UNIVERSITY OF PRETORIA

A comparison between the band-and-loop space maintainer with a loop-design fibre-reinforced composite space maintainer.

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"There can be no keener revelation
of a society's soul
than the way in which
it treats its children"

- Nelson Mandela-

Declaration and conflict of interest

I, Nicoline Potgieter, declare that this dissertation, entitled:

"A comparison between the band-and-loop space maintainer with a loop-design fibre-reinforced composite space maintainer"

is my own work and has not been submitted for any degree or examination at any other university. Moreover, all the sources that I have used or quoted have been indicated and acknowledged as complete references.

Furthermore, I declare that no competing interests, either financial or non-financial (e.g. political, personal, religious, academic, ideological, intellectual, commercial, etc.) exist with respect to this research. I do not hold stocks or shares in any organisation that stands to gain or lose financially from the publication of this manuscript. I do not hold any patents, nor am I currently applying for any patents related to the content of the manuscript. No funding has been received from any organisation that holds or has applied for patents related to the content of the manuscript.

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Nicoline Potgieter
November 2017

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First and foremost, all praise to God my saviour from who I get my strength.

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Abbreviations

SM	-	Space maintainer
BLSM	-	Band-and-loop space maintainer
FRCSM	-	Fibre-reinforced composite space maintainer
GIC	-	Glass ionomer cement
FRC	-	Fibre-reinforced composite
Mx	-	Maxilla
Md	-	Mandible
PI	-	Plaque index
sec	-	Seconds
Figure	-	Figure
mm	-	Millimetres
mg	-	Milligrams
AAPD	-	American Academy of Paediatric Dentistry
FRC	-	Fibre-reinforced composite
FPD	-	Fixed Partial Denture
mW/cm^2	-	Milliwatts per square centimetre
%	-	Percentage
yrs	-	Years

Summary

The band-and-loop space maintainer (BLSM) is a non-invasive device commonly used to maintain space after the early loss of a single deciduous tooth until the permanent tooth erupts. Unfortunately, however, these devices are difficult to fabricate, require laboratory work and are expensive. Clinically, they tend to fracture, bend or debond under occlusal forces and they are not considered aesthetic. These obvious limitations and challenges warrant the investigation of new materials and device designs for the treatment of premature single tooth loss.

The fibre-reinforced composite space maintainer (FRCSM) has many advantages and has been suggested as an alternative to the BLSM. This study considers the clinical failure rates and reasons for failure for a loop-design FRCSMs, as placement techniques have not yet been standardised.

The aim of the study was to comparatively investigate the *in vivo* failure rates (as well as the reasons for failures) of the loop-design FRCSM and the metal BLSM over a 6 month period. The data collected could be useful in the development of more successful FRCSMs.

A total of 20 space maintainers were placed – 10 BLSMs and 10 loop-design FRCSMs. For each BLSM placement, an orthodontic band was fitted around the anchor tooth and an alginate impression was taken. This impression, with the band in position, was sent to the dental laboratory for fabrication of the device. At a second appointment, the BLSM was fitted and cemented with glass ionomer cement. For each FRCSM placement, a unidirectional glass fibre bundle was positioned in a continuous loop design extending from the buccal to the lingual surface of the anchor tooth. The fibre

bundle was secured in position with a flowable composite, light-cured, and subsequently finished and polished.

Monthly follow-up appointments were scheduled over a six-month period and parents/ patients were instructed to report immediately for an emergency appointment if any problem or failure occurred between these arranged appointments. This ensured that the timing of (and reasons for) the failures of both types of device were accurately recorded.

With respect to the BLSM, the main reason for device failure was bending of the wire and subsequent impingement on the soft tissue. With respect to the FRCSM, the main reasons for device failure were debonding at the enamel-composite interface and fibre loop fracture. Within the six month follow-up period, both space maintainer types exhibited a 50% failure rate, but 30% of the failed FRCSMs could be repaired chairside whilst the failed BLSMs had to be refabricated in the laboratory. Although the results of this study do not show a significant statistical difference between the failure rates of the two space maintainer types tested ($p=0.53$), the FRCSM performed well clinically in that it was more easily repairable and remained clinically effective even in cases where the device broke.

From the data gathered during this study, it is recommended that further research be done on the effectiveness of the loop-design FRCSM when it is bonded to permanent teeth, and on whether this device would prove more successful if mechanical retention were enhanced when bonding the device to deciduous tooth enamel. Whilst this study has generated valuable new clinical information, the FRCSM cannot yet be confidently recommended as a reliable alternative to the BLSM. Further research on this topic (based on a larger sample size and with a longer follow-up period) is necessary.

Keywords

Single tooth space maintenance

Band-and-loop space maintainer

Fibre-reinforced composite space maintainer

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Chapter 1: Introduction and Literature Review

Loss of space due to early loss of deciduous teeth is a leading cause of malocclusion in paediatric dental patients in the deciduous and mixed dentition stages.[1] Where early deciduous tooth loss occurs, the placement of an effective space-maintaining device could reduce future occlusal discrepancies.[2]

Stainless steel band-and-loop devices are widely used for this purpose. These are non-invasive fixed devices that maintain space after the early loss of a single deciduous tooth until the permanent tooth erupts.[3] When placing such a device, an orthodontic band is cemented to an anchor tooth with a wire loop extending from the band on the anchor tooth over the premature extraction space to make contact with the non-anchor tooth. Common reasons for the failure of these band-and-loop space maintainers (BLSMs) include fracturing, bending, or de-bonding of their components under occlusal forces.[4,5] The average "survival period" of a BLSM is approximately 13 months, which in many cases is often insufficient time for the permanent tooth to erupt.[6] Furthermore, a long term study done by Sasa *et al.*[7] revealed that these devices have a success rate of approximately 10%. Thus, alternatives to the BLSM are being investigated.

Fibre-reinforced-composite material is known for its flexural and physical strength.[3,8] The fibre-reinforced-composite space maintainer (FRCSM) has been suggested as an alternative to the conventional stainless steel BLSM.[1,3,9,10] FRCSMs with different designs and etching times have been assessed in clinical studies. A mean FRCSM "survival period" of five months has been reported in the literature,[4,11] and FRCSM success rates over a six month period range from 27.5%[4] – 67%[1]. The relatively short survival period indicates the need for improvement of the FRCSM.

Various findings reported in the literature need to be considered in a bid to refine FRCSM placement techniques. Such refinements stand to lengthen the “survival period” of the FRCSM and enhance the ultimate success of these devices. The remainder of this chapter will review the relevant literature with respect to the basic rationale for space maintenance, the conventional BLSM, bonding to deciduous tooth enamel, and the use of fibre-reinforcement in paediatric dentistry.

1.1 The basic rationale behind space maintenance

The aetiology of premature deciduous tooth loss may include caries, trauma, ectopic eruption, congenital disorders, and arch length deficiencies causing premature resorption of roots.[11,12] The premature loss of a deciduous tooth commonly leads to space loss due to tilting, drifting and/ or rotation of the teeth mesial and distal to the edentulous site.[1] Potential consequences of space loss include impaction of unerupted permanent teeth, dental arch midline shift, and over-eruption of opposing teeth, all of which can lead to malocclusion and the impairment of oral functions such as speech and mastication.[1] The effective maintenance of an edentulous space, as a result of premature tooth loss, stands to reduce or eliminate these undesirable consequences. When a deciduous tooth is lost prematurely, it is therefore advisable to stabilise arch dimensions by positioning a space maintaining device in the premature extraction space.[2] The American Academy of Pediatric Dentistry (AAPD)[13] describes the goal of space maintenance as the prevention of arch length, width and perimeter loss through maintaining the relative positioning of the remaining dentition. Thus, effective space maintenance can help prevent the need for future extensive fixed orthodontic treatment in mild to moderate crowding cases.[14]

When deciding whether a space maintainer is needed, it is very important to consider the clinical situation of the individual in question.[15] According to the AAPD guidelines, factors to consider include: specific tooth lost; time elapsed since tooth loss; pre-existing occlusion; presence of a permanent successor tooth (including normal root development); amount of alveolar bone covering the permanent successor tooth; patient's health status; patient's cooperative ability; patient's current oral habits; and patient's oral hygiene status.[13] Additional factors include the patient's age, the jaw from which the tooth is lost (i.e. maxillary/ mandibular) and/ or the general dental spacing/ crowding of a given individual.[16] These factors can influence both the degree and the rate of space loss.[11]

The earlier a deciduous molar is extracted, especially if it is extracted before the eruption of the first permanent molars, the more drifting of the remaining teeth can be expected.[11] Thus, space loss tends to occur more in younger patients.[11] Both the rate and the degree of space loss are usually higher in the maxilla than the mandible.[11,17,18] Space loss tends to be greater with the premature loss of a second deciduous molar than with a first deciduous molar.[11,19,20] The most significant space changes tend to occur within four to six months after tooth extraction.[17,21] Thus, it is advisable to initiate space maintenance interventions as soon as possible after premature tooth loss.

The present study focuses on space maintenance following the premature loss of first deciduous molars. Space loss following the premature loss of a maxillary first deciduous molar is mostly due to mesial drifting of the teeth distal to the premature extraction space.[11,16,22] On the other hand, space loss following the premature loss of a mandibular first deciduous molar is mostly due to distal drifting of the teeth mesial to the

extraction site.[11,15,17,22] Figure 1.1 illustrates space loss following the premature loss of a first mandibular deciduous molar (74).

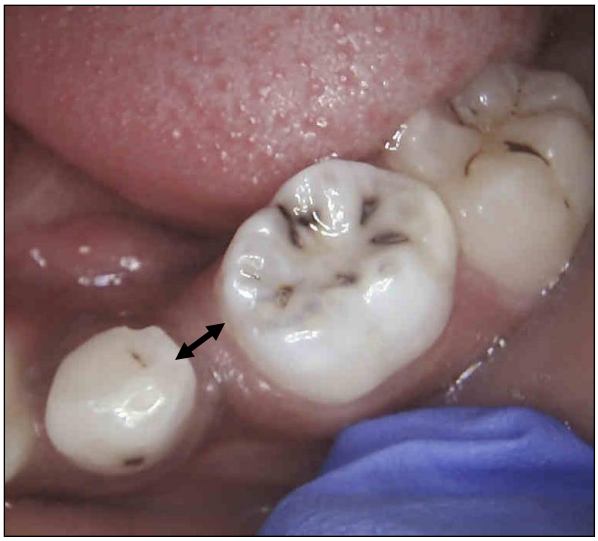

Figure 1.1: Space loss after the premature loss of a 74, illustrating distal drift of the 73

There is some controversy in the literature surrounding the placement of space maintainers in cases of premature first deciduous molar loss. Certain authors argue that since there is no statistical evidence that space loss will occur under such circumstances, space maintenance for the early loss of a first deciduous molar, especially in the maxilla, is not necessary.[15,23] It is important to note, however, that even in cases where space loss following premature loss of a first deciduous molar is deemed statistically insignificant, this loss may be clinically significant (as seen in Figure 1.1). Northway[24] concluded that although space loss following the loss of a first deciduous molar could not necessarily be proven, the long-term consequence of such losses could include impaction of the permanent canines. Thus, space maintenance is still advisable in such cases as a precautionary measure.

Currently, the placement of a space maintainer for a missing deciduous first molar is generally indicated in cases where the first permanent molars have not yet erupted and are not yet in a stable occlusion.[16,25] However, Alexander *et al*.[18] assert that not only occlusion, but also the degree of intercuspation are vital variables to bear in mind when deciding whether or not to place a space maintainer. They recommend that space maintainers for missing first deciduous molars also be placed where there is a cusp-to-cusp molar relationship. Space maintainers have also been advocated where anterior crowding is present to prevent the transfer of the malocclusion to the posterior segment.[16]

To summarise, premature loss of deciduous teeth is a common problem. Effective space maintenance plays a vital role in the long-term oral health of patients who experience premature tooth loss and should be available to all paediatric patients as part of their routine dental care. Unfortunately, many clinics in South Africa do not have access to the services of dental laboratories. Thus, space maintainers are not being placed as part of comprehensive dental treatment plans.

1.2 The band-and-loop space maintainer (BLSM)

Currently, where premature loss of a single deciduous tooth has occurred, the most commonly used fixed space maintainer is a stainless steel BLSM.[3] Where the missing tooth is a first deciduous molar, the BLSM can be cemented onto the second deciduous molar. Conversely, where premature loss of a second deciduous molar has occurred the BLSM can be cemented onto either the first permanent molar or the first deciduous molar as a reverse-BLSM.[12]

Fabrication of a BLSM entails fitting a pre-fabricated orthodontic band around the abutment tooth, taking an impression and sending the impressions with the band in place to a laboratory where the BLSM is fabricated on a model.[3] At a follow-up appointment, the custom-made BLSM is fitted and cemented.[3] The properties of glass ionomer cements (GICs) make them a popular choice for the cementation of BLSM bands. They can adhere to both enamel and metal,[26] release fluoride ions,[27] have antimicrobial effects, and are not moisture-sensitive.[7,28] Figure 1.2 illustrates a cemented BLSM.

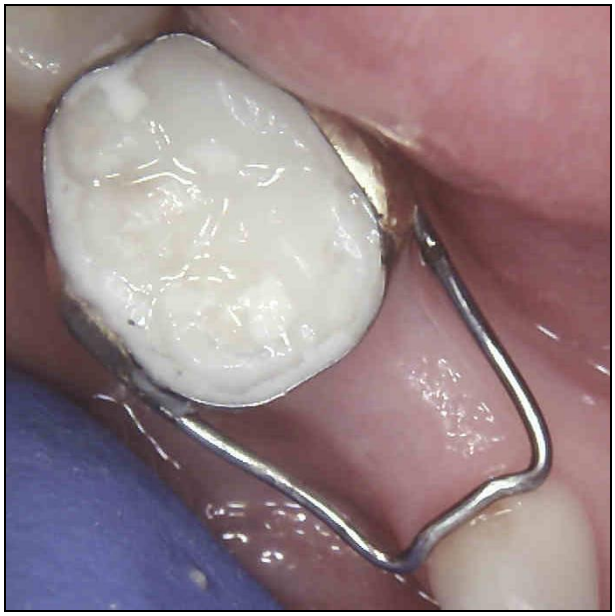

Figure 1.2: An example of a BLSM after cementation

Although the fabrication of a BLSM is relatively simple, it is not without its challenges. Achieving a good fit of the band around the anchor tooth is sometimes difficult. This is especially true when the anchor tooth is a deciduous molar due to the morphology of these teeth. Thus, patients often experience discomfort in the surrounding soft tissue during the fitting process, which might necessitate local anaesthesia.[1,9] A poor fitting BLSM leads to a delay in the final placement of the device, as a new impression has to

be taken and sent to the laboratory where either the existing BLSM is corrected, or a new BLSM is fabricated. BLSM fabrication is labour- and time intensive, requiring two appointments with a dentist as well as the services of a dental laboratory technician.[9] Furthermore, the expensive materials (i.e. impression trays/ materials, stone for casting, prefabricated bands, orthodontic wire, solder wire and equipment) used during this process by both the dentist and the technician contribute to additional cost inflation.[3]

Practitioners have shown considerable interest in determining the reasons behind BLSM failures. In a study by Sasa *et al.*[7] in which 40 patients who had been fitted with BLSMs were monitored for 40 months, the main reasons cited for BLSM failure were decementation, solder breakage, and the development of soft tissue lesions associated with the devices.

In general, cement failure, i.e. disintegration of the cement or debonding at the cement-enamel or cement-metal interface,[4, 7] is considered the most common reason for BLSM failure.[5, 9] Another common cause of BLSM failure is that the metal loops of these devices often bend and become embedded in the gingival tissues,[4] leading to gingival irritation or overgrowth.[7] Fracture, bending or dislodgement of BLSM loops cannot be repaired chairside. In the event of such an incident, the space maintainer is removed and refabricated in a dental laboratory. This removal process necessitates an additional dental appointment as well as additional laboratory costs. It also implies a level of additional risk, as the band would most likely need to be drilled off or removed with a posterior band remover, which can lead to iatrogenic damage to the abutment tooth. For private practitioners, this whole process may prove economically unviable as parents are often unwilling to incur additional costs associated with replacing the failed BLSM.

In addition to the labour intensiveness, high costs and risk of failure associated with stainless steel BLSMs, a further disadvantage is that they are not aesthetically pleasing,[4] and may pose a risk of metal allergy in susceptible individuals.[2,4]

Furthermore, whilst a correctly fitted and cemented BLSM band should protect tooth surfaces from bacterial colonisation,[29] loose bands, incomplete coverage of tooth surfaces, artificial ledges and bands that are placed too deeply, are associated with plaque accumulation, gingival inflammation, bacterial colonisation and possible periodontal destruction.[29,30,31]

Commercially available alternatives to the BLSM include devices from companies like DENOVO/ Unitek.[3] These devices eliminate the laboratory process by supplying prefabricated loops that can be fitted to the band chairside. Unfortunately these devices are expensive, not suitable for all clinical situations and not readily available in South-Africa. Furthermore, the challenges mentioned above also apply to these space maintainers.[3]

The obvious limitations and challenges associated with the conventional BLSM warrant the investigation of new materials and device designs for the treatment of premature tooth loss.[1]

1.3 Fibre-reinforced composites in paediatric dentistry

Fibre-reinforced composites were first described in the 1960s when glass fibres were used to reinforce polymethyl methacrylate.[32] According to Butterworth *et al.*,[33] “this group of materials is very heterogeneous depending on the nature of the fibre, the geometrical arrangement of the fibres and the overlying resin used.”

Fibres within a composite matrix are ideally bonded to a resin via an adhesive interface.[33] The role of these fibres is to enhance the structural properties of the composite material, whilst the resin matrix protects the fibres and fixes their geometrical arrangement.[33] Fibres indicated for chairside use are available in different compositions and fibre architectures and are summarised in Table 1.1 as adapted from Butterworth *et al*.[33,34]

Table 1.1: Classification of chairside fibre-reinforced composite products (Courtesy of Butterworth *et al.*[33])

PRODUCT	COMPANY	FIBRE TYPE	ARCHITECTURE
PRE-IMPREGNATED PRODUCTS			
Splint-it	Jeneric/Pentron	Glass	Unidirectional
Splint-it	Jeneric/Pentron	Glass	Weave
EverStick	Stick Tech Ltd	Glass	Unidirectional
IMPREGNATION REQUIRED			
Connect	Kerr	Polyethylene	Braid
DVA Fibres	Dental/Ventures	Polyethylene	Unidirectional
Fibre-splint	Polydentia Inc.	Glass	Weave
Fibreflex	Biocomp	Kevlar	Unidirectional
GlasSpan	GlasSpan	Glass	Braid
Ribbond	Ribbond	Polyethylene	Leno Weave

Fibre reinforcement enhances the mechanical properties (i.e. strength, rigidity, toughness, and fatigue resistance) of composite resin materials.[3,8,35,36] The use of fibre as a substructure under a composite resin can therefore improve the load-bearing capacity of that resin.[1,37,38] The fibre acts as a stress-bearing component with crack-

stopping or crack-deflecting mechanisms,[3,8,33,39] which ultimately improve the fracture behaviour of the composite resin material.[40,41]

Fibre-reinforced composites have been used successfully in paediatric dentistry for direct resin-bonded bridges with natural or prosthetic pontics, for splinting after trauma, as a support structure in large restorations, as a component of removable dentures, as intra-canal posts, and in orthodontic fixed space maintainers.[1,4,34,42-45] However, the need for further research on the clinical uses of fibre-reinforcement is acknowledged,[46] and its potential in the context of fixed space maintainers in the deciduous or mixed dentition phase has not yet been fully explored.[3]

1.4 The fibre-reinforced composite space maintainer (FRCSM)

Fibre-reinforced composite (FRC) applications seem generally promising in the field of paediatric dentistry.[34,43,44] More specifically, in the context of this dissertation, FRC's potential as the material basis of space maintainers is increasingly acknowledged.[4] The incorporation of a pontic into a fibre space maintainer is sometimes described as a fixed partial denture, which is one of the most promising applications of FRC.[47] In a recent systematic literature review by Ahmed *et al*.,[47] it was concluded that FRC fixed partial dentures demonstrate predictably good performance, have high survival rates, and can be considered for application in the medium-term management of single anterior or posterior tooth loss. Although published clinical studies of FRCSMs without pontics are few, the effectiveness of these devices has frequently been reported.[1,2,4,9,48]

The FRCSM has greater aesthetic appeal than a stainless steel device such as a BLSM, but this is not its only advantage.[4,49] The FRCSM is also minimally invasive,

does not impinge on soft tissue, and is easily removable.[4] Thus, it is far more readily accepted by paediatric patients than the BLSM.[9,49] The FRCSM demonstrates high durability[4,50] and is comparable to the stainless steel BLSM in terms of its physical strength.[3,8] The fibres in the FRCSM are easy to manipulate[4] and can be placed in such a way as to ensure adequate clearance between the fibre loop and the underlying tissue.[1,48]

Fabricating and fitting a FRCSM is relatively economical. The device has a simple design and can be placed in a single appointment.[2,48,50] Placement is quicker because the composite used cures on demand, unlike the cement used during the placement of a BLSM, which takes time to set.[2,4,49] No additional impression materials or orthodontic bands are required, and laboratory services and costs are avoided.[48, 50] Furthermore, a FRCSM can be repaired chairside (i.e. not requiring the services of a laboratory) and still maintain its original physical strength.[3]

The polished design of the FRCSM device facilitates the maintenance of good oral hygiene.[4] Furthermore, because bending of the FRCSM under occlusal forces is limited, the device does not impinge on, or cause trauma to underlying soft tissue.[1,4,48]

When the device needs to be removed, it can be carefully drilled off and the enamel polished without the underlying tooth structure being damaged. Even in cases where FRCSM failures were reported, no damage to the abutment teeth were noted.[48]

As with any composite, the materials used in FRCSM manufacturing is sensitive to moisture and dependent on placement technique.[79] It needs to be properly isolated and

placed according to the manufacturer's instructions.[79] Also, like the BLSM, the FRCSM neither prevents over-eruption of the opposing tooth,[50] nor restores function of the missing tooth.[4] However, these challenges can be overcome by the inclusion of a pontic in the design of the space maintainer. The materials used in FRCSMs allows for this, whilst that used in the BLSM does not.

Most recorded FRCSM failures have been attributed to debonding at either the enamel-composite interface or the composite-fibre interface.[1,4,9] This suggests that both bond strength and placement technique of FRCSMs need improvement.

1.4.1 Previous clinical studies on FRCSMs

Various authors have concluded that the FRCSM could be a viable alternative to the BLSM.[2,4,9,48] However, further research with respect to placement technique has been recommended,[4] as FRCSM designs and methods employed in the placement of these devices have not yet been standardised.

During a clinical study, Garg *et al.*[9] placed 30 FRCSMs (see Figure 1.3). These space maintainers, for single tooth loss only, were designed to have two fibres bonded to the lingual and buccal aspects of two anchor teeth adjacent to the edentulous area. They were constructed using Ribbond polyethylene fibres (Ribbond), and placed under rubber dam.

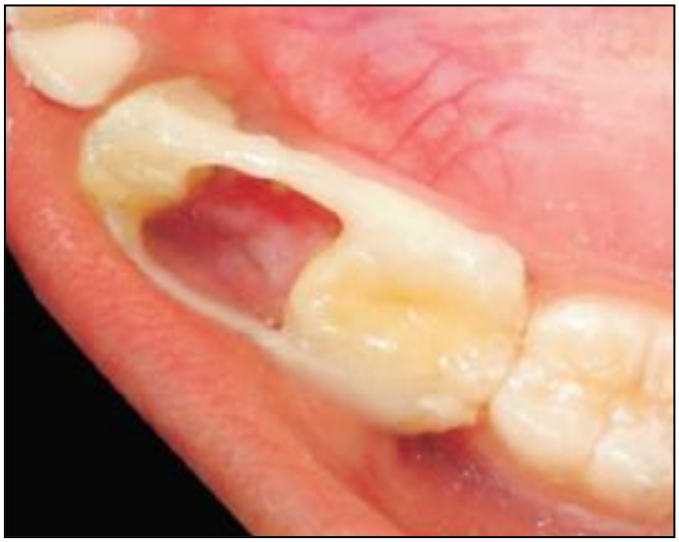

Figure 1.3: FRCSM with two separate fibres bonded to the buccal and lingual surfaces of two anchor teeth (Courtesy of Garg *et al.*[9])

Kargul *et al*.[2] reported on three FRCSM cases in 2003. These space maintainers were constructed using everStick glass fibres (Stick Tech) (see Figure 1.4).[2] In all cases, grooves were drilled in a mesio-distal direction for mechanical retention of the fibres. Both single and double edentulous areas were included in this study (see in Figure1.5).

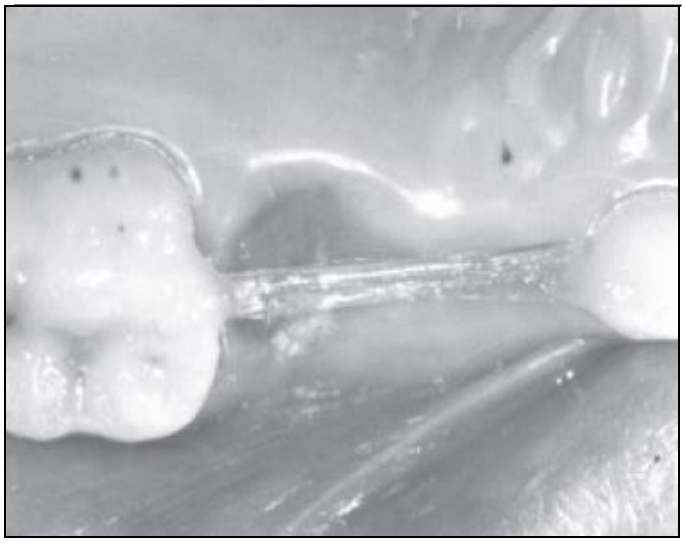

Figure 1.4: FRCSM with a single fibre bonded to the interproximal surfaces of two anchor teeth (Courtesy of Kargul *et al.*[2])

In 2005, Kargul *et al.*[48] reported on a further 23 space maintainers that were placed using the same technique and materials described in their 2003 study (see Figure1.5).[48] Once again, both single and double edentulous areas were included in this study. No rubber dam was used during placement.

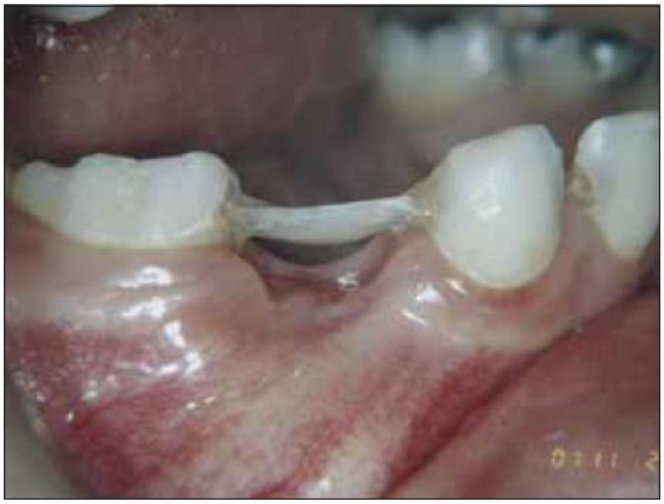

Figure 1.5: FRCSM with a single fibre bonded to the interproximal surfaces of two anchor teeth (Courtesy of Kargul *et al.*[48])

Kirzioğlu *et al.*[4] conducted a study in which they placed 40 FRCSMs. In each case, a single Splint-it glass fibre (Jeneric/Pentron) was bonded to the lingual/ palatal surfaces of the abutment teeth (see Figure1.6). In four of the cases, a pontic was included. No rubber dam was used during placement of the space maintainers.

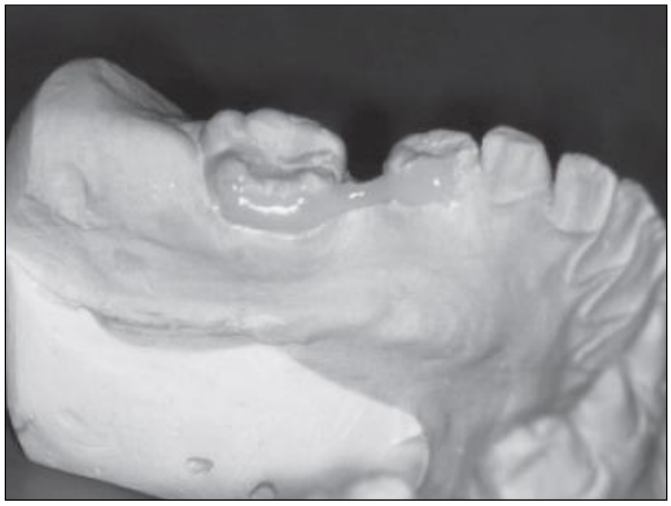

Figure 1.6: FRCSM with a single fibre bonded to the lingual surfaces of two anchor teeth (Courtesy of Kırzıoğlu *et al.*[4])

Subramaniam *et al.*[1] conducted a study using 30 FRCSMs. The technique employed for the placement of each FRCSM involved the bonding of a single glass fibre (Stick Tech) between the two abutment teeth adjacent to the premature extraction space as seen in Figure1.7.

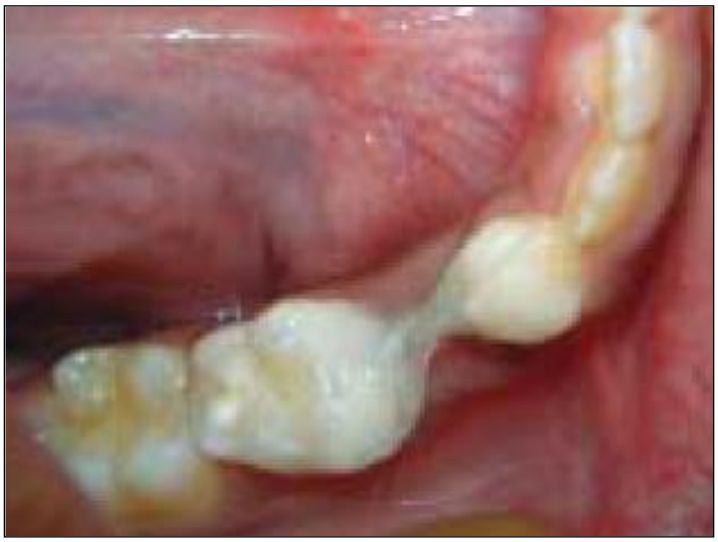

Figure 1.7: FRCSM with a single fibre bonded to the interproximal surfaces of two abutment teeth (Courtesy of Subramaniam *et al.*[1])

The findings from the abovementioned studies (outlined below) suggest that the FRCSM may be a viable alternative to the conventional fixed BLSM over short periods, but that placement technique and clinical success with respect to this type of space maintainer need to be evaluated further.[1,2,4,9,48]

1.4.2 Comparison of the BLSM with the FRCSM

Garg *et al.*[9] compared the performance of the BLSM with that of the FRCSM in 30 split-mouth cases (see Figure 1.7 for the FRCSM design). After six months, the causes and rates of failure for the different types of space maintainers were compared. For the BLSM, a failure rate of 63.3% was reported. The reasons for BLSM failures were cement loss (46%), loop fracture (6.7%), sub-gingival slippage of the band (6.7%), and band distortion (3.3%). For the FRCSM, a failure rate of 36.7% was reported. FRCSM

failures were attributed to debonding at the enamel-composite interface (16.67%), fracture of the fibre-frame (6.7%), and debonding at the fibre-composite interface (13.3%). The lower failure rate and quick placement time of the FRCSM, along with the fact that patients more readily accepted the FRCSM, led Garg *et al.*[9] to recommend that the FRCSM be considered as a favourable alternative to the BLSM.

Subramaniam *et al.*[1] also compared the BLSM with the FRCSM in 30 split-mouth cases (see Figure 1.7 for the FRCSM design). In that study, placement of the FRCSM involved the bonding of a single fibre between the two abutment teeth adjacent to the edentulous area. After 6 months, 56.7% of the BLSMs had failed, and after 12 months, 66.7% had failed. The main reasons cited for these malfunctions were cement failure (60%), and breakage/ caries/ gingival inflammation (6.7%). On the other hand, with respect to the FRCSM, failure rates of 33.3% and 46.7% were reported after 6 and 12 months, respectively. These FRCSM failures were mainly attributed to debonding at the enamel-composite interface (26.7%) and fibre frame fracture (16.7%). Subramaniam *et al.*[1] ultimately concluded that the FRCSM had a higher survival rate than the BLSM.

The studies reviewed above agree that the FRCSM could be a viable alternative to the BLSM. The present study explores a different FRCSM design with a view to addressing the main FRCSM failings identified by the abovementioned studies.

1.5 Bonding to deciduous tooth enamel

The ideal FRCSM should be successful irrespective of whether it is bonded to a permanent or a deciduous tooth. Bond strength to deciduous enamel is however lower than bond strength to permanent enamel,[51] especially if the deciduous tooth enamel is

demineralised.[52] Therefore, FRCSMs placed between deciduous teeth are more likely to fail than those placed between permanent teeth.[4] As pointed out in previous studies[1, 9] that the main reason for FRCSM failure is debonding at the enamel-composite interface. Therefore, it is essential to investigate how this bond might be strengthened.

Enamel microstructure comprises crystals arranged in prisms or rods, which run approximately perpendicular to the dentine-enamel junction towards the outer tooth surface.[53,54] The composition and thickness of tooth enamel can influence the strength of the bond between it and the composite.[55] The average growth time of a deciduous crown is 6 to14 months, as opposed to an average growth time of 3 to 4 years for a permanent crown.[56] Thus, compared to permanent teeth, deciduous teeth have thinner enamel (0.5 – 1 mm) which is less mineralised[55] and more prone to fracture.[57,58]

The enamel of both deciduous and permanent teeth is covered by an aprismatic layer.[59,60] Interestingly, it has been found that deciduous teeth have a thicker (up to 45 microns),[60] more uniform[56] aprismatic enamel layer than permanent teeth (which has an aprismatic layer of less than 5 microns thick).[60] The aprismatic enamel layer comprises hydroxyapatite crystals arranged parallel to one other and perpendicular to the enamel surface.[53,56] This uni-directional crystal orientation along with the relatively dense crystal arrangement result in fairly uniform dissolution and limited random porosity of the aprismatic layer.[55] The crystal orientation of deciduous enamel may therefore interfere with the acidic demineralisation process, affecting the quality and the strength of the bond between the enamel and the composite.[61]

The thicker aprismatic layer found in deciduous teeth needs to be penetrated by acid etching to achieve adequate bonding between the tooth and the composite material. Zachrisson[62] argued that the main reason for FRCSM debonding is inadequate preparation of the enamel surface. Although different authors have reported contradictory results,[61, 63] it has been suggested by Zilberman *et al.*[55] that the phosphoric acid etching time for deciduous teeth should be increased from 20 sec (i.e. the acid etching time for permanent teeth) to 60 sec in order to achieve sufficient dissolution of the aprismatic layer and expose the prismatic layer (see Figure1.8 and Figure 1.9).[55,64,65]

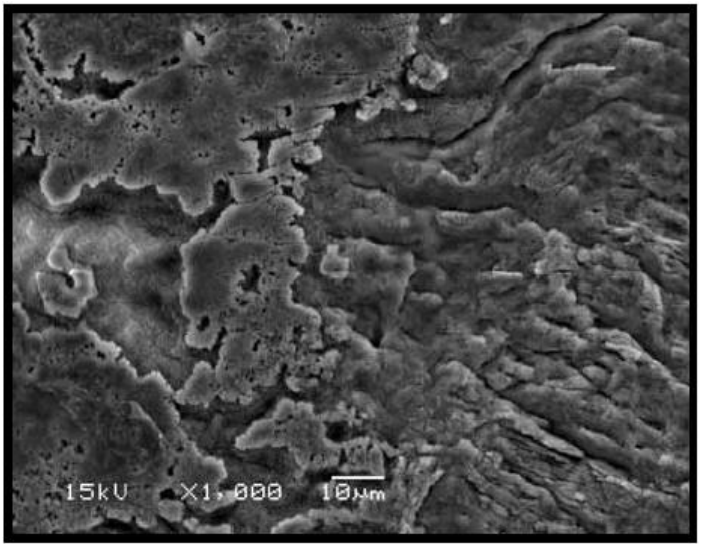

Figure 1.8: The effect of a 20 sec etching time on the enamel of a deciduous molar as observed by SEM at x1000 magnification. It can be seen that the acid has only affected the aprismatic layer. (Courtesy of Zilberman *et al*.[55])

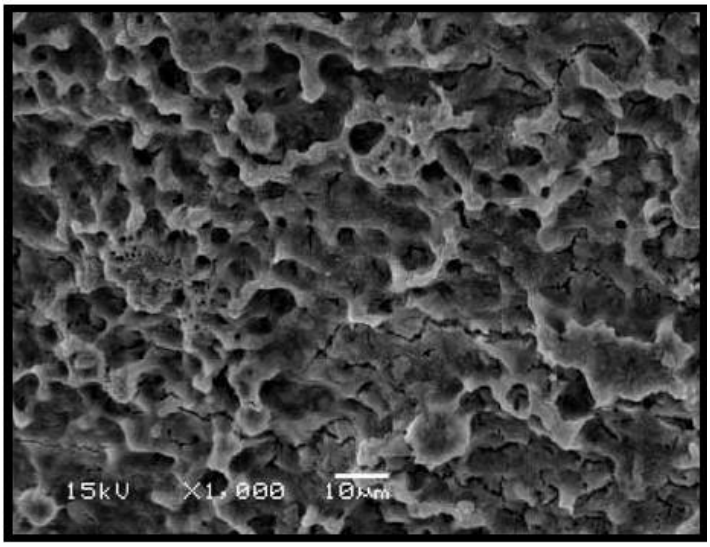

Figure 1.9: The effect of a 60 sec etching time on the enamel of a deciduous molar as observed by SEM at x1000 magnification (Courtesy of Zilberman *et al*.[55])

In some studies, even a 60 sec etching time revealed an amorphous substance with no evidence of prisms.[55,66] Indeed, an acceptable etch-pattern was only obtained after mechanical grinding of the deciduous tooth enamel followed by three minutes of acid etching.[55,67] Thus, it is important to critically evaluate whether a 60 sec etching time would prove sufficient when bonding a FRCSM to deciduous tooth enamel.

1.6 Rationale for the loop-design FRCSM

As mentioned previously, FRCSMs placed between two deciduous teeth have a higher failure rate than those placed between two permanent teeth.[4] Thus, this study focused specifically on developing a FRCSM for use in the deciduous dentition. The present study is based on the premise that any FRCSM design which proves to be successful for deciduous teeth should be even more successful for permanent teeth.

Unfortunately, it was not specified in the studies reviewed above whether fibres were bonded to deciduous or permanent teeth. The focus of these studies was the premature

loss of deciduous teeth, rather than the teeth used to anchor the FRCSMs.[1,9] This needs to be borne in mind when comparing the results of those studies with the results of this one (in which FRCSMs were only bonded to deciduous teeth).

The device tested in the present study was the loop-design FRCSM. In each case, the missing tooth was the first deciduous molar and the fibre was bonded to the second deciduous molar. This technique could also be applied in cases where second deciduous molars were prematurely lost, either as a reverse band-and-loop on the first deciduous molar or as a band-and-loop on the permanent molar (if it were fully erupted).

Shortcomings of the FRCSM studies reviewed previously include the fact that inevitable jaw growth and individual tooth movements were not taken into consideration when bonding the teeth adjacent to the edentulous space together.[1,2,4,9,48]
Indeed, to date, no long-term studies have been undertaken to explore whether bonding those teeth together might restrict growth, affect arch length, or possibly result in ankylosis.

Post-eruptive individual tooth movements are defined as “those made by the tooth after it has reached its functional position in the occlusal plane”.[68] This type of movement can be categorised into three groups: movements to accommodate the growing jaws, movements to compensate for continued occlusal wear, and movements to accommodate for interproximal wear.[54]

Movements to accommodate jaw growth continue until about 20 years of age, when jaw growth ceases. Such compensatory movement is related to condylar growth spurts

which separate the jaws and the teeth.[54] Histologically, when such movement occurs, the tooth socket position is readjusted through the formation of new bone at the alveolar crest and at the socket floor.[54]

Movements to accommodate for occlusal wear in the axial direction are most likely achieved by the same mechanism that leads to eruptive tooth movement, with the periodontal ligament playing a significant role in the process. Such movement is continuous, and is not restricted to a particular age group or developmental stage.[54]

Finally, movements to accommodate for interproximal wear are achieved by the mesial or approximal drift of individual teeth.[54] The forces causing mesial drift can be multifactorial. An anterior occlusal force occurs when teeth are brought into contact with one another and results in the mesial inclination of most teeth.[54] The contraction of trans-septal ligaments between the teeth along with the remodelling (by collagen phagocytosis) that occurs within these ligaments have been implicated in tooth movement.[54] Finally, forces generated by cheek and tongue pressure also influence tooth movement.[54]

When two anchor teeth are bonded together, they become rigidly splinted. This may result in complications like those associated with long-term splinting. Semi-rigid or flexible splinting allows for more normal physiological tooth movement, whereas rigid splinting leads to less tooth mobility than normal.[69,70] It has been demonstrated that long-term rigid tooth splinting may affect periodontal and pulpal health,[71] and may induce ankylosis.[69]

The loop-design FRCSM has been tested *in vivo* by other practitioners.[3,72] Kulkarni *et al*.[3] concluded that the device is comparable to the stainless steel BLSM in terms of its physical strength and degree of biofilm formation. Yeluri and Munshi[72] concluded that the loop design FRCSM may be clinically acceptable as an alternative to the BLSM, but recommended further clinical studies.

The present study is unique in that it represents the first clinical trial of the loop-design FRCSM in which the device was only bonded to deciduous teeth, and was not used to bond two adjacent anchor teeth together. Figure 1.10 shows an example of the loop-design FRCSM tested in the present study.

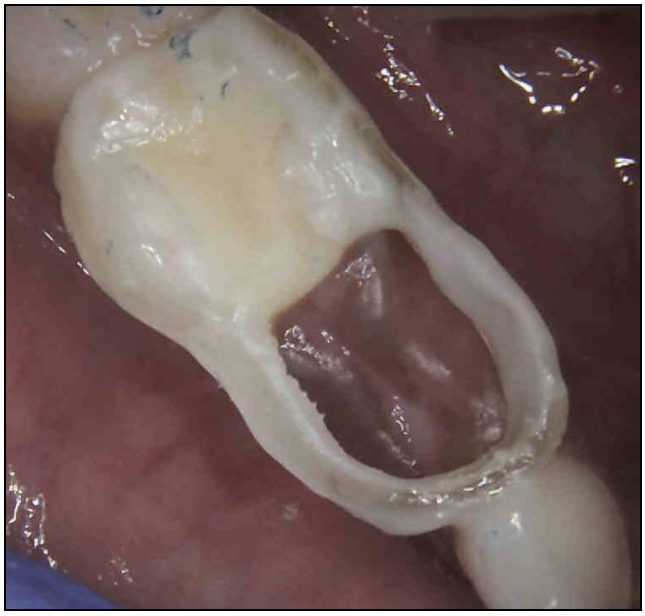

Figure 1.10: An example of a loop-design FRCSM tested in the present study

1.7 Plaque Index

Fixed orthodontic treatment tends to induce oral ecological changes such as a lowered pH environment, increased retentive sites for food particles, increased plaque accumulation, and increased retentive sites for *Streptoccus mutans*.[29,73,74] Balenseifen

and Madonia[73] reported higher concentrations of bacteria and carbohydrates per mg of dental plaque in patients receiving fixed orthodontic treatment. This can be attributed to the physical alteration of the oral microbial environment, which favours the proliferation of caries-associated microorganisms such as lactobacilli.[75] Although the presence of plaque alone does not necessarily cause caries, increased plaque accumulation increases orthodontic patients' risk for developing post-orthodontic decalcifications or caries.[29,73]

The maintenance of good oral hygiene is more challenging with intra-oral fixed devices, and a decline in oral hygiene practice allows plaque to accumulate. Plaque, if left undisturbed, becomes a platform for bacterial colonisation.[30] Furthermore, orthodontic patients often change their diets from hard to soft foods due to altered dental functionality and increased oral discomfort.[29] This could further increase their caries risk due to an overall increase in sugar exposure (from fluids especially), the enhanced retention of plaque (losing the abrasive function of chewing food), and/ or the impairment of salivary flow.[29]

Plaque accumulation (along with the subsequent demineralisation of enamel) and caries formation are serious concerns associated with fixed space maintainers, especially when these devices are placed on permanent molars.[2,4-6,76-78] It is therefore essential to make devices as non-plaque-retentive as possible, and to closely monitor a patient's oral hygiene throughout their fixed orthodontic treatment.

Chapter 2: Aims and Objectives

2.1 Aims

With the overarching goal of contributing towards the development of a successful FRCSM device, the aim of the present study was to compare a loop-design FRCSM with the BLSM over a 6 month period in terms of their *in vivo* failure rates, reasons for their respective failures and repairability.

2.2 Objectives

The objectives of the present study can be summarised as follows:

- To follow up the two different types of space maintainers (i.e. the BLSM and the FRCSM) over a 6 month period;
- To document all respective failures of the devices and to determine whether each failed device is repairable or not;
- To document the reason for each device failure;
- To ascertain whether failures are linked to placement position;
- To determine whether any associations exist between failures and patient demographics, i.e. age and/ or gender;
- To investigate whether a relationship exists between device failure rate and plaque index.

2.3 Potential value of the study

If a FRCSM can be shown to have a success rate comparable to that of the BLSM, clinicians could be advised to consider using the former instead of the latter. This could positively influence patient acceptance and lead to an increase in the number of space maintainers placed, decreasing the incidence of future occlusal discrepancies because of space loss.

Chapter 3: Materials and Methods

3.1. Study design

The present study took the form of a randomised, active, controlled experiment. It was an *in vivo,* two-group, parallel, exploratory comparative study which compared the performance of two groups of space maintainers (i.e. the FRCSM and the BLSM). The BLSM group was designated as the control group since BLSMs, which are currently the generally accepted space maintainer for premature loss of a single deciduous tooth, are already widely in use. Although some concepts of the current study are new, the methodology was constructed according to similar studies.[1,9]

The study was exploratory in that it sought to gather new evidence to address the gap in the literature with regards to the loop design FRCSM. Furthermore, the study endeavoured to identify possible problems with the FRCSM which would need to be addressed if a successful FRCSM is to be developed in the future.

3.2. Case selection

Previous clinical studies on FRCSMs (placed for the early loss of deciduous molars) focused on patients who were 6-8 yrs,[1] 7-14 yrs,[4] and 5-8 yrs[9] of age, respectively. Patients participating in the present study were all between the ages of 4 and 9 yrs, and thus in the mixed dentition stage before stable occlusion of the permanent molars is reached. BLSMs and FRCSMs were placed alternately as the patients presented so as to eliminate potential bias with regards to device assignment. However, in cases where a parent requested a space maintainer other than the one allocated to the patient, this

request was respected and the patient received the treatment of choice. However, such patients were then excluded from the study.

A total of 59 patients, each with a missing first deciduous molar, were screened for participation in the present study. Patients who did not fit the inclusion criteria (see section 3.2.2) were not considered. Fifteen patients who were screened (i.e. 25% of the total) were excluded because of damaged or restored buccal or lingual surfaces. For the purposes of the present study, it was important to compare the performances of the two space-maintaining devices on teeth with similar qualities. In practice however, damaged tooth surfaces are not considered a limiting factor for the placement of either FRCSMs or BLSMs. Twenty-three (39%) of the screened patients were excluded because their parents declined participation in the study due to the fact that a monthly, follow-up visit was required for a period of six months. Patient screening commenced on 1 December 2015, and took 16 months to accumulate 21 suitable study participants and acquire written informed consent from all respective parents/ guardians.

One participant (allocated to the FRCSM group) failed to return for the placement of their space maintainer. Because the space maintainer was never placed, this participant was excluded from the study. This resulted in a total of 10 participants per group as originally planned.

3.2.1 Sample size

Following consultation with a statistician, it was decided that no formal sample size estimation was necessary for the present study. This was an exploratory study comparing the failure rates of FRCSMs with those of BLSMs. It was anticipated that the

number of patients who would fit the strict inclusion criteria and be available for recruitment would be very limited. Thus, a nominal sample size of 20 (i.e. 10 patients per group) was decided upon.

Study participants were selected according to the inclusion and exclusion criteria specified below.

3.2.2 Inclusion criteria

To be selected for the present study, patients needed to present with the following attributes:

- Premature loss of a deciduous first molar (>1year before the expected exfoliation time);
- Anchor teeth with intact, undamaged, buccal and lingual bonding surfaces;
- Anchor teeth with more than half of the root length present.[1,4,9]

3.2.3 Exclusion criteria

Patients were deemed unsuitable for the present study if they presented with any of the following attributes:

- Teeth with compromised structure (i.e. demineralised enamel, caries, fractures, iatrogenic damage or existing restorations) in the intended bonding area;
- An abnormal dental condition (i.e. cross bite, an open bite, or a deep bite)[1,4 9];
- The inability to return for monthly follow-up appointments.

3.3. Ethical considerations

The Research Committee of the School of Dentistry at the University of Pretoria approved this study, as did the University's Ethics Committee. The project was duly registered with the number 523/2015 (see Appendix A).

Patients participating in this study had, of their own volition, reported for dental treatment at the Oral and Dental Hospital of Pretoria. They had been screened by the Department of Patient Management and referred to various departments to receive comprehensive treatment. Thus, all necessary dental treatment had been attended to before space maintenance issues were addressed. Patients screened for this study were selected from the general and theatre waiting list. No children on the list were given preferential treatment for the purpose of this study.

3.3.1 Consent and assent

Written (informed) consent was obtained from the parent/ legal guardian of each child who participated in the study (see Appendix B). In each case, a cover letter was attached to the consent form. This letter included a basic introduction, the contact details of the researcher, and an explanation of the following:

- The theory behind space maintenance;
- The nature and purpose of this study;
- The procedures to be followed;
- The risk and discomfort involved;
- The possible benefits of this study;
- The rights of the participant;
- Ethical approval;

- Information and contact details with respect to the researcher;
- The fact that there would be no compensation for participation in the study and
- Confidentiality.

In addition to parental consent, participants over the age of 7 gave their own informed assent (see Appendix C). The assent form provided information about the study in child-friendly language, and included pictures to explain the various procedures.

Parents/ legal guardians also gave written (informed) consent for clinical photos to be taken during the study for research and publication purposes (see Appendix D).

All parents/ legal guardians and children were given the option to refuse space maintenance treatment. Only patients and parents who gave informed written consent were included in this study. Furthermore, if a parent/ legal guardian or a patient requested removal of the device prematurely, their motivation for this decision was recorded, their request was granted, and that case was eliminated from the study.

3.4. Clinical procedures

The researcher selected all participants, placed all space maintainers, and performed all follow-up procedures personally. The placement techniques employed in this study are detailed in sections 3.4.1 and 3.4.2.

3.4.1 Placement of the FRCSM

The FRCSM design tested in this study differs from those tested in the clinical studies discussed in the literature review. In this study, to eliminate restrictions to normal physiological tooth movements and jaw growth, the teeth adjacent to the edentulous area were purposefully not bonded to one another.

The FRCSMs placed for the present study were manufactured using everStick Crown and Bridge fibre (everStick C&B, Stick Tech Ltd., Turku, Finland) which comprises glass fibres in a Bis-GMA/ PMMA (polymethylmetacrylate) matrix. Figure 3.1 illustrates the structure of an everStick glass fibre adapted from Stick Tech.[79] The fibres are pre-impregnated with light curing monomers which cross-link during the polymerisation of the overlying composite, forming a multiphase interpenetrating polymer network. This unique network facilitates the strong bonding of the fibres with composites, adhesives and composite resins.

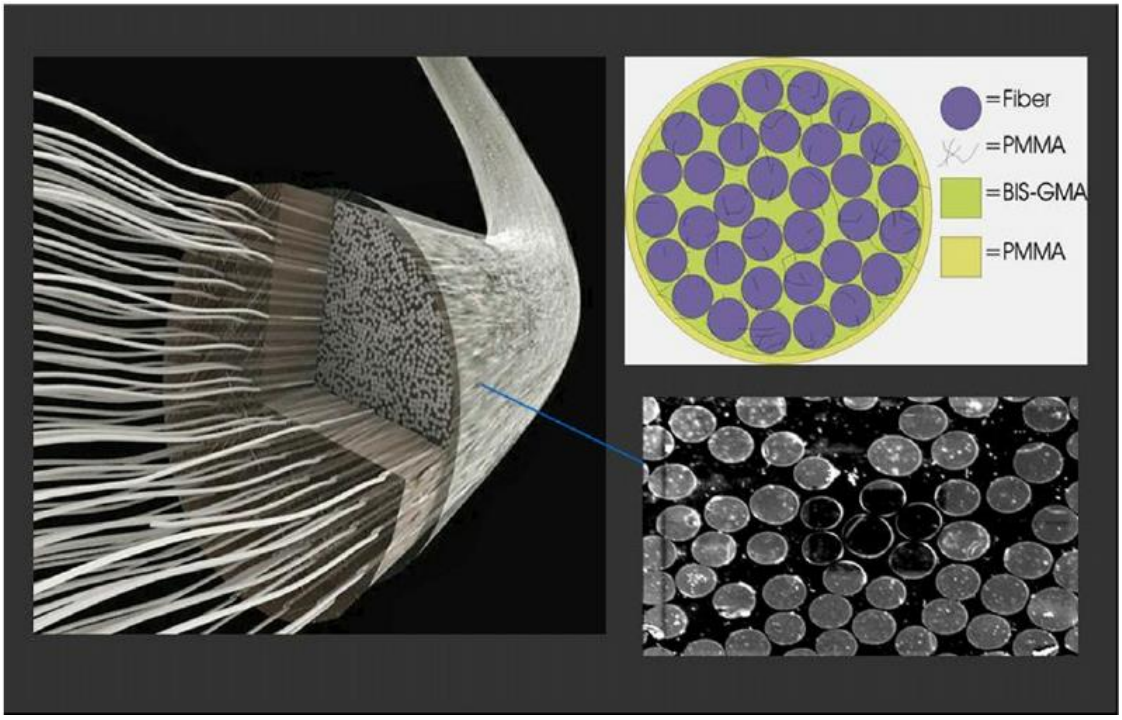

Figure 3.1: Schematic structure of reinforced glass fibre composite and SEM image of glass fibres (www.sticktech.com[80])

The FRCSMs were placed according to the following self-formulated, step-wise clinical procedure:

1. The anchor tooth, the saddle/ extraction area and the tooth anterior to the saddle/ extraction area were isolated with rubber dam;
2. The anchor tooth was prepared by cleaning the surfaces intended for bonding using pumice, water and a rubber polishing cup, to remove all plaque and surface accumulations;
3. The full mesio-distal widths of the buccal and lingual tooth surfaces were used for bonding. The surfaces were prepared by etching the enamel for 60 sec[55] with 34% phosphoric acid (Scotchbond universal etchant, 3M ESPE, St. Paul, USA). The everStick instruction manual[79] supports the literature reviewed in section 1.5 and recommends a 60 sec etch time to maximise bond strength;
4. The bonding agent (Adper Scotchbond 1XT adhesive, 3M ESPE, St. Paul, USA) was applied and light cured according to the manufacturer's instructions. For all light curing, the curing tip was kept within 1 mm of the tooth;
5. The uni-directional glass fibre bundle was placed in a continuous loop extending from the buccal to the lingual surface of the anchor tooth. The full buccal and lingual dimensions of the anchor tooth were used, and the fibre bundle was placed in the middle of the occluso-gingival dimension;
6. The glass-fibre bundle (everStick C&B, Stick Tech Ltd., Turku, Finland) was secured in position with a flowable composite (Filtek Supreme XTE Flowable, 3M ESPE, St. Paul, USA) and light cured on both the buccal and lingual surfaces for an initial 10 sec period. Close contact between the fibre bundle and the enamel was ensured by applying pressure to the bundle with a customised silicone refix forming aid. (everStick C&B, Stick Tech Ltd., Turku, Finland) (see Figure3.2);

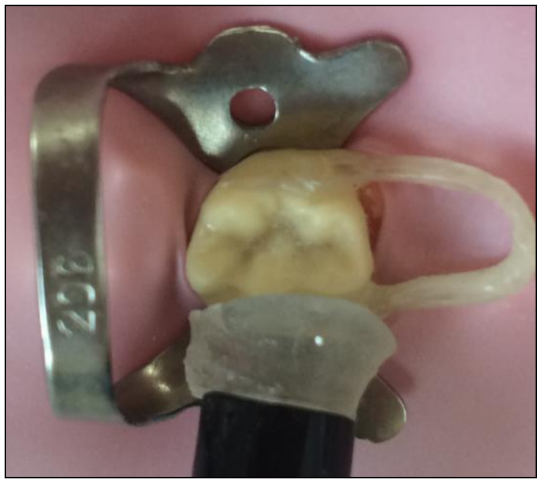

Figure 3.2: Pressure applied with the customised silicone refix forming aid during light curing

7. The loop was manipulated by shaping. Once in its ideal form, the fibre was wetted with unfilled adhesive resin[10] (Adper Scotchbond 1XT adhesive, 3M ESPE, St Paul, USA) using a bond applicator brush;
8. The entire loop was cured for 40 sec within 1 mm of the loop, at the positions indicated by stars (☆) on Figure 3.3, to cure the whole loop;
9. A matrix band was used to separate the deciduous canine from the composite. By using an instrument to apply pressure to the fibre (towards the matrix band) during light curing, a tight contact was created (see Figure 3.3);

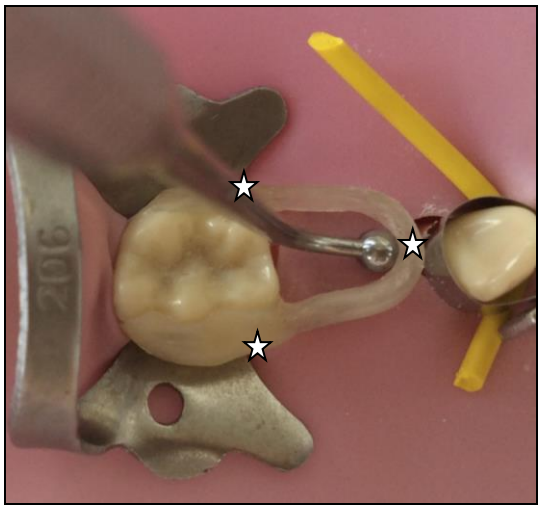

Figure 3.3: Applying pressure to the fibre to create a tight contact between the fibre and the tooth without bonding them together

10. Flowable composite (Filtek Supreme XTE Flowable, 3M ESPE, St. Paul, USA) was applied to cover the whole loop, and light cured for 40 sec;
11. An ELiTEDENT® Q-4 LED curing light was used to cure all of the samples. It was regularly tested with a Bluephase® meter which registered a consistent output of 1000–1100 mW/ cm^2;
12. The FRCSM was finished and polished using a yellow stripe, flame-shaped diamond finishing bur (DENTSPLY/ Maillefer, Ballaigues, Switzerland; ISO 806 314 249 504 012) and the Enhance polishing system (DENTSPLY, Milford, USA) (see Figure3.4 for a finished FRCSM);
13. If, at a follow-up appointment, a FRCSM had failed (see section 5.3.4) but could be repaired, it was repaired according to the bonding method described above.

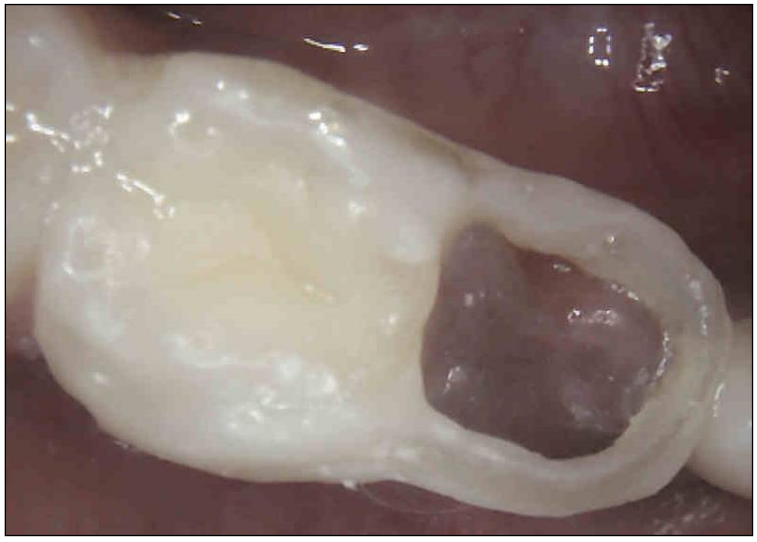

Figure 3.4: An example of a FRCSM immediately after placement

3.4.2 Placement of the BLSM

The BLSMs were placed according to the following step-wise clinical procedure[3]:

1. A prefabricated orthodontic band was selected for the abutment tooth by measuring the tooth's mesio-distal width with a calliper and selecting a band with the same internal diameter;
2. The band was fitted to the abutment tooth, and burnished against the grooves and contours of the tooth to ensure that it covered the tooth with a tight fit. The band could not easily be dislodged with a probe (see Figure 3.5);

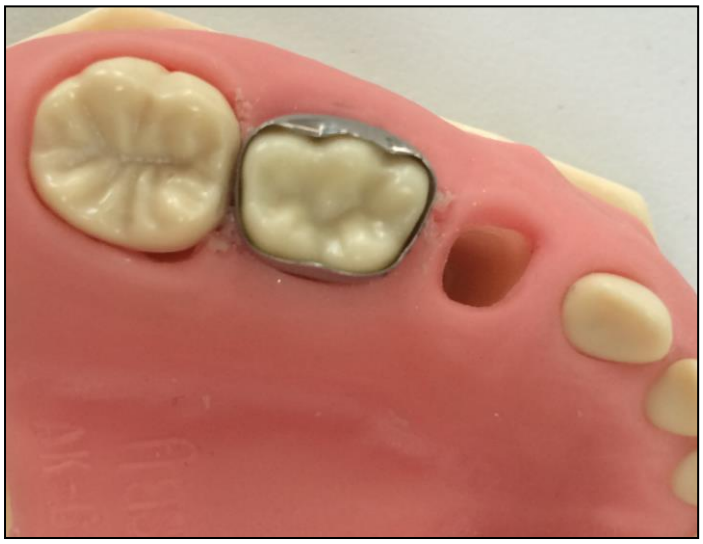

Figure 3.5: Fitted orthodontic band

3. An alginate impression was taken, after which the band was removed from the patient's mouth and stabilised in the impression. The impression was then sent to the dental laboratory for fabrication of the BLSM (see Figure 3.6);

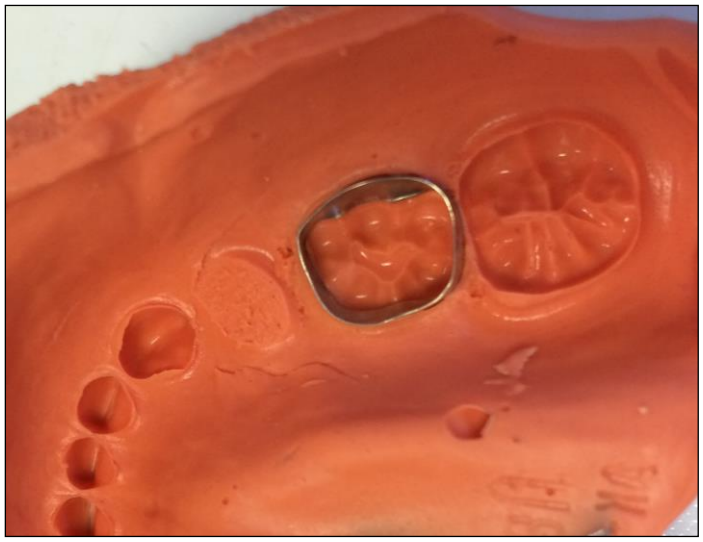

Figure 3.6: Alginate impression with orthodontic band in place

4. The BLSM was fabricated in a dental laboratory by a qualified dental technician, using 0.8mm wire;
5. At the next visit, the researcher fitted the BLSM, ensuring that it made tight contact with the tooth to which the loop extended;
6. The BLSM was cemented with a GIC (Fuji ORTHO, GC America, Illinois, America) according to the manufacturer's instructions (see Figure 3.7).

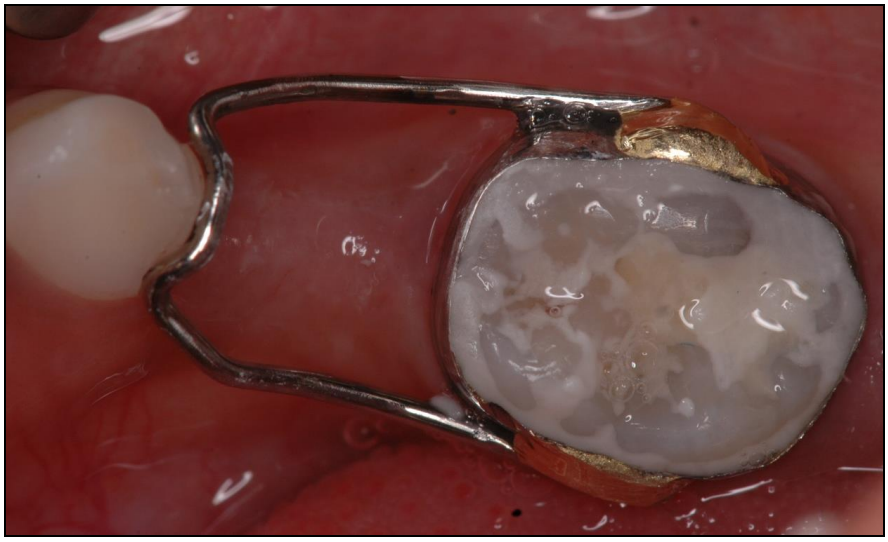

Figure 3.7: An example of a BLSM immediately after cementation

3.4.3 Plaque Index

A Plaque index, based on the O'Leary plaque control record,[81] was assessed for both types of space maintainers before placement and at each follow-up visit. At the initial control appointment, plaque-disclosing solution was painted on all exposed tooth surfaces before the device was placed.[81] After rinsing, a probe was used to examine the stained surfaces. The locations of the discoloured soft accumulations at the dento-gingival junction were recorded on the follow-up form.[81] Four surfaces on the abutment tooth and four surfaces on the tooth adjacent to the saddle area were evaluated, and a score out of eight was awarded (this was then converted to a percentage). This procedure was repeated at each follow-up appointment.

3.5. Follow-up and evaluation of space maintainers

Six follow-up appointments were scheduled for each participant over a period of 6 months. However, parents/ legal guardians and patients were instructed to report immediately for an emergency appointment if any problem/ failure occurred between scheduled appointments. This ensured that the timing of (and reasons for) device failures were accurately recorded.

At each follow-up appointment, the following took place:

1. The entire mouth was screened, with specific attention being paid to the anchor teeth and the space maintainers;
2. Plaque indices were recorded for the abutment and adjacent teeth, as explained in section 3.4.3;
3. Where a space maintainer had failed, this failure was recorded according to the failure criteria stipulated in section 3.5.1;

4. In addition to standard documentation on the patient's clinical file, a document entitled *"*Follow-up appointments*"* (Appendix E) was used to systematically record all follow-up and emergency appointments for each patient (see Appendix F for an example of a completed follow-up form);
5. Where a space maintainer had failed, the patient and their parent/ legal guardian were given a choice between repairing/ replacing the space maintainer or discontinuing with space maintenance treatment. Where they elected to continue, the case was recorded as a "fail" for the purposes of the study, and treatment was resumed.

According to other studies in the literature that were conducted over a six month period,[2,9] the mean survival rate of the FRCSM was approximately five months.[4,48] The FRCSMs which were retained for the full six month duration of the present study will be followed-up further at six monthly intervals. Long-term survival rates may be reported on in the future.

It is important that patients with space maintainers be monitored for complications arising from the device or from poor oral hygiene, and for the eventual eruption of the permanent tooth into the space.[14] At the end of this study, parents were asked to report for yearly check-up visits and to have their child's space maintainer removed as soon as the relevant permanent tooth erupted.

3.5.1 Failure criteria for a space maintainer

During the present study, as in previous comparative clinical studies,[1,9] a space maintainer was classified as having failed when it presented with any of the following attributes:

- Debonding at the fibre-composite or the band-cement interface;
- Debonding at the enamel-composite or the cement-enamel interface;
- Fracture of the fibre/ metal frame or
- Bending of the fibre/ metal loop to the extent that the device encroached on the soft tissue.

3.5.2 Data capturing

A case number, the date of device placement, and various relevant demographic details were recorded for each participant. Each device failure was recorded both in the relevant patient's personal clinical file and on a record document specifically designed for the purposes of the present study (see Appendix A). To ensure maximum accuracy, the "survival period" of each device was recorded in days. Thus, all space maintainers that maintained integrity for the full six month duration of the study were recorded as having "survived" for 180 days.

Results were collated by the researcher and verified by the supervisors of this study before being submitted to a statistician for analysis.

3.5.3 Statistical analyses

The present study was primarily concerned with comparing FRCSMs with BLSMs in terms of their longevity and the reasons for their failure where this occurred. It also represents an exploratory comparison between various aspects of these two methods of space maintenance. Furthermore, the study signifies a vital first step towards deciding whether FRCSMs should be advocated for regular clinical use.

Frequency tables were used to report on the monthly device failures for each group, the cases where failed devices were repaired, and the ages of the patients whose devices had failed. Contingency tables were then drawn to highlight distributions of space maintainers according to age and reasons for failure.

Statistical differences between the failure rates for different groups and subgroups were analysed using mean and median values. All statistical analyses for the purposes of this study were performed using SAS software, release 9.4 (SAS Institute Inc., Carey, NC, USA).

The two-sample t-test utilising mean values was used to determine whether apparent differences between the means for two groups were significant or random. The non-parametric Wilcoxon rank sum test was used to compare paired groups, essentially quantifying the differences between these groups and analysing these differences using median values. The purpose of the second test was to test the null hypothesis, which was that the two populations (i.e. BLSM patients and FRCSM patients) would exhibit the same continuous distributions.

Both statistical tests were used to evaluate device failure rates (calculated in days) between the following groups: BLSM patients and FRCSM patients; patients who had prematurely lost a tooth from the mandible and those who had prematurely lost a tooth from the maxilla; patients whose premature tooth loss had occurred on the right hand side of the mouth and those whose premature tooth loss had occurred on the left; males and females; and plaque index for FRCSM and BLSM placement.

Chapter 4: Results

Data were statistically analysed with the significance level set at $P<0.05$.

4.1. Failures and repairability of failed devices

During the six month follow-up period, five out of ten (50%) of both types of space maintainers failed. Table 4.1 reports the failure frequencies both monthly and cumulatively.

Table 4.1: Monthly and cumulative device failure frequencies

FAILURES	FRCSM	BLSM
Month 1		
Failure frequency	0	1
Percentage of total	0	10%
Cumulative frequency	0	1
Cumulative percentage	0	10%
Month 2		
Failure frequency	1	0
Percentage of total	10%	0
Cumulative frequency	1	1
Cumulative percentage	10%	10%
Month 3		
Failure frequency	1	1
Percentage of total	10%	10%
Cumulative frequency	2	2
Cumulative percentage	20%	20%
Month 4		
Failure frequency	1	0
Percentage of total	10%	0
Cumulative frequency	3	2
Cumulative percentage	30%	20%
Month 5		
Failure frequency	2	2
Percentage of total	20%	20%
Cumulative frequency	5	4
Cumulative percentage	50%	40%
Month 6		
Failure frequency	0	1
Percentage of total	0%	0
Cumulative frequency	5	5
Cumulative percentage	50%	50%

Table 4.2 reports the frequencies, both monthly and cumulatively, of repaired devices.

Table 4.2: Monthly and cumulative device repair frequencies

REPAIRS	FRCSM	BLSM
Month 1		
Repair frequency	0	0
Percentage	0%	0%
Cumulative frequency	0	0
Cumulative percentage	0%	0%
Month 2		
Repair frequency	1	0
Percentage	10%	0%
Cumulative frequency	1	0
Cumulative percentage	10%	0%
Month 3		
Repair frequency	1	0
Percentage	10%	0%
Cumulative frequency	2	0
Cumulative percentage	20%	0%
Month 4		
Repair frequency	0	0
Percentage	0%	0%
Cumulative frequency	2	0
Cumulative percentage	20%	0%
Month 5		
Repair frequency	1	0
Percentage	10%	0%
Cumulative frequency	3	0
Cumulative percentage	30%	0%
Month 6		
Repair frequency	0	0
Percentage	0%	0%
Cumulative frequency	3	0
Cumulative percentage	30%	0%

4.2. Reasons for device failures

The reasons for the various device failures recorded during this study, as well as the prevalence of these reasons, are summarised in Table 4.3.

Table 4.3: Reasons for recorded device failures

REASON FOR FAILURE	FRCSM n (%)	BLSM n (%)
FRCSM debonding at enamel-composite interface/ BLSM debonding at enamel-cement interface	2 (40%)	~
FRCSM debonding at composite-fibre interface/ BLSM debonding at cement-band interface	1 (20%)	~
Fracture of the fibre/ wire loop	2 (40%)	1 (20%)
Bending of the fibre/ wire and impingement on soft tissue	~	4 (80%)
Loss of contact with adjacent tooth	~	~
Total failures	**5 (100%)**	**5 (100%)**

4.3. Comparison of FRCSM and BLSM failure rates

Table 4.4 summarises the statistical comparison of failure rates for BLSMs and FRCSMs.

Table 4.4: Statistical comparison of BLSM and FRCSM failure rates

	FRCSM	BLSM	p-values
n	10	10	
Mean (+-SD)	145.6 (46.53)	150.7 (48.94)	0.525*
Median (IQR)	164.00 (136.0-180.0)	180 (146.0-180.0)	0.620**
Min/Max	44/180	35/180	

*Two-sample t-test
** Non-parametric Wilcoxon rank sum test

When comparing the failure rates of the two device types, the difference between the two means was 5.1, which is not statistically significant (p=0.525). The difference between the medians was 16, which is also not statistically significant (p=0.620).

4.4. Device failure versus device position

To evaluate whether device failure might be related to device position, the data for BLSM and FRCSM groups were combined. Table 4.5 summarises the monthly and cumulative device failure frequencies according to device position.

Table 4.5: Monthly and cumulative device failures according to device position

FAILURES	Mandible (n=12)	Maxilla(n=8)
Month 1		
Failure frequency	0	1
Percentage	0	12.5%
Cumulative frequency	0	1
Cumulative percentage	0	12.5%
Month 2		
Failure frequency	0	1
Percentage	0.0%	12.5%
Cumulative frequency	0	2
Cumulative percentage	0.0%	25.0%
Month 3		
Failure frequency	2	1
Percentage	16.7%	12.5%
Cumulative frequency	2	3
Cumulative percentage	16.7%	37.5%
Month 4		
Failure frequency	1	0
Percentage	8.3%	0
Cumulative frequency	3	3
Cumulative percentage	25%	37.5%
Month 5		
Failure frequency	3	1
Percentage	25%	12.5%
Cumulative frequency	6	4
Cumulative percentage	50%	50%
Month 6		
Failure frequency	0	0
Percentage	0%	0
Cumulative frequency	6	4
Cumulative percentage	50%	50%

By statistically comparing the failure rates of space maintainers placed in the mandible with those of space maintainers placed in the maxilla, it was found that the means for these two groups differed by 18.4, which was not statistically significant (p=0.402). However, the medians for the two groups differed by 15, which was not statistically significant (p=0.736). Table 4.6 provides a summary of this statistical analysis. As in the previous analysis, to ensure maximum accuracy, the "survival period" of each device was recorded in days. Thus, all space maintainers that maintained integrity for the full six month duration of the study were recorded as having "survived" for 180 days.

Table 4.6: Statistical comparison of device failures in the mandible and the maxilla

	Mandible	Maxilla	p-value
n	12	8	
Mean (+-SD)	155.5 (34.12)	137.1 (61.80)	0.402*
Median (IQR)	180.00 (137.0-180.0)	165.00 (96.0-180.0)	0.736**
Min/Max	90.0/180.0	35.0/180.0	

* Two sample t test

** Non-parametric Wilcoxon rank sum test

Probing the relationship between device position and device failure further, it was decided to test for a potential link between device failure and the side of the mouth that the space maintainer was placed. Of the 11 space maintainers placed on the right side of the mouth, 5 (i.e. 45%) failed. Of the nine space maintainers placed on the left side of the mouth, 5 (56%) failed. Table 4.7 summarises the monthly and cumulative device failure frequencies according to the side of the mouth where the devices were placed.

Table 4.7: Monthly and cumulative device failures according to side of the mouth

FAILURES	Right (n=11)	Left (n=9)
Month 1		
Failure frequency	1	0
Percentage	9%	0%
Cumulative frequency	1	0
Cumulative percentage	9%	0%
Month 2		
Failure frequency	1	0
Percentage	9.0%	0
Cumulative frequency	2	0
Cumulative percentage	18.0%	0%
Month 3		
Failure frequency	1	2
Percentage	9.0%	22%
Cumulative frequency	3	2
Cumulative percentage	27.0%	22%
Month 4		
Failure frequency	0	1
Percentage	0%	11%
Cumulative frequency	3	3
Cumulative percentage	27%	33%
Month 5		
Failure frequency	2	2
Percentage	18%	22%
Cumulative frequency	5	5
Cumulative percentage	45%	56%
Month 6		
Failure frequency	0	0
Percentage	0%	0
Cumulative frequency	5	5
Cumulative percentage	45%	56%

By comparing failure rates of space maintainers placed on the right and left sides of the mouth respectively, the difference between the two means was 5.38, which is not statistically significant (p=0.805). The difference between the medians for the two groups was 0, which is also not statistically significant (p=0.901).

Table 4.8 summarises the statistical comparison of space maintainer failure rates for the left and right sides of the mouth, respectively.

Table 4.8: Statistical comparison of device failures on the right and left sides of the mouth

	Right	Left	p-value
n	11	9	
Mean (+-SD)	145.73 (54.48)	151.11 (37.66)	0.805*
Median (IQR)	180.00 (146.0-180.0)	180.00 (136.0-180.0)	0.901**
Min/Max	35/180	90/180	

* Two sample t test
** Non-parametric Wilcoxon rank sum test

4.5. Device failures versus patient demographics

Of the 20 participants in this study, 11 were male and 9 were female. The ages of the participants are summarised in Table 4.9.

Table 4.9: Participant ages per group

AGE	FRCSM	BLSM	TOTAL (20)
4 years	1	1	2
5 years	4	2	6
6 years	1	3	4
7 years	3	1	4
8 years	0	3	3
9 years	1	0	1

It was observed that space maintainers placed for male patients failed sooner (139.36 days) than those placed for female patients (158.89 days). The two-sample t-test showed this to not be statistically significant (p = 0.37). The results of this analysis are summarised in Table 4.10.

Table 4.10: Comparison of device failure rates for male and female patients

	Male	Female	p-value
n	11	9	
Mean (+-SD)	139.36 (56.90)	158.89 (29.38)	0.365*
Median (IQR)	180.00 (90.0-180.0)	180.0 (148.0-180.0)	0.589**
Min/Max	35/180	96/180	

* Two sample t test

** Non-parametric Wilcoxon rank sum test

The limited sample size did not allow for a valid investigation of potential links between device failure rate and patient age group (see Table 4.11). Both parametric (ANOVA) (p=0.239) and non-parametric analyses (Kruskal-Wallis) (p=0.141) showed no statistically significant difference between the age groups.

Table 4.11: Statistical comparison of device failure rates for different age groups

	SM
4 Years	
n	2
Mean (+-SD)	158 (31.11)
Median (IQR)	158 (136-180)
Min/Max	136/180
5 Years	
n	6
Mean (+-SD)	152 (54.44)
Median (IQR)	180 (148-180)
Min/Max	44/180
6 Years	
n	4
Mean (+-SD)	180 (0)
Median (IQR)	180 (180)
Min/Max	180/180
7 Years	
n	4
Mean (+-SD)	138.5 (37.11)
Median (IQR)	142 (114-163)
Min/Max	90/180
8 Years	
n	3
Mean (+-SD)	93.67 (57.54)
Median (IQR)	96 (35-150)
Min/Max	35/150
9 Years	
n	1
Mean (+-SD)	180 (0)
Median (IQR)	180 (180)
Min/Max	180/180

4.6 Relationship between device type and plaque index (PI)

Statistically there was no significant difference in the degree of plaque accumulation between the BLSM and FRCSM patients (see Table 4.12).

Table 4.12: Statistical comparison of plaque indices for BLSM and FRCSM patients over six months

	FRCSM	BLSM	p-value
Month 1			
n	10	10	
Mean (+-SD)	62.50 (17.68)	57.50 (18.82)	0.548*
Median (IQR)	56.25 (50.0-75.0)	56.25 (50.0-75.0)	0.613**
Min/Max	37.5/87.5	25.0/87.5	
Month 2			
n	10	9	
Mean (+-SD)	58.75 (15.65)	48.61 (13.18)	0.147*
Median (IQR)	50.00 (50.0-75.0)	50.00 (37.5-62.5)	0.232**
Min/Max	37.5/87.5	25.0/62.5	
Month 3			
n	9	9	
Mean (+-SD)	47.22	40.28 (16.27)	0.254*
Median (IQR)	5.51 (50.0-50.0)	37.50 (25.0-50.0)	0.318**
Min/Max	37.5/50.0	25.0/62.5	
Month 4			
n	8	7	
Mean (+-SD)	40.63 (8.84)	41.07 (9.45)	0.926*
Median (IQR)	37.50 (37.5-50)	37.50 (37.5-50.0)	0.899**
Min/Max	25.0/50.0	25.0/50.0	
Month 5			
n	7	7	
Mean (+-SD)	23.21 (8.63)	30.36 (6.68)	0.109*
Median (IQR)	25.00 (12.5-25.0)	25.00 (25.0-37.5)	0.114**
Min/Max	12.5/37.5	25.0/37.5	
Month 6			
n	5	5	
Mean (+-SD)	27.50 (13.69)	25.00 (8.84)	0.740*
Median (IQR)	25.00 (25.0-25.0)	25.00 (25.0-25.0)	0.906**
Min/Max	12.5/50	12.5/37.5	

* Two sample t test

** Non-parametric Wilcoxon rank sum test

Clinically, it was observed that most patients' plaque indices increased after the placement of their space maintainer, and then decreased over time (see Figure 4.1).

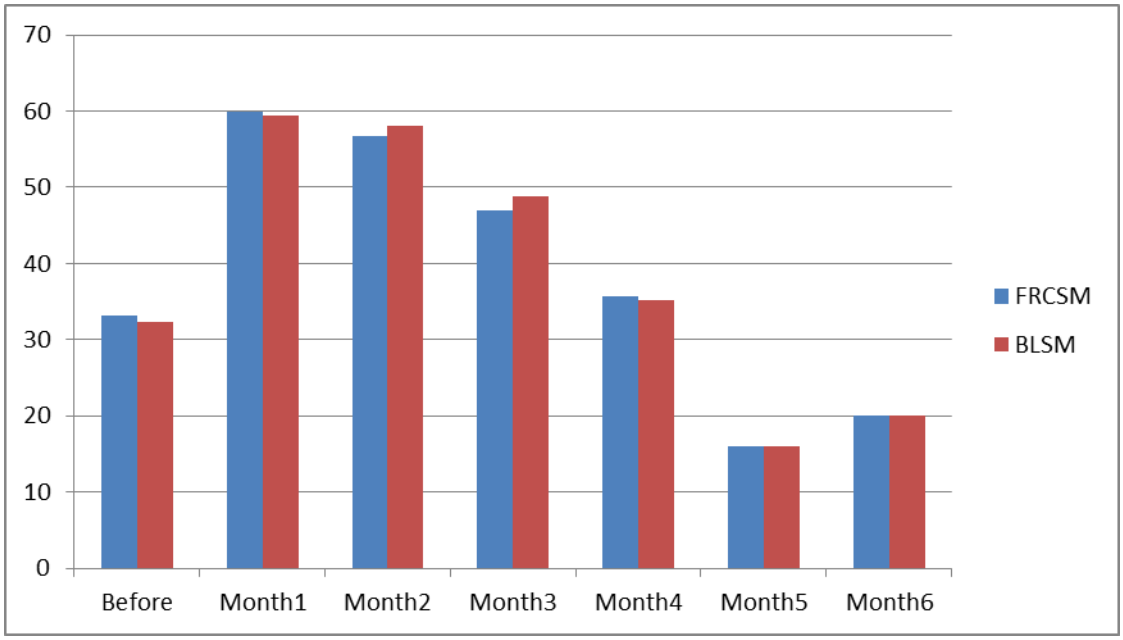

Figure 4.1: Average plaque indices for BLSM and FRCSM over the six month follow-up period

Chapter 5: Discussion

The similar failure rates and repairability of the FRCSM recorded in this study suggest that the loop-design FRCSM could be a viable alternative to the BLSM in the management of premature single tooth loss.

5.1. Participation

This study was based on a sample of 20 paediatric patients - 10 of whom were fitted with FRCSMs and 10 with BLSMs. The sample size may appear small, but it should be borne in mind that this study represents the first ever clinical trial of the loop-design FRCSM.

The small sample size can partly be attributed to the strict inclusion criteria established for the study. It was difficult to find patients who had lost a deciduous molar but had intact and unaffected buccal and lingual surfaces on the associated second deciduous molar. When one considers published studies based on larger sample sizes, one finds that their main inclusion criterion was just that participants had to present with premature single deciduous tooth loss,[1, 9] thus including patients who had lost either a first or a second deciduous molar. Some studies even included patients with both single and double edentulous spaces, thereby substantially enlarging the pool of potential participants.[2, 48]

The sample size for this study was further affected by ethical principles in that it was decided that no patients would be prioritised from the general or theatre waiting lists for

the benefit of this study. This meant that the researcher had to identify patients who met the inclusion criteria from the group of patients receiving comprehensive oral care.

A further factor which led to the relatively low sample size was the fact that the parents/ legal guardians of all participants had to agree to bring their children for monthly follow-up appointments for a six month period. This led a number of parents to decide against participation in the study, possibly due to associated travel costs and/ or leave implications for parents/ legal guardians and patients.

The drop-out rate recorded for the present study was 5% (i.e.1 child) who, before device placement, decided against participation in the study and did not return for the placement of the space maintainer. Two previous studies comparing the BLSM with the FRCSM over a six month period reported dropout rates of 30%[9] and 22%[1], respectively.

For the present study, the strategy employed to ensure patient attendance included scheduling appointments at times convenient for parents, and calling patients prior to all scheduled appointments to remind them to attend. They did also report promptly for assistance when devices failed.

5.2. Reasons for FRCSM failures

One of the main reasons (40%) for device failure in the FRCSM group was the breakdown of the enamel-composite interface as seen in Figure5.1. This supports the findings of previous studies, which is compelling, considering the present study's small sample size.[1,4,9] Subramaniam *et al.*[1] and Garg *et al.*[9] attributed 26.7% and 16.67% of FRSCM failures to this cause, respectively. The breakdown of this interface is attributed

to a relatively weak bond between composites and the aprismatic enamel of deciduous teeth.[1,9,50,55] Likewise, Kırzıoğlu et al.[4] attributed 32% of FRCSM failures to this cause. They reported that the enamel-composite interface broke down within just one month when fibres were placed without rubber dam. This emphasises the importance of moisture control during FRCSM placement to ensure good bond strength and increase the likelihood of ultimate device success.

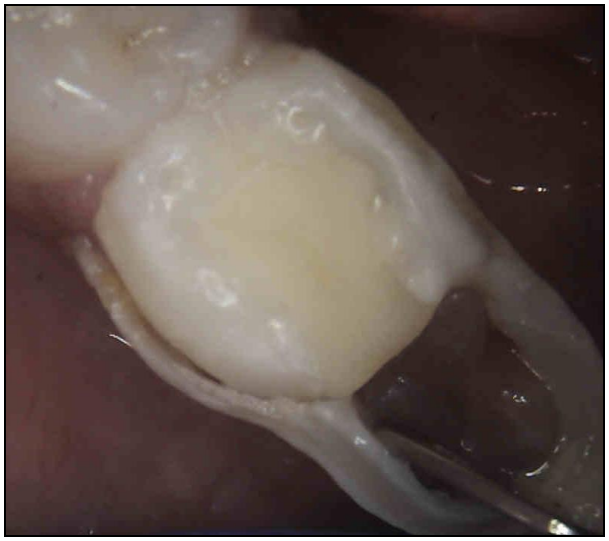

Figure 5.1: An example of enamel-composite interface failure on the functional cusp side

A second prevalent reason (20%) for device failure reported in FRCSM group was debonding at the fibre-composite interface. Previous authors have also cited this as a significant cause of FRCSM failure, attributing 4.2%[1] and 13.3%[9] of all recorded FRCSM failures to this cause, respectively. Debonding at the fibre-composite interface may be due to the strain placed on the fibre-composite bond during finishing, placement of the fibre in the bite, and/ or the wearing of the composite layer by the forces of mastication.[1,4,9] As FRCSM-related techniques are not yet standardised, differences in bonding agents, placement techniques, types of composite used and operator skill makes it difficult to compare these results and may contribute to the varied results reported in the literature.[1,2,9,48]

It is important to note that although three of the FRCSMs placed in the present study failed due to a breakdown at either the enamel-composite or fibre-composite interfaces, all 3 of them were repairable chairside. Therefore, technically, these space maintainers remained clinically functional and did not need to be removed or refabricated.

A further prevalent reason (40%) for the failure of FRCSMs placed in the present study was fracturing of the fibre frame. Previous studies attributed 6.7%[9] and 16.7%[1] of FRCSM failures to this cause, respectively. Fibre frames are thought to fracture due to mechanical stresses arising from the chewing of hard/ sticky foods, and/ or due to the over-eruption of the tooth opposing the edentulous area, which subsequently increases and concentrates masticatory forces on the fibre.[1,9,12] In the present study, FRCSM frames tended to break on the functional cusp side, as illustrated in Figure 5.2. This finding supports the results reported by Baroni *et al.*[76] who concluded that the mechanical stresses that a FRCSM is subjected to are more crucial when it comes to its longevity and long-term success than its design. The effects of masticatory forces and the degree of clearance between the fibre and the opposing tooth, especially when the fibre is bonded to the functional side of an abutment tooth, should be taken into consideration during the placement of a FRCSM. Improving bond strength on the functional side of an abutment tooth would be advantageous. This could be accomplished by, for example, embedding fibre and composite into a prepared groove on the buccal/ lingual surfaces to enhance mechanical retention. This should be further explored in the future.

Interestingly, both the FRCSMs which fractured in the present study retained contact with their non-abutment teeth (see Figure 5.2 for an example). Thus, although they were

recorded as failures according to the failure criteria, clinically they still fulfilled their space-maintaining purpose for up to six months. The unlikely successes of these two "broken" fibres suggest that since full loops tend to fracture on the functional cusp side, consideration should be given to bonding a half loop (rather than a full one) to the non-functional side of the abutment tooth. The success of half a loop should however be explored further.

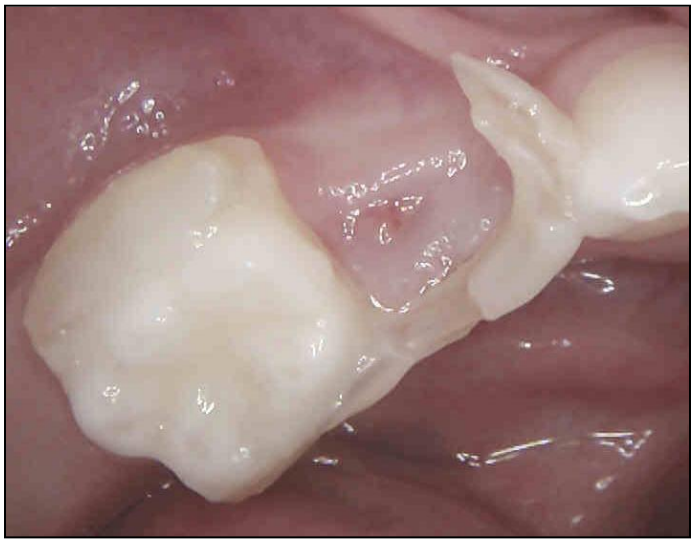

Figure 5.2: Fracture of the fibre frame on the functional cusp side of a 75

None of the FRCSM failures in the present study were attributed to impingement of the bent fibre loop on soft tissue. Fibre bending has never been reported as a reason for FRCSM failure. Furthermore, Subramaniam *et al.*[1] reported less trauma to the gingiva with FRCSMs compared with BLSMs. As the bending of fibres is limited under occlusal forces, they don't tend to impinge on or cause trauma to the underlying soft tissue.[1,4,48]

5.3. Reasons for BLSM failure

In the present study, 50% of the BLSMs failed during the six month study period. This is consistent with the results of a previous study which reported BLSM failure rates of 63.3%[9] over a six month period.

In previous studies, cement loss was found to be the main reason (46.7%[9] and 60%[1,5]) for BLSM failure. However, in the present study, only one band had failure of the cement. The reasons for these disparate outcomes may include differences in cement type, band fit, and moisture control measures. Cooperation and complete isolation during cementation remains a challenge with young patients.[9] However, none of the studies documented in the literature specify the use of rubber dam during cementation of a BLSM.[1,4,9]

More than 35 years ago, Croll[77] suggested using zinc phosphate or polycarboxylate cement to secure BLSM bands. However, GICs are now more widely applied.[5] Certain BLSM studies published in the literature do not indicate the type of cement used.[1] Thus, it is possible that in some of these studies, more moisture-sensitive cements or cements that are not indicated for orthodontic band cementation may have been used. Therefore the type of cement used may have contributed to their high decementation rates. The cement chosen for the present study was a GIC that is specifically indicated for the cementation of orthodontic devices.

Methods for band fit evaluation have not yet been standardised, nor is there agreement amongst practitioners regarding the amount of cement that should be used for band cementation. BLSM cement is subjected to a complex suite of stresses, both internal and at its interfaces with tooth enamel and the band interior.[82] It therefore seems

intuitive that the thickness of the cement between the tooth and the band could influence the band's vulnerability. Thus, the high number of cement loss failures reported in other studies[1,9] may have been significantly influenced by placement technique and operator skill.

In the present study, the main reason for BLSM failure (80%) was bending of the loop to impinge on soft tissue as illustrated in Figure 5.3.

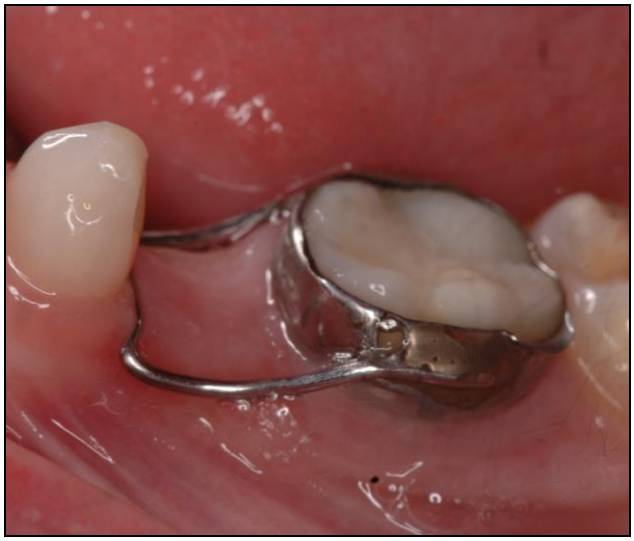

Figure 5.3: BLSM with bent wire impinging on soft tissue with signs of inflammation

Previous authors have attributed BLSM failure to distortion of the loop in 3.3%[9] and 9%[7] of cases, respectively. Intermittent functional loading on the space maintainer leads to high compressive stresses on the tooth next to the cantilever extension.[83] Bending of the loop with subsequent submergence of the wire in the gingiva have been attributed to a loss of contact between the loop and the non-attached abutment tooth.[77,84] Because previous studies focused on BLSMs placed on permanent teeth, these devices generally extended towards a first deciduous molar. Thus, the cantilever wires in those cases had a larger contact surface than those in the present study where all wires extended towards deciduous canines with smaller interproximal surface areas. It is also

important to bear in mind that the thickness of the wire used for BLSM construction were not specified in any of the previous studies comparing the BLSM with the FRCSM.[1,9]

For the present study, as in the study by Kara *et al*.,[3,84] all BLSM loops were constructed using round stainless steel wire with a diameter of 0.8 mm. The findings from the current study may indicate that this wire thickness is not inadequate for a BLSM without the support of an occlusal rest. Whilst recommended wire thickness is specified for active orthodontic devices, no specifications could be found for BLSM wire thickness and further research should be done to identify the most suitable wire thickness for these devices.

Sasa *et al.*[7] suggest that the tendency of paediatric patients to play or fiddle with their devices could contribute to the distortion of BLSM wires. During the present study, one child admitted to playing with the wire because it “felt funny” in his mouth (Figure 5.4).

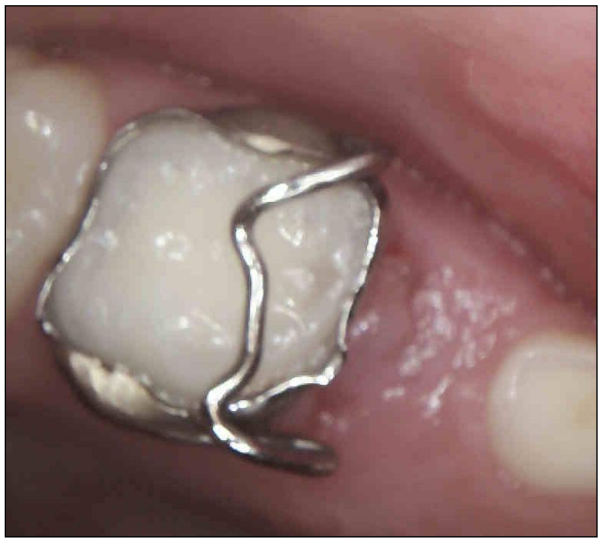

Figure 5.4: BLSM on a 55 with the loop bent towards the anchor tooth

Previous authors[7,9] did not specifically record the bending of a BLSM wire as an explicit reason for device failure. However, in those studies, wire bending may have been included in the category of soft tissue lesion formation, or may have constituted an "unspecified reason" for BLSM failure. The reasons provided and discussed above, may explain why bending of the wire has not been recorded as a main reason for failure in previous studies.[1,7,9]

In the present study, one BLSM failure (i.e. 20% of all BLSM failures) was attributed to a loop fracture (Figure 5.5). Previous studies on BLSMs over a six month period attributed 6.7%[1,9] and 9%[7] of failures to loop fracture, respectively. Another study with a 40 month follow-up period reported a higher incidence of loop fracture (22.2%[85]), suggesting that the likelihood that fracture may increase with time. Metal loop fracture is commonly attributed to poor device construction. Significant construction factors include incomplete soldering of joints, overheating of the wire, over-thinning of the joint, or thinning of the wire during polishing. [5,9,76,85]

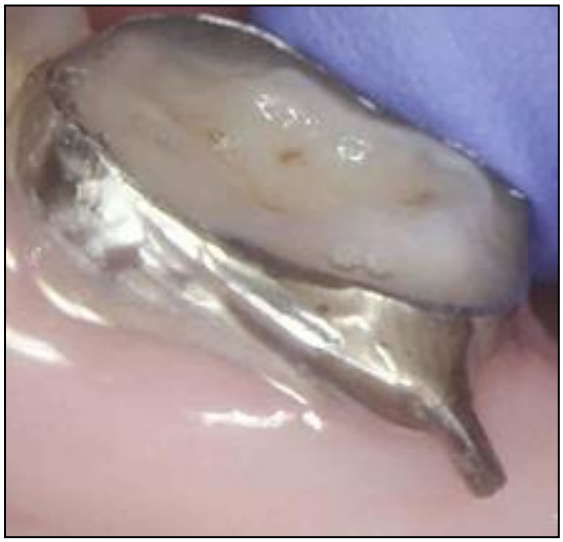

Figure 5.5: BLSM on a 75 with a fractured loop

Other reasons for BLSM failure cited in the literature include slippage of the band gingivally,[9] split bands, and reasons not specified.[5] None of these were noted during the present study. It is important to note that none of the failed BLSM devices in the present study could be repaired chairside.

5.4. Comparing FRCSM and BLSM failure rates

After six months, the overall failure rates (based strictly on the specified failure criteria) for the two types of devices tested were identical, at 50% each. Previous comparative clinical studies reported overall failure rates of 63.3%[9] and 56.7%[1] for the BLSM, and of 36.7%[9] and 33.3%[1] for the FRCSM over six months.

Kargul *et al.*[48] highlighted the influence of operator experience and patient selection on the degree of success of fixed space maintainers. In the present study, all space maintainers were placed by a single operator, i.e. the researcher, which eliminated the risk of operator-linked inconsistencies. Other relevant published studies do not indicate whether all of the space maintainers were placed by a single operator or not.[1,9]

Where the results of the present study differ from those of previous studies, this may be due to the influence of different techniques/ designs and different materials employed in the various studies. In an *in-vitro* study, Kulkarni *et al.*[3] compared the physical strengths of the Ribbond (glass) FRCSM, the Sticktech (polyethylene) FRCSM, and the conventional BLSM by subjecting them to the cantilever beam test. It was found that Ribbond samples sustained cracking where Sticktech ones did not, and it was concluded that the Ribbond FRCSM was comparable to the BLSM in terms of strength, whilst the Sticktech FRCSM was not. Thus, it seems that the type of fibre selected may

play a significant role in determining the success of a FRCSM. This needs to be investigated further. The results published by Kulkarni *et al.*[3] along with data gathered in the present study seem to suggest that glass fibres may be preferable to polyethylene fibres for the purposes of FRCSM construction. This needs to be researched further.

When comparing device failure rates, it is also important to consider the reparability of the different device types. Thirty percent of the failed FRCSMs in the present study were repairable chairside. None of the failed BLSMs were repairable and therefore had to be removed and refabricated by the dental laboratory. It is also important to note that the fractured FRCSMs were still making contact with the non-abutment tooth (see section 5.2). Thus, of the five failed FRCSMs, three could be repaired chairside and two were still clinically effective. On the other hand, all five failed BLSMs had to be completely refabricated. This means that, overall, the FRCSM performed much better from a clinical perspective.

5.5. Patient demographics and position of placement

The age of paediatric patients has been identified as an important factor in the degree of success of their space maintainers.[86] Younger patients are often less cooperative and tend to prefer a sticky-food diet. The unique anatomy of their deciduous molars makes it challenging to achieve proper band fit.[7,72,86] However, the relatively wide age range represented in the small sample for the present study made it impossible for significant links to be identified between patient age and device longevity.

Statistically, the present study did not reveal a relationship between device failure and device placement position. However, clinically, it is interesting to note that more failures

occurred in devices on the left side of the mouth (56%) than those on the right (45%). This observation contradicts the findings of previous studies, but that may well be due to the small sample size for the present study and the fact that the number of patients with devices installed on the left and on the right were not equal. Sasa *et al.*[7] reported a higher failure rate for BLSMs placed in the right of the mouth than those placed in the left, and conjectured that the right-handedness of the operator along with patients' tendency to chew on the right side of the mouth may have contributed to this finding.[7] Likewise, and although the reasons for these findings remain relatively obscure, other authors have also reported a higher failure rate for devices on the right side of the mouth than on the left.[1,4,6]

In the current study, equal device failures occurred in the maxilla and in the mandible (50% of failures in each). The median survival time for space maintainers placed in the maxilla (165 days) was slightly lower than for those placed in the mandible (180 days), but this difference was not statistically significant. Both Kargul *et al.*[48] and Sasa *et al.*[7] reported longer survival times for devices placed in the maxilla than for those placed in the mandible. Artun *et al*.[50] supported this finding and reasoned that occlusal trauma is more prevalent in the mandible than in the maxilla.

Although no scientific reason has yet been identified for the relationship between device success/ failure and device position, the findings from the present study concur with those from previous studies and highlight that operators should be especially careful and aware when fitting and placing space maintainers on the right side of the mouth, especially in the maxilla.

5.6. Plaque Index

No statistical difference was found between the plaque indices for the BLSM and the FRCSM. However, clinically, it was observed that most patients' plaque indices increased after the placement of their space maintainer, and then decreased over time (see Figure 4.1).

This trend may be linked to the fact that oral hygiene instructions were reinforced at every follow-up appointment. Occlusion and mastication, which lead to a polishing of the devices by normal abrasive function, may also have contributed to a decrease in PI over time. However, in the present study, no significant relationship between PI and device type emerged.

Recording the presence of plaque on individual tooth surfaces diagrammatically, using index forms, allows patients to visualise their own progress regarding plaque control. This seems to have a motivating effect on them.[81] Plaque accumulation was noted on the gingival thirds, as well as on the BLSM cement (sees Figure 5.6). This may be attributed to the creation of an artificial ledge, at the junction between the tooth and the band, which is prone to plaque accumulation.[29] It is well known that rougher surface areas are more plaque retentive than smoother ones. Composite is much more easily polished than GIC, which may be one of the reasons why plaque is more prominent on the cement.

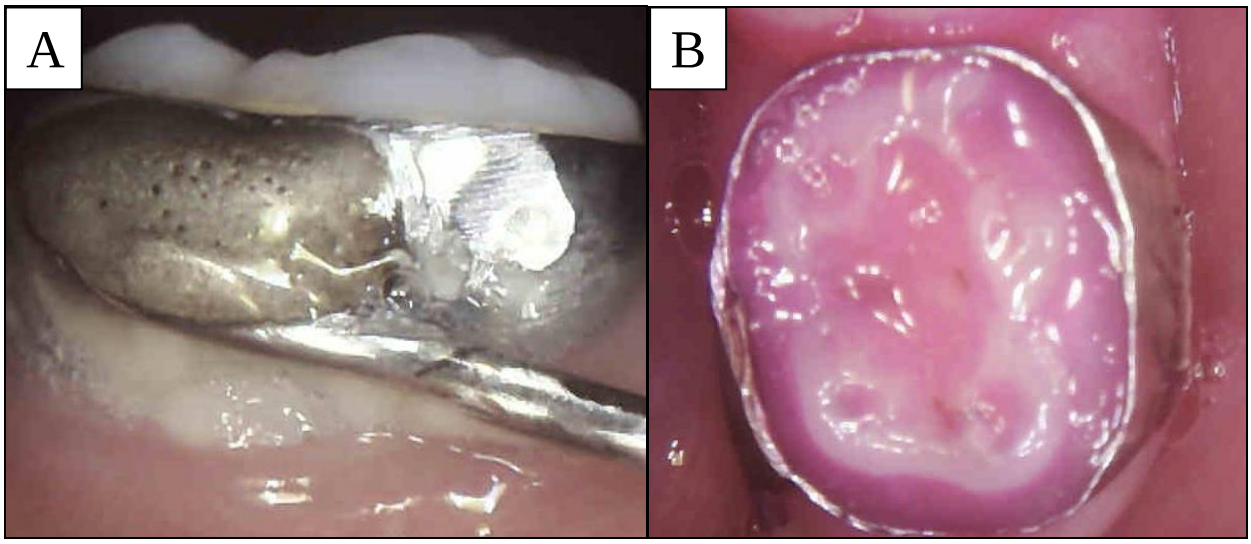

Figure 5.6: Plaque accumulation on **(A)** the gingival third of the band; **(B)** BLSM cement

For the FRCSM, it was noted that well-polished composite areas were not plaque retentive. However, in interproximal areas where polishing is challenging, plaque did indeed accumulate (Figure 5.7). This finding is in agreement with those of a previous study.[1]

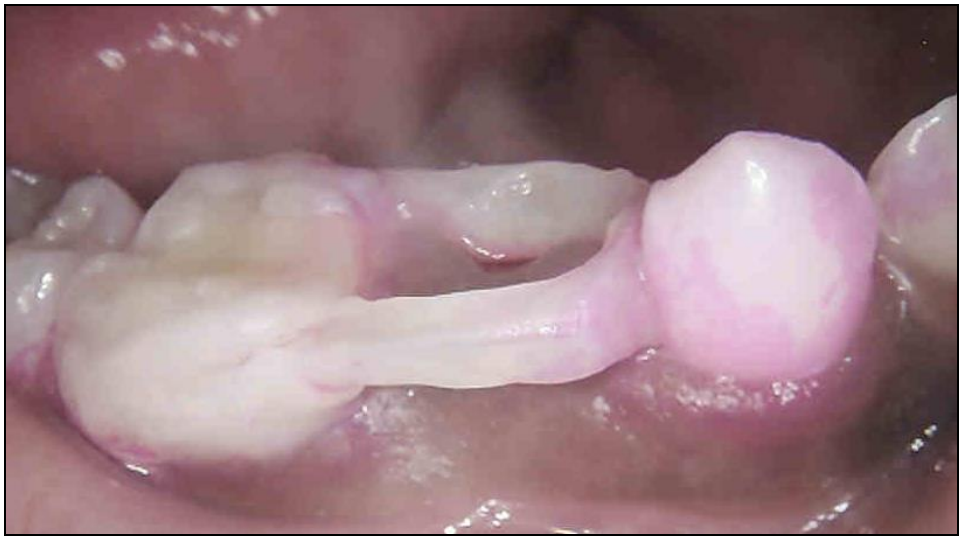

Figure 5.7: Limited plaque accumulation on well-polished areas of the FRCSM

Gingival areas on abutment teeth with fixed SMs exhibit a higher propensity for plaque accumulation.[4] However, as Kargul *et al*.[2] point out, the FRCSM does not make direct contact with adjacent periodontal tissues. This limits periodontal problems commonly associated with conventional, fixed SMs.

An *in-vitro* qualitative analysis comparing the bacterial colonisation of two types of FRCSM and a BLSM concluded that there was no significant difference in the *Streptococcus mutans* counts found on each of the various devices.[3] However, a higher bacterial count was found on Sticktech samples than on Ribbond samples. This may indicate that glass fibres are more prone to bacterial colonisation than polyethylene fibres, which is probably due to the higher surface roughness of the former.[3,87] Thus, polishing the surfaces of composites to limit plaque accumulation and bacterial colonisation is extremely important.

5.7. Coincidental findings

5.7.1. Parental and patient preference

During the study, it became evident that the FRCSM was more appealing to the patients' parents than the BLSM. The study was explained to parents with the aid of a model which provided examples of both the FRCSM and the BLSM. Parents were informed that FRCSMs and BLSMs would be allocated alternately as patients presented. Six of the parents immediately commented that they would prefer FRCSMs for their children due to the more pleasing aesthetics of these devices, and the fact that only one appointment would be required for placement. Four participants in the present study presented with two missing first deciduous molars. Each of these patients was

fitted with both a FRCSM and a BLSM (an example of such a case is shown in Figure 5.8).

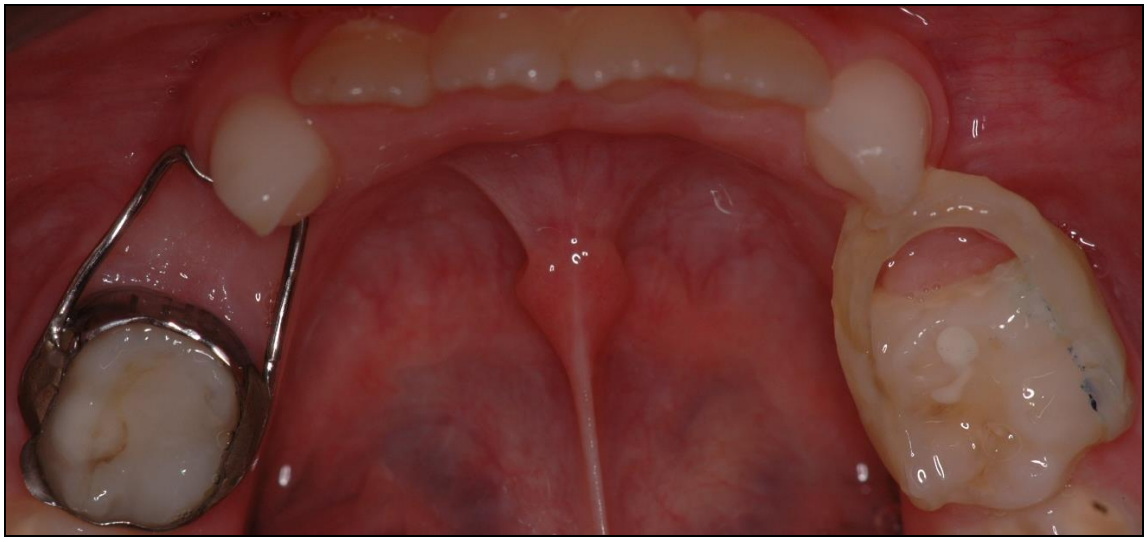

Figure 5.8: BLSM and FRCSM placed simultaneously for one patient

All four of the patients who received both types of space maintainers commented that they preferred the FRCSM. This may have been due to the FRCSM's superior aesthetics, and/ or the relative ease of its placement, and/ or its comfort in the mouth.[9,44,48,88] However, when patients were asked to elaborate on their preferences for the FRCSM rather than the BLSM, the main reason given was the discomfort experienced during BLSM band fitting and impression taking. This finding supports the results reported by Garg *et al.*,[9] who used the Wong-Baker Face Pain Rating Scale to identify patient preference during a split mouth study which compared the FRCSM with the BLSM. They found that the FRCSM was by far the preferred device.

As was the experience of other researchers,[9] impression taking for the BLSMs proved to be challenging with some children. One patient cried during an impression, whilst another could not tolerate the impression material in the maxilla due to a gag reflex. In

these cases, it was decided to fit a FRCSM instead. The FRCSM has the advantage, especially for paediatric patients, of being painless, and minimally invasive.

5.7.2. Placement in theatre directly after extraction

The longer the time period between the premature extraction/ loss of a tooth and the placement of a space maintainer, the higher the likelihood of space loss.[11] A FRCSM can be placed in theatre directly after an extraction procedure (using rubber dam to prevent excess moisture over the extraction site). Thus, space maintenance can be included as part of the comprehensive treatment plan, and can be performed while the patient is sedated or under general anaesthesia. This avoids the cost and inconvenience of a dental laboratory as well as the additional appointment associated with BLSM placement.

Indeed, in the present study, it proved convenient to place a FRCSM in theatre directly after an extraction. Follow-up visits indicated normal post-extraction healing of the extraction socket (see Figure 5.9).

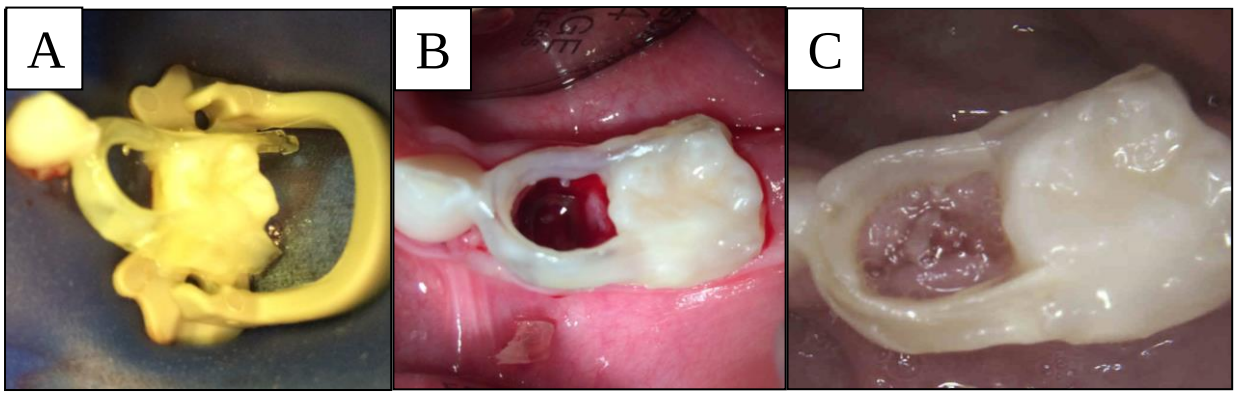

Figure 5.9: Placement in theatre: **(A)** rubber dam applied directly over an extraction site; **(B)** directly after placement; **(C)** one-week follow-up

5.7.3. Fibre manipulation

Placement of the FRCSM proved to be technique sensitive. Manipulation of the fibres to form a uniform loop was challenging, and not all of the FRCSMs placed had a perfect loop shape (as illustrated in Fig 5.10). However, this did not prove to affect the FRCSM failure rate as the non-uniform fibre loop was still intact after six months.

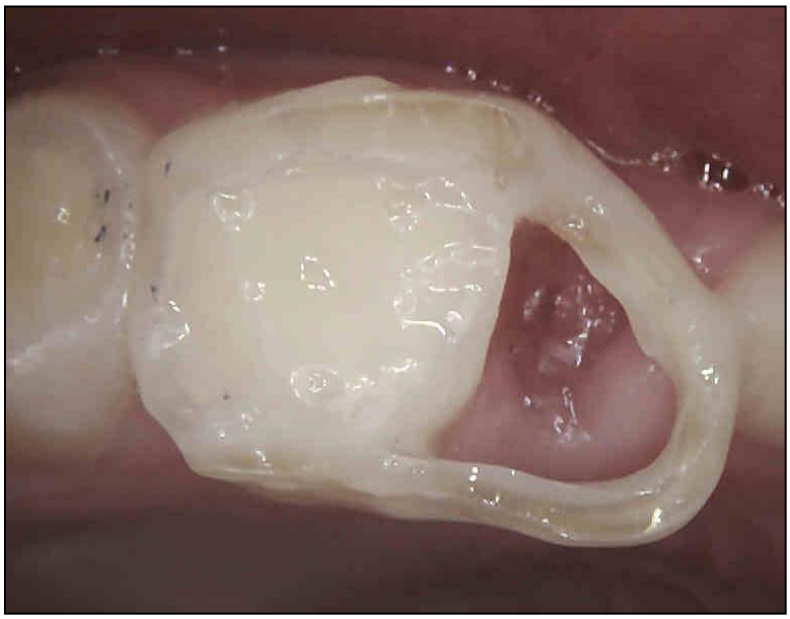

Figure 5.10: Imperfect fibre loop

5.7.4. Chipping of the composite in a FRCSM

During the study, it became evident that the composite covering the fibre would chip off over time (see Figure 5.11). Although this did not constitute a FRCSM failure in the present study, it has previously been reported as a device failure.[1] One patient reported that “a piece (of their FRCSM) broke off”. Chipping of the composite could influence plaque retention, patient comfort, device strength, and device longevity.[1] However, chips can be repaired chairside by adding flowable composite to the fibre.

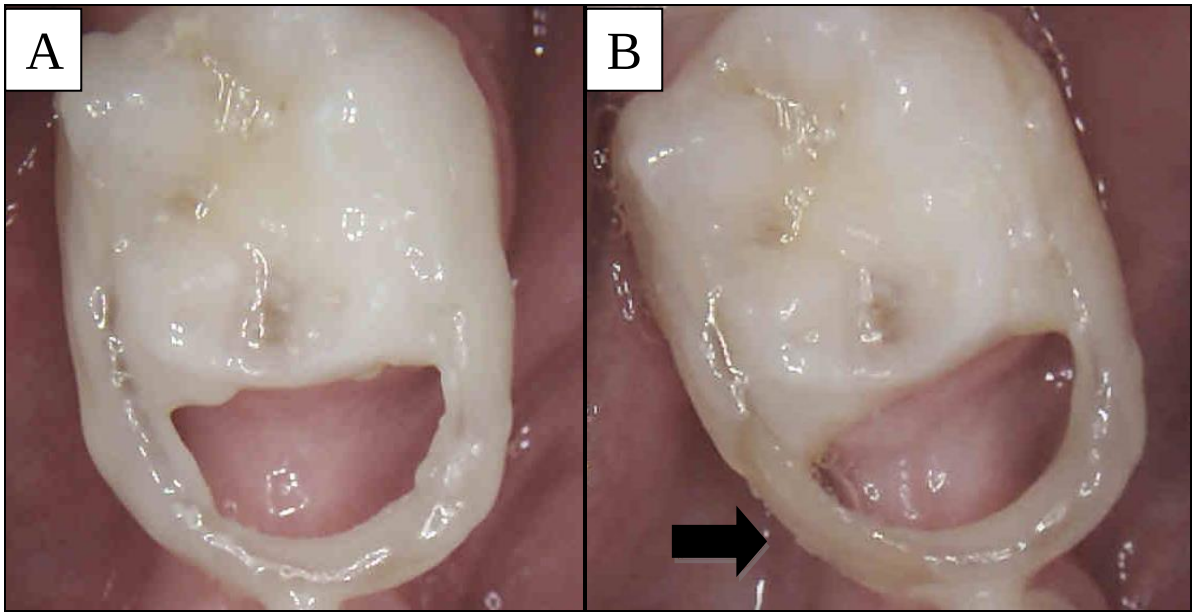

Figure 5.11: (A) FRCSM immediately after placement; **(B)** FRCSM three months after placement (black arrow indicates chipping)

5.8. Limitations of the study

It is acknowledged that the present study had the following limitations:

- Deciduous teeth exhibit variations in anatomy and tooth structure composition that may affect the bond between the tooth and the composite/ cement, e.g. demineralisation, enamel quality and enamel thickness.
- It has not been considered whether or how age, race or ethnic group may affect differences in deciduous tooth enamel composition or bond strength.
- Although post-study care and maintenance instructions were given to all parents/ patients, these instructions may not have been diligently followed by all. This may have led to the premature failure of certain space maintainers.
- Because of the limited sample size in this study, all results should be interpreted as descriptive and provisional, and not as conclusive.

Chapter 6: Conclusions and Recommendations

The present study has generated valuable new clinical information. Results indicate that the main cause of FRCSM failure was debonding, which suggests that it is necessary to work on techniques to improve bond strength. It is also recommended that further research be done on whether this device would prove more successful if mechanical retention were somehow enhanced when bonding FRCSMs to deciduous tooth enamel. It would also be good to investigate the effectiveness of the loop-design FRCSM in the context of permanent teeth. Although, statistically, there were no significant differences between the BLSM and the FRCSM in terms of their performance, further research based on a larger sample size and a longer follow-up period would be necessary before the FRCSM could be confidently recommended as a reliable alternative to the BLSM.

6.1 Recommendations to the Department of Health

Fibres can be used as space maintainers. Using FRCSMs instead of lab-constructed BLSMs would be more economical, making space maintenance more accessible. This will be beneficial especially for South African children - even in rural areas where dental laboratory services are not available. This should therefore be sufficient motivation for the Department of Health to provide the necessary fibres to all clinics as soon as FRCSM-related techniques are standardised.

6.2 Recommendations to fibre manufacturers

The present study represents a clinical trial of the loop-design FRCSM. Fibre has great potential as a component of fixed space maintainers. However, further research with regards to improving the bond strength between fibres and deciduous teeth is necessary. Also, manipulating fibre into a loop form is challenging; it may be beneficial to manufacture a pre-bent fibre form/ template against which it could be moulded.

6.3 Recommendations to fellow researchers

Further clinical studies with a larger sample size would be greatly beneficial to the development of a successful FRCSM, which would make space maintenance more accessible to all. Future research should focus on bond strength improvement (especially with respect to the bond between FRCSMs and deciduous anchor teeth), on testing this new loop-design FRCSM on permanent molars, and on the influences of different FRCSM materials on overall device success.

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Appendix A: Ethical clearance

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 22 May 2002 and Expires 20 Oct 2016.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 22/04/2017.

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

3/12/2015

Approval Certificate
New Application

Ethics Reference No.: 523/2015

Title: A comparison between the band-and-loop space maintainer with a loop-design fibre-reinforced composite space maintainer.

Dear Nicoline Potgieter

The **New Application** as supported by documents specified in your cover letter dated 2/12/2015 for your research received on the 3/12/2015, was approved by the Faculty of Health Sciences Research Ethics Committee on its quorate meeting of 3/12/2015.

Please note the following about your ethics approval:
- Ethics Approval is valid for 1 year
- Please remember to use your protocol number (**523/2015**) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, or monitor the conduct of your research.

Ethics approval is subject to the following:
- The ethics approval is conditional on the receipt of 6 monthly written Progress Reports, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

Dr R Sommers: MBChB; MMed (Int); MPharMed.
Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

☎ 012 354 1677 🖷 0866516047 deepeka.behari@up.ac.za http://www.healthethics-up.co.za
✉ Private Bag X323, Arcadia, 0007 - 31 Bophelo Road, HW Snyman South Building, Level 2, Room 2.33, Gezina, Pretoria

*** Kindly collect your original signed approval certificate from our offices, Faculty of Health Sciences, Research Ethics Committee, H W Snyman South Building, Room 2.33 / 2.34.*

Appendix B: Consent form

TITLE OF STUDY: A comparison of the band-and-loop space maintainer with a loop-design fibre-reinforced composite space maintainer.

Dear Parent/ Legal guardian,

1) INTRODUCTION

We invite your child to participate in a research study. This information leaflet will help you to decide if you want your child to participate. Before you agree for your child to participate, you should fully understand what is involved. If you have any questions that this leaflet does not fully explain, please do not hesitate to ask the doctor.

Early loss of baby teeth is a leading cause of skew permanent teeth. If a space maintainer is placed in the position where the baby tooth was, until the permanent tooth comes out, it can prevent future orthodontic problems. A metal band with a loop extending over the area of the lost tooth (Band-and-loop space maintainers (BLSM)) is widely used and a white fibre loop (Fibre-reinforced-composite space maintainer (FRCSM)) has been suggested and used as an alternative. Dr. Potgieter will show you examples of both on a model.

2) THE NATURE AND PURPOSE OF THE STUDY

The aim of this study is to evaluate the failure rates and reason for failure of space maintainers, determining which type of space maintainer performs best in the mouth over a 6 month period.

3) EXPLANATION OF PROCEDURES TO BE FOLLOWED

Space maintainers will be placed in the area where a first baby molar had to be extracted due to cavities / abscess formation. Adjacent teeth should be present and healthy. If your child gets the metal space maintainer, a metal band will be fitted around the tooth and an impression with clay-like material will be taken on the first visit and we will glue it to the tooth on the second visit. The white space maintainer only takes one visit during which it is measured and glued.

After the space maintainer is placed, your child should attend a monthly follow-up appointment for 6 months to monitor the space maintainer.

4) RISK AND DISCOMFORT INVOLVED

Only a little discomfort may be felt during the fitting and placement procedures. Possible risks include fracture/ bending/ loss of the space maintainer and plaque accumulation if good oral hygiene is not maintained. Your child may not like the device in the mouth and soft tissue irritation may occur if the loop presses against soft tissue.

5) POSSIBLE BENEFITS OF THE STUDY

Your child will benefit directly from the study by receiving space maintenance treatment. The data recorded in this research can benefit all children with regards to improving space maintenance devices.

6) WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Your child's participation in this study is entirely voluntary. You can refuse for your child to participate by not giving permission to place the BLSM or FRCSM for research. Your

child's withdrawal will not affect the restorative treatment plan in any way, and your child will be referred to the orthodontic department for further treatment.

7) HAS THE STUDY RECEIVED ETHICAL APPROVAL?

This study has received written approval from the Research Ethics Committee of the Faculty of Health Sciences at the University of Pretoria, telephone numbers 012 3541677 / 012 3541330.

Important ethical principles to be aware of are that no teeth will be extracted for the sole purpose of this study and that all materials and methods are well known and approved for dental use.

8) INFORMATION AND CONTACT PERSON

The contact persons for the study are Dr. N Potgieter. If you have any questions about the study please contact her at the following telephone numbers (012) 319 2932. All treatment and follow- up procedures will be done by Dr. N Potgieter.

9) COMPENSATION

Your child's participation is voluntary. No compensation or contribution will be given for your child's participation.

10) CONFIDENTIALITY

All identities will be kept strictly confidential. Research reports and articles in scientific journals will not include any personal information that may identify you or your child.

PARENT/ LEGAL GUARDIAN CONSENT TO PARTICIPATE IN THIS STUDY

I confirm that the person asking my consent to take part in this study has told me about nature, process, risks, discomforts and benefits of the study. I have also received, read and understood the above written information (Information Leaflet and Informed Consent) regarding the study. I am aware that the results of the study, including personal details, will be anonymously processed into research reports. I am participating willingly. I have had time to ask questions and have no objection to participate in the study. I understand that there is no penalty should I wish to discontinue with the study and my withdrawal will not affect any treatment in any way.

Participant's name: ……..... *(Please print)*
Parent/ Legal guardian signature: .....…… Date.....

Investigator's name: .....…… *(Please print)*
Investigator's signature: .....…… Date.….....

Witness's Name: .....……..... *(Please print)*
Witness's signature: .....…….. Date.….....

VERBAL INFORMED CONSENT

I, the undersigned, have read and have fully explained the participant information leaflet, which explains the nature, process, risks, discomforts and benefits of the study to the participant whom I have asked to participate in the study.

The participant indicates that s/he understands that the results of the study, including personal details regarding the interview will be anonymously processed into a research report. The participant indicates that s/he has had time to ask questions and has no objection to participate in the interview. S/he understands that there is no penalty should s/he wish to discontinue with the study and his/her withdrawal will not affect any treatment in any way. I hereby certify that the patient has agreed to participate in this study.

Participant's Name: ..... *(Please print)*

Person seeking consent: ..... *(Please print)*

Signature: ..... Date.....

Witness's name: ..... *(Please print)*

Signature: ..... Date.....

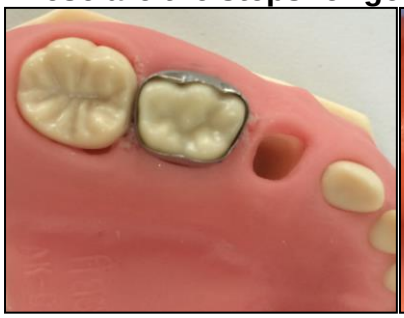
Appendix C: Assent Form

Assent form for Protocol Title:

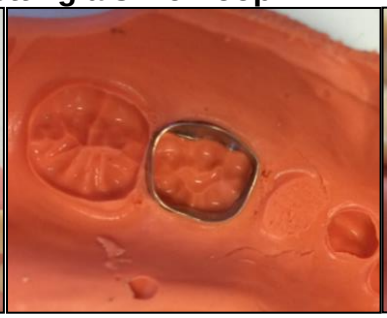
A comparison between the band-and-loop space maintainer with a loop-design fibre-reinforced composite space maintainer.

We wish to know if you would like to be part of a study, where a loop will be placed in the gap where you have lost a tooth. Without the loop the gap can close and there might not be enough space for a new tooth to come out causing skew teeth. This study will tell us how to make the loops better for other children like you. 10 Children will get silver loops and 10 will get white loops. The loops will be made by fitting and gluing it on to the tooth next to the gap.

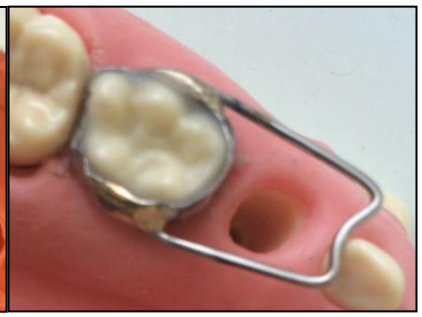
These are the steps for getting a silver loop:



Fit a band around the tooth

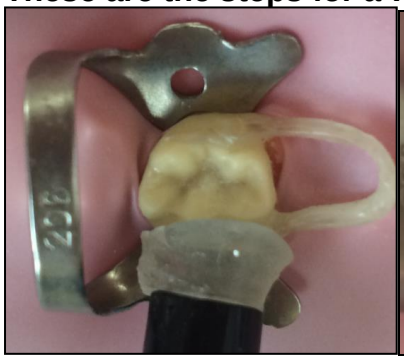


Cover the band with special clay

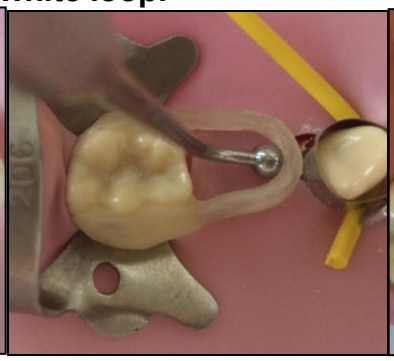


Glue the band and loop to the tooth

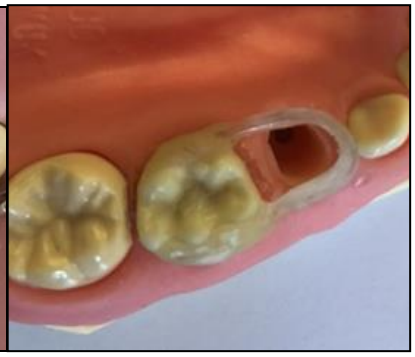
These are the steps for a white loop:



Make the teeth dry



Fit the white loop



Glue the white loop

The silver loop takes two visits and the white loop one visit. It might be a little uncomfortable during the fitting and gluing of the loops.

You will have to come and see Dr. Potgieter 6 times in 6 months. Every time you visit her, she will ask you how the loop is feeling in the mouth. There is a chance that your loop may break, bend or come loose. It is very important to tell her or your parents if you feel any problems with the loop. She will check if it is clean around the loop and teeth. She will also check if the loop is still in place, and fix or remove it if it is broken. You may decide at any time not to carry on with the study. No-one will force you to carry on or be cross with you.

Write your name below, if you understand what we are going to do and if you want to take part of this study.

	Your Name	**Person Obtaining Consent**	**Parent / Guardian / Nurse As Witness**
Name Please Print			
Signature			
Date			

Appendix D: Consent for Dental Images

Consent for Dental Images

Dear Patient,
The Oral and Dental Hospital of the University of Pretoria is a teaching hospital. Dental images or videos of dental procedures will help to expand the student's diagnostic abilities and knowledge. As a patient, you are under no obligation to consent to the taking of any form of dental images of yourself to be utilised for educational purposes.

Consent

I, (full name in print)

_____

hereby grant permission that any form of dental images and or dental videos being made of me/ my child/ my dependent/ the patient.

I consent voluntary that the dental images may:

- Be included in my dental record;
- Be applied for teaching and training;
- Be used in paper and or electronic health publications.

I confirm that all dental images were presented to me.
I, the undersigned understand the content of this consent form and my identity will remain confidential. I agree to non-payment of royalty fees.

_____
Signature patient/ parent/ guardian

_____
Signature of Dentist

_____ /
File No. Date

Toestemming vir Tandheelkundige Afbeeldings

Geagte Pasiënt,
Die Hospitaal vir Tand- en Mondheelkunde van die Universiteit van Pretoria is 'n opleidingshospitaal. Tandheelkundige afbeeldings of videos van tandheelkundige prosedures sal bydra om studente se diagnostiese vaardigheid en kennis uit te brei. As pasiënt is u onder geen verpligting om toestemming te verleen vir enige neem van tandheelkundige afbeeldingsmateriaal van uself vir opleidingsdoeleindes nie.

Toestemming

Ek, (volle naam in drukskrif)

_____

verleen my volle toestemming dat enige vorm van tandheelkundige afbeeldmingsmateriaal en of videos van my/ my kind/ my afhanklike/ die pasiënt gemaak mag word.

Ek verleen vrywillig toestemming dat die tandheelkundige afbeeldingsmateriaal:

- Ingesluit mag word in my tandheelkunde rekord;
- Aangewend mag word vir onderrig en opleiding;
- Gepubliseer mag word in geskrewe of elektroniese gesondheids-publikasies.

Ek bevestig dat alle tandheelkundige afbeeldings-material aan my getoon is.
Ek, die ondergetekende verstaan die inhoud van hierdie toestemmingsvorm en dat my identiteit nie openbaar gemaak sal word nie. Ek stem toe tot nie-betaling van fooie.

_____
Handtekening van pasiënt/ ouer/ voog

_____
Handtekening van Tandarts

_____ /
Lêer Nr. Datum

Appendix E: Follow-up appointments

CASE NR: _____

DEMOGRAPIC DETAILS: ***PI:*** _____

GENDER: M / F

AGE:

ANCHOR TOOTH NUMBER:

TYPE OF SM: FRSCM / BLSM

DATE OF PLACEMENT:

FOLLOW-UP APPOINTMENT 1 MONTH: _____ ***PI:*** _____

FAILURE CRITERIA	**PRESENT**
FRCSM DEBONDING AT ENAMEL-COMPOSITE INTERFACE / BLSM DEBONDING AT ENAMEL-CEMENT INTERFACE	Y / N
FRCSM DEBONDING AT THE COMPOSITE-FIBRE INTERFACE / BLSM DEBONDING AT THE CEMENT-BAND INTERFACE	Y / N
FRACTURE OF THE FIBRE /WIRE LOOP	Y / N
BENDING OF FIBRE/WIRE TO IMPINGE ON SOFT TISSUE	Y / N
LOSS OF CONTACT WITH ADJACENT TOOTH	Y / N

NOTES:

_____

_____

EMERGENCY APOINTMENTS BEFORE NEXT FOLLOW-UP:

_____

_____

FOLLOW-UP APPOINTMENT 2 MONTHS: _____ ***PI:*** _____

FAILURE CRITERIA	**PRESENT**
FRCSM DEBONDING AT ENAMEL-COMPOSITE INTERFACE / BLSM DEBONDING AT ENAMEL-CEMENT INTERFACE	Y / N
FRCSM DEBONDING AT THE COMPOSITE-FIBRE INTERFACE / BLSM DEBONDING AT THE CEMENT-BAND INTERFACE	Y / N
FRACTURE OF THE FIBRE /WIRE LOOP	Y / N
BENDING OF FIBRE/WIRE TO IMPINGE ON SOFT TISSUE	Y / N
LOSS OF CONTACT WITH ADJACENT TOOTH	Y / N

NOTES:

_____

_____

EMERGENCY APOINTMENTS BEFORE NEXT FOLLOW-UP:

_____

_____

FOLLOW-UP APPOINTMENT 3 MONTHS: _____ ***PI: _____***

FAILURE CRITERIA	PRESENT
FRCSM DEBONDING AT ENAMEL-COMPOSITE INTERFACE / BLSM DEBONDING AT ENAMEL-CEMENT INTERFACE	Y / N
FRCSM DEBONDING AT THE COMPOSITE-FIBRE INTERFACE / BLSM DEBONDING AT THE CEMENT-BAND INTERFACE	Y / N
FRACTURE OF THE FIBRE /WIRE LOOP	Y / N
BENDING OF FIBRE/WIRE TO IMPINGE ON SOFT TISSUE	Y / N
LOSS OF CONTACT WITH ADJACENT TOOTH	Y / N

NOTES:

_____

_____

EMERGENCY APOINTMENTS BEFORE NEXT FOLLOW-UP:

_____

_____

FOLLOW-UP APPOINTMENT 4 MONTHS: _____ ***PI: _____***

FAILURE CRITERIA	PRESENT
FRCSM DEBONDING AT ENAMEL-COMPOSITE INTERFACE / BLSM DEBONDING AT ENAMEL-CEMENT INTERFACE	Y / N
FRCSM DEBONDING AT THE COMPOSITE-FIBRE INTERFACE / BLSM DEBONDING AT THE CEMENT-BAND INTERFACE	Y / N
FRACTURE OF THE FIBRE /WIRE LOOP	Y / N
BENDING OF FIBRE/WIRE TO IMPINGE ON SOFT TISSUE	Y / N
LOSS OF CONTACT WITH ADJACENT TOOTH	Y / N

NOTES:

_____

_____

EMERGENCY APOINTMENTS BEFORE NEXT FOLLOW-UP:

_____

_____

FOLLOW-UP APPOINTMENT 5 MONTHS: _____

FAILURE CRITERIA	PRESENT
FRCSM DEBONDING AT ENAMEL-COMPOSITE INTERFACE / BLSM DEBONDING AT ENAMEL-CEMENT INTERFACE	Y / N
FRCSM DEBONDING AT THE COMPOSITE-FIBRE INTERFACE / BLSM DEBONDING AT THE CEMENT-BAND INTERFACE	Y / N
FRACTURE OF THE FIBRE /WIRE LOOP	Y / N
BENDING OF FIBRE/WIRE TO IMPINGE ON SOFT TISSUE	Y / N
LOSS OF CONTACT WITH ADJACENT TOOTH	Y / N

PI: _____

NOTES:

_____

_____

EMERGENCY APOINTMENTS BEFORE NEXT FOLLOW-UP:

_____

_____

FOLLOW-UP APPOINTMENT 6 MONTHS: _____

FAILURE CRITERIA	PRESENT
FRSCSM DEBONDING AT ENAMEL-COMPOSITE INTERFACE / BLSM DEBONDING AT ENAMEL-CEMENT INTERFACE	Y / N
FRCSM DEBONDING AT THE COMPOSITE-FIBRE INTERFACE / BLSM DEBONDING AT THE CEMENT-BAND INTERFACE	Y / N
FRACTURE OF THE FIBRE /WIRE LOOP	Y / N
BENDING OF FIBRE/WIRE TO IMPINGE ON SOFT TISSUE	Y / N
LOSS OF CONTACT WITH ADJACENT TOOTH	Y / N

PI: _____

NOTES:

_____

_____

EMERGENCY APOINTMENTS BEFORE NEXT FOLLOW-UP:

_____

_____

Appendix F: Example of a completed follow-up form

APPENDIX A: FOLLOW UP APPOINTMENTS CASE NR: 2

DEMOGRAPHIC DETAILS: T. Rukuni (Ruk0013) PI: 361.

GENDER: (M) F

AGE: 5yrs

ANCHOR TOOTH NUMBER: 65

TYPE OF SM: FRSCM (BLSM)

DATE OF PLACEMENT: 09.02.2016

FOLLOW UP APPOINTMENT 1 MONTH: 01.03.2016 PI: 631.

FAILURE CRITERIA	PRESENT
FRCSM DEBONDING AT ENAMEL-COMPOSITE INTERFACE / BLSM DEBONDING AT ENAMEL-CEMENT INTERFACE	Y (N)
FRCSM DEBONDING AT THE COMPOSITE-FIBRE INTERFACE / BLSM DEBONDING AT THE CEMENT-BAND INTERFACE	Y (N)
FRACTURE OF THE FIBRE /WIRE LOOP	Y (N)
BENDING OF FIBRE/WIRE TO IMPINGE ON SOFT TISSUE	Y (N)
LOSS OF CONTACT WITH ADJACENT TOOTH	Y (N)

NOTES: INTACT

EMERGENCY APOINTMENTS BEFORE NEXT FOLLOW UP:

FOLLOW UP APPOINTMENT 2 MONTHS: 07.04.2016 PI: 631.

FAILURE CRITERIA	PRESENT
FRCSM DEBONDING AT ENAMEL-COMPOSITE INTERFACE / BLSM DEBONDING AT ENAMEL-CEMENT INTERFACE	Y (N)
FRCSM DEBONDING AT THE COMPOSITE-FIBRE INTERFACE / BLSM DEBONDING AT THE CEMENT-BAND INTERFACE	Y (N)
FRACTURE OF THE FIBRE /WIRE LOOP	Y (N)
BENDING OF FIBRE/WIRE TO IMPINGE ON SOFT TISSUE	Y (N)
LOSS OF CONTACT WITH ADJACENT TOOTH	Y (N)

NOTES: INTACT

EMERGENCY APOINTMENTS BEFORE NEXT FOLLOW UP:

Page 1 of 3

FOLLOW UP APPOINTMENT 3 MONTH: 04.05.2016 PI: 251.

FAILURE CRITERIA	PRESENT
FRCSM DEBONDING AT ENAMEL-COMPOSITE INTERFACE / BLSM DEBONDING AT ENAMEL-CEMENT INTERFACE	Y (N)
FRCSM DEBONDING AT THE COMPOSITE-FIBRE INTERFACE / BLSM DEBONDING AT THE CEMENT-BAND INTERFACE	Y (N)
FRACTURE OF THE FIBRE /WIRE LOOP	Y (N)
BENDING OF FIBRE/WIRE TO IMPINGE ON SOFT TISSUE	Y (N)
LOSS OF CONTACT WITH ADJACENT TOOTH	Y (N)

NOTES: INTACT

EMERGENCY APOINTMENTS BEFORE NEXT FOLLOW UP:

FOLLOW UP APPOINTMENT 4 MONTHS: 08.06.2016 PI: 501.

FAILURE CRITERIA	PRESENT
FRCSM DEBONDING AT ENAMEL-COMPOSITE INTERFACE / BLSM DEBONDING AT ENAMEL-CEMENT INTERFACE	Y (N)
FRCSM DEBONDING AT THE COMPOSITE-FIBRE INTERFACE / BLSM DEBONDING AT THE CEMENT-BAND INTERFACE	Y (N)
FRACTURE OF THE FIBRE /WIRE LOOP	Y (N)
BENDING OF FIBRE/WIRE TO IMPINGE ON SOFT TISSUE	Y (N)
LOSS OF CONTACT WITH ADJACENT TOOTH	Y (N)

NOTES: INTACT

EMERGENCY APOINTMENTS BEFORE NEXT FOLLOW UP:

Page 2 of 3