A clinical study to evaluate the success of two commercially available aesthetic stainless steel crowns on primary molars

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Paediatric Dentistry

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Declaration

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Summary

Aim: The aim of this study was to evaluate the clinical and radiographic success of two commercially available aesthetic stainless steel crowns on carious primary molars. The objectives were to compare the crown types to each other, to assess the integrity of the aesthetic veneer facing, and to determine the level of parental satisfaction with posterior aesthetic stainless steel crowns.

Materials and methods: Ethical approval was obtained from the St James Hospital / Adelaide and Meath National Children's Hospital Research Ethics Committee. Patients who fulfilled specified inclusion criteria were enrolled in the study and consent obtained. Forty eight posterior aesthetic stainless steel crowns (24 NuSmile® Primary crowns and 24 Kinder Krowns™) were placed in 18 patients (11 male and 7 female) over a 6 month period. The age range was 2-9 years, with a mean of 5.44 years. The aesthetic veneer of first primary molars covered the buccal and occlusal surfaces while the veneer of all second primary molar crowns was limited to the buccal surface only. Two trained operators completed all treatments using local anaesthesia, local anaesthesia and inhalational sedation or general anaesthesia. A split mouth design was used with each patient receiving both crown types on two or four pair matched molars. Crowns were evaluated clinically every 3 months for 12 months, with bitewing radiographs exposed at the final review visit. Two other clinicians were trained and calibrated to blindly evaluate crowns according to specified clinical variables and one for radiographic variables. A visual analogue scale was used to determine parental satisfaction with this treatment option. A Cohen's kappa score was determined to assess the inter-examiner and intra-examiner reliability. Results were analysed using Fisher's exact test to determine any statistical differences between the crown types, and to determine the effect of clinical service on both crown types.

Results: One hundred percent of the crowns were successfully retained during the study period. Durability in terms of coronal seal was found to be comparable to that reported for conventional stainless steel crowns after 12 months. Overall, 81.3% had an intact facing and 83.3% were free of gingival inflammation after 12 months. Radiographically, 81% were considered successful. There was no statistical difference in the clinical and radiographic success of posterior NuSmile® Primary crowns and posterior Kinder Krowns™ when compared to each other. NuSmile® Primary crowns showed a statistically significant decrease in gingival inflammation from 6 to 12 months (p=0.024). It was noted that veneer facing wear was significantly more likely to occur with opposing aesthetic crowns (p=0.017). The technique for placing these crowns was found to be as easy to master as that of conventional stainless steel crowns and did not influence the behaviour management options used. No teeth required invasive pulp therapy because of the crown preparation. Parental satisfaction with these crowns was excellent despite some chipping and wear, with a mean satisfaction score of 9.3 out of 10.

Conclusions: There was no difference in the clinical and radiographic performance of posterior NuSmile® Primary crowns and posterior Kinder Krowns™ after 12 months. Despite some fracture and wear, the overall success of posterior aesthetic crowns was high and parental satisfaction was excellent. These crowns combine the durability of conventional stainless steel crowns with improved aesthetics and are proposed as a suitable alternative to conventional stainless steel crowns on primary molars where aesthetic demand is increased.

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1 Introduction & Literature Review

Improved standards of living and better education over the past 20 to 30 years has given rise to higher expectations for aesthetic dental treatment. The importance of aesthetics is dominant in current Western society, and has become a major influence in how we see others and are perceived ourselves. As aesthetic demands become more apparent for the permanent dentition, there is also a desire for aesthetic alternatives in the primary dentition.

While there is limited evidence on the potential psychosocial impact of unaesthetic restorations in primary teeth, facial appearance affects the development of social skills, peer relationships and self-esteem of children. An intact, properly maintained dentition is crucial for favourable facial aesthetics in children (Judd and Casas 1995), so optimal aesthetics should be the treatment goal where possible for the well-being of children and parents.

Stainless steel crowns (SSC) have proven superior longevity over alternative restorative options when full coverage is required in the primary dentition. However, they are not an aesthetic restoration and parents have expressed a dislike for their metallic appearance (Randall 2002). Achieving a cosmetically acceptable, durable and evidence based restoration for grossly decayed primary teeth is an ongoing challenge for dental practitioners.

The introduction of preveneered SSC offer a potential solution. These crowns allegedly combine the durability of conventional SSC with the cosmetics of composite resin, and can be placed successfully even with poor moisture control or haemorrhage (Waggoner 2002). The ability to bond white resin to metal offers the potential for wider acceptance of SSC and paves the way for an entirely new standard in paediatric dentistry (Carrell and Tanzilli 1989).

1.1 Epidemiology of dental caries in Irish children

Dental caries remains the single most prevalent oral disease in children. Epidemiological studies have shown that dental caries has a highly skewed distribution with wide geographical variation at both local and national levels (Vargas *et al.* 1998, North South Survey of Children's Oral Health 2006). Decay levels were found to be higher amongst those less well off in both the Republic of Ireland and Northern Ireland, regardless of water fluoridation status.

Although there has been a decrease in caries in both fluoridated and non-fluoridated populations in Ireland since 1984 (Whelton *et al.* 2006), the decayed missing filled teeth (dmft) level for 5 year olds had not decreased by the same magnitude as other age groups. Overall, only 63% of 5 year olds in fluoridated Republic of Ireland were free from visual caries and this figure fell to 45% for those in non-fluoridated Northern Ireland (North South Survey of Children's Oral Health 2006).

It was also reported that in the Republic of Ireland, 82% of the decay in 5 year olds and 56% of the decay in 8 year olds was untreated. Such high levels of untreated caries are of great concern, as it is likely that a proportion of these children will experience symptoms as a result of untreated dental caries. Previous toothache is a well recognised predictive factor for negative dental behaviour in the dental office (Ramos-Jorge 2006), and this type of classical conditioning may have a profound effect on the development of dental fear and subsequent treatment avoidance. In addition, premature loss of primary teeth often results in loss of arch length and consequences for the permanent successors at a later stage.

1.2 Dental caries in the primary dentition

It is broadly accepted that the development of dental caries requires the simultaneous interaction of a susceptible tooth, fermentable dietary substrate and cariogenic bacteria over time (Newbrun 1977). The caries process in primary teeth is essentially the same as that of permanent

teeth, but is modified by certain biological and anatomical factors (Seow 1998). It is postulated that young children can be at additional risk of caries due to factors that are unique to that age group, most especially frequent nursing habits. In addition, early colonisation of the oral cavity by *Streptococcus mutans* bacteria and enamel hypoplasia in the primary dentition may further predispose young primary teeth to the development of dental caries (Seow 1998).

There are well documented and important anatomical differences between primary and permanent teeth which account for their increased caries susceptibility (Randall 2002). The crown of a primary molar is bulbous with a narrow occlusal table and broad flat proximal contacts. The greatest convexity lies in the cervical one third of the crown. Primary teeth have proportionally less enamel and dentine than permanent teeth so the caries process can be rapid leading to more extensive destruction. The pulp horns are prominent and relatively large with a thin pulpal floor. Consequently, there is an increased potential for a carious lesion to involve the pulp. The rate of progression of a carious lesion in primary teeth is accelerated by these anatomical characteristics and is thought to progress at twice the rate of permanent teeth (Tinanoff and Douglass 2001).

Management of carious primary teeth is dictated by a number of factors. The age and cooperation level of the child will determine the most appropriate behaviour management route. The extent of the caries and the degree of moisture control will determine the most appropriate restorative technique. In addition to the size of the carious lesion, the amount of remaining tooth structure is often a major limiting factor in the choice of a successful restoration.

Furthermore, operator preference will influence material choice. The most commonly used restorative materials available are amalgam, resin composite and SSC (Seale 2002).

1.3 Stainless steel crowns

Humphrey first introduced the use of chrome-steel crowns to paediatric dentistry in 1950 (Salama and Myers 1992). SSC are prefabricated crowns that are adapted to the individual tooth and cemented with a suitable luting agent. Retention is obtained by contouring their flexible, thin margins, which allow the crown to spring into and be retained by undercut area apical to cemento-enamel junction of primary molars (Figure 1.3-1).

Over the years, manufacturers have evolved the SSC into a more realistic crown form with margins that are pre-trimmed, pre-crimped and pre-festooned (Table 1.3-1). Consequently, today's SSC are easier to place and often require minimal modification by the operator (Seale 2002). As a result of these variations, the indications for the use of SSC have expanded (Table 1.3-2). In addition to treating caries, SSC can be used to prevent recurrent disease. This is of particular benefit to patients with special needs where their ability to perform good oral hygiene is compromised (Kindelan et al. 2008). O'Sullivan and Curzon (1991) reported that SSC placed under GA were significantly more successful than amalgam or composite restorations, with only a 2% failure rate after a minimum 2 year follow up. Such studies have led to the proposal that SSC are indicated in patients undergoing restorative care under general anaesthesia if two or more surfaces are involved (Kindelan et al. 2008). SSC are also used successfully where children have developmental dental defects so that primary molars can maintain space for the permanent successors. SSC possess many advantages including full coronal coverage, good retention, ease of placement, durability, relative insensitivity to moisture, and low cost.

Figure 1.3-1 **Primary molar SSC;**
A: Pre-trimmed pre-contoured 3M™ ESPE™ Unitek,
B: Untrimmed, non-contoured 3M™ ESPE™
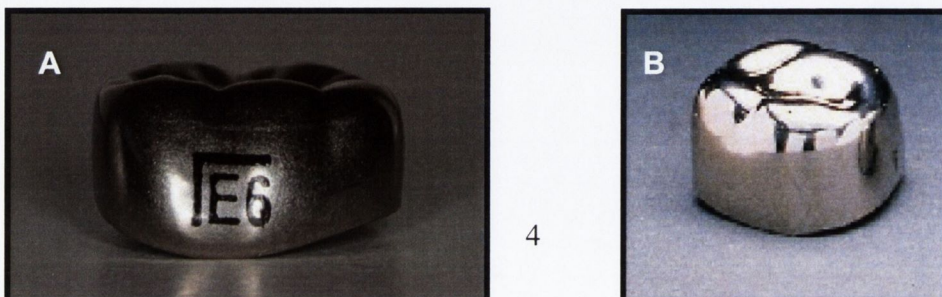
Preformed stainless steel crowns (SSC) are widely recognised as the most effective and durable restoration for extensively decayed primary molars, and extensive literature exists to support their use (Kindelan *et al.* 2008, Attari and Roberts 2006, Randall 2002, Fayle *et al.* 2001, Randall *et al.* 2000, Fayle 1999, Roberts and Sheriff 1990).

Table 1.3-1 Different types of a commercially available SSC

3M™ ESPE™	3M™ ESPE™ Unitek™
• Pre-trimmed, belled and partially contoured Pre-crimped at cervical margin • Duplicates anatomy for better fit	• Pre trimmed with parallel walls allows operator control • Shallow occlusal anatomy requires less tooth reduction • Thick occlusal surface

Table 1.3-2 Indications for SSC in primary molars

(Kindelan 2008, Randall 2002)
- Multisurface carious lesions
- Post endodontic treatment
- Primary teeth with localised or generalised developmental defects
- Restoration of cavity with wide proximal box / undermined enamel
- Fractured primary molars
- Extensive tooth surface loss (attrition, abrasion or erosion)
- Infraoccluded primary molars to maintain mesio-distal space
- Patients with a high caries susceptibility
- As an abutment for certain appliances (e.g. space maintainers)

1.4 Success of SSC vs. alternative restorative materials

Many studies have compared the durability of SSC with that of class II amalgams in the primary dentition. The overall survival rates of SSC are consistently shown to be superior to alternative materials (Table 1.4-1).

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Table 1.4-1   Studies comparing survival rates of SSC and alternative materials in primary teeth

Study	Eriksson et al. 1988	Roberts & Sherriff 1990	Papathanasiou 1994	Einwag & Dünninger 1996	Roberts et al. 2005
Design	Pro-spective	Pro-spective	Retro-spective	Retro-spective	Pro-spective
Duration	7years	10years	60months	8years	7years
Number	104 SSC 104 Amg controls	673 SSC 706 Amgs (CII)	604 restorations (128 patients)	66 SSC 66 Amg (multisurface) controls	1010 SSC 962 RMGIC (CII)
Amalgam (Amg) Survival	SR*: Amg 49% @3-5y	SR*: Amg 67%@ 5y RR*: 14.7% TFR*:11.6%	SR*: Amg 60%@ 5y	SR*: Amg <40%@4.5y	SR*: RMGIC 97.3%@ 7 y
SSC Survival	SR*: SSC 58% @3-5y	SR*: SSC 92%@ 5y RR*: 2.8% TFR*:1.9%	SR*: SSC 68%@ 5y	SR*: SSC >90%@4.5y 89%@ 8y	SR*:SSC 97%@ 7y
Comment	SSC placed on worst tooth SSC required 73 fewer follow-up visits SSC more cost effective	All CII Amgs were small in size 1 specialist operator (also the examiner) No defined exclusion or inclusion criteria	Multiple operators with varying skill level No evidence of training or calibration MST* Composite: 3y GIC :1y	Number of operators not specified No defined exclusion or inclusion criteria	All RMGIC minimal size with no buccal or palatal extension 1 specialist operator

SR*= survival rate;   RR*= replacement rate;   TFR*= true failure rate;   MST*= mean survival time

Amalgam is the benchmark against which other materials are compared given its historical and successful clinical use. An evidenced based review of the literature confirmed amalgam to be safe in terms of toxicity and refuted adverse health claims (Dodes 2001). There is strong evidence regarding the durability of amalgam, however a recent systematic review determined that although it remains the choice for class II lesions in primary molars, factors other than durability influence

its use (Kilpatrick and Neumann 2007). Parental demand for better aesthetics, concern over the potential adverse effects of mercury and environmental pollution has motivated manufacturers and dentists to promote alternatives.

A systematic review of tooth coloured materials for primary teeth was conducted by Chadwick and Evans in 2007. Twenty studies met the inclusion criteria for analysis. Results suggested that glass ionomer cement (GIC) should not be used to restore class II cavities. It was proposed that there is evidence regarding the success of resin modified glass ionomer cement (RMGIC) restorations, once used with a dentine conditioner and limited to small class II cavities. Results of a meta-analysis of tooth coloured materials for restoring proximal lesions in primary molars are in agreement with these findings (Toh and Messer 2007). The analysis concluded that RMGIC has the best overall success, superior to both compomer materials and resin composites, while the use of GIC significantly decreased the likelihood of success.

While there is evidence to support the use of resin materials in small proximal lesions in primary molars (Fuks *et al* 2000, Roberts *et al.* 2005, Chadwick and Evans 2007, Toh and Messer 2007) retrospective data suggests that SSC out-perform tooth coloured dental materials (Kindelan *et al.* 2008). SSC remain the restoration of choice for multisurface caries in primary molars (Fayle *et al.* 2001).

Since 2000, a number of publications have reviewed the use and efficacy of SSC (Randall 2000, Randall 2002, Seale 2002, Hickel *et al.* 2005, Attari and Roberts 2006, Innes *et al.* 2007, Kindelan *et al.* 2008).

A systematic review by Attari and Roberts (2006) concluded that although there was a lack of prospective, well controlled studies, data indicated the failure rate of a SSC to be very low compared to other materials. In contrast, the most recent Cochrane review of SSC (Innes *et al.* 2007) found no evidence of sufficient quality available to meet the inclusion criteria for appraisal (no randomised control trials: RCT). It was therefore surmised that no conclusion could be made as to whether SSC are indeed more successful than other materials for restoring primary molars.

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However, the authors were quick to point out that the absence of evidence for SSC should not be misinterpreted as lack of their efficacy. Interestingly, it was noted that there was a general bias among the studies toward placing the SSC on the more extensively decayed tooth and in spite of this, most studies reported greater success rates for the crowned teeth. The superiority of SSC in providing a full coverage coronal seal following indirect pulp therapy, pulpotomy and pulpectomy procedures in primary molars is well documented in the literature (Kindelan et al. 2008, Atari and Roberts 2006, Randall 2002, Fayle 1999). Restoration using a SSC following pulp therapy results in higher success rates than reinforced zinc oxide-eugenol (Farooq et al. 2000), amalgam (Holan et al. 2002, Al Zayer et al. 2003) and composite resin (Guelmann et al. 2005).

A randomised controlled trial of the controversial Hall technique (Innes et al. 2007) described the use of SSC to restore primary molars without any local anaesthetic or any caries removal, and reported favourable outcomes for this technique compared to control restorations after 24 months. There is evidence that exclusion of a carious lesion from the essential oral nutrients can halt progression (Griffin et al. 2008). Therefore, the SSC can arrest future caries activity (Innes et al. 2007).

Retrospective data suggests that SSC out-perform tooth coloured dental materials in large lesions (Kindelan et al. 2008). However, parents and children are dismayed by the poor appearance of these crowns and tooth coloured alternatives are being developed to satisfy the aesthetic demand.

1.5 Aesthetics of SSC

It is clear from the evidence that SSC possess numerous advantages over other materials for the restoration of primary molars; however their poor aesthetic appearance remains a major disadvantage.

1.5.1 Clinicians view regarding SSC

The restorative material preference of a dental practitioner when managing the primary dentition is established in dental school. Results from a European survey highlighted great diversity in teaching methods, opinions and material choices among university paediatric dental departments (Beurkle *et al.* 2005). Despite the widely reported superior success rates of SSC, they remain underused and an unpopular choice for the majority practitioners (Maggs-Rapport *et al.* 2000, Tran and Messer 2003). Although time pressure and the child's cooperation level were cited as clinical reasons for the infrequent use of SSC, many dentists believe that SSC are 'ugly', and are not cosmetically acceptable to the child or the parent (Threlfall *et al.* 2005, Randall 2002).

A California survey questioned 290 paediatric dentists regarding materials used for the restoration of class II cavities in primary molars (Pair *et al.* 2004). Forty percent of respondents reported primarily using aesthetic restorative materials, especially composite resin. The main reasons cited for this choice was patient preference (86%), and better aesthetics (78%).

With contemporary society focusing more on cosmetic importance, it seems appropriate to conclude that some practitioners consider SSC to be unacceptable and undesirable. There is a demand to improve aesthetics that will include the functional qualities of the SSC.

1.5.2 Restorative preferences of parents and children

The preferences of parents and children regarding restorative materials for primary teeth have been investigated. A review of the literature reported that parents have expressed a dislike of the appearance of a SSC, most especially regarding SSC on the lower first primary molar (Randall 2002).

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Peretz and Ram (2002) examined the preferences of parents and 124 children aged 4-12 regarding restorative materials for children's teeth. Although the main concern was given to the implication of a restorative material on the health of the tooth or body, 48% parents and 50% children preferred tooth coloured restorations for both primary and permanent teeth. Similarly, Fishman *et al.* (2006) showed that overall, children prefer composite resin the most and amalgam the least regardless of age or gender. Interestingly, Caucasian children preferred composite, while African-Americans preferred SSC.

1.6 *Alternative aesthetic restorative techniques for primary molars*

Numerous techniques have been attempted to produce an aesthetic full coronal coverage restoration for primary molars.

Composite resin crowns although highly aesthetic, require sufficient tooth structure for bonding, are highly technique sensitive and cannot be bulk cured. In a recent review of the literature, Waggoner (2002) noted that unless placed under ideal circumstances with the use of general anaesthesia (GA), the young child's potential for negative behaviour has a profound influence on the clinician's ability to successfully place such restorations.

The use of polycarbonate crowns (heat moulded acrylic resin) is often associated with fracture and dislodgement as they do not resist strong abrasive forces (Stewart *et al.* 1974, Lee 2002). There is no literature to support their use on primary molars and they are now rarely used even for anterior teeth (Waggoner 2006).

Given the proven durability of SSC, there have been several direct and indirect efforts to improve their appearance. The open-faced SSC has been described for both anterior and posterior teeth (Helpin 1983, Hartmann 1983, Roberts 1983). It involves cutting a window in the buccal wall of the cemented SSC and restoring this area with composite resin (Figure 1.6-1).

Although this technique improves the appearance, the metal is usually still visible thus compromising the aesthetic result. In addition, this process is time-consuming, technique sensitive, compromised by gingival bleeding and may display poor colour stability under oral conditions (Randall 2002, Yilmaz *et al.* 2008). Existing literature regarding open faced SSC is mostly limited to case reports and technical presentations.

**Figure 1.6-1   Open-faced SSC: buccal window cut (left),
                   restored with resin (right)**
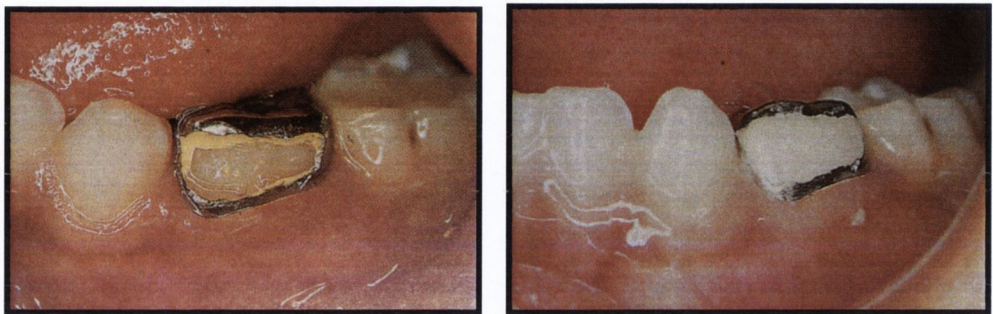
Pictures courtesy Duggal MS *et al*, Restorative Techniques in Paediatric Dentistry. An illustrated guide. 2nd edition (2002)

Another technique developed to combat the poor appearance of a SSC involves directly veneering the SSC with resin. This is achieved by use of an intermediate bonding agent onto a roughened SSC surface. Carrel and Tanzilli (1989) reported disappointing results using this technique, with a progressive loss of the facing over time. After one year, 41% of veneers had debonded and colour stability did not prevail. Wiedenfeld *et al.* (1994 & 1995) described a similar technique for chair side veneering of anterior SSC. The authors reported excellent aesthetics and high bond strengths; however, the number of steps involved prolongs treatment time which is undesirable when treating young children.

More recently, the preveneered SSC has been manufactured which decreases chair-side time. These crowns allegedly combine the durability of conventional SSC with the cosmetics of composite resin, and can be placed successfully even with poor moisture control or haemorrhage (Waggoner 2002).

1.7 Preveneered aesthetic SSC

Several manufacturers have developed and marketed preveneered crowns for primary anterior and posterior teeth. Many materials have been used including resin composite, thermoplastics or epoxy which is attached, bonded or coated over the stainless steel (Hosoya *et al.* 2002). Most aesthetic posterior crowns consist mainly of a conventional SSC to which a composite facing has been bonded. The composite veneer covers various surfaces of the crown from buccal and occlusal alone to inclusion of the mesial and distal surfaces, and some brands also supply crowns with only a buccal facing (Figure 1.7-1).

The facing varies in thickness but it is important to realise that the use of any facing restricts the ability to crimp and custom fit that surface to the contour of the tooth (Figure 1.7-2). The addition of resin creates a SSC with an increased thickness (1.5-2 mm occlusally) compared to a conventional SSC (0.2 mm), and therefore more extensive tooth preparation is required to allow for proper fit and occlusion (Figure 1.7-3).

Manufacturers recommend that preveneered crowns fit passively to the tooth and are seated with light digital pressure to minimise stress and the development of micro fractures in the facing. Since their introduction in the mid 1990s, the use of pre-veneered crowns to improve the aesthetics of anterior teeth has received greater attention than their posterior counterparts (Figure 1.7-4). However, an increasing number of posterior pre-veneered crowns are now commercially available (Table 1.7-1). From the limited existing research, the disadvantages of pre-veneered SSC include their increased cost, limited crimping ability and need for increased tooth preparation (Ram *et al.* 2003). Individual posterior crowns are approximately five times more expensive than a conventional SSC. Their main limitation however, lies in the potential for veneer failure, as loss of the facing may render these crowns unaesthetic (Waggoner 2006).

Figure 1.7-1   Preveneered SSC (NuSmile® Primary Crowns): Lower second
                primary molar with buccal facing only (left) and lower first primary
                molar with full coverage (right)

Figure 1.7-2   Crimping a preveneered SSC.
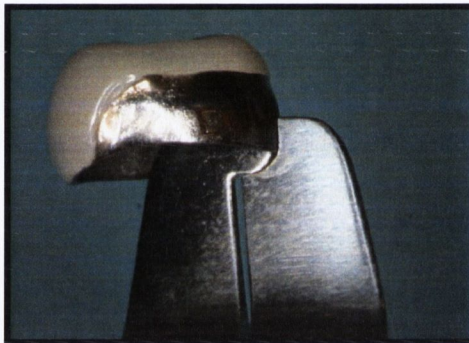
Figure 1.7-3   Increased thickness of a lower first primary molar preveneered
                NuSmile® SSC compared to a conventional SSC (3M™ ESPE™)

Figure 1.7-4   Anterior NuSmile® Crowns

Table 1.7-1   Commercially available posterior preveneered aesthetic SSC

Crown	Company	Additional information
NuSmile® Primary Crowns	Orthodontic Technologies	Composite resin faced SSC over an alumina blasted surface Buccal only of full coverage facing 1st and 2nd primary molars 2 shades: extra light, new light 7 sizes / €23.30* each CE approved Anterior crowns also available
Kinder Krown™	Mayclin Dental Studios	Composite resin facing over a fenestrated SSC Incisal lock feature Buccal only of full coverage facing 1st and 2nd primary molars 2 shades: pedo1, pedo2 6 sizes / €16.73* to €23.70* each Anterior crowns also available
Cheng™ Crowns	Peter Cheng Orthodontic Laboratory	Pure resin faced SSC over a metal meshwork 1st and 2nd primary molars 1 shade / 6 sizes / €25.50* each Anterior crowns also available
Pediatric Esthetic White C.F. Crowns	Space Maintainers Laboratory™	Resin faced SSC 1st primary molar 1 shade / 7 sizes / €16.00* each

(*Calculated according to current exchange rate: 1 USD = 0.729201 EUR)

1.8 Bite force in the primary dentition

As preveneered SSC are being chosen for aesthetic value, the strength and durability of the composite veneer is of clinical importance. The composite veneer must possess sufficient strength to withstand occlusal loads. Several studies have reported on the average bite force of a young child with varying results (Table 1.8-1).

Table 1.8-1   Mean maximum bite force in children

Study	Subject age (years)	Number of subjects	Mean maximum bite force (Newtons) (1N=102g)	Standard Deviation (Newtons)
Bakke et al. 1990	5-10	17	356.9	± 64.3
Rentes et al. 2002	3.5-5	30	234.66	± 42.98
Braun et al. 1996	6-8	Not specified	78	Not specified
Kamegai et al. 2005	3-5	73	196	± 96.1
	6-8	486	296.3	± 128.1
	9-11	533	393.3	± 138.5
Gavião et al. 2007	3-5.5	15	235.12	± 44.48

Bakke et al. (1990) calculated an average unilateral isometric bite force of 356 Newtons measured across permanent first molars, with no difference between right and left sides.

It has been reported that bilateral bite force changes during growth and development (Kamegai et al. 2005, Braun et al. 1996). Braun et al. described an increase from 78 Newtons at 6-8 years to 176 Newtons at 18-20 years. Reported values were lower than Bakke et al. (1990) as the bite force was measured across the first primary molar region. Braun et al. (1996) postulated no gender related bite differences exist until the

post-pubertal period when males develop greater muscle mass. In contrast, Tsai (2004) noted that males had a statistically significant larger maximum bite force than females in the primary dentition.

The association between different types of occlusions and bite force magnitude has been examined with conflicting results (Rentes *et al.* 2002, Kamegai *et al.* 2005, Tsai 2004). Rentes *et al.* reported no significant differences among normal occlusion, cross bite and open bite in the primary dentition. Interestingly, bite force magnitude for those without a normal occlusion was in fact higher that for those children with a normal occlusion. In contract, both Tsai and Kamegai *et al.* determined that children with a normal occlusion had a significantly larger bite force than those with a malocclusion.

Anecdotally, it was not recommended to place anterior preveneered SSC in children with crossbites due to likely fracture of veneering resin (Waggonner 2006), and it seems there is still some controversy in this area given the conflicting reports that exist in the literature (Rentes *et al.* 2002, Kamegai *et al.* 2005, Tsai 2004).

1.9 Bonding resin to SSC; strength and integrity

Randall (2002) recognised the need for improved aesthetics in primary molar crowns by means of a strongly bonded, tooth coloured veneer.
Several studies have examined the efficacy of bonding resin composite materials to stainless steel. Historically, the junction between resin and nickel chromium alloys demonstrated poor stability under simulated oral conditions (Carrell and Tanzilli 1989). Recently, Khatri *et al.* reported similar mean bond strengths for conventional composite resin (20.78 KN) and nanocomposite resin (21.04 KN) to sand-blasted anterior SSC (Khatri *et al.* 2007).

Salama and el-Mallakh examined the effect of different SSC surface preparations prior to veneering with compomer *in vitro* (Salama and el-

Mallakh 1997). Surface preparation techniques included sandblasting and soldered cleats. Bond strengths were weakest when the veneer was applied to an untreated metal surface (2.99 MPa = Mega Newton/m^2), thus highlighting the importance of metal surface preparation to increase surface area prior to bonding.

The clinical success of 18 open-faced SSC and 15 veneered SSC on posterior primary teeth after 18 months was examined by Yilmaz and Koçoğullari (2004). The aesthetic veneering of the SSC was added in the laboratory after the initial fitting; however it is notable that this technique is unsuitable for generalised use in clinical paediatric dentistry. The crowns were evaluated for retention of the aesthetic material, with loss of one third or more recorded as a failure. Although no significant differences in the outcomes of the two types of aesthetic SSC was noted, the maxillary crowns exhibited a higher success rate than those in the lower arch. Since the crowns were unevenly distributed between upper and lower teeth in this study, such conclusions must therefore be interpreted with caution.

For preveneered SSC, manufacturer bonding techniques are proprietary and surface preparation techniques are unknown, but examination reveals certain differences between the crown types. NuSmile® crowns appear to have an alumina sandblasted intermediate coating beneath the resin veneer. Cheng™ crowns rely on a type of welded metal meshwork to mechanically interlock the veneer. Kinder Krowns™ and C.F. crowns have perforations in the metal to allow for mechanical retention in addition to chemical bonding of the veneer. Kinder Krowns™ have labelled this the 'incisal lock' feature of their product.

Veneer loss can occur due to a cohesive, adhesive or mixed failure of bonding. A cohesive failure is obtained if a crack propagates through the bulk of the material resulting in loss of a section of the veneer (Figure 1.9-1). An adhesive or interfacial failure relates to the veneer separating from the underlying metal (Figure 1.9-2).

Figure 1.9-1   Graphic representation and clinical photograph of cohesive failure
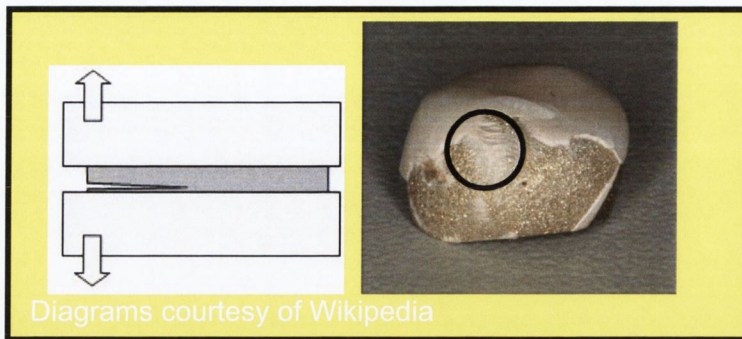
Figure 1.9-2   Graphic representation and clinical photograph of adhesive failure
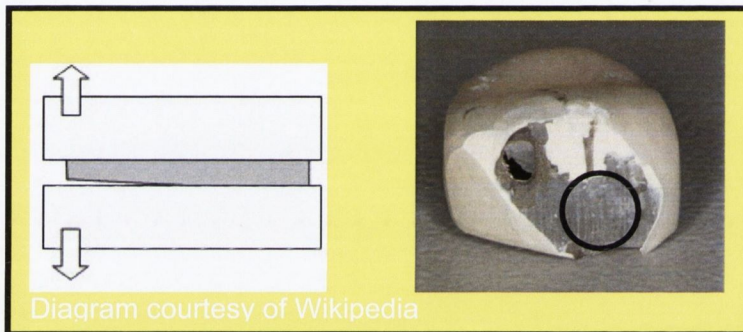
1.10 Colour stability

It has been suggested that all the composite facings of commercially available anterior crowns are liable to colour changes and more prone to fracture after heat sterilization, and consequently the manufacturers recommend cold sterilization procedures (Wickersham *et al.* 1998). In a clinical setting, repeated try-in of crowns may be necessary for size selection and contamination is likely. It is therefore essential to be able to adequately heat sterilise preveneered crowns from a cross-infection standpoint and to have the ability to reuse crowns given their increased cost.

Wickersham examined 35 Kinder Krowns™ and 35 NuSmile® crowns following various sterilization procedures (Wickersham *et al.* 1998).

Sterilization techniques included steam autoclave, Chemicalve method and 2% glutaraldehyde solution (Table1.10-1).

No surface changes were observed following any sterilization method. The only technique that caused colour changes noticeable to the human eye was the Chemicalve method. Significantly less force was required to fracture the facings of Kinder Krowns™ after sterilization by 2% glutaraldehyde. Interestingly, this was the only significant decrease in fracture resistance yet this cold method of sterilization is recommended by the manufacturer. There was a non-significant trend for decreasing fracture resistance values with steam autoclaving for both crown types compared to controls.

The Chemicalve method appeared to affect veneer strength of both crown types the least. In fact, fracture resistance of Kinder Krowns™ actually increased following this procedure. Contrary to the manufacturer's instructions, this *in-vitro* study recommends steam sterilization techniques for both Kinder Krowns™ and NuSmile® crowns, as it produced neither significant changes in fracture resistance nor clinically detectable colour changes.

Table 1.10-1   Sheer strengths (PSI) of preveneered SSC

(Wickersham *et al.* 1998)	Kinder Krowns™	NuSmile®
Controls	86.71 ± 28.86	124 ± 22.08
Steam autoclave (121°C, 15PSI, 20 minutes)	81.87 ± 9.89	109 ± 25.26
Steam autoclave (132°C, 30PSI, 8 minutes)	78.28 ± 22.43	105.71 ± 32.92
Chemicalve with formaldehyde vapour (132°C, 15PSI, 20 minutes)	91.00 ± 29.68	121.71 ± 23.44
2% Glutaraldehyde (75 °F,10 hours)	74.0 ± 13.41	137.57 ± 26.69

1.11 Gingival response to SSC

The cervical margin of a SSC must be placed approximately 1mm subgingivally to acquire sufficient mechanical retention (Kindelan *et al.* 2008). Various studies have examined the gingival response to the placement of a SSC and produced conflicting results (Henderson 1973, Webber 1974, Myers 1975, Durr *et al.* 1982, Einwag 1984, Guelman 1988, Sharaf and Farsi 2004, Fuks *et al.* 1999, Ram *et al.* 2003). The main area of conflict is regarding the relationship between plaque levels, SSC defects and the development of gingival inflammation (Table 1.11-1).

The clinical performance of preveneered aesthetic primary molar SSC using conventional SSC as control has been compared (Fuks *et al.* 1999, Ram *et al.* 2003). The first was a pilot study prospectively following 11 NuSmile® Primary crowns (Orthodontic Technologies, Houston, Texas, USA) and 11 control SSC (brand not specified) on primary mandibular molars (Fuks *et al.* 1999). After 6 months, the periodontal health and modified gingival index scores of the conventional SSC were superior, with all the aesthetic SSC displaying poorer gingival health. However, not only was this sample size too small to draw useful conclusions, but the gingival health of the teeth to be crowned was not evaluated pre-operatively. Interestingly, in a retrospective follow up of the same crowns after 4 years, Ram *et al.* (2003) found no difference in the periodontal health status of both types of SSC.

Overall, it would seem appropriate to conclude that a SSC may have an effect on the surrounding gingival tissue, although any effect on the gingival health is usually clinically insignificant. It remains good practice to ensure that a SSC is placed as accurately as possible to minimise the development of defects in crown fit. Furthermore, encouraging immaculate oral hygiene not only decreases the potential for gingivitis adjacent to a SSC but is also imperative for maintaining overall optimal oral health.

Table 1.11-1   Studies evaluating gingival response to primary molar SSC

Study	Design	Subjects	SSC	Comments
Henderson 1973	Retro-spective	64 children age 4-13y	139	Always some degree of inflammation no matter how accurate fit due to differences in form & contour of SSC and natural tooth
Myers 1975	Retro-spective	47 children age 4-12y	110	Significant association between crown defects and clinical evidence of gingivitis due to plaque accumulation
Durr *et al.* 1982	Retro-spective	45 children age 4-12y	101	Most SSC had at least 1 defect in fit. Moderate correlation between plaque index and gingival index of non-ideal SSC
Sharaf & Farsi 2004	Retro-spective	177 children age 3.5-12y	254	No direct effect on gingival health or interproximal bone levels but oral hygiene level main risk factor in health of gingival surrounding SSC
Webber 1974	Pro-spective	99 children age groups <8 & >8y	99 and contra-lateral controls	SSC do not adversely affect gingival health regardless of patients' oral hygiene status. Slight gingival changes in 8-12yr old subjects due to physiological changes
Einwag 1984	Retro-spective	Not specified	188 1° & 2° molars	SSC use on primary molar leads to clinically acceptable irritation of gingiva Recommend replacing permanent molar SSC with cast crown by age 15
Guelman *et al.* 1988	Retro-spective	36 children age 9-12y	36 and 36 contra-lateral controls	A well adapted SSC on second primary molar does not affect periodontal health of adjacent first permanent molar

1.12 Anterior preveneered SSC

The majority of available literature relating to preveneered SSC focuses on laboratory studies for anterior aesthetic preveneered crowns.

1.12.1 In vitro studies anterior preveneered SSC

Superior long term aesthetics of anterior preveneered crowns depends on the stability of the labial veneer. Two main studies examined the force required to fracture the veneer (Table 1.12-1).

Table 1.12-1   Mean force required to dislodge anterior SSC veneers in different studies

	Waggoner & Cohen 1995	Baker *et al.* 1996
	Force Newtons ± standard deviation	Force Newtons ± standard deviation
Kinder Krown™	397.2 ± 53	406.1 ± 121.9
NuSmile® crowns	447.2 ±78.5	445.7 ± 80.9
Cheng™ crowns	511.9 ± 83.4	479.5 ± 76.9
Whiter Biter II	686.5 ± 181.4	362.5 ± 96.1

Waggoner and Cohen (1995) reported the mean force to produce veneer failure was lowest for Kinder Krowns™ but this value was not significantly different from NuSmile® or Cheng™ crowns. Whiter Biter II crowns required significantly more force for failure than the other crown types. Whiter Biter II crowns (White Bite Inc, LA Grange, KY, USA) differ from the resin composite veneered crowns as it has a flexible thermoplastic veneer. These crowns are no longer available and have been replaced by the Dura Crown (Space Maintainers Laboratory™, Chatsworth, California, USA).

The authors concluded that the average force to break the veneer in all these crowns was greater than that the average bite force of a child as reported by Bakke *et al.* (1990) (Table1.8-1). It is interesting to note that

the values found were also far greater than the average bite forces determined by Braun *et al.* (1996), which is perhaps more relevant for comparison with occlusal forces of primary molars. In addition, the authors noticed that the mechanism of veneer loss was different between different crown types. Whiter Biter II exhibited adhesive failure while the others three crowns experienced a mixed cohesive-adhesive failure (Waggoner and Cohen 1995).

In a similar study, Baker *et al.* reported the mean force required to produce failure was comparable for NuSmile® crowns and Kinder Krowns™ (Baker *et al.* 1996). Again, it was found that the manner of veneer failure was different. Whiter Biter II crowns failed with a characteristic plastic deformation, the other crown types displayed mixed cohesive/adhesive failure and proved brittle in comparison. Kinder Krown™ failure was characterised by multiple cracks, Cheng™ crowns exhibited chipping, and NuSmile® crowns displayed loss of the facing just gingival to the incisal edge, thus exposing the alumina blasted surface.

The methodology and results of these two studies differ as Waggoner and Cohen immersed the crowns in water for 24 hours while Baker *et al.* immersed crowns for 90 days before thermocycling. It was suggested that water absorption may play a role in strength of the veneers. As composite resins tend to absorb water over time, water submersion may act as a plasticiser thus affecting the composite strength and explaining the differences in the results gleaned from each study.

The effect of crimping and cementation on retention of anterior preveneered crowns *in vitro* has been examined (Guelmann *et al.* 2003, Gupta *et al.* 2008). Guelmann *et al.* (2003) reported NuSmile® crowns showed statistically less retention than all other crowns when cemented only. Kinder Krowns™ were significantly more retentive than all other crown types when crimped and cemented. The authors concluded that a combination of crimping and cementing was best for all crown types. However, it was notable that preveneered SSC have a limited crimping capacity. Gupta *et al.* (2008) reported that the mean force required to

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fracture the veneer was comparable for crimped and noncrimped NuSmile® anterior crowns (511 and 510 newtons respectively). However, the crimped crowns were associated with greater veneer surface loss.

Given the potential for veneer failure of preveneered SSC, it is appropriate to consider the possibilities for repair. Yilmaz and Yilmaz (2004) investigated the strength of flowable composite resin or a crown and bridge veneering resin used to repair anterior NuSmile® crowns *in vitro*. It was determined that shear forces of the repair materials were less (158 to 226 Newtons) than the bond forces of the original veneer material (385 Newtons).

1.12.2 *In vivo studies anterior preveneered SSC*

Although there is *in vitro* evidence that preveneered crowns withstand static loading forces greater than those generated by an average child, there is clinical evidence that demonstrated veneer fracture and compromised aesthetics. Table 1.12-2 summarises the existing clinical studies regarding anterior preveneered SSC.

It is interesting to point out that for some studies (Roberts *et al.* 2001, Shah *et al.* 2004), a larger number of subjects were eligible for inclusion, however only a small sample size was evaluated. Patient recruitment was problematic, and it was recognised that many eligible participants were either not interested or unavailable. This phenomenon highlights the inherent difficulties with clinical studies of this nature.

Parental satisfaction with different types of preveneered aesthetic anterior SSC has been studied and reported a unanimously high approval for this type of restoration (Roberts *et al.* 2001, Shah *et al.* 2004, Champagne *et al.* 2007). Interestingly, the most recent of these studies found that the child's perceived satisfaction had a direct influence over the parents overall satisfaction (Champagne *et al.* 2007). Indeed, very high parental satisfaction rates have been repeatedly reported regarding anterior

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preveneered crowns, in spite of the fact two studies stated that many crowns demonstrated chipping of the facing over time (Roberts *et al.* 2001, Shah *et al.* 2004). To date, no studies have investigated the levels of parent or child satisfaction with posterior preveneered aesthetic SSC.

Table 1.12-2   In vivo studies of anterior preveneered SSC

Study	Design	Methods	Main Findings
Croll & Helpin 1996	Case report	Cheng™ crowns	• Important advantages but not without limitations • Shade looked artificial • Appropriate case selection is paramount • Procedure can save time and give excellent result
Roberts *et al.* 2001	Retrospective cross sectional	12 children 35 maxillary Whiter Biter II crowns Evaluated after 3 years	• All crowns were retained • 33% partial chipping • 25% facings completely lost • Increased overjet led to more resin failure (likely due to increased trauma risk) • Increased overbite led to less resin failure • Parental satisfaction highly positive
Shah *et al.* 2004	Retrospective	12 children 46 Kinder Krowns™ Placed under GA Evaluated after mean 1.5 years	• 13% facing completely lost (but remained white due to underlying opaque layer) • 11% partial facing lost • Increased facing failure with increased overjet • 24% had mild gingival inflammation • High level parental satisfaction
MacLean *et al.* 2007	Retrospective	226 NuSmile® (new light shade) Present for mean of 12.9 months Multiple operators	• Majority appeared natural • Only 4% matched shade • Colour stable over time • 86% resisted facing fracture • 99% successfully retained • Canines least used and least successful • 91% had excellent aesthetics after 6 months

1.13 Posterior preveneered SSC

1.13.1 In vitro studies of posterior preveneered SSC

There is only one known published study examining posterior preveneered crowns *in vitro* (Yilmaz et al. 2008). This recent study examined the repair of posterior preveneered SSC. A total of 22 artificially fractured NuSmile® posterior crowns were repaired using two different techniques (Table 1.13-1). Results indicated that both repair materials gave similar aesthetic outcomes and shear bond strength values comparable to the original veneer material. In addition, the original veneer material required higher force to fracture than those previously reported for NuSmile® anterior SSC.

These results are inconsistent with a previous study by the same author regarding repair of anterior NuSmile® crowns (Yilmaz and Yilmaz 2004). The authors postulated that this difference may be due to variations in repair materials used.

Table 1.13-1   Mean force required to fracture the original veneer material and both repair materials

	Groups	Number	Mean force (Newtons) ± standard deviation
	NuSmile®	22	870.6 ± 190.5
1	NuSmile® + Panavia + Tetric Flow	11	835.3 ± 180.5
2	NuSmile®+ Monopaque + Tetric Flow	11	763.2 ± 127.8

It is pertinent to highlight the many limitations that exist with *in vitro* research, which complicate the extrapolation of data to the *in vivo* situation. One of the main flaws when assessing veneer material strength in the laboratory is that static loading of the crowns is artificial, as *in vivo* forces do not occur in a simple axial direction and it therefore difficult to simulate. Forces in the mouth are considered to be dynamic and involve fatigue due to loading over time.

Given the lack of research regarding posterior aesthetic SSC one must extrapolate data from reports concerning anterior preveneered SSC. However, no direct comparison can be made regarding veneer strength and fracture resistance given the differences in the nature and pattern of occlusal forces between anterior and posterior teeth. Shearing forces predominate anteriorly while grinding forces are generated posteriorly. It is plausible to assume that anterior shearing forces from static loads are easier to replicate and evaluate in the laboratory situation.

1.13.2 In vivo studies of posterior preveneered SSC

To date, there are only two clinical studies evaluating posterior preveneered SSC (Fuks et al. 1999, Ram et al. 2003). In the first pilot study, the authors compared 11 conventional SSC with 11 NuSmile® mandibular molar crowns in a split mouth design (Fuks et al. 1999). Crowns were re-evaluated after 6 months. Although the preveneered SSC demonstrated poorer gingival health than the conventional SSC group, none displayed chipping of the veneer facing. In this study, no reduction of the facial bulge was carried out, despite manufacturer instruction for circumferential preparation to ensure adequate seating and avoid distortion of the buccal gingival tissue. Additionally, the status of the opposing tooth was not specified.

The same authors retrospectively followed up these crowns after 4 years of service (Ram et al. 2003). Ten out of the original 11 subjects were available for reassessment. The preveneered crowns had not changed colour after 4 years and remained brighter than natural teeth. It is notable that the newer more natural NuSmile® shade "new light" was not yet available at the time of this study. At this stage, no differences in gingival health were noted between the conventional and preveneered SSC. However, all of the preveneered crowns presented with chipping of the facing and consequently poor aesthetic appearance. The degree of chipping was rated as 'partial' for all crowns involved and none displayed complete loss of the facing. The authors concluded that NuSmile® preveneered crowns were very expensive, bulky and lacked a natural

appearance. Inherent limitations exist with both these studies. The evaluation was limited to mandibular molars for financial reasons, thus providing no evidence of the performance of maxillary molar preveneered SSC. Furthermore, there was no evidence of training or calibrating of the examiners. Also, given the obvious differences between the crown types, a blind assessment was not possible.

The lack of *in vivo* studies for the use of preveneered SSC is disappointing but perhaps unsurprising. Waggoner (2006) identified the inherent difficulties with obtaining good prospective clinical data when the subjects comprise a cohort of young children who are most likely to develop dental caries. Difficulties with behaviour management, parental consent and reluctance on the part of the clinician are all obstacles to performing well controlled, prospective clinical research.

Companies such as NuSmile® have recently developed university programme packages in conjunction with the American Academy of Pediatric Dentistry Foundation (AAPD®). In addition to becoming a corporate sponsor, NuSmile® are offering to donate products and materials for pediatric dentistry residency programmes wishing to incorporate NuSmile® crowns into their teaching curriculum. This venture is likely to result in an increased use of these aesthetic crowns, both in university teaching and in private dental practice in the United States in future years. With current increasing demands for evidence-based dentistry, it is important that these new techniques be scientifically evaluated in order to justify their use.

A recent Cochrane review identified an urgent need for well designed RCTs to compare different types of restorative materials in primary teeth (Yengopal *et al.* 2009). The need for evidence regarding the clinical performance of posterior preveneered SSC is apparent. The observation of a tangible gap in the literature concerning these commercially available products led to the proposal of the present study.

1.14 Aims and Objectives

1.14.1 Study Aims

1) To compare the clinical and radiographic success of posterior NuSmile® Primary Crowns and Kinder Krowns™.

2) To compare the clinical success of these preveneered primary molar crowns with conventional SSC.

1.14.2 Study Objectives

1) To compare posterior NuSmile® Primary and Kinder Krowns™ as restorative options for primary molars.

2) To assess numerous clinical variables related to preveneered crowns: crown retention, effect on gingival health, stain resistance, veneer facing fracture, facing wear, gingival margin extension, occlusion, alignment and proximal contacts.

3) To assess the level of parental satisfaction with posterior preveneered SSC.

1.14.3 Null Hypothesis

1) There will be no difference in the clinical and radiographic success of the posterior NuSmile® Primary Crowns and Kinder Krowns™.

2) There will be no difference in the durability of posterior NuSmile® Primary Crowns, Kinder Krowns™ and conventional SSC.

2 Materials and Methods

2.1 Study population

The study population was drawn from patients referred to the Department of Paediatric Dentistry of the Dublin Dental School and Hospital and the Paediatric Dental Department of The Adelaide and Meath Incorporating the National Children's Hospital (AMNCH) in Tallaght, County Dublin, Ireland. The study period was from January 2008 to June 2009.

2.2 Inclusion and exclusion criteria

All patients who met the inclusion criteria were eligible for participation. Inclusion criteria were specified both for the patient and for the teeth involved. Specified inclusion and exclusion criteria are shown in Table 2.2-1.

Table 2.2-1   Inclusion and exclusion criteria

	Inclusion Criteria	Exclusion Criteria
Patient	• Fit and healthy (ASA* I or II) • Patient <10 years old • SSC required on two restorable pair matched first or second primary molars • High caries risk • Informed consent achieved	• ASA* ≥ III • Endocarditis prophylaxis required • Informed consent not achieved
Tooth	• Multisurface caries • Post endodontic treatment • Developmental defects of tooth structure • Severe erosion • Presence of opposing tooth	• Acute infection • Presence of sinus • Infra-occlusion • Mobility • Internal root resorption • Exfoliation imminent • Absence of opposing tooth

(* American Society of Anesthesiologists five category physical status classification system)

2.3 Study design

2.3.1 Permission and consent

Ethical approval was attained from the Saint James Hospital / AMNCH Research Ethics Committee (Appendix 7.1)

Each potential participant and parent / guardian was approached by a member of the study team. The study was explained and initial request for participation was sought. Pictorial information leaflets (Appendix 7.2) were given at least one week in advance of obtaining consent to allow the participant and parent due consideration time. No financial benefits were offered or attempts made to coerce participants to enroll in the study. At a subsequent visit, informed consent was obtained using a consent form (Appendix 7.3) signed by the parent or guardian of the child, a member of the study team and an independent witness. This was achieved prior to commencement of the treatment.

2.3.2 Confidentiality

Children were allocated a participant number for identification purposes. All consent forms and data collection sheets were stored in a locked cabinet and computerised records were stored on a password-protected computer. Information regarding the treatment was available only to the study team members.

2.4 Pre-operative planning

2.4.1 Preventative advice

All children presented for an initial visit to instigate a high caries risk preventative regime (SIGN publication 47). This involved instruction in oral hygiene procedures, methods to optimize fluoride exposure and dietary counseling.

2.4.2 Clinical photographs

Pre-operative, perioperative and post-operative photographic records were taken for a number of participants where possible. Photographic records were then used to depict clinical outcomes within the thesis text.

2.4.3 Radiographic examination

Standardised baseline bitewing radiographs were exposed prior to treatment, if not taken previously at the assessment stage. This was undertaken so that all radiographs were exposed in the same standardised manner. This was achieved as follows:

- Films: E-speed, size 0 (Kodak, Carestream Health Inc., Rochester, New York 14608, USA).

- Bitewing holder: Hawe Kwik-Bite (Kerr Corporation, Orange, CA 92867, USA).

- Exposure setting of 63Kv, 0.2 seconds

For very young participants who were unable to tolerate an intra-oral film, radiographs were exposed during general anaesthesia prior to tooth preparation.

2.4.4 Orthodontic separators

In a minority of patients, 1.52 mm orthodontic separators (American Orthodontics, Sheboygan, Wisconsin 53081, USA) were placed on the study teeth at a pre-treatment visit. This procedure was indicated if obvious space loss had occurred between the first and second primary molar (Figure 2.4-1) and was carried out for all participants treated under local anaesthesia and for a minority of participants prior to treatment under general anaesthesia.

Figure 2.4-1   **Orthodontic separators in place**
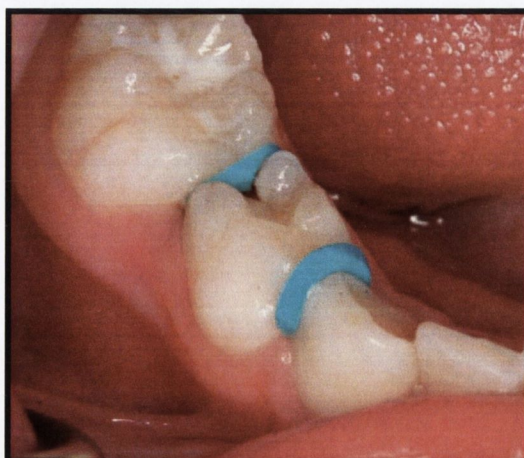
2.4.5 Behaviour management options

Each participant was assessed to determine the most appropriate setting for treatment. Determining factors were based on the child's age, level of co-operation for dental treatment, magnitude of treatment required and parental preference.

Treatment options included:

- Local anaesthesia (LA)
- Combination of LA and nitrous-oxide and oxygen inhalational sedation
- General anesthesia (GA)

2.5 Armamentarium

2.5.1 Aesthetic Preveneered SSC

Two types of commercially available aesthetic preveneered posterior stainless steel crowns were used in this study (see Table 2.5-1).

I.   **NuSmile® Primary Crowns** (Orthodontic Technologies, Houston, Texas, USA).

II. **Kinder Krowns™** (Mayclin Dental Studios, Minneapolis, Minnesota, USA).

Each company used a different bonding system to attach the resin to the underlying metal. However, the exact manufacturers' bonding mechanisms remain proprietary. The individual companies were contacted by telephone and emailed by the principal investigator to discuss the proposed study and both agreed to participate.

The veneer covering of all first primary molar crowns incorporated both the buccal and occlusal surfaces. The veneer covering of all second primary molar crowns included the buccal surface only. Pictorial information of both crown types are shown in Figures 2-5-1 to 2.5-10.

New crowns were used for each participant, thus avoiding any concerns regarding potential adverse effects of sterilization procedures on the veneer (as discussed previously), or the effects of any previous crown manipulation.

Table 2.5-1   Properties of NuSmile® Primary Crowns and Kinder Krowns™
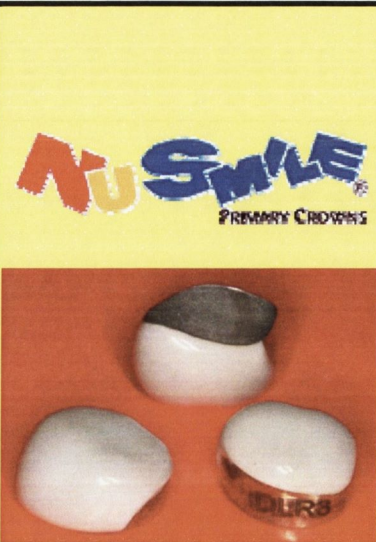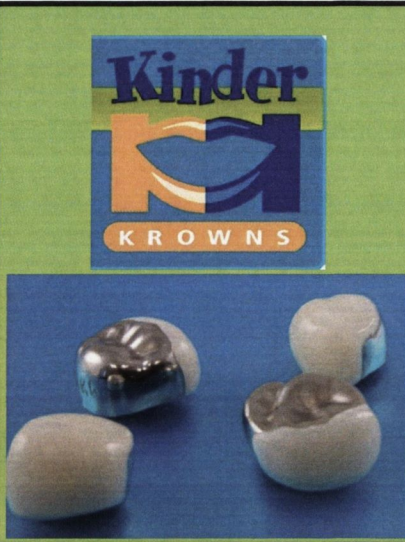
	NuSmile Primary Crowns	Kinder Krowns
Bonding mechanism	Veneer bonded directly to alumina-blasted SSC base	IncisalLock™ feature: fenestrated SSC base to enhance bond strength and aid reparability
Veneer coverage	Full coverage Buccal only	Full coverage Buccal only
Shades	Extra light (lightest) New light	Pedo 1 (lightest) Pedo 2
Sizes	7 sizes D and E right and left upper and lower numbered	6 sizes D and E right and left upper and lower colour-coded
Cost	~ € 23.30 each (full coverage)	~ € 23.70 each (full coverage)
CE Mark	Yes	No

Figure 2.5-1   Fitting surface of a conventional SSC (3M™ ESPE™)

Figure 2.5-2   Alumina blasted fitting surface of NuSmile® Primary Crowns
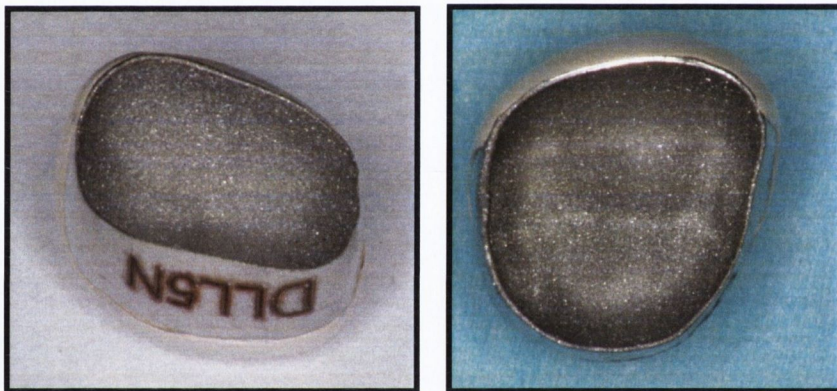
Figure 2.5-3   Fenestrated fitting surface of Kinder Krowns™; full veneer coverage (left), buccal facing only (right)

Figure 2.5-4   Full veneer coverage first primary molar SSC: occlusal view.
NuSmile® (left), Kinder Krown™ (right)
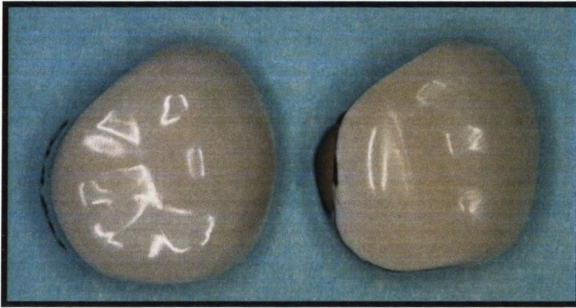
Figure 2.5-5   Full veneer coverage first primary molar SSC: buccal view.
NuSmile® (left), Kinder Krown™ (right)
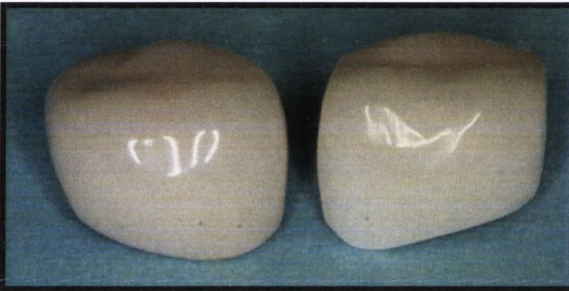
Figure 2.5-6   Full veneer coverage first primary molar SSC: lingual view.
NuSmile® (left), Kinder Krown™ (right)

Figure 2.5-7   Full veneer coverage first primary molar SSC: proximal view.
NuSmile® (left), Kinder Krown™ (right)

Figure 2.5-8   Buccal veneer coverage second primary molar SSC: occlusal view.
NuSmile® (left), Kinder Krown™ (right)

Figure 2.5-9   Buccal veneer coverage second primary molar SSC: buccal view.
NuSmile® (left), Kinder Krown™ (right)
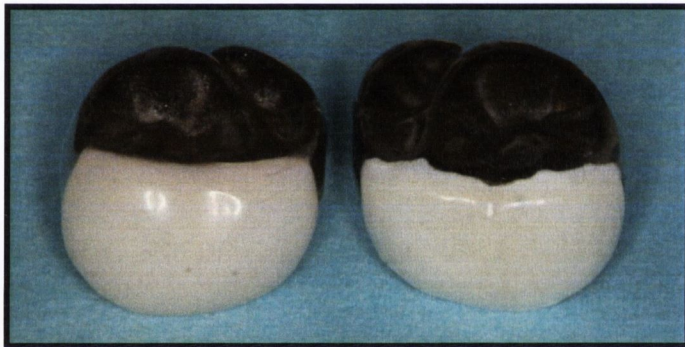
Figure 2.5-10   Buccal veneer coverage second primary molar SSC: proximal
view.
NuSmile® (left), Kinder Krown™ (right)
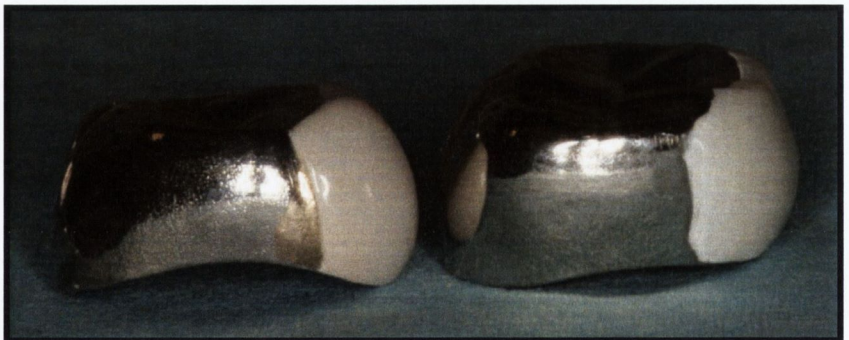
2.5.2 Burs

Coarse occlusal and flame friction grip diamond burs were used for the crown preparation and for refinement procedures (Table 2.5-2) (Kerr Corporation, Orange, CA 92867, USA). New burs were sterilized in a steam autoclave prior to use. New burs were used for each participant.

Table 2.5-2   Crown preparation burs

Occlusal	Flame
Short shank	Short shank
714620-coarse	714600-coarse
Kerr FG SS630	Kerr FG SS216
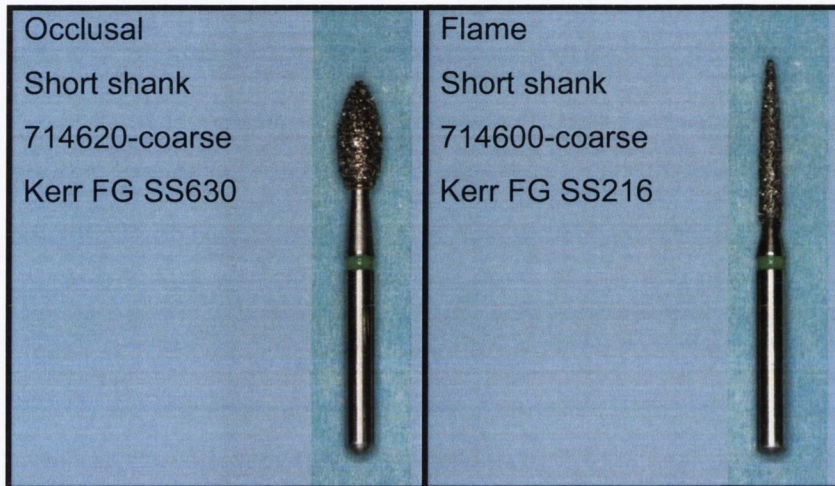
2.5.3 Local anaesthesia

Topical anaesthesia was used prior to injecting local anaesthetic in all cases other than those patients treated under general anaesthesia. Infiltration local anaesthesia was administered prior to crown preparation in all patients; no inferior dental blocks were required.

- Topical anaesthetic: Benzocaine gel (20%) (Topicale™, Premier Dental Products Co., Plymouth Meeting, PA 19462, USA).
- Local anaesthetic: Xylocaine 2% 1:80,000 (Lignospan Special, Septodont, Deproco UK Ltd., Kent, UK).

2.5.4 Rubber dam

A standard 5X5 rubber dam (Coltène/Whaledent, Langenau, Germany) was used in all cases and secured with an appropriate clamp.

2.5.5 Pulp therapy medicaments

The pulp status was assessed following caries removal prior to completing crown preparation. Subsequent pulp therapy included protective lining, indirect pulp therapy or ferric sulphate pulpotomy

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according to pulpal diagnosis. All pulp therapy procedures were carried out according to current best practice guidelines. The following medicaments were used:

- Intact pulpal liner:
  - → Vitrebond™ (3M ESPE™ Dental Products, 3M Centre, St. Paul, MN 55144, USA).
- Indirect pulp therapy:
  - → Dycal® (DENTSPLY International World Headquarters, York, PA 17405-0872, USA).
  - → Vitrebond™ (3M ESPE™ Dental Products, 3M Centre, St. Paul, MN 55144, USA).
- Pulpotomy materials:
  - → 15.5% Ferric sulphate (Astringedent®, Ultradent Products Inc., Utah 84095, USA).
    - → Reinforced Zinc Oxide Eugenol cement (Masterdent, Dentonics, Inc., North Carolina 28110, USA).

2.5.6 Crown luting cement

Ketac™ Cem Aplicap™ Permanent Glass Ionomer Luting Cement was used to lute each crown (3M ESPE™ Dental Products, 3M Centre, St. Paul, MN 55144, USA). The capsule was activated for 2 seconds with the Aplicap Activator, mixed for 8 seconds using a high speed mixer (approximately 4300 oscillations per minute), and then applied with the Aplicap Applier to dispense cement into the crown. Excess cement was removed with water spray and knotted floss.

2.6 Crown allocation

A split mouth design was used in order that both crowns were exposed to a similar oral environment and oral hygiene habits. Pair matched molars were randomly designated to receive a NuSmile® crown or a Kinder Krown™. A NuSmile® crown was always placed first by the operator. The decision to commence on the right or left side of the mouth was decided by a coin toss. Adjacent aesthetic crowns were not placed in this study as to do so may require excessive interproximal tooth preparation.

2.7 Crown preparation

The manufacturers' guidelines provided the foundation to develop a step-by-step customised tooth preparation and crown fitting guideline (operations manual) that was followed by each operator during crown placement (Table 2.7-1). Figures 2.7-1 to 2.7-10 illustrate various examples to demonstrate the technique.

Table 2.7-1   Customised method used for crown placement

Step	Procedure undertaken
1	Local anaesthetic was administered
2	The tooth was isolated with rubber dam using appropriate clamp
3	The mesiodistal crown dimension was approximated (about 2 sizes smaller than a conventional SSC)
4	2 mm occlusal reduction was performed using coarse occlusal bur
5	Caries was removed using stainless steel rosehead burs
6	Appropriate pulp therapy was performed or an appropriate protective base was placed over the pulp
7	Proximal contacts were broken using coarse tapered flame bur. 1.5 mm circumferential reduction was completed extending 2 mm subgingivally using coarse flame bur
8	Bulk reduction was completed: approximately 30% overall bulk reduction. Feather-edged margin created subgingivally
9	Sharp corners were refined. The preparation was checked to ensure absence of step or ledge subgingivally
10	The lingual aspect of the crown was crimped slightly if indicated. Crimping was avoided on the veneered surface or in close proximity to the veneer-metal interface
11	Crown was tried in to ensure a passive fit subgingivally without distorting the gingival tissues. The crown was seated using light digital pressure only
12	Occlusion was checked if possible in centric and excursive movements. Further occlusal reduction of the preparation was considered if crown was determined to be in hyperocclusion. The external veneer surface was not adjusted
13	Crowns were washed and dried using compressed air. Crown was then cemented using Ketac-Cem® (3M ESPE™)
14	Following cement set, excess was removed using wet gauze and knotted floss pulled through the contact points

Figure 2.7-1   Rubbed dam isolation

Figure 2.7-2   Occlusal tooth reduction
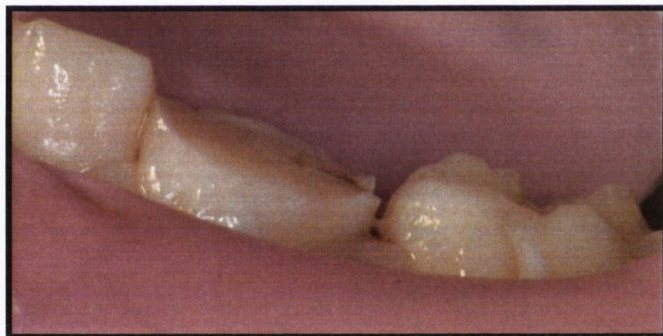
Figure 2.7-3   Caries removal and pulpal protection

41
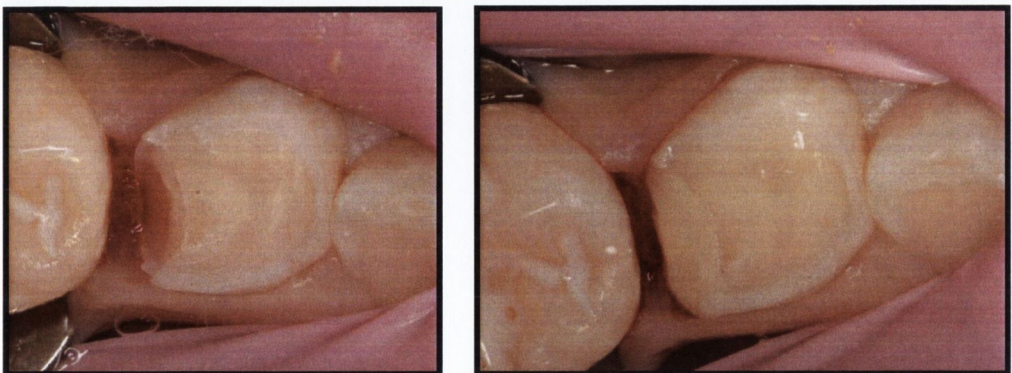
Figure 2.7-4   Proximal slices

Figure 2.7-5   Circumferential subgingival bulk preparation
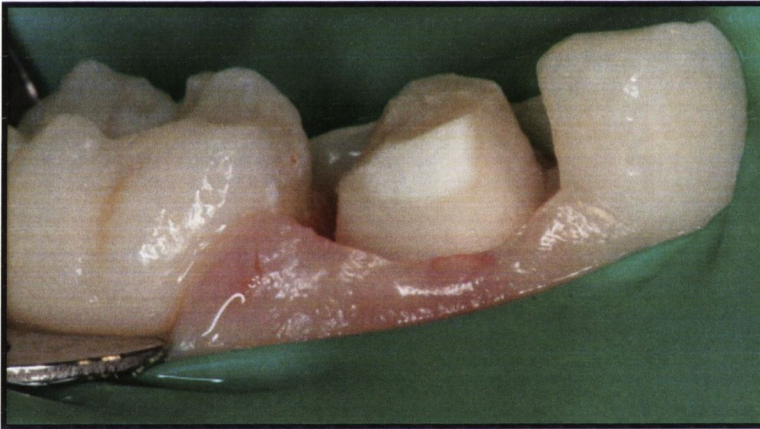
Figure 2.7-6   Smooth line angles and completed preparation
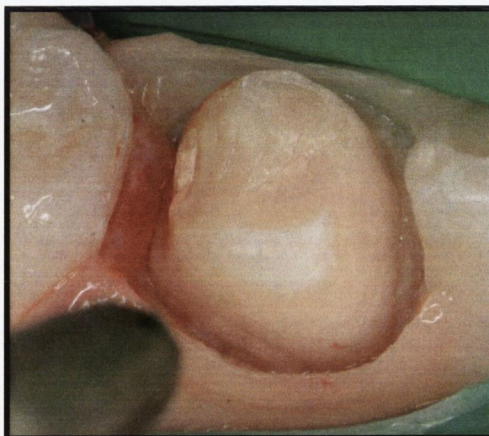
Figure 2.7-7   Crown try-in
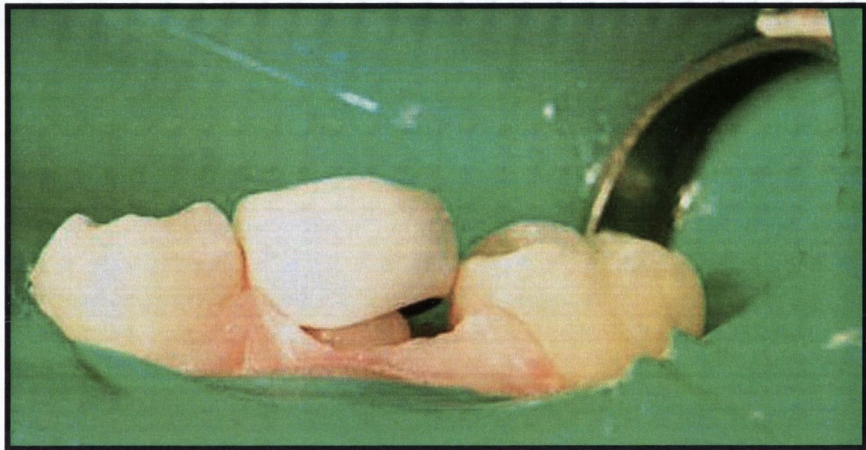
Figure 2.7-8   Crimping

Figure 2.7-9   Crown cementation

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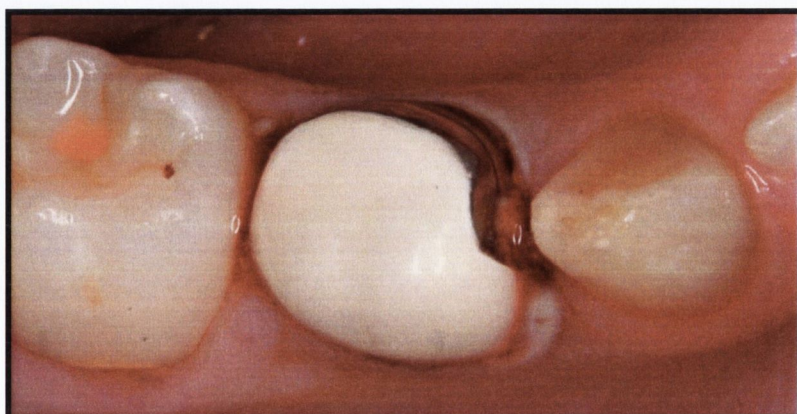
Figure 2.7-10   Completed crown
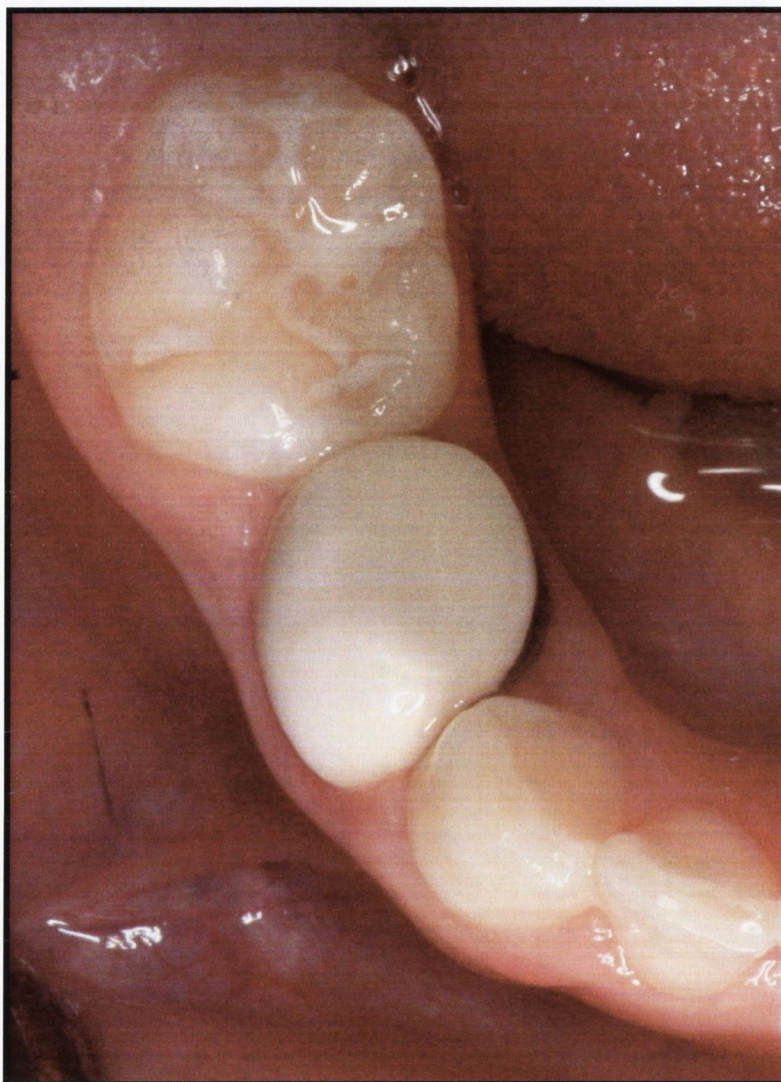
2.8 Operators

Two trained operators with experience in paediatric dentistry performed treatment in all participants (Dr Rona Leith and Dr Anne O'Connell). Training included participation in a hands-on course, crown preparation practice on typodont teeth, and studying DVDs of crown preparation supplied by the manufacturers. Both operators were instructed to follow the operations manual to ensure crowns were fitted in a similar manner.

2.9 Examiners

Two blinded examiners with experience in paediatric dentistry alternatively reassessed crowns at review visits (Dr Eimear Norton and Dr Shaunine Gallagher). Given the similarities in appearance of both crown types, it was possible to assess crowns in a blind manner. Both examiners were trained and calibrated on numerous days with an interval of at least one week between calibration sessions (World health Organisation, Oral Health Surveys, Basic Methods).

2.10 Training and calibration

Examiners were trained twice and then calibrated on four separate occasions. The final two sessions were used to test examiners on intra-examiner and inter-examiner agreement. Microsoft® Office Power Point presentations were composed for the purpose of training and calibration respectively. Both contained numerous clinical and non-clinical photographs of the individual variables to be assessed. The data collection form is shown in Appendix 7.4. Results were collected and entered into a Microsoft® Office Excel spreadsheet for further analysis.

2.11 Initial data capture

Following the initial visit to deliver preventative advice, baseline data for the teeth to be crowned was recorded on designated data capture sheets prior to and during treatment (Appendix 7.5).

2.11.1 Clinical Pre-operative Tooth Status

At the treatment visit, the tooth number and individual indication for SSC requirement was documented (Appendix 7.5). Each study tooth was assigned a score for plaque and gingival status by the principal operator. The Plaque Index (PI) (Loë 1967) (Table 2.11-3) and a customised version of the Modified Gingival Index (MGI) (Loë and Silness 1963, Lobene *et al.* 1986) were used for this purpose. The widely used MGI was chosen because it eliminated the need for periodontal probing which is considered unsuitable for a young patient cohort. The MGI (Table 2.11-1) was further customised into a 0-3 score system by combining the two original scores for mild inflammation into a single score (Table 2.11-2). This was performed in order to facilitate and ease calibration of the examiners.

Table 2.11-1   Modified Gingival Index (Lobene *et al.* 1986)

Score	Clinical features
0	Absence of inflammation
1	Mild inflammation: slight change in colour, little texture change of any portion of, but not the entire marginal or papillary gingival unit
2	Mild inflammation: criteria as above, but involving the entire marginal or papillary gingival unit
3	Moderate inflammation: glazing, redness, oedema, and/or hypertrophy of the entire gingival unit
4	Severe inflammation: marked redness, oedema, and/or hypertrophy of the marginal or papillary gingival unit; spontaneous bleeding, congestion or ulceration

Table 2.11-2   Customised Modified Gingival Index: codes and criteria used in assessment
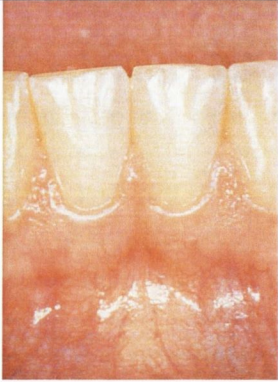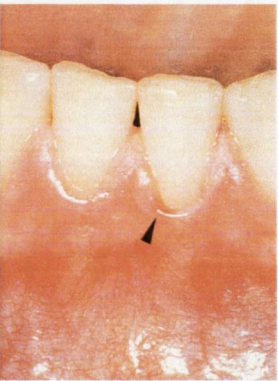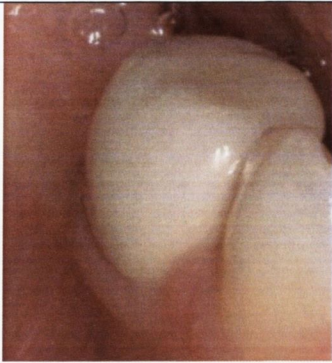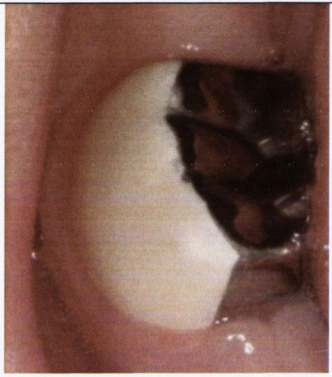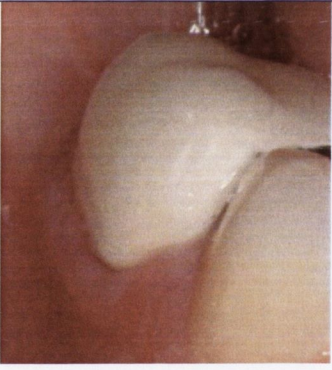
Score	Clinical features	Clinical picture
0	Absence of inflammation	
1	Mild inflammation: slight change in colour, little texture change of any portion of, but not the entire marginal or papillary gingival unit	
2	Moderate inflammation: glazing, redness, oedema, and/or hypertrophy of the entire gingival unit	
3	Severe inflammation: marked redness, oedema, and/or hypertrophy of the marginal or papillary gingival unit; spontaneous bleeding, congestion or ulceration	

Table 2.11-3   Plaque Index (Loë 1967): codes and criteria used in assessment

Score	Clinical features	Clinical Picture
0	Absence of plaque deposits in gingival area. No plaque on visual inspection or after probing.	
1	A film plaque adhering to the free gingival margin and adjacent area of the tooth. Plaque not seen on visual inspection but disclosed after running probe along gingival margin.	
2	Moderate accumulation of plaque which can be seen by the naked eye. This score was allocated if the plaque accumulation was limited to the crown gingival margin.	
3	Abundance of plaque. This score was allocated if an accumulation of plaque extended onto further crown surfaces other than the crown gingival margin alone.	

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2.11.2 Clinical post-operative tooth status

Variables determined during crown preparation were documented. The pulp status was recorded including type of endodontic therapy performed. The type and size of crown chosen for each molar was recorded as well as adaption methods used including crimping, trimming and any occlusal adjustment. The status of the opposing tooth was noted.

Patients were discharged following provision of post-operative instructions. If crowns were placed during multiple visits using local anaesthetic only, a further treatment visit was scheduled approximately one week later. Patients who had comprehensive care under general anaesthetic were reviewed 7 to 10 days post-operatively by the principal operator.

2.12 Review intervals

Participants were recalled for examination at 3, 6, 9 and 12 month intervals. Data was recorded using data collection sheets for clinical outcome (Appendix 7.6).

Bitewing radiographs were re-exposed 12 months following treatment. This yearly radiographic interval was in accordance with current guidelines for patients diagnosed as high caries risk (Espelid *et al.* 2003). All post-operative bitewing radiographs were exposed by the principal operator using a standardised technique as described above (Section 2.4.3).

2.13 Clinical outcome data

At every review visit, each participant was assessed by one of the trained and calibrated examiners. Variables for clinical outcome were scored and recorded on specified data collection sheets (Appendix 7.6). If during reassessment a crown displayed multiple categories of a particular variable, the examiners were instructed to allocate a score in accordance with the most severe category.

2.13.1 Crown Retention

A dichotomous scale was used to describe crown retention as follows:

0= Present; 1= Absent

A further score of 2 for recemented crowns was allocated by the principal operator if indicated, as it would not be known to the examiner.

2.13.2 Customised Modified Gingival Index

Following visual inspection, scores were allocated to each crown (Table 2.11-2)
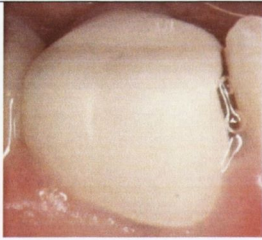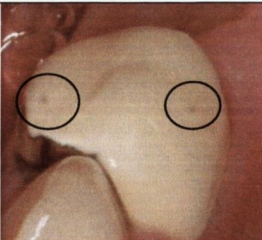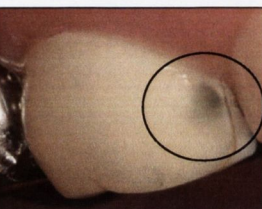
2.13.3 Plaque Index

Scores were allocated following visual and tactile inspection. A blunt periodontal probe was passed over the gingival crown margin and inspected for debris (Table 2.11-3)

2.13.4 Stain Resistance

A review of the literature failed to identify a suitable user-friendly index to assess staining. Therefore, a staining index was developed in which staining of the veneered portion of the crown was scored according to severity. Due to the subjective nature of this categorization, values were allocated according to area of stain (Table 2.13-1).

Table 2.13-1   Codes and criteria used in assessment of staining
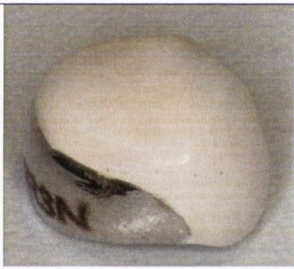
Score	Staining magnitude	Clinical Picture
0	No staining	
1	Minor staining: Pin-point dimension only	
2	Noticeable staining: Staining of greater than pin-point dimension	

2.13.5 Buccal and Occlusal Facing Fracture

Buccal facing fracture was scored for all preveneered SSC (Table 2.13-2). Occlusal facing fracture was scored only for full coverage preveneered crowns (all first primary molars). Examiners were trained in scoring fractures using photographs of artificially fractured preveneered crowns as no clinical pictures of fractures were available at time of calibration. On the occlusal surfaces, fracture was differentiated from wear as having rough edges. Examination involved visual inspection and use of a blunt periodontal probe to explore surface roughness if indicated.

Table 2.13-2: Codes and criteria used in assessment of buccal and occlusal facing fracture

Score	Magnitude of facing loss	Buccal Fracture	Occlusal Fracture
0	Intact		
1	<50% surface chipped		
2	>50% surface chipped		
3	Complete loss		

2.13.6 Facing Wear

Wear of the veneered occlusal surface was also calibrated using photographs of artificially worn veneered surfaces. Potential difficulties were expected in measuring wear within the veneer surface and the authors additionally noted that it would not have been possible to differentiate between actual wear and any occlusal adjustment that may have been carried out during crown fit. For this reason, it was decided to classify wear as present only if the metal underlying crown surface was visible to assist inter-examiner reliability at reassessment visits (Table 2.13-3). Examination involved visual inspection and use of a blunt periodontal probe to explore surface roughness if indicated. Wear was differentiated from fracture as having smooth edges.

Table 2.13-3   Codes and criteria used in assessment of facing wear

Score	Wear	Picture
0	None	
1	Cuspal only: metal visible	
2	>Cuspal: metal visible	

2.13.7 Gingival Margin Extension

Marginal extension of the crowns were examined visually only and scored as either subgingival or supragingival.

0= Subgingival
1= Supragingival

2.13.8 Occlusion

Care was taken to ensure that the correct position of maximum intercuspation was reached before examining the occlusion. Following rehearsal, the patient was asked to bite firmly onto standard 40 μm blue articulating paper (Bausch Articulating Papers, Nashua, NH, USA). Examination of the occlusion was carried out using visual and tactile inspection of marked contact points and scored as follows:

0= Contact: at least one marked contact point visible
1= No contact: no marked contact points visible

2.13.9 Opposing Tooth

The status of the opposing tooth was noted both prior to crown placement and again during each re-examination visit and scored as follows:

0= Natural tooth
1= Restored tooth: any form of restoration including amalgam, composite, resin modified glass ionomer, glass ionomer and fissure sealant
2= SSC
3= Preveneered aesthetic SSC
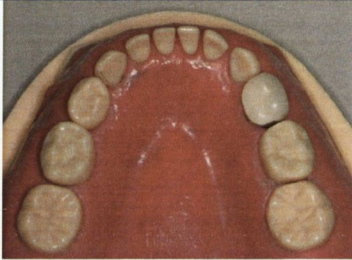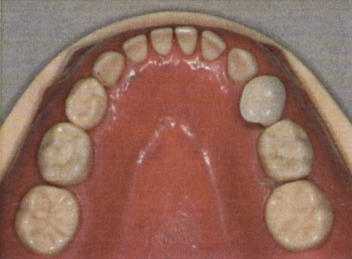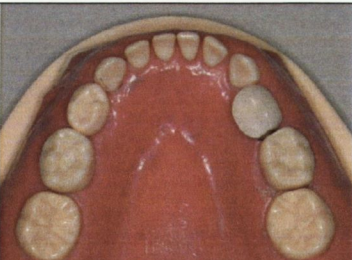
2.13.10   Crown Alignment

Alignment of the crowns was scored using visual inspection of the crown relative to arch form (see table 2.13-4).
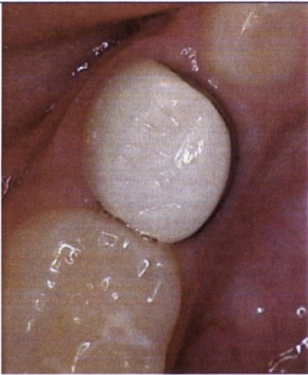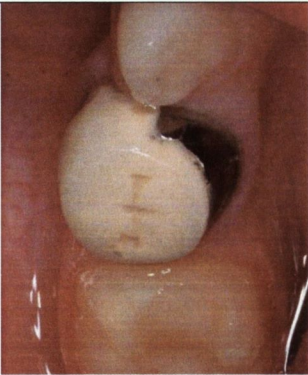
Table 2.13-4   Codes and criteria used in assessment of crown alignment

Score	Alignment	Picture
0	Normal: Crown alignment in accordance with arch form	
1	Rotated: Crown rotated buccally or lingually relative to arch form	
2	Mal-aligned: Crown displaced in buccal or lingual lateral direction relative to arch form	

2.13.11 *Proximal Contacts*

Proximal contacts were evaluated using a visual and tactile examination. Dental floss was passed between the contact point of adjacent first and second primary molars. Proximal contacts were only assessed for crowns with an adjacent primary molar. Contact points with a primary canine was not evaluated due to the potential difficulty in differentiating between an iatrogenic open contact during crown placement, and presence of the physiological primate space distal to the lower primary canines. In addition, proximal contact points between the second primary molar and first permanent molar were not included in contact point assessment as many participants were in the primary dentition only (Table 2.13-5).

Table 2.13-5   Codes and criteria used in assessment of proximal contacts

Score	Proximal Contact	Clinical Picture
0	Contact closed: Adjacent primary molar present Good contact point visible Floss meets resistance	
1	Contact open: Adjacent primary molar present Poor or no visual contact Poor or no resistance to passing floss	

2.14 Radiographic outcome data

Bitewing radiographs were exposed at the 1 year review visit. All radiographs were exposed by the principal investigator in a standardised manner (see Section 2.4-3).

Training was achieved using a Microsoft® Office PowerPoint presentation detailing the procedure and numerous radiographic examples. Two calibration sessions followed (one week apart) from which the level of intra examiner agreement was determined. Following training and calibration, the examiner was asked to blindly evaluate crown adequacy based on presence of a horizontal overhang (see Figure 2.14-1). Dichotomous variables were used and the crowns were subsequently scored as either radiographically adequate or inadequate. Assessment was based on visual inspection using an illuminated light box under lens magnification (X2, Lysta AS, Denmark). Where an overhang was detected, the examiner was asked to obtain a measurement with an electronic digital calliper (Powerfix, model Z22855, London, UK). The radiographic width of the overhanging crown was also measured. As the exact crown size was noted during fit, the corresponding actual crown width was also able to be measured. This value was then compared with radiographic crown measurement thus enabling the actual overhang size to be determined. The unknown variable was determined according to the following formula:

$$\frac{\text{Actual size crown}}{\text{X-ray size crown}} = \frac{\text{Actual size overhang}}{\text{X-ray size overhang}}$$

This data was entered into a Microsoft® Office Excel spreadsheet for further analysis (Appendix 7.7).

Figure 2.14-1   Radiographs illustrating crown adequacy / inadequacy
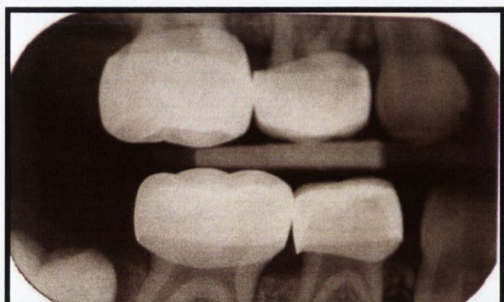
Inadequate study crown 54; overhang   Adequate study crown 74; no overhang
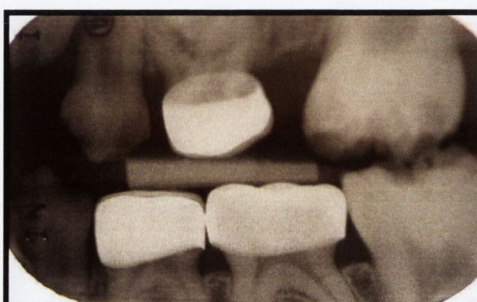
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2.15 Criteria for clinical and radiographic success

The criteria for clinical and radiographic success are outlined in Table 2-15-1. Radiographic crown adequacy was determined by absence of a horizontal overhang indicative of an oversized crown.

Table 2.15-1   Criteria of Clinical and Radiographic Success

Clinical Success
• Retention of crown
• Absence of facing fracture
• No adverse effects on gingival health
Radiographic Success
• Crown adequacy

2.16 Visual Analogue Scale (VAS) for parental satisfaction

A VAS was used to score levels of parental satisfaction at the 1 year review visit. A horizontal VAS was used as it is reported to be preferential to a vertical VAS (Wewers and Lowe 1992). Parents were presented with the VAS by an independent person and were asked to consider the size, shape and shade of the crowns in their assessment, and to provide an overall score by marking a vertical line (on a 100 mm horizontal line) at the position that expressed their overall level of satisfaction (Appendix 7.8). Data was then entered into Microsoft® Office Excel for analysis.

2.17 Statistical evaluation

All data were recorded on Microsoft® Excel 2007 (Microsoft Inc., Redmond, WA, USA). Graphic representation of the descriptive data was generated by Microsoft® Excel 2007. Statistical analysis was carried out using SPSS version 14.0 for Windows® statistical software (SPSS Inc. Headquarters, Chicago Illinois, USA). Inter and intra examiner calibration was analysed using the Cohen's Kappa test. Data regarding clinical variables was collapsed to produce dichotomous rather than categorical variables. Contingency tables were then generated from the collapsed data and the Fisher's Exact test was used to test for statistical significance, with the level of significance set at $p < 0.05$.

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3 Results

3.1 CONSORT diagram

A diagram to show the flow of participants through each stage of the study is shown in Figure 3.1-1

Figure 3.1-1   Flow of participants through the study

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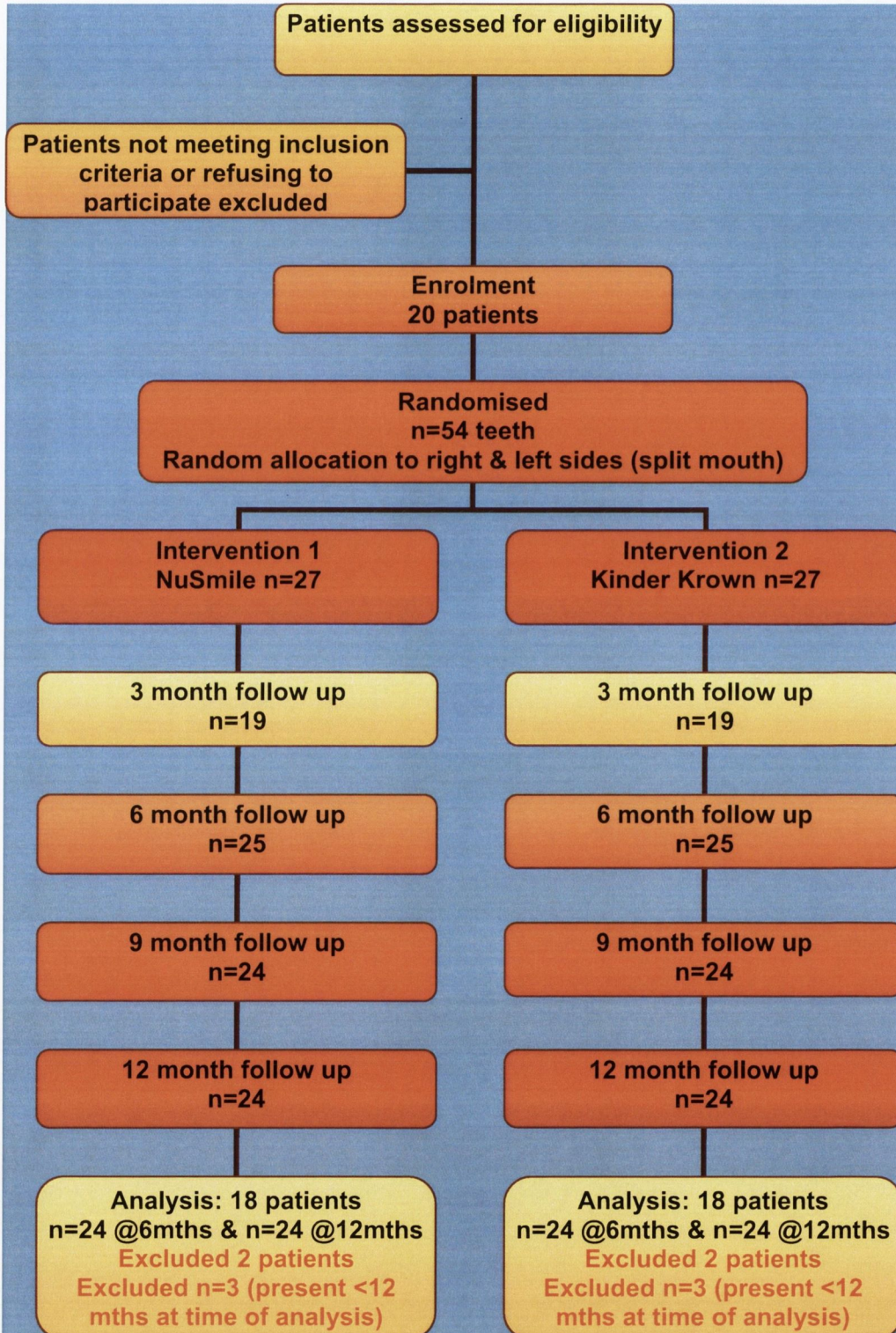
3.2 *Descriptive data*

The study population was sourced from the Paediatric Assessment Clinics of the Dublin Dental School and Hospital and the AMNCH, Tallaght, Co. Dublin between January 2008 and June 2009. A total of 20 patients with 54 teeth were eligible for inclusion. Two patients with 6 teeth were excluded from the final analysis as the crowns had been present for <1 year at time of analysis. The following figures and tables represent the data for the 18 patients and 48 teeth included in the final analysis. Table 3.2-1 shows the gender distribution among the study participants.

Table 3.2-1   Gender distribution in the study group

	Number	Percentage
Males	11	61%
Females	7	39%

The mean age was 5.44 years with a range of 2-9 years. The median and mode were both 6 years of age. Figure 3.2-1 shows the age distribution among the study participants.

Figure 3.2-1   Distribution of age among study participants
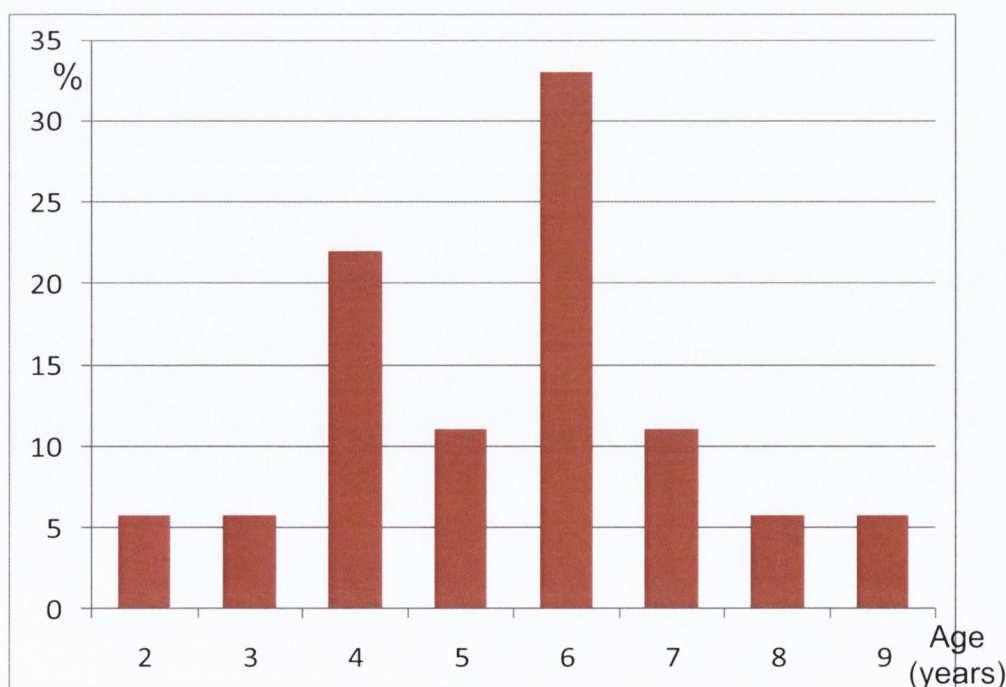
3.3 Treatment data

The indications for crown placement varied from early childhood caries (ECC) to developmental defects of tooth structure including amelogenesis imperfecta (AI), dentinogenesis imperfecta (DI) and localised areas of enamel hypoplasia. The distribution of each diagnosis among the study participants is shown in Figure 3.3-1.

Figure 3.3-1   Distribution of indications for crown placement
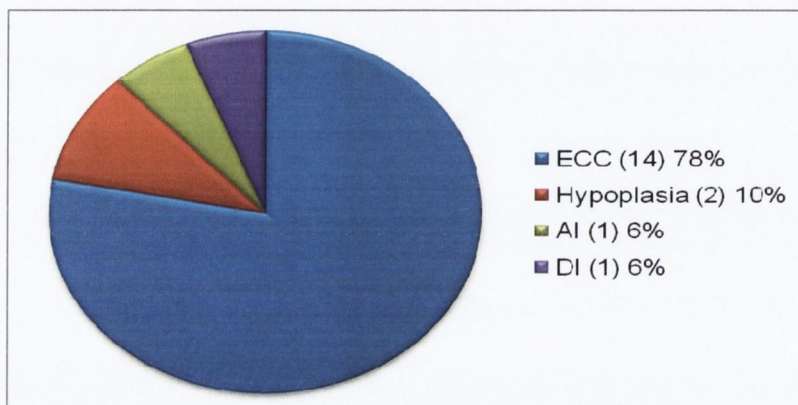
The different behaviour management options used included local anaesthesia alone (LA), local anaesthesia and nitrous oxide inhalational sedation (LA/N$_2$O) and general anaesthesia (GA). The distribution is shown in Figure 3.3-2. It was found that the use of these crowns did not influence the behaviour management option chosen. Crown placement was found to be acceptable using local anaesthesia alone and the decision to carry out the dental treatment using sedation or general anaesthesia was based on other patient management issues.

Figure 3.3-2   Distribution of behaviour management options
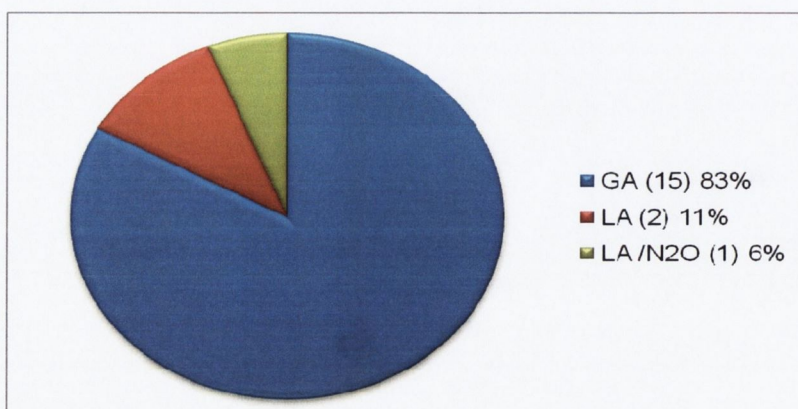
The number of crowns received by each participant varied from a minimum of 2 to a maximum of 4 (Figure 3.3-3). No patient received 4 second primary molar crowns.

Figure 3.3-3   Distribution of number of crowns received
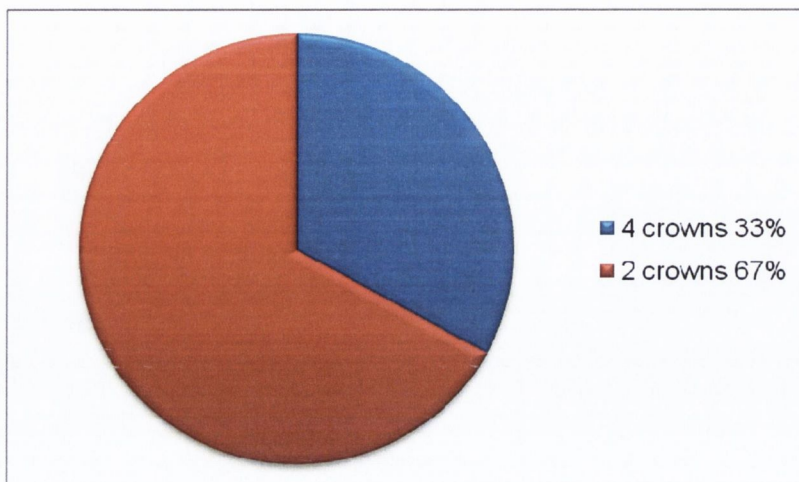
Crowns were assigned in a split mouth design to either both the first or both the second primary molars. The distribution of the tooth type and location of the crowns are shown in Figures 3.3-4 and 3.3-5.

Figure 3.3-4   Distribution of type of tooth crowned
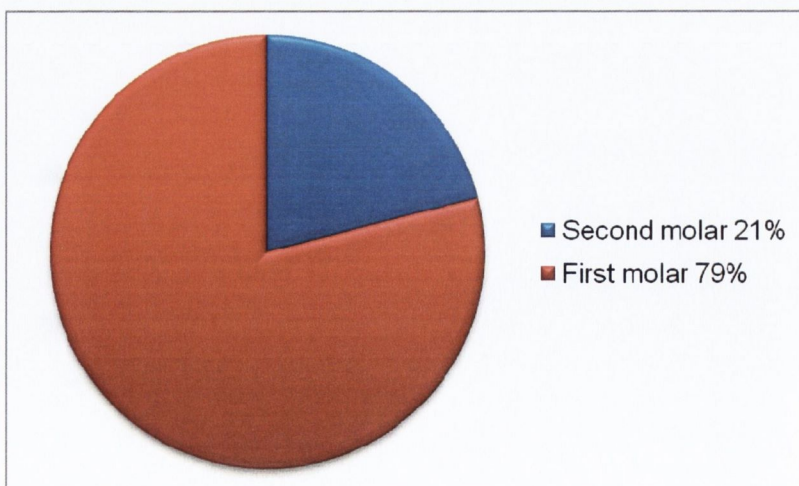
Figure 3.3-5   Distribution of crowns in maxillary and mandibular arch
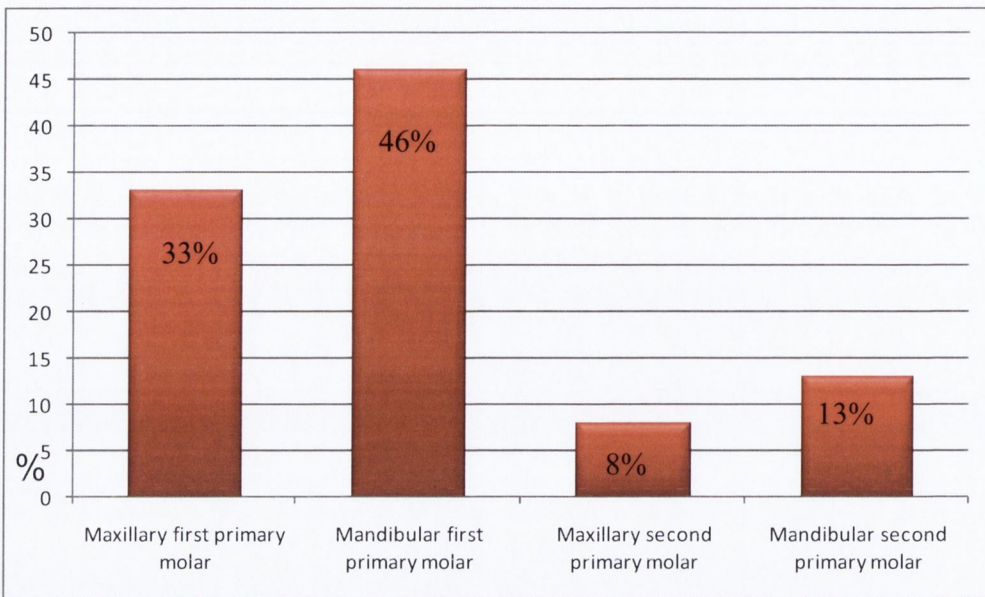
The pulp status of each tooth was noted prior to crown preparation. Appropriate pulp therapy was provided where indicated. The tooth reduction for the aesthetic SSC preparation did not encroach on the pulpal space in any circumstance. The distribution of pulp therapies used in the study participants is shown in Figure 3.3-6.

Figure 3.3-6   Distribution of pulp therapies used
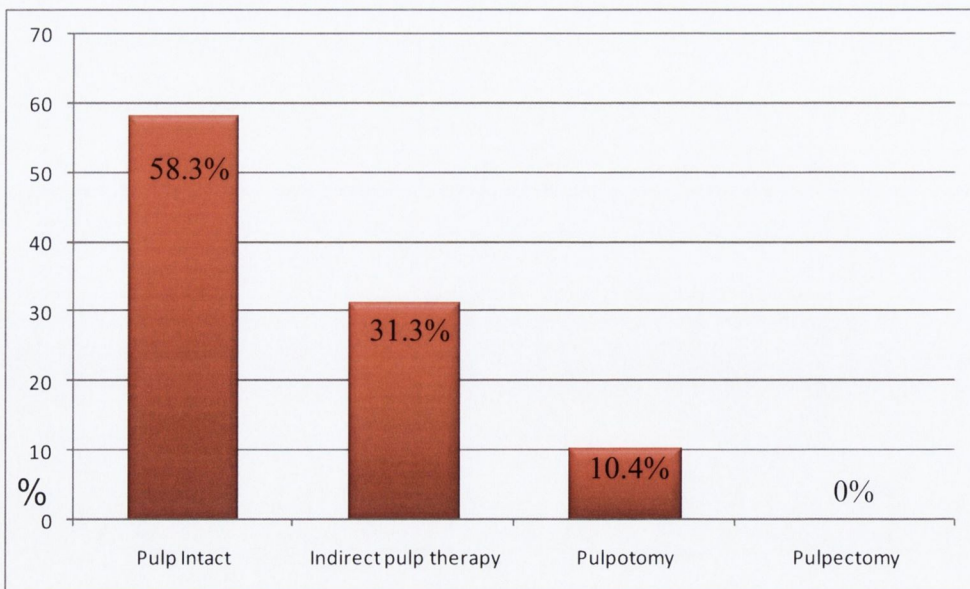
The distribution of crown sizes used for each crown type is shown in Table 3.3-1. Overall for both Kinder and NuSmile, the most common crown size used was size 3 for first primary molars and size 2 for second primary molars.

Table 3.3-1   Distribution of crown sizes used

Crown	Size2	Size3	Size4	Size5	Total
All NuSmile	10	10	4	0	24
All Kinder	7	9	7	1	24
NuSmile 1st molar	6	9	4	0	19
Kinder 1st molar	4	8	6	1	19
NuSmile 2nd molar	4	1	0	0	5
Kinder 2nd molar	3	1	1	0	5

3.4 Clinical Parameters

3.4.1 Examiner calibration

Following training and calibration of 2 examiners, one examiner was used to assess the clinical crown parameters at each review visit. It was considered necessary to have 2 calibrated examiners in order to assure that at least one could be available during the lengthy clinical reassessment period. The examiners were alternatively used during this period. The results of the final two calibration sessions were analysed to determine the examiner calibration scores. The examiners were not calibrated in certain objective clinical variables such as crown retention, status of opposing tooth and presence of occlusal and proximal contacts. Cohen's Kappa test values were obtained to assess the intra and inter-examiner agreement for each clinical variable. A Kappa score of 1 indicated total agreement, >0.8 indicated good agreement, 0.6-0.8 indicated substantial agreement and 0.4-0.6 indicated moderate agreement (World health Organisation, Oral Health Surveys, Basic Methods). A summary of all the results are shown in Table 3.4-1 and 3.4-2.

Table 3.4-1   Cohen's Kappa values for inter-examiner agreement

Clinical variable	Kappa score
Modified Gingival Index	1
Plaque Index	0.667
Staining	1
Buccal Fracture	0.688
Occlusal Fracture	1
Wear	1

Table 3.4-2   Cohen's Kappa values for intra-examiner agreement

Clinical variable	Kappa score Examiner 1 (EN)	Kappa score Examiner 2 (SG)
Modified Gingival Index	1	1
Plaque Index	0.83	0.84
Staining	1	1
Buccal Fracture	0.688	1
Occlusal Fracture	1	1
Wear	1	1

3.4.2 Modified Gingival Index (MGI)

3.4.2.1 MGI: effect of crown

The effect of both crown types on the modified gingival index scores were assessed both at 6 and 12 months. No crown displayed a MGI score of 3 at any time point. At 12 months, only 2 crowns (both Kinder) displayed a MGI score of 2 (moderate inflammation). The overall distribution of results at 6 and 12 months are summarised in Table 3.4-3.

Table 3.4-3   MGI scores at 6 and 12 months

MGI	NuSmile 6 mths	Kinder 6 mths	NuSmile 12 mths	Kinder 12 mths
0	13	12	21	19
1	7	11	3	3
2	4	1	0	2
3	0	0	0	0
Total	24	24	24	24

Fisher's exact test revealed no significant different between Nusmile and Kinder crowns in terms of displaying inflammation (MGI score of 0) or no inflammation (MGI score of 1, 2 or 3) at 6 months (p=1) or 12 months (p=0.7). The statistical results are presented in Tables 3.4-4 and 3.4-5.

Table 3.4-4   Cross-tabulation of crown and MGI scores at 6 months

mgi6 * crowns Crosstabulation

| | | | crowns | | Total |
			nusmile	kinder	
MGI at 6 months	no infl	Count	13	12	25
		% of Total	27.1%	25.0%	52.1%
	infl	Count	11	12	23
		% of Total	22.9%	25.0%	47.9%
Total		Count	24	24	48
		% of Total	50.0%	50.0%	100.0%
No significant difference: Fisher's exact test: p=1					

Table 3.4-5   Cross-tabulation of crown and MGI scores at 12 months

mgi12 * crowns Crosstabulation

| | | | crowns | | Total |
			nusmile	kinder	
MGI at 12 months	no infl	Count	21	19	40
		% of Total	43.8%	39.6%	83.3%
	infl	Count	3	5	8
		% of Total	6.3%	10.4%	16.7%
Total		Count	24	24	48
		% of Total	50.0%	50.0%	100.0%
No significant difference: Fisher's exact test: p=0.701					

3.4.2.2 *MGI: effect of Time*

It was noted that the number of crowns with gingival inflammation decreased over time. Eleven NuSmile crowns displayed inflammation at 6 months and 3 at 12 months. This improvement over time was found to be statistically significant (p=0.024). The number of Kinder crowns with inflammation decreased from 12 at 6 months to 5 at 12 months. This decrease was not significant (p=0.069). These results are shown in Tables 3.4-6 and 3.4-7.

Table 3.4-6   Cross-tabulation of effect of time on NuSmile MGI

mgi * timenu Crosstabulation

			Time / nusmile		Total
			6months	12 months	Total
MGI	no infl	Count	13	21	34
		% of Total	27.1%	43.8%	70.8%
	infl	Count	11	3	14
		% of Total	22.9%	6.3%	29.2%
Total		Count	24	24	48
		% of Total	50.0%	50.0%	100.0%

Significant difference: Fisher's exact test: p=0.024

Table 3.4-7   Cross-tabulation of effect of time on Kinder MGI

mgi * timek Crosstabulation

			Time / kinder		Total
			6 months	12 months	Total
MGI	no infl	Count	12	19	31
		% of Total	25.0%	39.6%	64.6%
	infl	Count	12	5	17
		% of Total	25.0%	10.4%	35.4%
Total		Count	24	24	48
		% of Total	50.0%	50.0%	100.0%

No significant difference: Fisher's exact test: p=0.069

3.4.3 Plaque Index

The overall results for plaque index are shown in Table 3.4-8. Statistical analysis using the Fisher's exact test to assess the presence or absence of plaque demonstrated no significant differences between NuSmile and Kinder crowns at 6 months (p=1) or 12 months (p=0.517). Results are shown in Tables 3.4-9 and 3.4-10. The effect of time on PI was unremarkable and therefore not analysed further.

Table 3.4-8   Plaque Index scores at 6 and 12 months

PI	NuSmile 6 mths	Kinder 6 mths	NuSmile 12 mths	Kinder 12 mths
0	4	4	8	5
1	12	16	13	17
2	6	4	3	2
3	2	0	0	0
Total	24	24	24	24

Table 3.4-9   Cross-tabulation of crown and PI scores at 6 months

pi6 * crowns Crosstabulation

			crowns		Total
			nusmile	kinder	
PI at 6 months	no plaq	Count	4	4	8
		% of Total	8.3%	8.3%	16.7%
	plaq	Count	20	20	40
		% of Total	41.7%	41.7%	83.3%
Total		Count	24	24	48
		% of Total	50.0%	50.0%	100.0%
No significant difference: Fisher's exact test: p=1					

Table 3.4-10   Cross-tabulation of crown and PI scores at 12 months

pi12 * crowns Crosstabulation

			crowns		Total
			nusmile	kinder	
PI at 12 months	no plaq	Count	8	5	13
		% of Total	16.7%	10.4%	27.1%
	plaq	Count	16	19	35
		% of Total	33.3%	39.6%	72.9%
Total		Count	24	24	48
		% of Total	50.0%	50.0%	100.0%
No significant difference: Fisher's exact test: p=0.517					

3.4.4   Staining

3.4.4.1   Staining: effect of crown

No significant differences were noted in the staining of either crown at 6 months (p=1) or 12 months (p=0.67). Results are shown in Tables 3.4-11 to 3.4-13.

Table 3.4-11   Staining scores at 6 and 12 months

Stain	NuSmile 6 mths	Kinder 6 mths	NuSmile 12 mths	Kinder 12 mths
0	22	22	20	22
1	2	1	4	1
2	0	1	0	1
Total	24	24	24	24

Table 3.4-12   Cross-tabulation of crown and staining at 6 months

stain6 * crowns Crosstabulation

			crowns		Total
			nusmile	kinder	
Stain at 6 months	no	Count	22	22	44
		% of Total	45.8%	45.8%	91.7%
	yes	Count	2	2	4
		% of Total	4.2%	4.2%	8.3%
Total		Count	24	24	48
		% of Total	50.0%	50.0%	100.0%
No significant difference: Fisher's exact test: p=1					

Table 3.4-13   Cross-tabulation of crown and staining at 12 months

stain12 * crowns Crosstabulation

			crowns		Total
			nusmile	kinder	
Stain at 12 months	no	Count	20	22	42
		% of Total	41.7%	45.8%	87.5%
	yes	Count	4	2	6
		% of Total	8.3%	4.2%	12.5%
Total		Count	24	24	48
		% of Total	50.0%	50.0%	100.0%
No significant difference: Fisher's exact test: p=0.666					

3.4.4.2 Staining: effect of time

At 6 months, 2 of the 24 NuSmile crowns displayed minor staining, at 12 months this number had increased to 4. This increase was not found to be significant (p=0.666) and the results are shown in Table 3.4-14. The corresponding results for Kinder crowns showed no time effect. Overall, only one crown had minor and another had noticeable staining at 6 months with no new cases of staining at 12 months.

Table 3.4-14   Cross-tabulation of effect of time on NuSmile staining

stain * timenu Crosstabulation

			Time / nusmile		Total
			6 months	12 months	
Stain	no	Count	22	20	42
		% of Total	45.8%	41.7%	87.5%
	yes	Count	2	4	6
		% of Total	4.2%	8.3%	12.5%
Total		Count	24	24	48
		% of Total	50.0%	50.0%	100.0%
No significant difference: Fisher's exact test: p=0.666					

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3.4.5 Buccal facing fracture

Fracture of the buccal surface was scored for all 48 crowns. Overall, only 1/24 NuSmile and 1/24 Kinder crowns displayed buccal facing fracture with <50% of the facing surface involved in both cases. Results are summarised in Table 3.4-15. Fisher's exact test revealed no significant differences between the crown types and buccal facing fracture (p=1) as shown in Table 3.4-16. There was no change in number of fractured crowns between 6 and 12 months and therefore no effect of time was noted.

Table 3.4-15   Buccal fracture scores at 6 and 12 months

Buccal fracture	NuSmile 6 mths	Kinder 6 mths	NuSmile 12 mths	Kinder 12 mths
0	23	23	23	23
1	1	1	1	1
2	0	0	0	0
3	0	0	0	0
Total	24	24	24	24

Table 3.4-16   Cross-tabulation of crown and buccal fracture at 6 months

bf6 * crowns Crosstabulation

			crowns		
			nusmile	kinder	Total
Buccal fracture at 6 months	no	Count	23	23	46
		% of Total	47.9%	47.9%	95.8%
	yes	Count	1	1	2
		% of Total	2.1%	2.1%	4.2%
Total		Count	24	24	48
		% of Total	50.0%	50.0%	100.0%
No significant difference: Fisher's exact test: p=1					

3.4.6 Occlusal facing fracture

Fracture of the occlusal surface was only scored for the 38 first primary molar crowns. Overall, 8 crowns had occlusal facing fracture at 12 months. Of these, only one displayed fracture involving >50% of the occlusal surface (Table 3.4-17).

Fisher's exact test showed there was no significant difference between NuSmile and Kinder crowns in terms of occlusal facing fracture at 6 months (p=0.604) or at 12 months (p=0.232) as shown in Tables 3.4-18 and 3.4-19. Furthermore, there was no significant difference detected between occlusal facing fracture over time for either crown type.

Table 3.4-17   Occlusal fracture scores at 6 and 12 months

Occlusal fracture	NuSmile 6 mths	Kinder 6 mths	NuSmile 12 mths	Kinder 12 mths
0	18	16	17	13
1	1	3	1	6
2	0	0	1	0
3	0	0	0	0
Total	19	19	19	19

Table 3.4-18   Cross-tabulation of crown and occlusal fracture at 6 months

of6 * crowns Crosstabulation

			crowns		
			nusmile	kinder	Total
Occlusal fracture at 6 months	no	Count	18	16	34
		% of Total	47.4%	42.1%	89.5%
	yes	Count	1	3	4
		% of Total	2.6%	7.9%	10.5%
Total		Count	19	19	38
		% of Total	50.0%	50.0%	100.0%
No significant difference: Fisher's exact test: p=0.604					

Table 3.4-19   Cross-tabulation of crown and occlusal fracture at 12 months

of12 * crowns Crosstabulation

			crowns		
			nusmile	kinder	Total
Occlusal fracture at 12 months	no	Count	17	13	30
		% of Total	44.7%	34.2%	78.9%
	yes	Count	2	6	8
		% of Total	5.3%	15.8%	21.1%
Total		Count	19	19	38
		% of Total	50.0%	50.0%	100.0%
No significant difference: Fisher's exact test: p=0.232					

3.4.7 Facing Wear

3.4.7.1 Facing wear: effect of crown

Wear of the facing and exposure of the metal subsurface was scored for all 48 crowns. Overall, 3 crowns showed wear at 6 months and 8 at 12 months as shown in Table 3.4-20. Of these, only NuSmile crowns displayed facing wear such that the area of metal exposed was greater than the cuspal dimension.

Statistical analysis compared any type of crown wear with no crown wear. Fisher's exact test showed no significant differences between wear of NuSmile and Kinder crowns at 6 months (p=1). Although more NuSmile that Kinder crowns showed wear at 12 months, this difference was not significant (p=0.245). These results are presented in Tables 3.4-21 and 3.4-22.

Table 3.4-20   Facing wear scores at 6 and 12 months

Wear	NuSmile 6 mths	Kinder 6 mths	NuSmile 12 mths	Kinder 12 mths
0	23	22	18	22
1	0	2	4	2
2	1	0	2	0
Total	24	24	24	24

Table 3.4-21   Cross-tabulation of crown and facing wear at 6 months

fwear6 * crowns Crosstabulation

			crowns nusmile	crowns kinder	Total
Facing wear at 6 months	no	Count	23	22	45
		% of Total	47.9%	45.8%	93.8%
	yes	Count	1	2	3
		% of Total	2.1%	4.2%	6.3%
Total		Count	24	24	48
		% of Total	50.0%	50.0%	100.0%
No significant difference: Fisher's exact test: p=1					

Table 3.4-22   Cross-tabulation of crown and facing wear at 12 months

fwear12 * crowns Crosstabulation

			crowns		Total
			nusmile	kinder	
Facing wear at 12 months	no	Count	18	22	40
		% of Total	37.5%	45.8%	83.3%
	yes	Count	6	2	8
		% of Total	12.5%	4.2%	16.7%
Total		Count	24	24	48
		% of Total	50.0%	50.0%	100.0%
No significant difference: Fisher's exact test: p=0.245					

3.4.7.2 Facing wear: effect of time

There was no difference in the number of Kinder crowns with facing wear at 6 and 12 months and thus no effect of time was noted.

However the number of NuSmile crowns displaying facing wear increased from one at 6 months to six at 12 months. Fisher's exact test showed that this increase with time was not significant (p=0.097) (Table 3.4-23).

Table 3.4-23   Cross-tabulation of effect of time on NuSmile wear

wear * timenu Crosstabulation

			Time / Nusmile		Total
			6 months	12 months	
Wear	no	Count	23	18	41
		% of Total	47.9%	37.5%	85.4%
	yes	Count	1	6	7
		% of Total	2.1%	12.5%	14.6%
Total		Count	24	24	48
		% of Total	50.0%	50.0%	100.0%
No significant difference: Fisher's exact test: p=0.097					

3.4.8 Gingival margin extension

Overall, 47/48 crown margins were scored as subgingival at 6 and 12 months with no significant differences between NuSmile and Kinder (p=1) (Table 3.4-24).

One crown (NuSmile) was scored as having a supragingival margin extension, detected at 6 months. This crown was noted to be tipped

disto-lingually and insufficiently seated buccally thus accounting for the partially supragingival margin seen mesio-buccally. This crown is illustrated below in Figure 3.4-1.

Table 3.4-24   Gingival margin extension at 6 and 12 months

Margin	NuSmile 6 mths	Kinder 6 mths	NuSmile 12 mths	Kinder 12 mths
0	23	24	23	24
1	1	0	1	0
Total	24	24	24	24

Figure 3.4-1   Supragingival margin located mesially on tooth 75
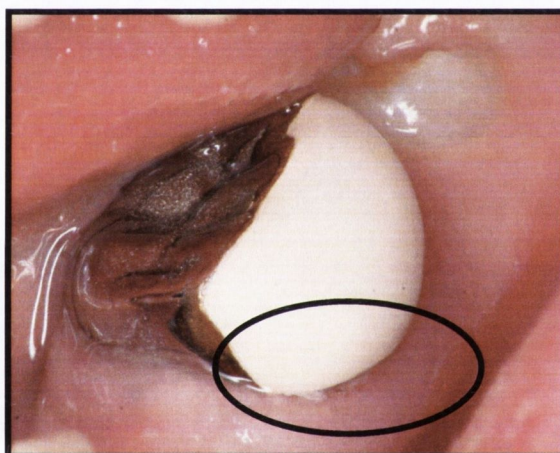
3.4.9 Occlusion

All crowns were found to be in occlusion after 6 months as shown in Table 3.4-25. At 12 months it was noted that 3 crowns (two first and one second primary molar) in 2 patients had developed mild and moderate infraocclusion relative to the adjacent teeth (marginal ridge level lies above and at the contact point of the adjacent tooth respectively). These 3 crowns were no longer in occlusal contact in MIP.

No significant difference was noted between the occlusion of NuSmile and Kinder crowns at 12 months (p=1). All of the remaining 45 non-infraoccluded crowns maintained their occlusal contacts in MIP at 12 months.

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Table 3.4-25   Occlusion at 6 and 12 months

Occlusion	NuSmile 6 mths	Kinder 6 mths	NuSmile 12 mths	Kinder 12 mths
0	24	24	22	23
1	0	0	2	1
Total	24	24	24	24

An example of one of the infraoccluded crowns and its subsequent open occlusal contact in MIP is depicted in Figure 3.4-2 and 3.4-3.

Figure 3.4-2   Infraocclusion of crown on tooth 84
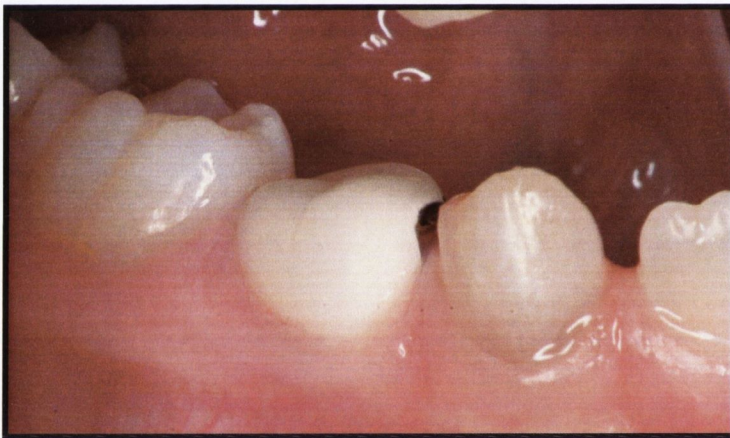
Figure 3.4-3   Visually open occlusal contact of infraoccluded tooth 84 in MIP
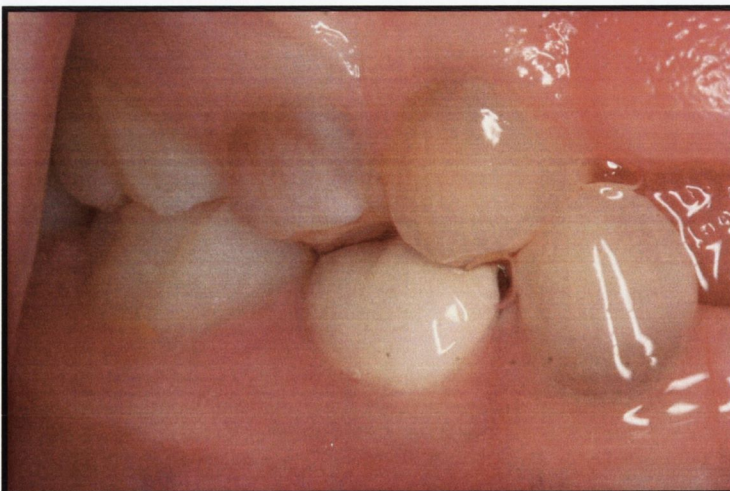
3.4.10 Opposing Tooth

The distribution of the status of the teeth opposing the study crowns are shown in Table 3.4-26.

Table 3.4-26   Status of the opposing tooth at 6 and 12 months

Opposing tooth	NuSmile 12 mths	Kinder 12 mths
0 (Natural tooth)	3	5
1 (Other material)	5	5
2 (SSC)	4	2
3 (Aesthetic SSC)	12	12
Total	24	24

It was noted that half of all 48 crowns were opposed by another aesthetic SSC. All of these first primary molar crowns displayed increased levels of occlusal fracture and wear compared to crowns opposing another surface type (natural tooth, fissure sealant, restoration or traditional SSC) as shown in Table 3.4-27.

Table 3.4-27   First primary molar crown occlusal fracture and wear at 12 months versus status of opposing tooth

Opposing tooth	Occlusal fracture at 12 months	Wear at 12 months
Other (14)	1	0
Aesthetic SSC (24)	7	8
Total 38	8	8

Seven of the 8 first primary molar crowns that displayed occlusal veneer fracture at 12 months were opposing another aesthetic SSC. Analysis failed to show any statistical difference for this finding (p=0.216) (Table 3.4-28).

Interestingly, all 8 crowns displaying wear of the occlusal facing at 12 months were crowns opposing another aesthetic SSC. This association was statistically significant (p=0.017) as shown in Table 3.4-29.

Four of the 6 patients with 24 opposing aesthetic SSC had some or all of their second primary molars extracted. Therefore these first primary molars were loaded with the entire occlusal force during function. All of the crowns with the most severe occlusal fracture and wear occurred among these patients with opposing first primary molar aesthetic SSC without second primary molars.

Table 3.4-28   Cross-tabulation of effect of opposing tooth on occlusal fracture for first primary molar crowns

opptooth * OF12mths Crosstabulation

| | | | OF12mths | | |
			no	yes	Total
opptooth	other	Count	13	1	14
		% of Total	34.2%	2.6%	36.8%
	acro wn	Count	17	7	24
		% of Total	44.7%	18.4%	63.2%
Total		Count	30	8	38
		% of Total	78.9%	21.1%	100.0%
No significant difference: Fisher's exact test: p=0.216					

Table 3.4-29   Cross-tabulation of effect of opposing tooth on occlusal wear for first primary molar crowns

oppotooth * wear Crosstabulation

| | | | wear | | |
			No	Yes	Total
oppotooth	other	Count	14	0	14
		% of Total	36.8%	.0%	36.8%
	acro wn	Count	16	8	24
		% of Total	42.1%	21.1%	63.2%
Total		Count	30	8	38
		% of Total	78.9%	21.1%	100.0%
Significant difference: Fisher's exact test: p=0.017					

3.4.11 Alignment

All the crowns bar one (Kinder) were scored as having normal alignment at 6 and 12 months. The distribution is shown in Table 3.4-30. This one crown was rotated in a mesio-buccal direction relative to the arch alignment (Figure 3.4-4). This rotation caused the mesial metal surface to

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be visible from the anterior view thus compromising the aesthetics (Figure 3.4-5). It is notable however that this phenomenon also occurred with some non-rotated crowns due to the position and extension of the veneer-metal interface. No significant difference was found between NuSmile and Kinder crowns (p=1) in relation to alignment.

Table 3.4-30   Distribution of results for crown alignment

Alignment	NuSmile 6 mths	Kinder 6 mths	NuSmile 12 mths	Kinder 12 mths
0	24	23	24	23
1	0	1	0	1
2	0	0	0	0
Total	24	24	24	24

Figure 3.4-4   Rotated alignment of crown on tooth 64
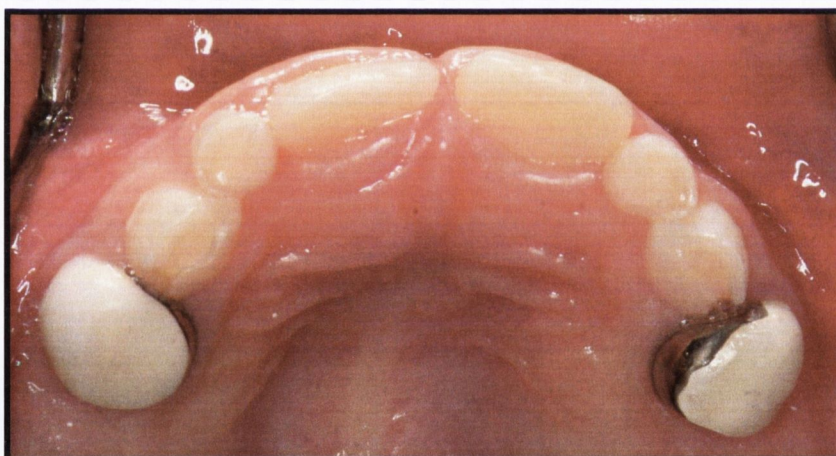
Figure 3.4-5   Mesial metal visible on anterior view of rotated crown 64
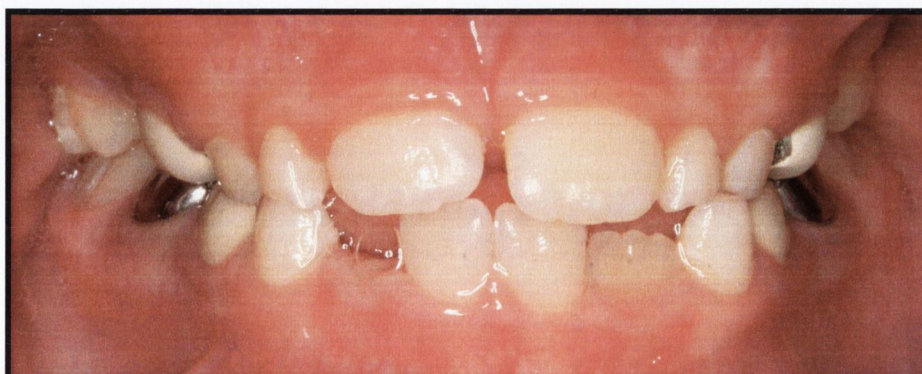
3.4.12 Proximal contact

Nineteen crowns had an adjacent tooth extracted and were therefore excluded from assessment of proximal contact. This high number is due extractions was due to the fact that many patients presented with severe early childhood caries affecting multiple primary molars, some of which were deemed unrestorable. In addition, during general anaesthesia, a previously symptomatic tooth with pulpal involvement or a tooth with little coronal tissue remaining was more likely to be extracted than retained in order to avoid a repeat anaesthesia in the event of pulpal or restoration failure in the future.

Of the remaining crowns evaluated (n=29), only one crown (Kinder) displayed a poor proximal contact between the primary molars at 12 months (Table 3.4-31). It was noted that this crown was one of the infraoccluded teeth recorded during examination of the occlusion (Figure 3.4-2). A proximal contact had been present at 6 months when the infraocclusion was less marked.

All of the remaining crowns were scored as having a good proximal contact which met resistance to floss. There were no significant differences between the crown types at 12 months and no significant effect of time was noted.

Table 3.4-31   Distribution of results for proximal contacts

Proximal contact	NuSmile 6 mths	Kinder 6 mths	NuSmile 12 mths	Kinder 12 mths
0	15	14	15	13
1	0	0	0	1
Total	29		29	

3.5 Clinical Success

The overall percentage of clinically successful crowns as determined according to the specified criteria is shown in Table 3.5-1.

Table 3.5-1   Overall clinical success

Criteria for clinical success	Numbers of successful crowns at 12 months	Percentage of success
Retention of crown	48/48	100%
Absence of facing fracture	39/48 (one crown had both buccal and occlusal fracture)	81.25%
No adverse effects on gingival health	40/48	83.3%
Combined clinical success: No facing fracture AND no adverse effects on gingival health	32/48 (one crown had both inflammation and fracture)	67%

3.6 Radiographic Data

3.6.1 Examiner Calibration

Following training of one radiographic examiner, a calibration test was applied determine the level of agreement. Training was carried out on 2 separate occasions and 2 calibration sessions followed one week apart. A Cohen's Kappa test value was obtained to assess the intra-examiner agreement in detecting the presence of a radiographic overhang (Table 3.6-1).

Table 3.6-1   Cohen's Kappa values for intra-examiner agreement

Radiographic variable	Kappa score
Overhang	0.842 (substantial agreement)

3.6.2 Radiographic Success

A total of 42 crown images were of sufficient radiographic quality to include in the final radiographic analysis, representing 88% of the total patient sample reviewed clinically.

It was not possible to obtain post-operative radiographs for one very young patient due to limited cooperation. Bitewing radiographs were able to be obtained for the remaining 17 patients but a further 4 images were excluded from radiographic analysis radiographs due to insufficient quality. Coincidentally, all 4 of these crowns were located on lower left primary first molars, 3 were Kinder Krowns and 1 was NuSmile.

A horizontal overhang was detected in 8 crowns (19%). All overhangs were located on the distal aspect of the crown. As the presence of an overhang determined crown adequacy, 81% were determined to be adequate and a radiographic success, with 19% scored as radiographic failures (Table 3.6-2).

Table 3.6-2   **Distribution of radiographic success and failure**

	Overhang	Radiographic Success	Radiographic Failure
No	34	81%	
Yes	8		19%
Total	42	100	

Overhang presence or absence was compared with the corresponding MGI scores at 12 months to determine any relationship.

Where a positive horizontal overhang was observed (8 crowns), measurements were taken to determine the actual overhang size from the radiographic overhang measurement. These values were intended to be compared to the MGI scores at 12 months to determine if an

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association existed between size of overhang and severity of MGI score (Table 3.6-3).

No significant correlation between the presence of radiographic overhang and MGI at 12 months was evident for either crown type (p=0.319). Results are presented in Table 3.6-4.

Table 3.6-3   Comparison of overhang size and MGI score at 12 months

Radiographic Overhang (mm)	Actual Overhang (mm)	Location	Crown	MGI @ 12 months
1.04	1.05	Distal	Kinder	1
0.72	0.62	Distal	Nusmile	1
0.95	1.01	Distal	Kinder	0
0.57	0.49	Distal	Nusmile	0
0.98	0.99	Distal	Kinder	0
0.57	0.55	Distal	Kinder	0
0.97	0.99	Distal	Nusmile	0
0.66	0.67	Distal	Nusmile	0

Table 3.6-4   Cross-tabulation of radiographic overhang and MGI at 12 months

mgi12 * overhang Crosstabulation

			overhang		
			no	yes	Total
MGI at 12 months	no infla	Count	30	6	36
		% of Total	71.4%	14.3%	85.7%
	infla	Count	4	2	6
		% of Total	9.5%	4.8%	14.3%
Total		Count	34	8	42
		% of Total	81.0%	19.0%	100.0%
No significant difference: Fisher's exact test: p=0.319					

3.7 Visual Analogue Scale

All parents expressed high levels of satisfaction with the appearance of the aesthetic crowns despite some chipping and wear. The results of the parental VAS ranged from 6.7 to 10 with a mean score of 9.27. The distribution of the results for each participant is illustrated in Figure 3.7-1. It was notable that although a horizontal VAS is reported to be a convenient and rapidly administered tool (Wewers and Lowe 1990), many parents found the abstract concept of the VAS difficult to comprehend and lengthy explanation was required.

Figure 3.7-1   Distribution of VAS scores
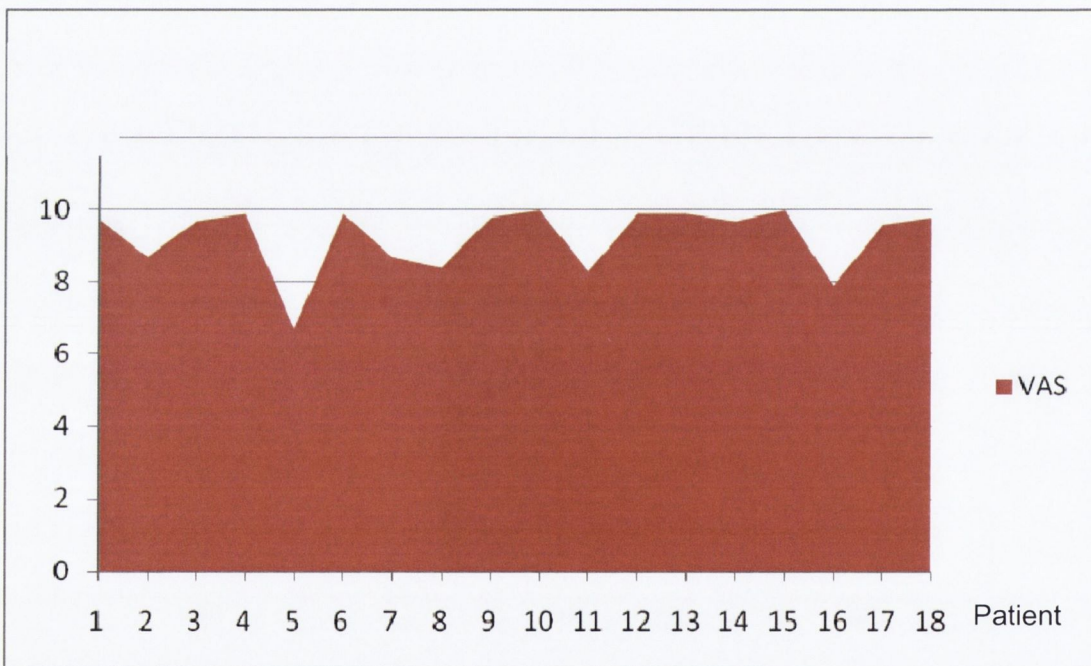
4   Photographic examples of completes cases

4.1   Modified Gingival Index

Figure 4.1-1   Modified Gingival Index: score 0
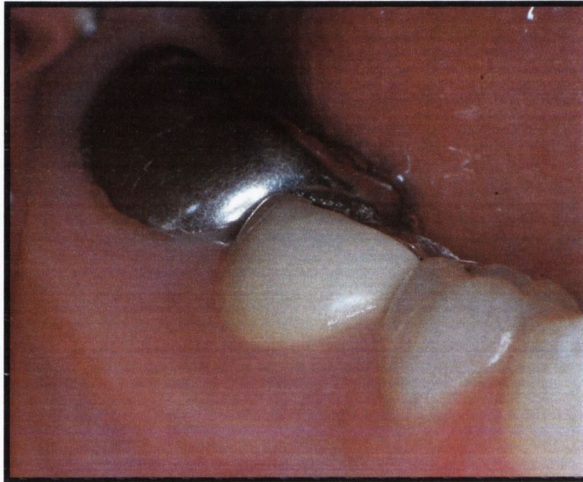
Figure 4.1-2   Modified Gingival Index: score 1

Figure 4.1-3   Modified Gingival Index: score 2

4.2 Staining

Figure 4.2-1   Minor staining (NuSmile)
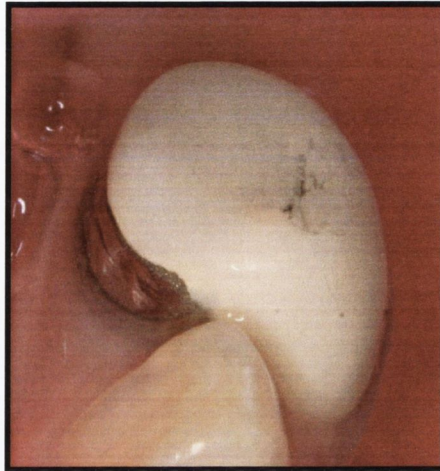
Figure 4.2-2   Noticeable staining (Kinder)
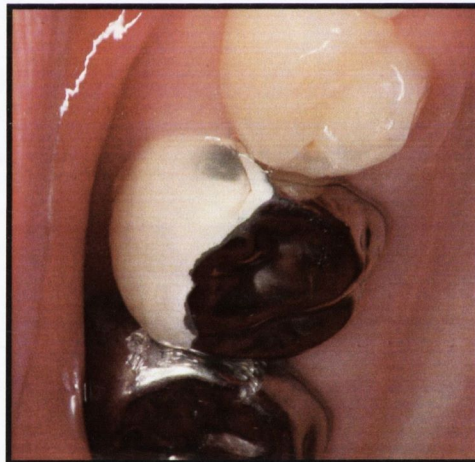
4.3 Buccal facing fracture

Figure 4.3-1   Buccal fracture (Kinder) <50% surface
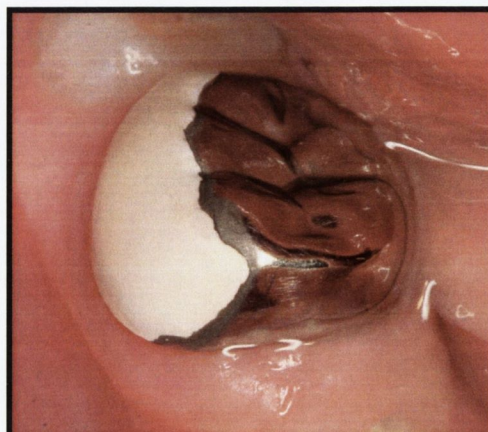
4.4   Occlusal facing fracture

Figure 4.4-1   Occlusal facing fracture (NuSmile) over time, 3, 6, 9, 12 months
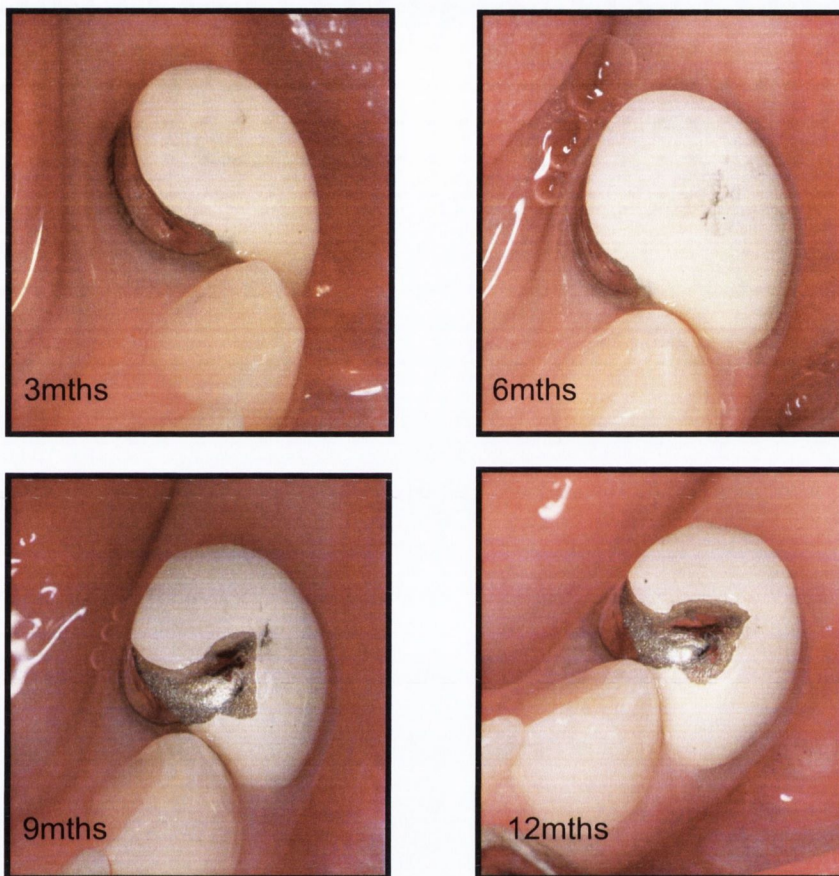
Figure 4.4-2   Occlusal fracture (Kinder) <50% surface
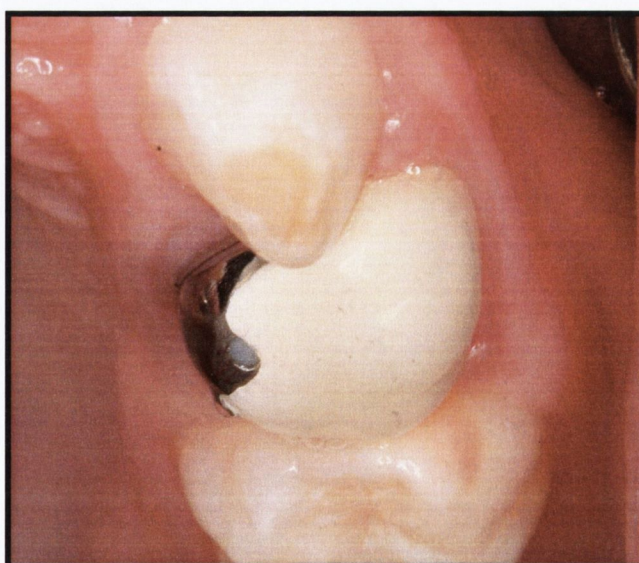
Figure 4.4-3   Occlusal fracture (Kinder) <50% surface
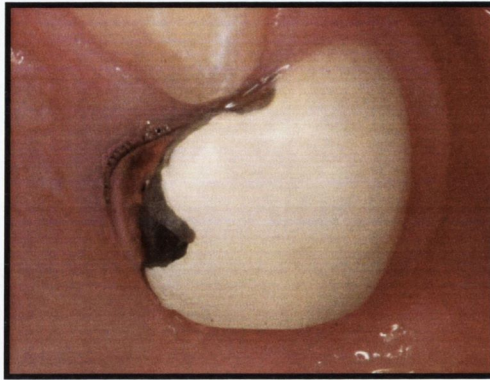
Figure 4.4-4   Occlusal fracture (NuSmile) <50% surface
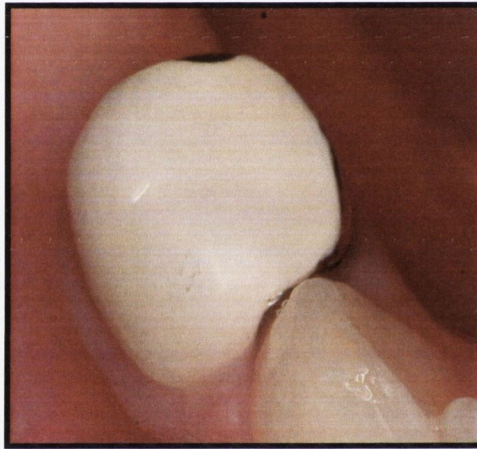
Figure 4.4-5   Occlusal fracture (NuSmile) >50% surface
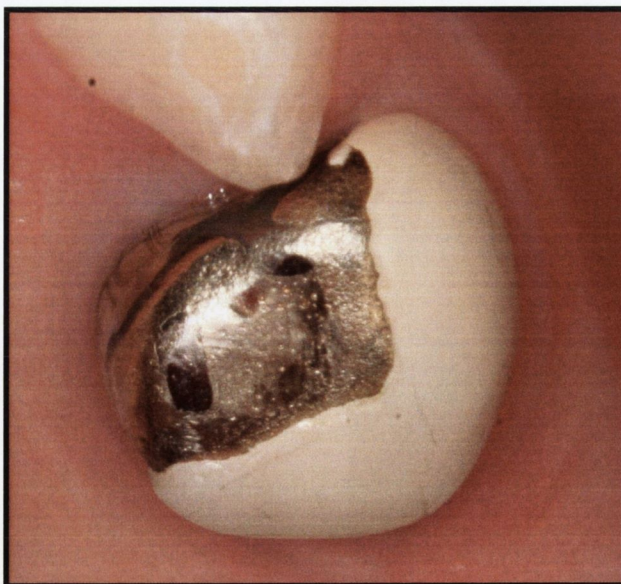
4.5 Facing wear

Figure 4.5-1   Wear at cusp tips only (NuSmile)
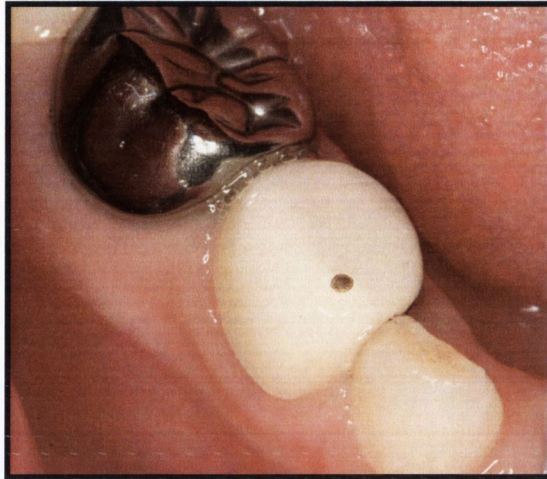
Figure 4.5-2   Wear at cusp tips only (NuSmile)
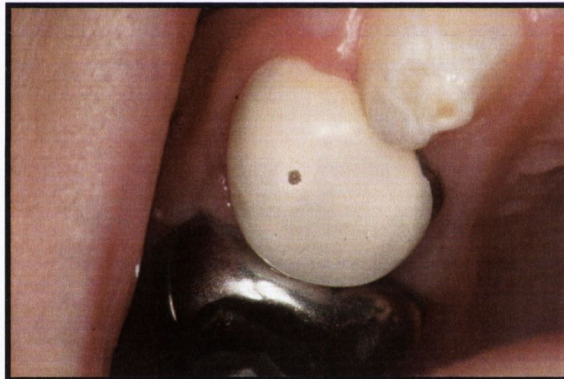
Figure 4.5-3   Wear >cuspal (NuSmile)

4.6   Completed clinically successful cases

Figure 4.6-1   Successful lower first primary molar crowns in a patient with early childhood caries
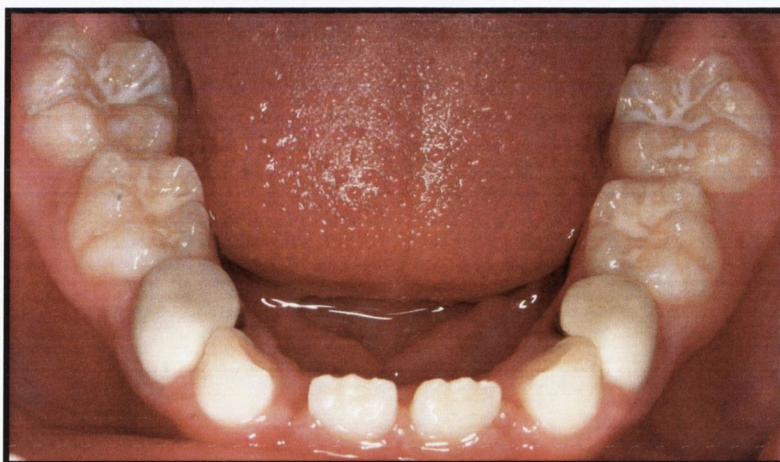
Figure 4.6-2   Successful lower first primary molar crowns in a patient with dentinogenesis imperfecta
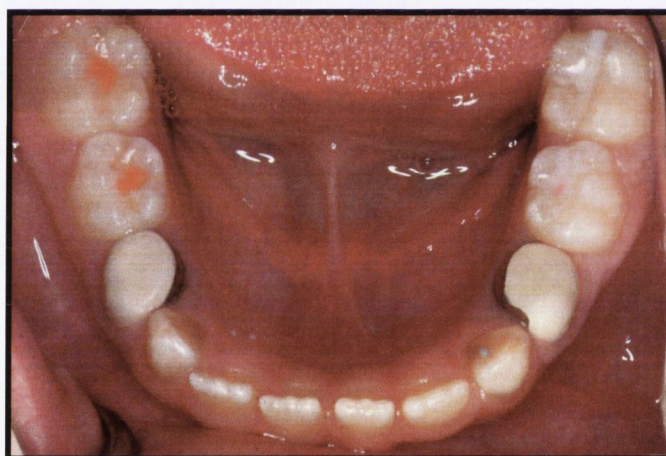
Figure 4.6-3   Successful opposing first primary molar crowns (NuSmile)
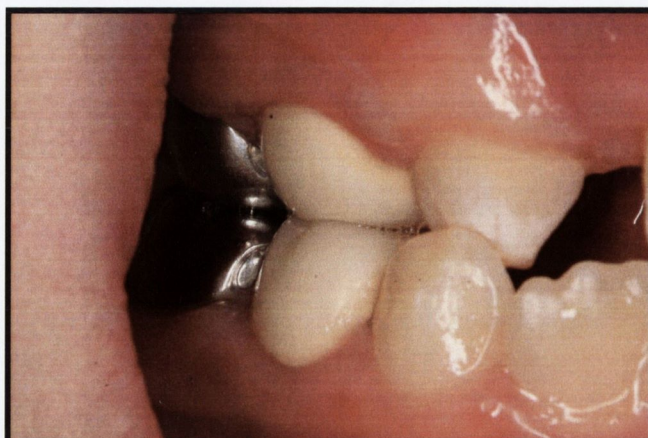
Figure 4.6-4   Successful upper first primary molar crown (NuSmile)
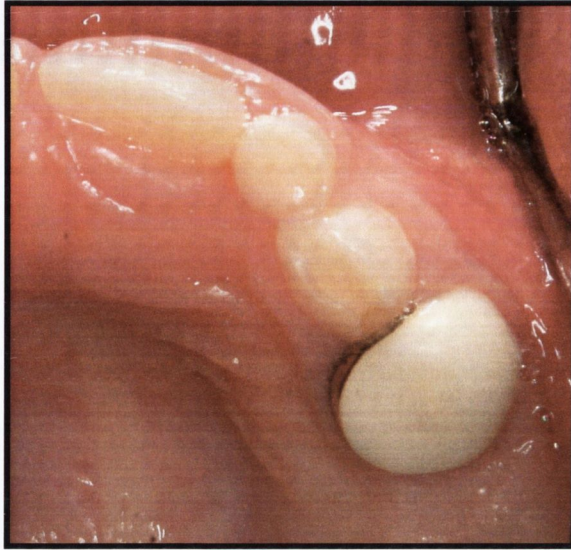
Figure 4.6-5   Successful lower first primary molar crown (Kinder)
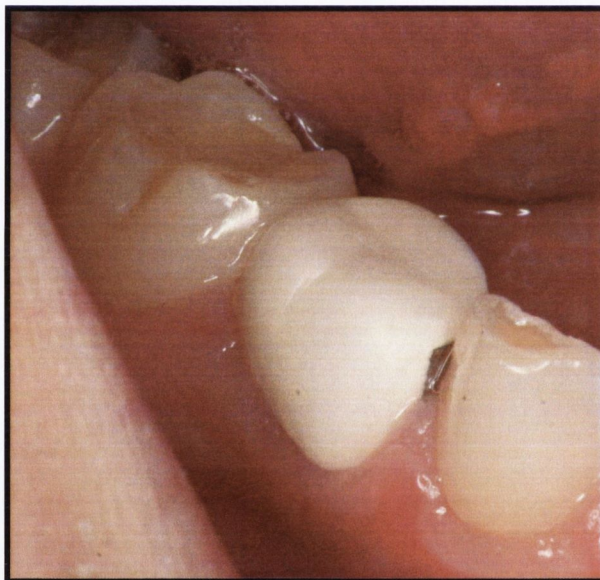
Figure 4.6-6   Successful four first primary molar crowns in a patient with amelogenesis imperfecta

Figure 4.6-7   Successful lower second primary molar crowns
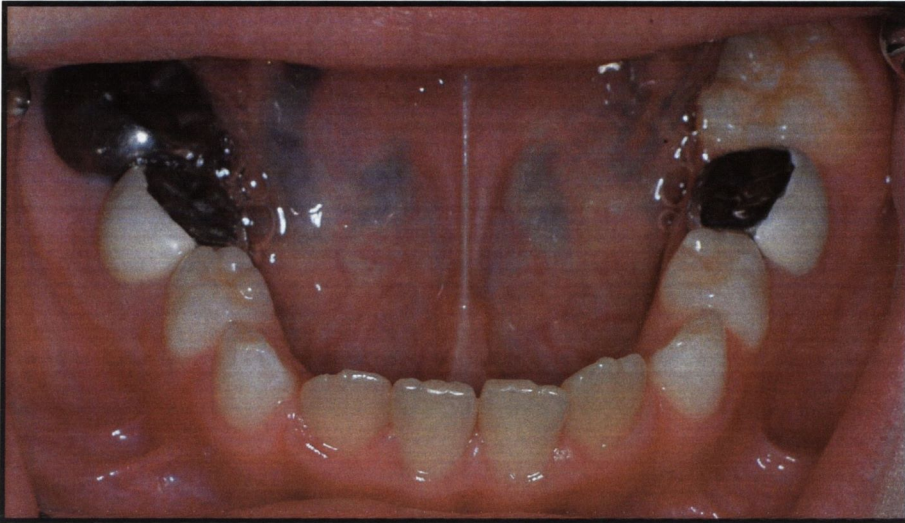
Figure 4.6-8   Successful upper second primary molar crown (NuSmile)

Figure 4.6-9   Successful lower second primary molar crown (Kinder)
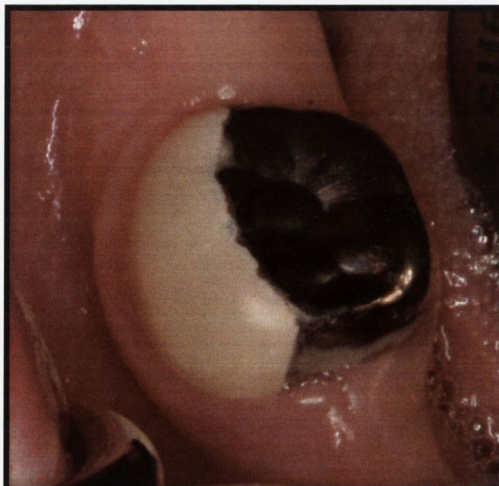
5 Discussion

There is an increasing demand from parents for placement of aesthetically pleasing dental restorations for their children's teeth (Zimmerman MS *et al.* 2009, Peretz and Ram 2002). The vast majority of the literature regarding preveneered aesthetic SSC focuses on anterior crowns, which have been successfully used. This study is the first to clinically evaluate two different types of posterior preveneered SSC in a split mouth design.

A total of 48 crowns in 18 patients were analyzed after 12 months. As there is only one previous study regarding the use of posterior preveneered SSC (Fuks *et al.* 1999, Ram *et al.* 2003), there was little evidence on which to base a power calculation. It was our aim to enrol as many participants as possible during the study period, with a goal of at least twice that of the 22 crowns placed by Fuks *et al.* (1999). A retrospective power calculation was undertaken based on the variable of crown facing fracture; however it is noteworthy that assumptions had to be made in order to achieve this (Appendix 7.9).

Overall, patient and parent satisfaction with the aesthetic crowns was found to be excellent. The results of the VAS ranged from 6.7 to 10 with a mean score of 9.27. Such scores reflect unanimously high levels of parental satisfaction with this treatment option. Questioning revealed that on the whole, parents could not tell the difference between the crown types and expressed no individual preference for NuSmile® or Kinder™ crowns. Although this study did not specifically record the children's opinion due to the varying age range, the majority of children who had both preveneered aesthetic SSC and conventional SSC placed expressed a preference for the aesthetic variety. This result is unsurprising since the evidence suggests that children prefer white fillings over silver regardless of age or gender (Fishman *et al.* 2006).

It was observed that the colour of the crowns used matched well with the adjacent teeth, and was more natural than previously reported (Croll and Helpin 1996, MacLean *et al.* 2007). The shades used in this study were 'new light' NuSmile® Primary crowns and 'pedo2' Kinder Krowns™. These are an improvement on the original lighter shades offered by the crown companies, and were found to have a more natural appearance in our study group, a finding that is in agreement with Hosoya *et al.* (2002).

The results indicate that overall there was no significant difference in the clinical and radiographic performance of posterior NuSmile® Primary crowns and posterior Kinder Krowns™ after 12 months, thus accepting the null hypothesis.

Durability of preveneered aesthetic SSC can be compared to conventional SSC in terms of crown retention and pulpal protection. After 12 months, all study crowns maintained an adequate coronal seal and remained free of adverse pulpal sequelae. These clinical variables are comparable to the expected performance of conventional SSC as evidenced by the literature (Randall 2000, Randall 2002, Seale 2002, Attari and Roberts 2006, Kindelan *et al.* 2008). This led us to accept that there was no difference in durability of Kinder™ Krowns and NuSmile® Primary crowns and conventional SSC after 12 months. However, it is considered important to follow up the performance of these crowns longterm in order to accurately compare their longevity and durability with that of conventional SSC.

All crowns were successfully retained after 12 months, as expected from previous studies (Ram *et al.* 2003, Roberts *et al.* 2001, Shah 2004, MacLean *et al.* 2007). This finding indicates that the limited crimping ability (the opportunity to crimp is on the non-veneered portion only) does not appear to affect crown retention. Very few crowns were crimped in the present study as to do so eliminated the passive fit. All crowns in this study were retained despite this lack of crimping.

Overall, 81.3% of both NuSmile® and Kinder™ Krowns were clinically successful with an intact veneer facing. Ram *et al.* (2003) previously reported that all of the 10 NuSmile® crowns studied had partial chipping after 4 years in service. It was not specified whether this finding affected the patient or parent satisfaction levels. The corresponding result for absence of adverse effects on gingival health was 83.3%. Ram *et al.* 2003 also reported a decrease in inflammation over time.

Overall radiographic success was 81% for 42 crowns, although it is notable that the presence of a radiographic overhang was not associated with an increase in gingival inflammation and may therefore be considered a 'failure' for academic purposes only. Ram *et al.* (2003) found all crowns to be radiographically adequate in terms of bone resorption, however only 10 crowns were evaluated and the presence of an overhang was not specifically investigated.

The majority of crowns in this study were placed on lower first primary molars. Usually these teeth are highly visibly during function and parents reportedly dislike metal restorations most on this particular tooth (Randall 2002). Second primary molars are much less noticeable in the smile and this is reflected in the fact that fewer were selected for inclusion in this study where adjacent molar crowns were indicated.

The buccal surface is the main visible surface of a second primary molar; therefore it was decided to restore these teeth with crowns incorporating a preveneered buccal surface only. To the author's knowledge, these crowns have never been studied clinically. The crown manufacturers propose that less tooth reduction is required to fit an aesthetic SSC with only one veneered surface. However, experience gained during this study proved otherwise. It was found that the amount of tooth reduction required to passively fit these crowns was almost equivalent to that for full coverage aesthetic SSC, yet without the full aesthetic benefit. With the benefit of hindsight it would have been perhaps more useful to have used

second primary molar crowns with full composite veneer coverage in order to be more comparable with the first primary molar crowns.

It has been reported by the manufacturers that a learning curve is required for technical placement of these crowns. This was indeed found to be the case during the preparatory phase of this study and the operators considered pre-operative training to be useful. Once mastered however, the technique itself was found to be very manageable and did not influence the behaviour management options used. It was possible to place aesthetic SSC just as easily under local anaesthesia alone as under general anaesthesia. In fact some patients who had aesthetic SSC placed under local anaesthesia in this study were as young as 5 years of age. Although the results indicate that the majority of patients in this study (15/18) were treated under general anaesthesia, the decision to choose this behaviour management option was based on other issues related to patient management. The operators found no difference in the ease of placement between the two crown types, however the crown identification system of NuSmile® was considered more operator friendly (NuSmile® print crown size and type on the crown (Figure 2.5-6) while Kinder™ Krowns use a colour coded index system on the internal aspect of the crown).

It is notable however, that the investigators perceived difficulties in placing adjacent posterior aesthetic SSC due to space constrictions. This could be considered a contra-indication to their use. In a situation where adjacent primary molars require full coverage, it is recommended that the aesthetic variety be chosen for the first primary molar and a conventional SSC for second primary molar. This situation was achieved in a number of study patients and led to an acceptable aesthetic result.

Another clinical situation where placement of these crowns may be restricted is where space loss occurs between primary molars. This is a relatively common consequence of long standing interproximal carious lesions. While orthodontic tooth separation can be used to regain some

space, when severe space loss occurs even the smallest preveneered crown size cannot be utilised. In this situation a conventional SSC is more appropriate as there is an unrestricted crimping ability, a phenomenon that is limited on all preveneered SSC.

It has been suggested that a pulpotomy procedure may be required due to the likelihood of pulpal exposure following the extensive occlusal tooth preparation. The results of this study are inconsistent with this proposal as almost 90% of teeth were crowned without pulpal exposure or invasive pulp therapy. The remaining 10% required a pulpotomy procedure due to extensive caries and not due to crown preparation. This was a welcome finding as it suggests that the tooth preparation required for aesthetic SSC is somewhat more conservative than previously thought.

Although differences were noted between the clinical performance of Kinder™ and NuSmile® crowns, these were not statistically significant. The incidence of fracture in our study is in agreement with the *in vitro* studies of Waggoner and Cohen 1995 and Baker *et al.* 1996, who reported no significant differences between the mean force to produce fracture for Kinder Krowns™ or NuSmile®. Only 8 crowns displayed occlusal veneer fracture at 12 months, and of these, Kinder™ Krowns outnumbered NuSmile® by a factor of 3, although the most severe fracture magnitude was detected in a NuSmile® crown. With regard to wear, the situation was reversed with NuSmile® outnumbering Kinder™ Krowns by a factor of 3. No significant differences were detected between the success rates of upper and lower preveneered SSC, although more upper crowns displayed both occlusal veneer fracture and facing wear. This finding was contrary to the study by Yilmaz and Koçoğullari (2004) who reported that crowns in the maxillary arch had a higher success rate.

Staining was noticed on 6 crowns after 12 months. Twice as many NuSmile® crowns were stained, but the only crown with severe staining was a Kinder™ Krown. This crown had internalised staining within the veneer surface noted at the 3 month review visit (Figure 4.2-2). This may

have been due to the introduction of micro fractures into the material during crown placement. This finding highlights the importance of using gentle digital pressure to seat these crowns and of ensuring a passive fit. Overall, staining was an infrequent finding and where present was exclusively localised with no cases of generalised staining or colour change noted. This colour stability over time was also reported by Ram *et al.* (2003) and MacLean *et al.* (2007). However, from sequential clinical photographs it was possible to detect that staining of the veneer sometimes preceded fracture of the crown facing (Figure 4.4-1). It would be useful to follow up the stained crowns for any association with future facing fracture.

No significant difference was found in the pre-operative gingival inflammation scores when compared with those after 12 months. While some crowns displayed a firm rolling of the cervical gingiva after crown placement, it was without redness or swelling. This implies that although aesthetic preveneered crowns are bulky and placed 2mm subgingivally, they do not adversely affect the gingival health of primary molars. In fact, many more teeth were scored as having gingival inflammation pre-operatively than at 12 months post-treatment. It is probable that this improvement in gingival health is related to the absence of plaque retaining carious lesions post-operatively and an improvement in oral hygiene procedures following encouragement and instruction at multiple review visits.

Kinder[TM] Krowns displayed more cases of inflammation and more severe scores at 12 months. This difference was not found to be significant. Both NuSmile[®] and Kinder[TM] Krowns showed an improvement in gingival health over time, consistent with the existing literature (Fuks *et al.* 1999, Ram *et al.* 2003). The relationship between plaque index and gingival inflammation is well documented in the literature (Loë *et al.* 1965). This association was not specifically analysed in this study as the split mouth design enabled both crown types to be exposed to similar oral hygiene habits. In addition, crowns were randomly assigned to right and left sides

in order to eliminate the potential for variations in tooth brushing habits affecting the outcome.

The results for the other clinical variables assessed (crown retention, gingival margin extension, occlusion, alignment and proximal contact) failed to show any significant differences between NuSmile® and Kinder Krowns™. It is the opinion of the investigator that such variables are primarily related to appropriate crown placement and not due to individual differences between the crown types.

Overall, statistical significance was obtained for two clinical variables. Firstly, a significant reduction in the number of NuSmile® crowns with inflammation occurred between 6 and 12 months (p=0.024). This reduction of gingival inflammation over time for NuSmile® crowns agrees with the only other clinical study available (Ram *et al.* 2003). A corresponding significance for Kinder™ Krown was not established in the present study (p=0.069).

The second statistically significant variable was in relation to the effect of the opposing tooth on occlusal facing wear. All of the crowns that displayed facing wear of any magnitude were those occluding on opposing aesthetic preveneered crowns (all opposing aesthetic SSC were first primary molars). Opposing aesthetic SSC were statistically more likely to display facing wear than aesthetic SSC opposing another surface type (p=0.017). This phenomenon is related to the nature of the occlusal forces on the veneer material. It is anecdotally believed that following placement of a 'high' conventional SSC, a spontaneous occlusal equilibration occurs by overeruption of adjacent teeth or intrusion of the SSC. This would lead one to propose that the same situation in preveneered aesthetic SSC leads to wear of the composite veneer material during equilibration, which may occur more readily than other tooth movements. As many of the patients who received opposing aesthetic SSC were treated using general anaesthesia, it is possible that some crowns were placed high in the occlusion, as adequate occlusal

scrutiny is not possible during this procedure. For those crowns placed under local anaesthesia, the occlusion was checked during try in stage and if deemed to be 'high', further tooth preparation was carried out. No occlusal adjustments were made to the crowns regardless of anaesthesia option used, yet only those opposing another aesthetic SSC displayed facing wear.

Another possible explanation for the increased amount of fracture and wear amongst opposing aesthetic SSC relates to the occlusion. Many patients with opposing aesthetic SSC occluded only on these molar pairs. It is plausible that the full burden of the occlusal load focused exclusively on opposing aesthetic SSC accelerated veneer wear and fracture. This theory was further substantiated by the fact that the most severe wear and fracture scores were found in two patients with this occlusal scenario. While it is possible that facing wear and subsequent reduced material thickness increases fracture potential, it was not possible to directly relate wear and fracture in the results of this study. A minority of crowns had both fracture and wear simultaneously, but it was not feasible to determine which occurred first as they were diagnosed concurrently at review visits.

A number of findings of clinical importance were realised during the course of this study. As these crowns are chosen for their aesthetic value, the integrity of the composite facing is crucial. A total of 18.75 % of all 48 crowns displayed some type of fracture leading to the conclusion that the veneer strength is not always greater than the average bite force of a child as reported in the literature (Bakke *et al.*1990, Waggoner and Cohen 1995, Baker *et al.* 1996). However, the vast majority of crowns with fractures remained aesthetic in the patients smile, and the occurrence of chipping did not detract from the parental satisfaction scores as evidenced by the VAS results.

On the other hand, it was observed by the investigators that certain design features slightly compromised the overall aesthetic value of these

crowns. The mesial composite metal interface was visible from the buccal side on some crowns. It became apparent that crowns with a right angled junction were less aesthetic than those whose veneer extended further onto the proximal crown surface (Figure 5.1-1). This phenomenon was more commonly seen with Kinder™ Krowns than NuSmile®. The manufacturers should be encouraged to rectify this feature in order to optimise crown aesthetics.

5.1

Figure 5.1-1   Visible veneer-metal interface
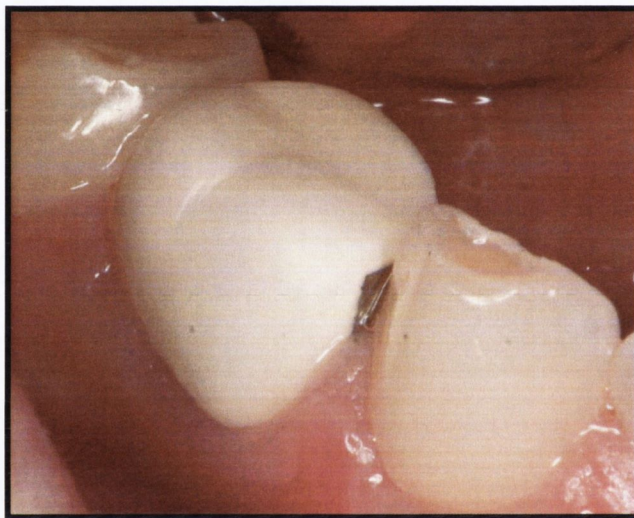
The type of veneer failure was also interesting. Fracture of NuSmile® crowns was mostly adhesive and exposed the alumina blasted surface, already noted by Baker *et al.* 1996. An adhesive failure proved to be the most sizeable and also the most unaesthetic (Figure 4.4-5). The failure of Kinder Krown™ however was characterised by a mixed cohesive-adhesive failure within the veneer, echoing the results of Waggoner and Cohen (1995). Exposure of the underlying white opaque layer following fracture of Kinder Krown™ was not noted in this study, although Shah *et al.* (*2004*) reported the occurrence of this phenomenon which preserved the cosmetic appearance following fracture of anterior Kinder Krowns™.

Only one Kinder Krown™ displayed cracks within the veneer surface, which has been suggested as their characteristic failure pattern by Baker *et al.* (1996). It is noteworthy however that the above studies examined

artificially fractured anterior preveneered SSC, a situation that cannot be considered comparable with posterior preveneered SSC *in vivo.*

One might speculate that differences in the morphology of brands of posterior preveneered SSC may influence veneer retention and failure. Kinder Krowns™ tend to have more anatomy included in the occlusal surface and a thinning of the veneer on the occluso-lingual aspect. Indeed, it was in this region that most occlusal fractures occurred in Kinder Krowns™(Figure 4.2-2 and 4.2-3). NuSmile® crowns on the other hand have a flatter buccal cusp and a veneer that overlaps the occluso-lingual area (Figure 2.5-6). These differences in crown morphology potentially affect the distribution of forces, however no differences were found in the present study indicating that crown anatomy did not influence veneer wear or fracture.

An interesting observation was noted when examining the performance of Kinder Krowns™. As previously mentioned, these crowns have perforations in the metal base to enhance veneer retention through an "incisal lock" feature. The veneer of one of these crowns was noted to be fractured down to metal exposing this subsurface perforation filled with cement (Figure 4.4-2). It is of concern that further wear may lead to microleakage through this perforation thus compromising the coronal seal, a situation that does not exist with NuSmile® crowns given their intact metal base. On the other hand, it is possible that these perforations aid repair procedures, as suggested by the manufacturers.

Anecdotally, it was not recommended to place anterior preveneered SSC in children with crossbites due to likely fracture of veneering resin (Waggonner 2006). Although no such recommendation exists regarding posterior preveneered SSC, it is possible that this may also be of concern. One of the patients included in this study presented with a unilateral posterior crossbite, and after 12 months crowns appeared to be unaffected by this anomaly. In fact, the severity of the crossbite actually improved following placement of 4 posterior aesthetic SSC. This may be

have been due to an opening up of the bite and removal of premature deflective contacts following establishment of a newly restored occlusal dimension (Figures 5.1-2 and 5.1-3).

Figure 5.1-2   Posterior crossbite pre-operatively

Figure 5.1-3   Reduction in posterior crossbite postoperatively
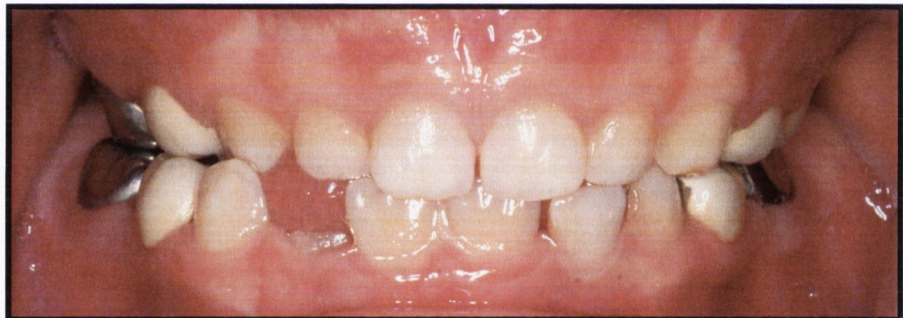
Another interesting finding was in relation to infraocclusion of 3 teeth with preveneered SSC during the course of this study. Of these, 2 were lower first primary molars (in the same patient) and one was a lower second primary molar. The prevalence of infraoccluded primary teeth is in the order of 8.9% of 3-12 year olds (Kurol 1981). While we do not fully understand the aetiology of infraocclusion is unlikely to be related to crown placement. Nevertheless, it would be of interest to follow this phenomenon over time to determine if any further infraocclusion occurs.

Crowns that displayed facing loss (fracture or wear) were still considered aesthetic by the parents and at no time was a request for veneer repair made. However, it would of interest to examine their reparability. Yilmaz *et al.* (2008) reported that it was possible to repair NuSmile® posterior

crowns *in vitro* to produce a shear bond strength that is equivalent to the original veneer material. Such a procedure could render fractured crowns aesthetic and assessment of this repair technique *in vivo* would be a useful area for further research.

It is intended that placement of a SSC on a primary molar last the lifespan of the tooth until exfoliation. Although the results of this study are promising, they are restricted by the relatively short follow up time. It is the intention of the author to act as a co-investigator in continuing to follow up this study into the future. Only then will definitive comparisons be able to be made with conventional SSC. The positive results of this study to date, lead the authors to propose these crowns as a suitable aesthetic alternative to conventional SSC in carefully selected patients.

6 Conclusions

This research shows that posterior preveneered SSC can be used successfully for the restoration of carious primary molar function and aesthetics.

Similar clinical and radiographic success was found in both commercially available NuSmile® Primary crowns and Kinder™ Krowns, with no significant differences noted in their respective performance. The overall clinical success rate for resisting facing fracture after 12 months was 81.3%. A total of 83.3% of all crowns were free of gingival inflammation at 12 months. These results are comparable to other similar studies using anterior and posterior SSC over a similar time period. The radiographic success was also high at 81%, and no correlation was found between presence of a radiographic overhang and gingival inflammation.

There were no significant differences between NuSmile® and Kinder™ Krowns with regard to any of the clinical variables examined. While gingival health of both crown types improved with time, the decrease in inflammation was only found to be significant for NuSmile® Primary crowns.

While the majority of crowns resisted facing fracture and wear, a small number displayed fracture and wear of the facing after 12 months. Of these the vast majority were of a minor nature. It was noted that crowns opposing another aesthetic SSC were significantly more likely to display wear after 12 months than crowns opposing any other type of tooth surface, but this result could have been influenced by the limited posterior occlusal support in a number of these cases.

The procedure in placement of a preveneered SSC, while less forgiving than that of a conventional SSC, was found to be very manageable following training. Furthermore, it did not influence the behaviour management options chosen for the patients. This is of great clinical

importance in paediatric dentistry, as any technique carried out on young children must be able to be executed under varying circumstances in order to be clinically useful.

The results of this study suggest that the clinical performance of posterior preveneered SSC is comparable to that of conventional SSC after 12 months in service. Although extended follow up is required, the results showed that crowns were predictably retained 100% of the time and maintained an adequate coronal seal. No deleterious effects on pulpal health were noted. It is also noteworthy that the degree of tooth preparation required to fit these crowns did not require exposure of the pulp and subsequent pulpotomy, as has been previously suggested. In this study almost 90% of crowns were successfully placed without the need for invasive pulp therapy (i.e. pulpotomy). It was also observed that no adverse sequelae occurred in placing crowns in children with different occlusal discrepancies including posterior crossbite. However, placement of adjacent preveneered SSC is likely to require excessive tooth preparation, and should be approached with caution.

Both NuSmile® Primary crowns and Kinder™ Krowns possess a major advantage over conventional SSC due to their superior aesthetics. Parental satisfaction with these crowns was found to be excellent, with no preference expressed for either product. The vast majority of preveneered SSC resisted fracture and wear after 12 months and those that did display these features continued to remain aesthetic in the patients smile. Overall, the crown colour was observed to have a more natural appearance than previously reported. The main disadvantage in using these crowns lies in their increased cost and their potential for veneer fracture. It is recommended that parents be informed of this possibility prior to use.

Posterior preveneered SSC offer a potential solution to the ongoing challenge paediatric dentists' face in achieving a cosmetically acceptable and durable restoration for primary teeth. These crowns combine the

durability of a conventional SSC with the cosmetics of composite resin, while being less technique sensitive.

There is a paucity of studies in the literature regarding clinical use of posterior preveneered SSCs and it was for this reason that the present study was undertaken. The aims were achieved by comparing the clinical and radiographic success of posterior NuSmile® and Kinder Krowns™, and comparing their success with that of conventional SSC after 12 months. There was no difference in the clinical and radiographic success of the posterior NuSmile® and Kinder Krowns™ therefore accepting the null hypothesis.The promising results to date enable the investigators to propose posterior preveneered aesthetic SSC as a suitable aesthetic alternative to conventional SSC for the restoration of carious primary molars in certain clinical situations.

7 Appendices

7.1   Copy of ethical approval

**THE ADELAIDE & MEATH
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September 28th 2007
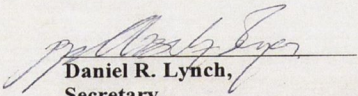
**Re: A Clinical Study to Evaluate the Success of Two Commercially Available
Aesthetic Stainless Steel Crowns on Primary Molars.**

*Please quote this reference in any follow up to this letter: 2007/09/21 Chairman's
Action.*

Dear Dr. Leith,

Thank you for your recent submission of the above proposal to the SJH/AMNCH
Research Ethics Committee.
The Chairman, having reviewed your proposal has, on behalf of the Committee, given
ethical approval to the proposed study.

Yours sincerely,

Daniel R. Lynch,
Secretary,
SJH/AMNCH Research Ethics Committee

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7.2   Patient information sheet

7.2.1   Patient information sheet: Page 1

Patient Information Sheet

A clinical study to evaluate the success of two commercially available aesthetic (white covered) stainless steel crowns on primary molar teeth.

Introduction:

Your child requires a crown or "cap" on his/her baby back teeth (molars). It is important to hold on to the baby back teeth in order to have space for the second adult teeth to grow / erupt. As baby back teeth are rather small, it is often difficult to fill them with a regular filling when they have a large hole. Crowns are the best option to build up the tooth and keep it covered and in place until your child is older and the tooth is shed naturally. Baby back teeth are normally shed around 10-12 years of age.

Stainless steel crowns are the standard of care when a child has a badly broken down baby back tooth. Normally, the dentist chooses a stainless steel silver coloured crown to fit over the baby back tooth. The dentist files down the baby tooth with a drill so the crown can fit over it and then sticks the crown on with tooth cement. These crowns are usually easy to put on the tooth and tend to last many years until the tooth falls out naturally. Sometimes however, parents feel that shiny silver crowns don't look nice because of their colour, especially if they are visible when a child is smiling.

Stainless Steel Crowns
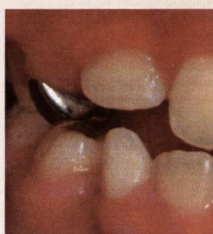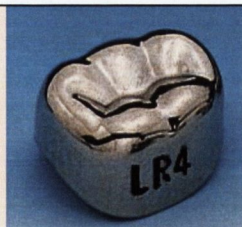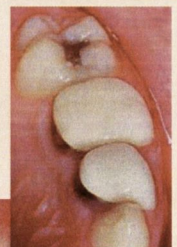
White Covered Stainless Steel Crowns

We are using two different types of white covered stainless steel crowns in this study. They look very similar and are put on the baby back tooth in the same way as a regular silver stainless steel crown. We will place one of each type on different back teeth in your child's mouth. We hope to find out if there is any difference between them over time, or if one is better than the other. We also hope to compare these new crowns with conventional stainless steel crowns to find out if they perform equally well.

1.NuSmile crowns   2. Kinder Krowns

What does this involve?

First, the dentist will examine the tooth and usually take a small x-ray picture to make a diagnosis.

For each crown, your child's back tooth will be numbed up and then filed down with a drill.

The dentist will then select a white covered crown and fit it over a tooth on one side of your child's mouth, and then select the other type of white covered crown for the other side. This enables us to compare the crowns on each side of your child's mouth.

We will review the success of these crowns at 3, 6, 12 and 18 months by examining the tooth and may take a small x-ray picture if appropriate.

What happens after the study?

Your child will be reviewed and monitored by staff of the Paediatric department in the Dublin Dental Hospital as long as necessary.

Where will this treatment take place?

Your child will have their white covered crowns placed in the
1. Dublin Dental Hospital.
Your child will have their white covered crowns placed in
2. Tallaght Hospital (Adelaide and Meath, National Children's Hospital)

All review visits will take place in the Dublin Dental Hospital.

Who will be treating my child?

One of 2 dentists will carry out treatment on your child, Dr Rona Leith and Dr Anne O'Connell.

You can contact either dentist at any time if you have questions or concerns.

What are the benefits?

The benefit of using white covered stainless steel crowns is that your child's baby back teeth are rebuilt and protected. The stainless steel part of the crown underneath give the tooth the strength it needs, and the white covering allows the crown to blend in with the other teeth. These crowns will give your child a more natural looking smile.

Are there risks involved?

White covered crowns are similar to regular stainless steel crowns. White covered stainless steel crowns have a white facing that is joined to the surface of a stainless steel crown underneath. It is possible sometimes that bits of it wear down or chip off over time from biting and chewing or hitting the tooth too hard. If this happens, the tooth underneath still remains protected by the strong metal portion of the crown. However, we can sometimes add more white covering over the chipped part or replace the crown if chipping occurs. As with all dental procedures, success is not guaranteed and some crowns are not successful. If this happens we will carry out any further necessary treatment on the baby tooth.

Do I have to take part?

No, you do not have to be a part of this study. If you decide that you do not want your child included in the study we will still carry out treatment of your child's back tooth. It will not affect your right to treatment.

Can I withdraw my child from the study?

Yes, you can decide to withdraw from the study at any point even if you have been involved at the start. If you quit, you will not be penalised and will not give up any benefits that you had before entering the study.

Confidentiality:

Your child's identity will remain confidential. His/her name will not be published and will not be disclosed to anyone outside the study group.

Confidentiality of Information:
Your child will be identified on all records/data by his/her hospital number. Access to your child's records and data from this study will be limited to the dentists in the research group. Any computerised information will be stored on password-protected computers with restricted access. The study data will be kept for 5 years after the study is completed in a locked cabinet but will not be used for any future unrelated studies without your permission.

Access to Data:
The data collected regarding your child will be available for you to see at any point during the study by asking a team member.

Compensation:
Your dentists are covered by standard malpractice insurance.
Nothing in this document restricts or curtails your rights.

Stopping the study:
You understand that your dentist may stop your participation in the study at any time without your consent.

Permission:
This study has been approved by the Dublin Dental School and Hospital. The study has ethical approval from St. James's hospital and AMNCH Joint Research Ethics Committee.

Use of the data:
The results from this study will be presented as part of a thesis in the primary researcher's (Dr Rona Leith) Doctorate Degree. It is also hoped that the findings will be published in a suitable dental journal or in lecture format so others can benefit from the information.

Further Information:
You can get more information or answers to your questions about the study, your participation in the study, and your rights, from:

- Dr Rona Leith, Department of Public and Child Dental Health, Dublin Dental School and Hospital, Lincoln Place, Dublin 2. Phone: 01 6127303
- Dr Anne O'Connell, Consultant/Senior Lecturer, Department of Public and Child Dental Health, Dublin Dental School and Hospital, Lincoln Place, Dublin 2. Phone: 01 6127303

7.3 *Consent form*

7.3.1 **Consent form: Page 1**

<div style="border:1px solid black; padding:1em;">

Consent Form

A clinical study to evaluate the success of two commercially available aesthetic (white covered) stainless steel crowns on primary molar teeth

(Department of Public and Child Dental Health, Dublin Dental School and hospital, Lincoln Place, Dublin 2.)

This study and this consent form have been explained to me.

I understand that my child requires crowns on his/her baby back teeth (molars). I understand that two types of white covered stainless steel crowns will be used to restore these teeth (NuSmile crowns and Kinder Krowns).
I agree to data being collected on the outcome of these crowns and used in this study.

I also give permission for the data from my child's treatment to be included in the overall findings of this research, which will be published in relevant dental literature.

My dentist has answered all my questions to my satisfaction. I believe I understand what will happen if I agree to be part of this study.

I have read, or had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree for my child to be part of this research study, though without prejudice to my legal and ethical rights. I have received a copy of this.

I understand that I may withdraw from the study at any time and that it will not affect my future treatment.

PARTICIPANT'S NAME:_____
PARTICIPANT'S SIGNATURE:_____
DATE:_____

</div>

7.3.2 Consent form: Page 2

If the subject is a minor (under 18 years old) the signature of parent or guardian must be obtained:

NAME OF CONSENTOR, PARENT or GUARDIAN:_____

SIGNATURE:_____

RELATION TO PARTICIPANT:_____

Where the participant is capable of comprehending the nature, significance and scope of the consent required, but is physically unable to sign written consent, signatures of two witnesses present when the participant gave consent to the dentist:

NAME OF FIRST WITNESS:_____ SIGNATURE:_____

NAME OF SECOND WITNESS:_____ SIGNATURE:_____

Statement of investigator's responsibility:

I have explained the nature, purpose, procedures, benefits, risks of, or alternatives to, this research study. I have offered to answer any questions and fully answered such questions.
I believe that the participant understands my explanation and has freely given informed consent.

Dentist's signature_____
Date:_____

7.4 Examiner calibration form

Calibration 1:

Picture	1	2	3	4	5	6	7	8	9	10
Plaque index 0= no plaque 1= film at gingival margin 2= moderate accumulation 3= abundance of plaque										

Picture	1	2	3	4	5	6	7	8	9	10
Modified Gingival index 0= healthy 1= mild inflammation, involving some papilla 2= moderate inflammation 3= severe inflammation										

Picture	1	2	3	4	5	6	7	8	9	10
Stain resistance 0= no staining 1= minor staining 2= noticeable staining										

Picture	1	2	3	4	5	6	7	8	9	10
Facing fracture: Buccal surface 0= intact 1= <50% surface chipped 2= >50% surface chipped 3= complete loss										

Picture	1	2	3	4	5	6	7	8	9	10
Facing fracture: Occlusal surface 0= intact 1= <50% surface chipped 2= >50% surface chipped 3= complete loss										

Picture	1	2	3	4	5	6	7	8	9	10
Facing wear 0= no wear 1= wear at cusp tips only 2= > cuspal wear										

7.5 *Initial data collection form*

Initial Data				
Date				
Patient number				
Age				
Relevant medical history				

Tooth #				
Indication for crowning Multisurface caries Coronal seal Dev defect				
Pulp status Intact IPT Pulpotomy Pulpectomy				
Crown used Nusmile (size) Kinder (size)				
Crimping Yes/No Method				
Trimming Yes/No Method				
MGI 0= healthy 1= mild inflam 2= moderate inflam 3= severe inflam				
Plaque Index 0= no plaque 1=film at gingival margin 2=moderate accumulation 3= abundance of plaque				
Occlusal adjustment Yes/No Method				
Opposing tooth Natural Restored: material				

7.6 Clinical outcome data collection sheet

Clinical Outcome

Hospital Number				Date			

Review Visit

	1	2	3	4
TOOTH #				
Crown retention 0= present 1= absent 2= recemented				
Modified Gingival index 0= healthy 1= mild inflammation, involving some papilla 2= moderate inflammation 3= severe inflammation				
Plaque index 0= no plaque 1= film at gingival margin 2= moderate accumulation 3= abundance of plaque				
Stain resistance 0= no staining 1= minor staining 2= noticeable staining				
Facing fracture: Buccal surface 0= intact 1= <50% surface chipped 2= >50% surface chipped 3= complete loss				
Facing fracture: Occlusal surface 0= intact 1= <50% surface chipped 2= >50% surface chipped 3= complete loss				
Facing wear 0= no wear 1= wear at cusp tips only 2= > cuspal wear				
Gingival marginal extension 0= subgingival 1= supragingival				
Occlusion 0= contact 1= no contact				
Opposing tooth 0= natural tooth 1= restored tooth 2= SSC 3= aesthetic crown				
Alignment relative to arch form 0= normal alignment 1= rotated 2= mal-aligned				
Proximal contacts 0= good, resistance with floss 1= poor / no contact				

7.7 Radiographic outcome data collection sheet

Px	Area	Able to measure: Yes / No	Overhang: Yes / No	Position (M / D)	Xray Size overhang (mm)	Xray Size crown (mm)	Actual size crown (mm)	Actual size overhang (mm)
1	LLD							
1	LRD							
2	LRE							
2	LLE							
3	LRD							
3	LLD							
4	ULD							
4	URD							
4	LLD							
4	LRD							
5	LRE							
5	LLE							
6	ULE							
6	URE							
7	LLE							
7	LRE							
8	LLD							
8	LRD							
9	LRD							
9	LLD							
10	LRD							
10	LLD							
11	ULD							
11	URD							
11	LLD							
11	LRD							
12	URD							
12	ULD							
12	LRD							
12	LLD							
13	URE							
13	ULE							
14	ULD							
14	URD							
14	LLD							
14	LRD							
15	URD							
15	ULD							
16	URD							
16	ULD							
16	LRD							
16	LLD							
17	ULD							
17	URD							
17	LLD							
17	LRD							

7.8 Visual analogue scale

Patient number: Date:

Visual Analogue Scale of parental satisfaction with white covered stainless steel crowns.

Please place a mark across the horizontal line at a point that best expresses your feelings between the two extremes.

    0   10
  Not _____ Very
satisfied   satisfied

Signature:

7.9 Retrospective Power Calculation

Sample size estimation for two proportions in independent groups using the chi-squared test:

Requirements

- Choose power
- Choose significance level
- Choose size of effect

Sample size question:

How many crowns are required in order to have an 80% power of detecting clinically important differences in success rates (facing fracture) of 25% between the two crown types and a two sided significance level of 0.05?

Assumption: success rate of 60% in the group having the lowest success rate.

If power is 80%: required sample size is $16 \div (\text{standardized difference})^2$

If power is 90%: required sample size is $21 \div (\text{standardized difference})^2$

(Lehr's Formula for crude sample size estimates)

Standardised difference = 0.63

$16 \div (0.63)^2 = 16 \div 0.39 =$ **41 in each group at power of 80%**

Total sample size required = 82 crowns

$21 \div (0.63)^2 = 21 \div 0.39 =$ **54 in each group at power of 90%**

Total sample size required = 108 crowns

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