. The model equation can be written as:

$$DMFT = 0.34 + 0.88(hypomin) + 0.04(dmfs) -$$
$$0.24(brush\ once - 0.32(brush\ twice) + 0.32(brush\ unknown)$$

The linear model predicts that, after two years, a child who has a baseline dmfs of 10, hypomineralised first permanent molars and an unknown brushing frequency can expect to have an occlusal caries increment of about 2 DMFT. The model also predicts one child in fifty with zero baseline dmfs, no hypomineralised first permanent molars and brushes at least twice a day will have one first permanent molar tooth with occlusal caries. The R^2 value for the model was relatively low and in keeping with findings from other studies (Granath, 1991; Dummer et al. 1990b).

Hypomineralisation and caries

The regression model indicates that the presence of hypomineralised first permanent molars had a strong effect on the occurrence of first permanent molar caries (almost one more carious tooth). After twenty-four months, the logistic regression of individuals with first permanent molar caries experience indicated a nearly 12-fold increased risk of caries among children with hypomineralisation, Table 53. When individual tooth data were used in the logistic regression with the GEE to control for the correlation between teeth within an individual, the risk of occlusal caries for hypomineralised first permanent molars was higher than analysis based on individuals, Table 55. However, the correlations between teeth were relatively low (0.30–0.00) and, in this instance, the assumption of independence between teeth would not have affected the parameter estimates greatly (DeRouen et al. 1991). Poisson regression indicated a 7-fold increased rate of occlusal first permanent molars caries among children with hypomineralised molars, Table 56.

Although this study found an increased risk of caries with the presence of hypomineralised molars, there appears to be a lack of agreement within the dental literature on the exact mechanism of the relationship. An early case study found that hypomineralised teeth were no more likely to decay than

normal teeth (Toller 1959). A Swedish study found that children with hypomineralised teeth developed caries earlier, frequently had more irregularly shaped restorations and presented treatment difficulties (Koch *et al.* 1987). Two recent studies also reported conflicting findings (Ellwood and O'Mullane 1996; Li *et al.* 1996). Li *et al.* (1996) found higher risk of caries among children presenting with enamel hypomineralisation compared with children without hypomineralisation. Ellwood and O'Mullane (1996) found that when children were categorised, using the TF index of fluorosis, according to the severity of enamel opacities (hypomineralisations), children with a higher severity score (indicating presence of more severe opacities) had a lower caries index scores. However, the caries experience of children with demarcated opacities (more severe hypomineralisations not associated with fluorosis) was higher than the caries experience of children without demarcated opacities.

In the present study, many children (16 out of 47) with hypomineralised teeth had had them restored and 9 children with hypomineralisation had these teeth recorded as being carious. It is possible that hypomineralised teeth were more likely to be restored for reasons other than caries, for example, hypomineralised teeth are more likely to experience sensitivity due to the loss of enamel and subsequent exposure of dentine. Therefore, the association observed could be that of hypomineralisation and treatment decisions.

The overall prevalence of hypomineralisation observed in this study was 0.14, which compares with a prevalence of 0.15 found by Koch *et al.* (1987), in Sweden, among a cohort displaying high prevalence of hypomineralisation. The present study did not record the severity of hypomineralisation, only its presence or absence was scored. The association, if any, between severity of hypomineralisation and caries could not therefore be examined. However, the examiner was instructed to record as hypomineralised only those lesions which

definitely could be ruled out as cases of mild fluorosis, and only the first permanent molars were scored, therefore the association was more site specific than in other studies. It is likely that only the more severe cases of enamel hypomineralisation were recorded in this study. Other studies have shown that children with more 'severe fluorosis' tend to have more caries than their counterparts without fluorosis (Driscoll *et al.* 1986; Forsman 1974; Mann *et al.* 1990). Driscoll *et al.* (1986) hypothesised that severely fluorosed teeth may be more at risk of caries because structural irregularities in these teeth lead to enamel fracture and allow plaque and debris to accumulate more easily and form areas of stagnation, which can lead to caries development.

Past deciduous tooth caries experience and molar caries

The present study found increased numbers of first permanent molars with caries experience as deciduous tooth caries experience increased. The linear regression model indicated a 0.4 DMFT increment for every 10 deciduous surfaces affected by caries at baseline (Table 51), and the logistic regression indicated a 10% increased risk of individuals experiencing first permanent molar caries for one more deciduous tooth surface affected by caries at baseline, Table 53. The risk of molar caries at twenty-four months was marginally higher after intra-individual correlation between the molars was controlled, Table 55. Poisson regression indicated a 9% increased rate of first molar caries occurrence with one additional baseline deciduous surface affected by caries, Table 56. The risk of molar caries remained constant for the two years for deciduous caries experience. Deciduous tooth caries experience has been shown in other studies to be strongly associated with subsequent caries development in permanent molars (Gray *et al.* 1991; Raadal and Espelid 1992; Steiner *et al.* 1992).

Toothbrushing frequency and caries increment

Multiple linear regression and logistic regression indicated that frequency of toothbrushing was of marginal statistical significance in first permanent molar caries increments after two years; it had a relatively weak influence on caries occurrence during the first twelve months. Poisson regression, which took account of time at risk of each individual tooth, indicated a stronger effect of frequency of toothbrushing on caries after two years. Children who brushed their teeth at least once a day were less likely to get caries than children who brushed irregularly (RR=0.51 for once a day brushers and RR=0.39 for twice a day brushers).

The possibility of bias twards the null effect from misclassifying individuals into toothbrushing groups has been discussed previously. It is possible that individuals over-reported their true toothbrushing frequency, either because they felt themselves to be at a higher risk of decay experience or because they felt more frequent brushing to be more socially acceptable. Although in this instance the reporting was done by the parents of child participants and there is likely to be minimal over-reporting. What ever the reason, such misclassifications from over-reporting are likely to bias the estimates towards the null effect and the finding of a statistically significant effect in this study suggests that the effect may be even stronger.

A one-way analysis of variance to test the effect of frequency of toothbrushing on plaque levels found no statistically significant difference in plaque levels among the different brushing groups. It is likely therefore that the caries preventive effects of frequent brushing were due more to the frequency of exposure to fluoride toothpastes than to the mechanical cleansing action of toothbrushing. Similar findings of lower caries experience among frequent toothbrushers have been reported (Ainamo and Parviainen 1989; Chesters *et al.* 1992; Moorhead *et*

al. 1991). Ainamo and Parviainen (1989) attributed the lower caries levels among frequent brushers to more frequent exposure to fluoride from fluoride toothpastes and suggested that toothbrushing may contribute to caries reduction if fluoride toothpastes were used. A survey of experts for the reasons behind the caries decline indicated that the majority felt fluoride toothpastes were of major importance (Bratthall *et al.* 1996).

The finding of a stronger caries preventive effect of frequency of toothbrushing after two years and a relatively weak effect after the first year is of interest. Hujoel *et al.* (1994) found, in a re-analysis of a Xylitol caries preventive trial, a stronger preventive effect of the test agent in the second year on newly erupted teeth. They suggested that this may be due to a 'lag' effect commonly observed with preventive programmes, and also that maturation of newly erupted teeth under favourable physico-chemical conditions conferred longer term benefits. In the present study, the teeth of frequent brushers were more likely to mature under favourable conditions (frequent exposure to low-dose fluoride from fluoride toothpastes), resulting in reduced caries incidence after a period of time (two years).

Plaque and caries increment

This study found lower levels of plaque among both the test and control group after twelve months and a statistically significantly lower plaque level for the whole cohort at twelve months compared with the level at baseline, *p* <0.05. The reduction in plaque level during the second year was smaller than the reduction during the first year and plaque level at the end of second year was similar to the level after the first year. This study does not explain the reasons for the reduced plaque levels. The majority of teeth were only partially erupted at the commencement of the study, and it is possible that as the teeth came into functional occlusion they became easier to clean by mechanical actions such as

chewing and toothbrushing (Thylstrup and Fejerskov 1994). Furthermore, as the study progressed the children may have become more proficient in their mechanical plaque control practices as they matured physically. It is highly unlikely that plaque reduction of the magnitude observed in this study would have any clinical significance.

It is also possible that some 'spillover' of oral hygiene knowledge occurred. Ashley and Sainsbury (1981) noted that spillover effects of oral health education may have affected the findings of their study. In the present study, group randomisation was used to minimise the risk of 'spillover' (Buck and Donner 1982). However, all the clinicians were part of one administrative area and communicated with each other regularly, so it is possible that information on the test procedures, despite instructions not to discuss these, could have reached clinicians in the control clinics, influencing their management of the control group.

In this study, the presence of plaque had no statistically significant effect on the occurrence of dental caries on the pits and fissures of the first permanent molars. Early studies used plaque indices designed to measure plaque for periodontal health and did not specifically measure plaque in the pits and fissures (Bellini et al. 1981). In this study, the distribution of plaque on the occlusal pits and fissures was mapped onto drawings of occlusal morphology of the first permanent molars. Carvalho et al.(1989) also mapped the distribution of plaque on the occlusal surfaces and demonstrated a close association between plaque accumulation and incipient caries, and caries was found in areas where thick plaque was present. Although in their study the examiners were not blind to the status of the participants. Plaque thickness appears to be implicated in the carious process (Newman 1986); the present study did not measure the thickness of the plaque. Although the relationship between plaque and dental

caries has been well established, the relationship appears to be stronger for smooth surface lesions than for pit and fissure lesions (Newman 1986).

Socio-economic factors and caries increment

This study did not find socioeconomic (SES) factors to be important in the incidence of caries. Poorer oral health outcomes for children from lower SES groups have been shown in other studies (Brown *et al.* 1990; Carmichael *et al.* 1984; Carmichael *et al.* 1989; Hausen *et al.* 1981). The variable used in this study for SES was an ecological variable; attributes derived from groups (census derived SES at the collector district level) were assigned to individuals. A recent West Australian study found a lower level of misclassification when individuals were assigned a SES level derived from information collected at the collector district level compared with SES defined at the residential post code level (Hyndman *et al.* 1995). In this study, there is likely to be some misclassification of individuals; however, the type and extent of misclassification could not be determined. The misclassification in this study is more likely to be *non-differential* rather than *differential* because the classification of exposure (SES determined by location of residence) and disease (caries occurrence) were independent of each other (Rothman 1986). If the misclassification was non-differential then it would have biased the effects towards the null hypothesis (Rothman 1986).

In dental research, area-based measures have been used to examine differences in oral health experiences among individuals (Ellwood and O'Mullane 1995; Locker and Ford 1994). In comparing the ability of an area-based measure of social inequality with household income to discriminate oral health status, Locker and Ford (1994) found household income was a better discriminator than an area-based measure. They concluded that area-based measures can be useful because information for classifying individuals is easily obtained, area-based

measures are able to identify differences in health status between sub-groups with similar standards of living, area-based measures can measure the independent effects living in a particular area has on the health status, and area-based measures can serve as a tool in identifying and directing resources to areas with greatest needs.

Locker and Ford (1996) further explored the utility of area-based measures to predict health outcomes among the elderly by comparing the effects on oral health of self-reported household income with the mean income of a census defined area (Locker and Ford 1996). They found that self reported income was a better predictor of the rated health variables than the area mean income, but the area-based measure had independent effects on oral health when self-reported income was controlled. Also, the effect measures of the two variables were broadly similar; for example odds ratio for edentulousness was 2.6 for reported individual income and 2.1 for area-based income. They also noted that although the potential for misclassification was high its effects were lessened by reducing the numbers of elderly persons in the sample, and, by using area-based measures, non-response bias to questions on household income can be reduced.

A recent Australian study also found independent effects of income and education on caries experience in children after controlling for fluoride exposure (Slade *et al.* 1996b). It is possible that because participants in the present study were from geographically close areas that the SES levels among the participants were quite uniform and may not have contributed towards differences in disease levels between SES levels. Thus a finding in this study of no independent effects of SES (as defined in this study) on caries occurrence should be interpreted with caution.

The socioeconomic level of participants in this study was relatively low (mean SES = 953 ± 105). While low SES tends to be associated with higher levels of caries occurrence (so increasing the power of the study), it has been argued that health education programmes create or widen health inequalities between low and high socioeconomic groups (Schou and Wight 1994). Higher socioeconomic groups are more likely to put into practice the preventive strategies recommended in dental health education programmes (Gift 1986). Clinicians in this study reported a lack of interest by the parents of some of the children in the test programme. Few parents whose child attended the school at which the dental clinic was situated attended for their child's dental appointments and some parents did not comply with the oral hygiene recommendations. This is in contrast to the situation reported by Carvalho *et al.* (1992) in Nexø where, although the participants had lower SES than the national average, parents were closely involved.

Health education and caries increment

The health education component of the test programme aimed to motivate the parent(s) and child to improve the child's oral hygiene practice and to maintain it at a high level for a period of time. Patient motivation is an extremely important facet of health education (DeBiase 1991), and it may be that a health education programme where clinician and patient interaction were brief (at most 10–15 minutes once every six months) was inadequate to produce a strong and lasting influence on health behaviour. It has been suggested that health education programmes may be effective in increasing the knowledge level, but have minimal influence in changing behaviour (Rayant 1979; Rayant and Sheiham 1980). An intensive oral health education programme (fortnightly sessions) conducted among 11–13 year-old children in Denmark found little difference in oral health indices between the groups, but found an improvement in knowledge and attitude towards oral health (Agerbæk *et al.* 1979). A recent

meta-analysis concluded that dental health education programmes were effective in improving knowledge levels, had a positive effect on plaque control in the short term, had no effect on caries levels, and had equivocal effects on changing dietary habits (Kay and Locker 1996). However, the analysis was only able to include 7 out of 143 studies published between 1982 and 1994, the remainder were excluded because of poor quality.

Preventive treatments and caries

Twice yearly professional cleaning programmes have been shown to be of limited value in the control of caries (Ripa *et al.* 1976). It is therefore of interest that such a programme (this study) was able to achieve similar levels of caries prevention compared with a programme of selective fissure sealing and application of topical fluorides. The control group children were provided with sealants selectively. It may be that the criteria applied in caries risk assessment to select children were not sensitive or specific enough to identify 'at risk' children. It is also possible that the preventive procedures that were implemented for the identified children were not sufficient to prevent the occurrence of caries. Studies elsewhere have shown that even though clinicians are able to identify high risk children and provide extra preventive treatments, high caries risk children still experienced higher caries increments compared with low caries risk children (Seppä *et al.* 1991; Varsio and Vehkalahti 1996).

The participants in this study were residents of a community with an optimally fluoridated water supply and the majority were using fluoride toothpastes. It is possible that neither the test nor the control procedure added anything to the already high baseline prevention these children were receiving. Also, it has been suggested that the carious challenge to the children who experienced caries may be so great that present day preventive procedures may not provide adequate protection (Alanen *et al.* 1994; Seppä *et al.* 1991).

In the present study the probability of a child who has received fissure sealants developing caries later (nearly half the children in test group and one-third of the children in the control group in the first year) is higher than that reported in the literature elsewhere (Bravo et al. 1996; Ripa 1993; Williams et al. 1996). It may be that children who received sealants have already shown themselves to be at high risk of caries (as judged by previous deciduous tooth caries experi-ence), and in these children additional preventive efforts may have little effect on caries. It is also possible that, by the time preventive treatments were pro-vided, the carious process was too advanced to arrest. Children within SDS are being seen at relatively longer recall intervals and may not have been seen at a time when their teeth were at greatest risk of experiencing caries. By the time an at-risk child was seen for a recall appointment, the tooth might already have developed a cavity. In which case, other sound teeth could have received preventive treatment (that is sealants) and the at risk children may then appear to experience caries despite receiving preventive treatments.

Use of multivariate model to predict molar caries

A multivariate logistic model was used to determine the utility of the model as a caries screening test. The close association between deciduous tooth caries experience and subsequent permanent molar caries has been used in a number of caries prediction models (Gray et al. 1991; Raadal and Espelid 1992; Steiner et al. 1992). Gray et al. (1991) reported sensitivity of 0.63 and specificity of 0.88 when the cut-point was dmft ≥ 4, and sensitivity and specificity of 0.68 and 0.67, respectively, when the cut-point was dmft ≥ 1. Raadal and Espelid (1992) reported sensitivity of 0.71 and specificity of 0.79 when the cut-point was at 4 dmft and sensitivity and specificity of 0.80 and 0.40, respectively, when the cut-point was dmft ≥ 1. In the present study, using first permanent molar caries experience at twenty-four months as the validating criterion (DFT≥1), sensitivity of 0.67 and specificity of 0.61 were obtained when the cut-point was

dmfs≥1, Table 62. The caries increment in this study was low (DMFT = 0.3 after two years) compared with the two-year caries increment of 0.6 DMFT in the study by Raadal and Espelid (1992). The low positive predictive values in the present study also reflected the low caries prevalence of the study population.

The sensitivity and specificity values increased when hypomineralisation and baseline dmfs were combined. The ROC curve analysis indicated an improvement in prediction of 19% over the use of dmfs alone and 14% over using hypomineralisation alone (Figures 2–4); addition of further variables did not result in improved prediction models. In using the combined variables, the logistic model indicated that a cut-point of 4 dmfs for a child without hypomineralisation would maximise both sensitivity and specificity at about 0.72, Figure 5. From the Figure, a cut-off probability of about 0.14 would maximise both sensitivity and specificity, both about 0.72. The model can be used to estimate the cut-points for hypomineralisation and dmfs to obtain the desired sensitivity and specificity. The model in logit form is:

$$\ln\left(\frac{p}{1-p}\right) = a_0 + a_1 x_1 + a_2 x_2 + \ldots\ldots$$

where p is interpretable as the probability of an event occurring.
The model is:

$$\ln\left(\frac{0.14}{1-0.14}\right) = -2.27 + 2.47(hypo) + 0.11(dmfs)$$

The model indicates that for a child without hypomineralisation, the cut-point dmfs to achieve sensitivity and specificity of 0.72 is approximately 4 dmfs. For a child who has hypomineralised permanent teeth, the value for dmfs calculates as a negative number, which is meaningless in the context of caries and can be interpreted as indicating that in the presence of hypomineralisation, baseline caries experience is not a clinically significant factor in predicting first permanent molar caries. The low positive predictive values obtained in the

present study indicates that the chosen criteria will still misclassify a large number of children.

The cut-point for classifying children depends on the aim(s) of screening. If the aim is to select all children likely to experience caries so that preventive treatment can be directed at them, then a criterion with high sensitivity should be used. If, however, the screening seeks to eliminate children who will not get caries then a screening test with high specificity should be used. Ideally, a screening criterion should achieve both a high sensitivity and a high specificity.

In this study, the best concurrent sensitivity and specificity values that were obtained by using hypomineralisation and baseline dmfs as screening criteria were 0.72, a positive predictive value (PPV) of 0.29 and a negative predictive value (NPV) of 0.94, Figure 5. If this cut-point was used to decide which children were provided with preventive treatments on their first permanent molars, then 29% of children provided with preventive treatment would benefit (PPV = 0.29) and 28% of these would have been provided with preventive care unnecessarily because they would not have developed caries anyway (false positive = 0.28). In the group not provided with preventive care, only 6% could have benefitted from preventive care (NPV = 0.94) in addition to 28% of children who were not provided with preventive care because they were wrongly classified as not being at risk (false negative = 0.28).

The modest predictive ability of the criteria used in this study may be a result of the participants residing in an optimally fluoridated area. A recent study found reduced caries predictive ability of variables that had good predictive power in low fluoride areas when tested among children in an optimally fluoridated area (Twetman and Petersson 1996).

Studies that have examined the issue of predicting caries suggest that screening tests with sensitivity below 0.75 and specificity below 0.85 are not useful (Disney *et al*. 1992; Raadal and Espelid 1992). However, in the context of provision of health care, decisions have to be made (and are being made) on the allocation of limited resources to maximise health benefits. Resources would be allocated efficiently if individuals who could benefit from preventive treatments were identified and provided with appropriate treatments, and individuals who would not benefit from preventive care were also identified and excluded from the preventive programme (Sheiham and Joffe 1991; Stamm 1991). Thus a screening test which can assist in the clinical decision-making would be of value, even if it does not reach the levels of an ideal screening test.

In dentistry, the consequences of a false positive test, where individuals are classified as high risk when in fact they are low risk, are not as severe as in medicine, where a false positive test may lead to inappropriate therapies with adverse, possibly fatal, consequences (a false positive person in dentistry is likely to receive more preventive care). This is unlikely to do any harm, although it will increase the cost of the preventive programme based on that screening criterion. However, a false negative result could have more severe consequences because individuals would then be falsely reassured as to their caries risk status while remaining at risk of caries. Thus in screening to determine risk status in dentistry, a test with high specificity and moderate sensitivity may be acceptable. The development of a screening test using the data from this study may provide an acceptable working solution. However, the results should be viewed as tentative, and the development of a screening test as exploratory. Further development of the screening test with validation of the criteria among different populations is necessary before its use can be recommended while recognising that a screening strategy will always be tentative given that changes in prevalence will affect the usefulness of the screening test.

Post-eruptive period and caries risk

This study found that most of the caries occurred during the first twelve months (0.26 DFT/child) and there was only a modest caries increment during the second twelve months (0.05 DFT/child), Table 48. That newly erupted teeth are at a high risk of caries has been reported in other studies (Carlos and Gittelsohn 1965; Fukada *et al.* 1982; Vehkalahti *et al.* 1991; Virtanen and Larmas 1995). Carlos and Gittelsohn (1965) used survival analysis and found that first permanent molars experienced high rates of caries during the first few post-eruptive years. Other studies have reported a constant risk of caries to first permanent molars, continuing for up to ten years after eruption (Richardson and McIntyre 1996; Ripa *et al.* 1988). The follow-up time of the present study is relatively short (two years) and a longer observation period is required before any definitive conclusions can be made regarding the long term risk of caries on the first permanent molars.

Deciduous tooth caries increments

The present study found previous deciduous caries experience, presence or absence of hypomineralised first permanent molars and sex were strongly associated with the occurrence of deciduous tooth caries. The multiple linear regression equation of deciduous caries increment can be written as (Table 56):

$$\Delta \, \text{dmfs} = 0.15 + 0.71(\textit{hypomin.}) + 0.48(\textit{sex}) + 0.17(\textit{baseline dmfs})$$

The regression equation indicates that a child who is female and has hypomineralised first permanent molars and has 4 deciduous surfaces affected by caries at baseline can expect to have two new deciduous surfaces affected by caries within two years. Only one boy in seven without hypomineralised first permanent molars and no deciduous caries experience can expect to have one new deciduous surface affected by caries within two years.

This study does not explain the association between deciduous caries increment and hypomineralised first permanent molars. It is interesting to speculate whether the conditions leading to the development of hypomineralised first permanent molars had affected the deciduous teeth and thus similarly placed them at a greater risk of caries. In this study, whether or not hypomineralisation affected the deciduous dentition was not assessed. Further research is required before the relationship observed in this study can be explained. Higher risk of caries among females has been reported in other studies (Ashley and Sainsbury 1981; Sutcliffe 1973), and is usually attributed to the earlier eruption of teeth among girls, which exposes the teeth to risk of caries earlier. The close association between past caries experience and caries increment has also been reported in other studies and is the most reliable single predictor of caries occurrence (Demers *et al.* 1990; Hausen *et al.* 1994). The test or control status of the participants had no statistically significant effect on the occurrence of deciduous surface caries.

SUMMARY OF FINDINGS

The findings from this study suggest no difference in effects between a combined professional tooth cleaning and oral health education programme, and a selective fissure sealing and topical fluoride application programme in controlling pit and fissure caries in newly erupting first permanent molars, nor in the control of deciduous tooth caries. This study confirms the relative importance of past caries experience and toothbrushing frequency as factors to consider in determining subsequent caries development. The presence of hypomineralised first permanent molars was positively associated with the likelihood of first permanent molar caries.

Cost-effectiveness of preventive programmes

A cost-effectiveness analysis of the two programmes was also conducted as part of the study, and because of the finding of no statistically significant difference in preventive effects between the two programmes, the analysis can be viewed as a cost minimisation analysis (Drummond *et al.* 1987). The professional cleaning and oral health education programme was more costly than the standard SDS preventive programme. Labour cost was a major component of the total programme cost (almost 75%).

In this study, the time taken to perform various clinical procedures was used as a basis for estimating labour costs. Mackie and Lennon (1984) obtained estimates of procedure times by requesting general dentists (n=26) to complete a questionnaire on the time taken to complete specified preventive treatments. In their study, the mean time and standard deviation for fissure sealing a tooth was 11.0 ± 4.2 minutes. An additional tooth sealed in the same quadrant required 4.1 ± 3.0 minutes. A full mouth professional cleaning required a mean time of 8.1 ± 5.0 minutes. The time estimates were higher than those obtained in the present study (three minutes per tooth to be sealed and five minutes for professional cleaning).

The difference in time for the application of fissure sealants between the studies may be partly explained by the fact that the material used in the SDS (a glass-ionomer cement, GIC) requires less preparation time than BIS-GMA-based sealants. For example, there is no requirement to etch the tooth prior to placing the GIC sealant. Also, in the SDS, clinicians usually control moisture during sealant placement using cotton wool rolls or 'dry guards' and do not use a rubber-dam. The study by Mackie and Lennon (1984) also included the time spent with the patient by the dentist before and after the procedure. In the present study, only the time taken to perform the procedure was recorded. The time for

professional cleaning was similar, and the small difference in time between the studies may be explained by the fact that the clinicians in the present study may have provided professional cleaning to the first permanent molars only (the range of time for professional cleaning varied from 5 to 15 minutes).

Woodward et al. (1995) obtained time estimates from information derived from a management information system of a publicly funded dental service in Canada. The mean time for providing fissure sealants was 11.5 minutes (95% CI 9.5–13.5) and the mean time for professional cleaning was 24.8 minutes (95% CI 16.3–33.3). However, the authors did not report how many teeth were sealed in the time nor the extent of the professional cleaning, therefore direct comparisons between studies could not be made. Also, there could be differences in the materials used for fissure sealing which may partly explain the differences in time for application of sealants between the studies. The reported time by Woodward et al. (1995) also included non-procedural and administrative time.

In the present study the cost-effectiveness analysis was conducted from the perspective of the SDS, and direct costs of care to participants (loss of wage, transport costs, time away from school etc.) were not examined. An analysis of the number of visits made by study participants suggests that, in the first year of the study, participants in the test programme faced more costs than control participants but in the second year the costs were similar.

The cost effectiveness analysis indicates that the test programme fits into cell two of the table on possible outcomes of a cost-effectiveness analysis (Table 13) and it would be economically inefficient to adopt the test programme because it produced statistically equivalent health benefits compared with the standard programme at greater cost. The results of the analysis were not very sensitive to

variations in labour costs, the discount rates and risk differences. However, in the present study all the children in the test programme were provided with professional cleaning and individually tailored dental health education and recall intervals. In a population with low levels of disease occurrence, standardised preventive care for everyone would be inappropriate and inefficient, and a strategy of targeted preventive care may be more appropriate (Hausen *et al.* 1994).

There is, therefore, a potential to reduce the cost of the test programme by applying selection criteria (as was done for the control group) to determine who will receive preventive care. If the test group children were selected for preventive care in the same way as children in the control group (baseline dmfs ≥ 3 received preventive care) then 127 out of 177 children would not have received specific preventive care, which would have reduced the cost of the test programme considerably. If the costs of treatment in the test programme in the present study had been applied to this selected group (50 out of 177), then the test programme would have cost approximately $60 per year for a cohort of 100 children. Although this assumes that children not provided with professional cleaning would not develop caries.

POLICY IMPLICATIONS

The cost effectiveness analysis indicates that the test programme as implemented in the present study clearly does not warrant adoption under the circumstances (costs, disease levels) of the SDS in WA. The trial also indicated that the two methods of preventing occlusal pit and fissure caries produced statistically equivalent health effects. Given that there is scope to reduce the costs of the test programme (by applying selection criteria), the cost-effectiveness of the test programme could be improved. The cost reducing potential of the control programme is limited and better targeting of the current selective preventive

care programme would, at most, eliminate the minor difference in favour of the test programme.

It is of interest that the two programmes produced statistically equivalent health outcomes, especially since other studies have shown no (or reduced) caries preventive effects of less frequently performed professional cleaning (Agerbæk *et al.* 1977; Badersten *et al.* 1975; Ripa *et al.* 1976). It may be, as suggested earlier, that neither the test nor the standard programme added to the already high background prevention these children were receiving from fluoridated water and regular use of fluoride toothpastes. In this case, the current policy of selective preventive care for newly erupting first permanent molars should be re-examined.

The strategy of selective preventive care is based on the finding that distribution of caries is skewed with many individuals not experiencing any caries and few individuals experiencing high rates of caries. A selective preventive programme is aimed at achieving the following:

1. Preventive care is provided to those most in need.

2. Greater effectiveness of preventive procedures by targeting those in need.

3. Provision of appropriate levels of care to individuals.

4. Cost-efficient delivery of preventive services by matching the need for preventive care with the provision of preventive care (Stamm *et al.* 1988).

However, the strategy of preventive care to 'high risk' individuals has been criticised for its failure to treat the causes underlying disease occurrence and for requiring those identified as high risk to adopt behaviours which do not conform to the social norm (Rose 1992). The results of such an approach are felt to be only palliative because the root cause of the disease is not tackled and successes are temporary, and because the strategy requires individuals to behave in a

manner not consonant with the prevailing social norms, it will ultimately fail (Sheiham and Joffe 1991).

The 'high risk' strategy also requires a screening test which can accurately differentiate between those who will and will not get the disease. The screening process reduces a disease continuum into a dichotomy, high risk versus low risk, and the 'high risk' strategy applied on the basis of screening fails to have an affect on the vast majority of individuals who are low risk but produce most of the burden of disease (Rose 1992). However, in a community where population-based preventive strategies such as community water fluoridation and fluoride toothpastes are already in place (as in WA) then economic considerations may dictate the necessity for a targeted preventive strategy. From a public health perspective, universal preventive care (no matter how efficacious) will not be cost-effective if only a small proportion of the population ends up getting the disease (the net gain from prevention in this instance will be low).

In the Australian context, Spencer *et al.* (1994) identified three circumstances in which the use of targeted high risk strategies can be considered. Firstly, when the exposure to risk and disease is positively skewed and disease experience is confined to a minority; secondly, when there exist a high coverage of population based strategies which allows for the pragmatic introduction of high risk strategy, with modifications to the existing delivery systems; and thirdly, the existence of a strong support for research on risk identification and efficacy of interventions (Spencer *et al.* 1994). These conditions currently prevail in Australia and in Western Australia.

The findings from this study suggest adoption of both a targeted 'high risk' strategy and a population-based preventive strategy. A targeted strategy, including fissure sealing and health education, may be appropriate for

individuals who present with hypomineralised first permanent molars. The finding that increased frequency of toothbrushing contributes towards reduced caries incidence may be appropriately utilised within a population-based approach, incorporating mass education of children and the wider community, enlisting the toothpaste manufacturers where appropriate and using the established school dental service network.

CONCLUSIONS AND RECOMMENDATIONS

The study suggests that frequency of toothbrushing was an important factor in the control of occlusal caries in newly erupting first permanent molars. The lack of an association between plaque levels and caries occurrence suggests that mechanical cleansing action of brushing was of less importance in caries control. It was more likely that the preventive effects of frequent toothbrushing was due to the frequent application of fluoride by brushing with a fluoride toothpaste, as suggested in other studies (Ainamo and Parviainen 1989; Berenie *et al.* 1973). It is recommended that all children with newly erupting permanent molars be encouraged to brush twice-a-day with a fluoride toothpaste.

The strong effect of hypomineralised permanent molars on the risk of caries occurrence (on deciduous and permanent teeth) warrants further investigation. In the present study, over 60% of children with hypomineralised first permanent molars experienced caries on the first permanent molars. It is recommended that further epidemiological studies be undertaken to establish the causes of hypomineralised teeth. Children with such teeth should receive intensive preventive care, such as fissure sealing of all newly erupted molars. In the present study, it was noted that one-third of children with hypomineralised molars in the control group did not receive fissure sealants.

Deciduous tooth caries experience was clearly associated with the occurrence of occlusal caries in the first permanent molars. However, the ability of past caries experience alone to predict future occlusal caries occurrence was poor. A combined prediction model, including the presence or absence of hypomineralised first permanent molars, improved the sensitivity and specificity of prediction, but the positive predictive value remained low. It is likely that, as the prevalence of disease declines, the search for a more accurate predictor of caries will become more important, but the economic gains from a more accurate prediction will become less. At the same time, the development of a predictive model which is simple to use and easy to apply in field situations will become more difficult. The predictive model developed in this study has potential as a screening criterion. It is recommended that the predictive model be validated in a larger field trial.

Also the finding that children with deciduous caries experience at a young age (mean age 6 years) is a predictor of future caries occurrence suggests that causal factors for caries experience may become established at a relatively young age. Further studies are needed to determine the age at which an individual becomes 'primed' for caries. Until then, preventive programmes for younger children may need to be established.

The findings in this study suggest that there is a high risk of occlusal caries of the first permanent molars during the year of tooth eruption and considerably reduced risk of caries after the first post-eruptive year. Possibly, shorter intervals between examinations during the first year after eruption, to allow preventive care for newly erupting teeth, would be of benefit and reduce the occurrence of occlusal caries. The findings also suggest that the first permanent molars among this study population have a lower risk to caries than reported in other studies (Ripa *et al.* 1988; Vehkalahti *et al.* 1991). However, the findings

are based on a relatively short observation period and estimates of caries risk are applicable only for the period of observation. A longer follow-up period would allow a more precise estimate of the risk of caries. It is recommended that the participants in the present study be monitored longitudinally for several years, to obtain estimates of caries risk for a longer period. This would capitalise on the work already done in this study.

Findings from the present study suggest that the professional cleaning programme with tailored dental health education instruction and recall intervals was no better at preventing occlusal caries in newly erupting molars than the standard selective preventive care programme of the SDS. Lack of a statistically significant difference in caries outcome between the two programmes also suggests a possibility of no added benefit by either programme. The strong level of background prevention may have masked the relatively weaker effects of the two programmes. It has been suggested that, to study relatively weak preventive effects (such as oral hygiene measures), studies should be conducted in an environment where strong background preventive factors are absent (Sutcliffe 1989). In the present study, it was not possible (even if it had been desirable) to isolate the participants from the fluoridated community water supply and the widespread use of fluoride toothpastes. To examine the effects of oral hygiene measures on caries occurrence, development of a longitudinal study design which excludes the effects of strong preventive agents is required. Consideration should be given to the conduct of randomised trials in communities where fluoride agents are not used or widely available. The findings also suggest that further research on relatively weak (and costly) preventive strategies may not be necessary in areas with strong preventive agents such as fluoridated water supply.

The findings also suggest questioning the appropriateness of undertaking a professional cleaning programme as a major preventive strategy to control caries. A strategy which has been adopted in some parts of Scandinavian countries (Ekstrand *et al.* 1997). The present study found this strategy has higher resource costs (more frequent recall examinations) and achieved equivalent health outcomes compared with a strategy based on targeted preventive care which used less resources. The strategy also has the potential to generate dependency (more reliance on professional care).

Finally, the possibility that the current SDS policy of selective fissure sealing may not be adding anything to the background prevention requires further investigation. A policy of selection implies an ability to accurately discriminate between those who will and will not experience caries. Current predictive models are only able to achieve modest success in predicting which individuals will experience caries (Hausen *et al.* 1994; Hausen 1997). It is recommended that a randomised trial be conducted to determine the effectiveness of the current SDS policy of selective preventive care to prevent occlusal caries on the newly erupted permanent molars.

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The twelve-month findings of this study has been accepted for publication.
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APPENDICES

Dental Services is a branch of the Health Department of Western Australia. Its mission is:

> To promote and improve the oral health of all the people in Western Australia, (Business Plan for Dental Services, 1995).

The Service acts as a direct provider of dental services to eligible groups and as a provider of financial assistance to disadvantaged groups to enable them to access care through the private sector. Dental Services provides free primary dental care (basic preventive and restorative care), through the School Dental Service, to eligible schoolchildren in Western Australia (children aged 5–17 years). It also provides subsidised comprehensive dental care directly to the financially and geographically disadvantaged groups and identified special groups (aged in nursing homes, homebound, institutionalised and handicapped) through the Perth Dental Hospital, and through Community General Dental Clinics located throughout the State. The Service also provides financial assistance to eligible, geographically disadvantaged, individuals to obtain care from local private practitioners.

Dental care to the adults is provided by general dentists (specialist care is also available). The School Dental Service is staffed by dental therapists (dental auxiliaries trained to provide a limited range treatments) who work under the control of a dentist. For administrative purposes, the State is divided into regions (3), with a senior dentist managing each region. Each region is further subdivided into areas (8–9), each staffed by a dentist and up to 16 dental therapists responsible for providing care to approximately 14 000 schoolchildren. Specialist dental care, such as orthodontics, is available through the private sector, or if eligible, can be accessed through the specialist services at the Perth Dental Hospital.

Appendix B
ORAL HYGIENE INDICES

Plaque Index (Silness and Löe 1964)

The index measures the amount of plaque present on the gingival third of the tooth surface. For both the Plaque Index and the Gingival Index the scores are summed over the index teeth and the mean value is calculated.

Score	Description
0	No plaque in the gingival area.
1	Thin plaque adhering to gingival third of tooth surface removed by running probe across the tooth surface.
2	Tooth surface is covered with plaque which is visible to the naked eye.
3	Tooth surface is covered with abundance of plaque and debris.

Gingival Index (Löe and Silness 1963)

Score	Description
0	Normal gingiva.
1	Gingiva appears slightly inflamed but no bleeding on gentle probing.
2	Gingiva appears inflamed and bleeds on gentle probing.
3	Gingiva is severely inflamed. There is ulceration and spontaneous bleeding.

Oral Hygiene Index (OHI: Debris Index) (Greene and Vermillion 1960)

Score	Description
0	Tooth surface is free of visible plaque.
1	Plaque is visible and is confined to the gingival third of the tooth surface.
2	Plaque is visible and at least two-thirds of the visible tooth surface is covered.
3	More than two-thirds of the visible tooth surface is covered with plaque.

The scores are summed over all the teeth examined and the mean value calculated. The Debris Index and the Calculus Index may be combined or presented separately.

Oral Hygiene Index (OHI: Calculus Index) (Greene and Vermillion 1960)

Score	Description
0	No supra- or subgingival calculus present.
1	Supragingival calculus present and is covering at least one-third of the gingival tooth surface.
2	Supragingival calculus is present on at least two-thirds of the gingival tooth surface and some subgingival calculus is also detected.
3	More than two-thirds of the tooth surface is covered with calculus and a continuous band of subgingival calculus is present.

Quigley and Hein Index (Quigley and Hein 1962)

The extent of plaque detected after the teeth have been stained with disclosing solution is measured. The method is similar to the OHI with additional two categories between 0 and 1 of the OHI. The scores are summed over all the index teeth and the mean value calculated.

Score	Description
0	No plaque.
1	Flecks of stain at the gingival margin.
2	Definite line of plaque at the gingival margin.
3	Plaque present up to gingival third of tooth surface.
4	Plaque present up to two thirds of the tooth surface.
5	Plaque present on more than two third s of the tooth surface.

Patient Hygiene Performance Index (PHP) (Podshadley and Haley 1968)

The PHP index is a variant of Debris Index of the OHI. The teeth are scored after staining with a disclosing solution. An index tooth is divided into five regions by dividing a tooth into three segments vertically and horizontally. Mesial and distal vertical thirds make up the first two subdivisions; the remaining middle third is divided horizontally into three equal divisions extending from the neck of the tooth to the tip of the incisal edge. Scoring is based on the presence or absence of debris in the designated regions; 0 if absent and 1 if present. The PHP score is obtained by summing the score of all the index teeth (six teeth in total) and then dividing the summed score by the number of index teeth scored.

Gingival Bleeding Index (GBI) (Ainamo and Bay 1975)

The gingival crevice of the test site is probed gently with a blunt probe and if bleeding is detected within about ten seconds after probing the site is scored positive. The positive scores are expressed as a percentage of the total number of sites scored.

Visible Plaque Index (Ainamo and Bay 1975)

The occurrence of visible plaque on the mesial, buccal and lingual surfaces of all the teeth in the right side of the jaw is recorded and can be expressed as a proportion of sites with plaque over all sites examined.

Appendix C1

Parent information and consent

Dear parent/guardian

Your child...has been chosen to take part in a trial of a special dental health programme aimed at preventing decay on the chewing surfaces of newly erupting permanent molar teeth. Your child will receive toothbrushing instructions and have his/her teeth cleaned with a fluoride–containing paste. You will also be provided with dental health information to help maintain your child's dental health. Your child will be seen at regular intervals and receive care at the Dental Therapy Centre your child normally attend. The special dental health programme will begin in September 1994 and end in November 1996.

Your child will continue to receive normal dental care through the Dental Therapy Centre. You can withdraw your child from the special dental health programme at any time and continue to receive normal dental care at the Dental Therapy Centre.

An appointment has been arranged for your child (see attached card for date and time) to have a dental examination from the dentist coordinating the special dental health programme. If you wish to take part in the special programme please complete the slip below and bring it with you to the appointment. If you do not wish to take part in the special programme could you please notify the Dental Therapy Centre to cancel the appointment.

Yours faithfully

Peter Arrow
Dental Officer

....

I allow .... to participate in the special dental health programme as outlined. I have read and understood the procedures involved. I also understand that I can withdraw my child from the special programme at any time and continue to have my child receive normal care at the Dental Therapy Centre.

Signed parent/guardian.................................   Date...........................

Parent information and consent

Dear parent/guardian

Your child..has been chosen to take part in a trial of a dental health programme aimed at preventing decay on the chewing surfaces of newly erupting permanent molar teeth. Your child will receive normal dental care provided by the School Dental Service through the Dental Therapy Centre he/she currently attends. As part of the programme your child will be dentally examined once a year for three years by the dentist coordinating the dental programme.

An appointment has been arranged for your child (see attached card for date and time) to have a dental examination from the coordinating dentist. If you wish to take part in the programme please complete the slip below and bring it with you to the appointment. If you do not wish to take part in the special programme could you please notify the Dental Therapy Centre to cancel the appointment.

Your child's participation in the programme will not affect your child's ongoing dental care from the School Dental Service and you can withdraw your child from the programme at any time without affecting your child's existing dental care with the School Dental Service.

Yours faithfully

Peter Arrow
Dental Officer

....

I allow .... to participate in the dental health programme as outlined. I have read and understood the procedures involved. I also understand that I can withdraw my child from the programme at any time and continue to have my child receive normal care at the Dental Therapy Centre.

Signed parent/guardian...................................   Date...........................

Name...DOB................Sex

m f □ □

1 2 3 4
| | | | |

Exam date.............................School..

Address... DTC....................

5 6 7 8
| | | | |
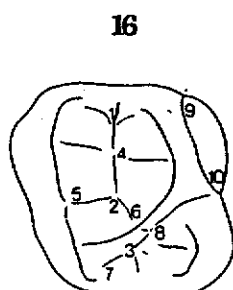
16

eruption stage

unerupted   □
part erupted □
fully erupted □

26
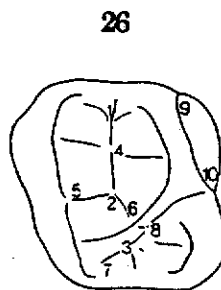
eruption stage

unerupted   □
part erupted □
fully erupted □

9 10 11 12
| | | | |

13 14 15 16
| | | | |
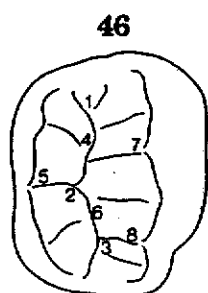
46

eruption stage

unerupted   □
part erupted □
fully erupted □

36
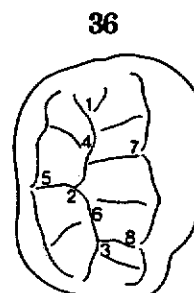
eruption stage

unerupted   □
part erupted □
fully erupted □

17 18 19 20
| | | | |

21 22 23 24
| | | | |

25 26 27 28
| | | | |

<u>Treatment received</u>

16	none—□	filling—□	f/s—□	F⁻—□
26	none—□	filling—□	f/s—□	F⁻—□
36	none—□	filling—□	f/s—□	F⁻—□
46	none—□	filling—□	f/s—□	F⁻—□

29 30 31 32
| | | | |

<u>Status of molars</u>   <u>deciduous dentition</u>

	16	**26**	**36**	**46**
sound	□	□	□	□
sound/FS	□	□	□	□
sound/fld	□	□	□	□
caries	□	□	□	□
caries/LSC	□	□	□	□

55 54 53   63 64 65
○ ○ ○ │ ○ ○ ○
○ ○ ○ │ ○ ○ ○
85 84 83   73 74 75

dmfs =..........

33 34 35 36
| | | | |

37 38 39 40
| | | | |

No. of visits............   time taken per visit (mean)...............

brushing frequency.........   type of toothpaste..........................

41 42 43 44
| | | | |

45 46 47 48
| | | | |

219

Appendix E
Trial Procedures

Examine each child in the dental chair under a dental light. Clinically assess plaque distribution on occlusal surfaces of the first permanent molars using the dental mirror and probe. Disclose with disclosing solution (optional). Carry out toothbrushing instructions with the child and parent. Explain the process of caries initiation and progression, especially the importance of plaque accumulation in the carious process. Instruct the parent to brush the child's teeth twice a day with a fluoride toothpaste and provide the parent and child with dietary information and counselling. Complete the session by cleaning the child's teeth with the cleaning paste using bristle brushes on occlusal surfaces and rubber cups on smooth surfaces. Place the child on a recall interval based on the following criteria:

Criteria for assessment of recall intervals

	Score value	
	1	2
Cooperation of the parents	Good	Poor
Active lesions within the dentition	No	Yes
Stage of eruption of permanent first molars	Full occlusion	Partly erupted
occlusal surfaces of permanent first molars	Caries free or arrested lesion	Active lesion

Score	Recall interval
8	6 months
7	7 months
6	8 months
5	9 months
4	12 months

Record patient visits in the DT1 and on the DT 15 as per normal SDS procedures. Also record the time taken for the entire procedure in the DT1 (in five minute units as per the current DHE recording). At each recall visit carry out the same procedures for each child. If any of the first permanent molars requires treatment (ie. fissure sealing, PRR or fillings) advise Peter Arrow of the child's name, tooth/teeth requiring treatment and the site/s involved.