SURVIVAL OF LABORATORY FABRICATED SPACE MAINTAINERS

by

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Abstract

Objective:
Few studies have examined the longevity of a large sample of space maintainers. The aim of this research was to determine if appliance, patient or provider factors played a role in the success and survival of laboratory-fabricated fixed space maintainers.

Methods:
A retrospective chart review was conducted of laboratory-fabricated fixed passive space maintainers inserted between January 1, 2000 and December 31, 2003 in a metro Vancouver pediatric dentistry/orthodontic practice. Appliances were followed until removal or, if still in use, to study’s end point; no observations were censored. Patients lost to follow-up were excluded. All appliances had been prepared and inserted using a consistent, meticulous technique. If an appliance failed prematurely, reasons for failure, e.g. cement loss, solder breakage, eruption interference, were recorded. Other data collected included child’s date of birth, gender, cement type, caries rate, oral hygiene score and patient cooperation at the time of appliance placement. Statistical analyses included descriptive statistics, Kaplan-Meier and the Mantel-Cox Log-rank survival analysis.
Results:

Of the original sample of 1218, 892 appliances were analyzed. The sample included band and loop (B&L), lingual holding arch (LHA) and Nance appliances from 692 subjects. Subjects were analyzed by specialty: pediatric (n=370), orthodontic (n=322). The mean age at insertion was 9(2) years. For sixty-five percent of subjects (n=452), appliances were deemed ‘successful’ i.e., “did what the clinician expected”. After controlling for the effect of other explanatory variables, type of space maintainer (p<0.03), patient gender (p=0.003) and age at insertion (p<0.0001) were all significantly related to success. Mandibular B&Ls had the longest median survival time (time for half of appliances to fail, MST) of 38 months; maxillary B&Ls, the lowest MST of 22 months. The MST of LHA and Nance were 25 months and 26 months, respectively. In the failure group, no statistical significant differences were found in the MST of space maintainers when appliance type was considered.

Conclusion:

The majority of the space maintainers lasted their anticipated lifetime. Appliance type, patient gender and age at insertion were significantly associated with outcomes.
Preface

Ethical approval for this research was granted by The University of British Columbia’s Clinical Research Ethics Board, (certificate number H11-00938) and, concurrently, by The University of North Carolina Institutional Review Board, for statistical support (certificate number 07-1654).
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Glossary

**Success** – appliance still in place at the time of review or removed by clinician after being judged clinically successful.

**Failure** – appliance is loose, lost or broken at time of review i.e. before end of intended life expectancy or had to be removed due to interference with tooth eruption or causing gingival irritation.

**Mean survival** – the average survival time of appliances, provided that complete data is known (i.e. no censoring) (Norman and Streiner, 2000). Note, some studies used the terms mean survival and median survival interchangeably.

\[
\text{Mean survival} = \frac{(\text{time to outcome})}{(\text{number of subjects who reached the outcome})}
\]

**Pooled mean survival** – average of mean survival if several appliances are studied.

**Median survival time** for *successful* appliances - the length of time for half of the successful appliances to be successful, only if there is no censoring (Norman and Streiner, 2008).

**Median survival time** for *failed* appliances – the length of time for half of the failed appliances to fail, only if there is no censoring (Norman and Streiner, 2008).

**Censoring** - refers to situations where the exact survival time is not known due to insufficient information (Norman and Streiner, 2008) (i.e. the duration of follow-up ends before appliance failure occurs).
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Dedication

I would like to dedicate this dissertation to my family and friends with a special feeling of gratitude to my parents for their endless love and support over the years.
1 Introduction

One of the challenges in pediatric dentistry is the management of untimely loss of primary teeth and subsequent space control issues that develop with time, growth and maturation of the dental arch. Untimely loss of primary teeth may be caused by dental caries (Ghafari, 1986), trauma (Borum and Andreasen, 1998), ectopic eruption of the first permanent molars (Ghafari, 1986), severe dental crowding (Ghafari, 1986) or systemic disorders (Ghafari, 1986; Hartsfield, 1994; Borum and Andreasen, 1998).

Dental caries is the main reason for the premature loss of teeth in the primary dentition (Alsheneifi and Hughes, 2001; Jovino-Silveira et al., 2005; Mansour Ockell and Bagesund, 2010) and remains a common problem in today’s children. According to the latest Canadian Health Measures Survey (2007-2009), about one in four children aged six to eleven years had at least one tooth that was decayed, missing or filled (dmft).

Not all teeth with caries require extraction. Although pulp therapy is commonly used to restore teeth with pulp exposure from dental caries, dental extraction is still the preferred method of treatment for extensively decayed teeth in noncompliant or medically compromised patients. It may be best practice to
insert a space maintainer after the extraction of a primary molar to prevent undesirable tooth movement, especially when adequate space exists and all unerupted teeth are at the proper stage of development (Daly and Walker, 1990).

Another common dental concern in the growing child is tooth-size arch-length deficiency (TSALD). Indeed, dental crowding is the most common type of malocclusion (Proffit et al., 2007). Both genetic and environmental factors are implicated in the development of arch length deficiency, leading to crowding (Hoffding and Kisling, 1978a; Proffit et al., 2007).

Premature loss of primary teeth due to trauma, caries or congenital condition may contribute to malocclusion if space for the permanent successor is not maintained (Ghafari, 1986). Leeway space is defined as the size differential between primary molars, canines and permanent premolars and canines. Since the mesial-distal distance occupied by primary molars always exceeds that of permanent premolars, strategic management of this space using fixed appliances has been shown to be useful in treating cases of minimal crowding (5mm or less). This type of space management facilitates future non-extraction treatment and prevents or minimizes space loss caused by the premature loss of primary teeth (McDonald, 2010). Leeway space management may involve the strategic interproximal reduction of one or more primary teeth (primary canine, first molar and second molar) with the subsequent placement of a bilateral space maintainer.
near the end of the mixed dentition (McDonald, 2010). If implemented appropriately, leeway space management may result in preservation of up to five millimetre of the leeway space (Dugoni et al., 1995; Brennan and Gianelly, 2000). This approach may also result in better long-term incisor stability (Dugoni et al., 1995; Brennan and Gianelly, 2000).

This literature review will address the consequences of premature loss of primary teeth, recommended approaches to space management and choice of space maintainers, and problems associated with space maintainers. The current body of literature on space maintainer survival and the significance of this study will also be reviewed.
2 Literature review

The literature reviewed relevant to this research study included consequences of early space loss; indications and contraindications for space maintenance; treatment planning for space maintainer use; effectiveness and longevity of space maintainers and finally, factors associated with space maintainer failures.

2.1 Consequences of early primary teeth loss

The severity of arch length deficiency after premature loss of primary teeth or severe caries is affected by several factors. These include the dental age of the patient, amount of space lost, the number and location of teeth lost, the presence of oral habits, and most importantly, severity of dental crowding (Kennedy, 1978; Daly and Walker, 1990). Time elapsed since dental extraction, individual eruption pattern, presence of dental anomalies, intercuspation of the dentition and sequence of eruption are also found to be important in determining the severity of arch length loss (Kennedy, 1978).

Premature primary tooth extraction may lead to abnormal changes in the connective tissue and delay eruption of successor teeth (Posen, 1965; Suri et al., 2004). Posen (1965) analyzed data from children who were part of the Burlington growth study, of which the main racial group studied was Caucasian. Children who had undergone unilateral extraction of primary molars were
selected. By comparing the left and right sides of the oblique film, Posen (1965) was able to discern differences in the eruption time of permanent premolars in relation to the time of the primary molar extraction. The eruption of premolars was delayed in children who had lost primary molars prematurely at ages four and five and accelerated after premature loss of primary molars at age eight (Posen, 1965). Fanning (1962) took records of four boys and four girls, each who experienced the unilateral loss of one primary molar. Accelerated eruption and early emergence of the successor were observed when the successor was in a later period of dental development at the time of primary molar extraction (Fanning, 1962; Posen, 1965). Further to that, Anderson and Popovich’s study (1981) on permanent molar emergence found that the emergence of second permanent molars was delayed relative to that of the second premolars when mandibular first permanent molars’ emergence was delayed relative to that of the permanent central incisors.

Premature loss of primary teeth might also contribute to eruption disturbance of succedaneous teeth; for example, impaction of an erupting tooth as a result of space loss (Northway, 2000) (Figure 1). Indeed, there is extensive evidence that premature space loss leads to problems such as crowding, ectopic eruption, tooth impaction, crossbite formation and dental midline discrepancies (Hoffding and Kisling, 1978b; a; Kennedy, 1978; Kisling and Hoffding, 1979a; b; c; Daly and Walker, 1990; Durward, 2000). Tipping of the first permanent molar after
premature loss of the second primary molar has also been observed (Hoffding and Kisling, 1978a). The extent to which these disturbances occur depends on the timing of tooth loss, the severity of crowding and the actual tooth which was lost (Kisling and Hoffding, 1979a; c; b).

![Panoramic radiograph of a child in late mixed dentition exhibiting impaction of maxillary second premolars (#1.5 and #2.5) as a result of early space loss.](image)

Figure 1: A panoramic radiograph of a child in late mixed dentition exhibiting impaction of maxillary second premolars (#1.5 and #2.5) as a result of early space loss.

Consequences of early primary tooth loss specific to a particular tooth are discussed below.

### 2.1.1 Early loss of primary maxillary incisors

Primary maxillary incisors are often profoundly affected by extensive caries in children with severe early childhood caries (Hallett and O'Rourke, 2006). If not detected early enough or left untreated, extractions are a common treatment. The effect of premature loss of primary maxillary incisors on speech development
and arch length is unclear. No significant differences were found in the articulatory abilities of children with histories of premature loss of four maxillary primary incisors compared to children with histories of normal exfoliation (Gable et al., 1995). Moreover, any sound distortions that a child may produce will likely self-correct when the missing teeth are replaced by their permanent successors (Riekman and el Badrawy, 1985; Gable et al., 1995). Usually, little space is lost in the anterior region if primary canine occlusion is established. When space loss occurs, it is usually caused by anterior segment crowding or by the loss of primary incisors before eruption of primary canines (Clinch and Healey, 1959; Ghafari, 1986; Durward, 2000). Therefore, early loss of primary incisors is not an indication for space maintenance unless aesthetics are a concern (Durward, 2000).

2.1.2 Early loss of primary canines

Primary canines may exfoliate prematurely as a result of severe arch length deficiency in the anterior segment (Gianelly, 1995) or may need to be extracted to relieve dental crowding (Bradbury, 1985; Alsheneifi and Hughes, 2001). Early loss of primary canines may lead to a decrease in arch perimeter and possible permanent canine impaction (Kau et al., 2004). Early unilateral loss of
primary canines may lead to distal movement and tipping of the permanent incisors, resulting in a midline discrepancy (Ghafari, 1986; Durward, 2000). It has been reported by Kau et al. that the mesial movement of the mandibular permanent molars is the main contributor to the loss of arch perimeter (Kau et al., 2004). On the other hand, Sayin and Turkkahraman (2006), argued that the loss of arch perimeter is mainly due to retrusion of the lower incisors with minimal changes in molar positions. The discrepancy might be a result of differences in experimental designs: Kau's study followed patients over a lengthy period of time (2-year period) but made measurements based only on dental casts, whereas Sayin’s study had a shorter follow-up period (one year) but collected data on both dental casts and cephalometric radiographs. The third difference between the two studies was that the subjects in Kau’s study had more initial dental crowding (6mm) than those in the Sayin study (1.6mm).

### 2.1.3 Early loss of primary first molars

There is no consensus on the effect of early loss of primary first molars on arch perimeter. Early loss of primary first molars may lead to distal movement of the primary canines if the tooth is lost during the eruption of the permanent lateral incisors (Lin and Chang, 1998; Lin and Lin, 2007). However, Lin argues that this space loss, albeit statistically significant, is not of sufficient clinical significance to warrant the use of a space maintainer (Lin and Chang, 1998; Lin and Lin, 2007). In the mandible, the premature loss of primary first molars may lead to a
reduction in space as a result of the distal movement of the primary canine (Cuoghi et al., 1998; Lin and Chang, 1998). In the maxilla, the premature loss of primary first molars could lead to space loss from the distal movement of the primary canine (Lin and Chang, 1998; Padma Kumari and Retnakumari, 2006; Lin and Lin, 2007) and the mesial movement of the second primary molar (Northway, 2000).

Studies by Lin et al. confirm that the space lost in the region of the primary maxillary first molar in children (aged 5.1 to 7.2 years) is attributed to the distal drifting of the primary canine (Lin and Chang, 1998; Lin and Lin, 2007). In this retrospective study (Lin and Chang, 1998) with a relatively small sample size (n=21), study casts taken at the initial and follow-up examinations were compared to determine if there was any difference in leeway space, arch width, arch length and arch perimeter. The untreated contralateral side was used as a control. Despite the statistically significant reduction in leeway space on the treatment side, there were no significant differences in arch width, arch length and arch perimeter. Hence, the authors concluded that the space change was mostly due to the distal movement of the primary canine after the premature loss of the primary first molar. This conclusion was in agreement with the studies by Kisling and Hoffding (Kisling and Hoffding, 1979a; c) as described below.
Kisling et al. found that there was no change in molar relationship after the loss of the first primary molars in either arch. However, only in the mandible, did a significant space reduction was observed (Hoffding and Kisling, 1978b). Mandibular incisor position, however, was affected especially when there was abnormal muscular pressure from the lower lip, a deep bite, or moderate crowding (Kisling and Hoffding, 1979c).

More space was lost when there was concurrent extraction of a primary second molar (Northway et al., 1984) which might lead to impaction of the permanent canines (Northway, 2000). Northway (2000) and Lin (2007) also did not find significant change in the position of the first permanent molar. Further, the prospective longitudinal controlled study by Macena et al. (2011) demonstrated that there was no significant change in arch measurements from the premature loss of the first primary molars in either arch. Although Northway (2000) recognized the possible adverse effect (i.e. mesial eruption of first premolar resulting in canine impaction) from early maxillary primary first molar extraction, he did not recommend using a space maintainer. Rather, he recommended either disking mesial of E’s with subsequent space regaining, or placing appliances to distalize the molars.
2.1.4 Early loss of primary second molars

If the primary second molars are lost before the eruption of the permanent first molars, mesial tipping, migration and/or rotation (maxillary) of the first permanent molar (Wright and Kennedy, 1978; Durward, 2000) may result.

Hoffding and Kisling, in a series of studies on premature loss of primary teeth in a group of Danish children, observed that premature loss of primary molars led to a change in occlusion in the permanent dentition and worsening of posterior segment crowding on the side of the tooth loss (Hoffding and Kisling, 1978a; b). Moreover, they found that the drifting pattern was dependent on dental age at time of extraction, space conditions, eruption path and time, intercuspation, different muscular functions and type of tooth lost (Kisling and Hoffding, 1979c).

Macena (Macena et al., 2011), in her longitudinal prospective clinical trial, investigated space changes after the premature loss of primary first and second molars among Brazilian children (n=55, aged six to nine years old). A split-mouth design was used to compare the extraction space, arch length and arch perimeter changes with the non-extraction side. Sequential dental casts were taken at time of extraction and at three, six, and ten months post-extraction. All subjects had minimal initial dental crowding. This study found that only the group of children with unilateral premature loss of the mandibular second primary
molars exhibited significant dimensional alterations at the ten month follow-up. The major effect was mostly observed in the first three months after tooth loss (Macena et al., 2011). Significant changes in the space left by the extraction of the primary second molars in both the maxillary and mandibular arches were found, but the space loss in these arches “behaved” differently. The maxillary arch tended to “recover” the lost space within six months of the second primary molar extraction, contrary to what was found in the mandibular arch. Unfortunately, due to the small sample size, large standard deviations and short clinical follow-up, it is difficult to make clinical recommendations based on this study alone.

2.2 Indications for use of space maintainers

The goals for space maintenance in children are two-fold: 1) to prevent loss of arch length, width and perimeter as a result of premature loss of primary teeth (2011), and 2) to preemptively utilize the leeway space in the management of certain type of mandibular incisor crowding, thereby easing malocclusion (Gianelly, 1995; Brennan and Gianelly, 2000).

Although the use of space maintainers to prevent or reduce the severity of malocclusion in the permanent dentition has been questioned (Lin and Lin, 2007; Laing et al., 2009; Woods, 2010; Lin et al., 2011), it is generally accepted that
space maintainers are indicated in situations where there is premature loss of a primary second molar (especially before the eruption or while permanent molars are actively erupting), when anchorage is required for orthodontic treatment or where leeway space is required to relieve mild crowding. However, such decisions must be guided by individual factors (Brothwell, 1997; Laing et al., 2009). When the tooth involved is a primary first molar, the use of a space maintainer is not clear-cut. Kisling and Hoffding (1979c) observed that early loss of mandibular first primary molars following the eruption of the first permanent molar did not change the sagittal molar relationship but did affect the incisor position, especially when there was abnormal muscular pressure from the lower lip, a deep bite, and moderate crowding. By contrast, space maintenance in the maxillary arch after the early loss of a primary first molar is usually not indicated unless the molars are in an end-on class II molar relationship (Kisling and Hoffding, 1979a). If the premature loss of the maxillary primary first molar could lead to mesial eruption of the succedaneous premolar or permanent canine impaction, disking of the primary second molar is preferred (Northway, 2000).

Durward (2000) reviewed considerations related to the specific need for space maintainers. If the child will require comprehensive orthodontic treatment at a later date, space maintainers are necessary only for those for whom space loss will make the malocclusion markedly worse. Space maintainers might also help prevent or minimize asymmetry since an asymmetrical malocclusion is more
difficult to treat.

2.3 Contraindications of space maintainers

Although space maintainers are usually indicated after premature loss of primary teeth, some cases are not suitable for placement of space maintainers.

Space maintainers should not be inserted if the patient has poor oral hygiene, is deemed ‘high’ caries risk and demonstrates poor attendance (Laing et al., 2009). Patients with high caries risk before orthodontic treatment are known to be at a higher risk of developing caries than a low caries risk group (Al Mulla et al., 2009). Furthermore, space maintainers are not needed when the succedaneous teeth are about to erupt. When arch length deficiency is severe, space maintainers may be completely contraindicated because extraction of permanent teeth might be part of the overall treatment plan. Spaced dentitions generally do not require space maintenance. If a significant amount of space loss has already occurred, then space ‘regaining’ is more appropriate than space maintenance. If there is good intercuspation between the maxillary and mandibular dentition or if there is sufficient over-eruption of the antagonist, then space maintenance is customarily not required (Kennedy, 1978). Finally, if the successor tooth is congenitally absent, adjacent teeth may be allowed to drift naturally to close the space rather than holding the space for future implants (Kennedy, 2009).
2.4 Types of laboratory-fabricated space maintainers

Space maintainers can be categorized based on how they are made (laboratory fabricated versus pre-fabricated chair-side) and on how they are anchored to the teeth (removable versus fixed). Removable appliances are more expensive than fixed appliances because of increased lab fees (Hermanson et al., 1985). Moreover, they are likely not the ideal appliances for children because of the need for exemplary patient compliance. By contrast, fixed space maintainers decrease the need for patient compliance and are less bulky than removable space maintainers. However, fixed space maintainers are not without problems. Because fixed appliances require a cemented orthodontic band, the problem of enamel decalcification under the band warrants consideration and has been reported (Gorelick et al., 1982; Ogaard, 1989; Al Maaitah et al., 2011). Additionally, bands of fixed space maintainers often became loose around the abutment because of cement loss (Qudeimat and Fayle, 1998; Moore and Kennedy, 2006; Fathian et al., 2007; Sasa et al., 2009).

The types of space maintainers analyzed in this study were fixed, laboratory-fabricated space maintainers that were cemented to the teeth. The appliances were intended only to be removed by the dental practitioner when the need arose.
Figure 2: Clinical photographs of appliances (A- Nance appliance, B-lingual holding arch, C-band and loop)

2.4.1 The band and loop appliances (B&Ls)

A band and loop appliance is a space maintainer used in cases of unilateral posterior space loss or bilateral mandibular posterior space loss prior to the eruption of the permanent mandibular incisors. The abutment tooth adjacent to
the edentulous space supports the band and loop. It is constructed by soldering a loop of heavy gauge wire (0.9mm) to the band. The loop needs to closely adapt to the edentulous space and be wide enough buccolingually so that the succedaneous tooth can erupt without interference. Because of the loop’s limited strength, band and loop appliances are usually reserved for cases where there is single tooth loss. Bilateral band and loops may also be used in the same dental arch when there is bilateral loss of primary molars after the eruption of the permanent first molar, but before the eruption of permanent incisors. Some modifications of the band and loop have been created, such as addition of an occlusal rest to prevent mesial tipping of the adjacent tooth, and reinforcing the loop to use for a long span space maintainer (Bijoor and Kohli, 2005). The disadvantages of the band and loop are 1) supra-eruption of the opposing teeth and 2) lack of functional replacement for the missing tooth (Daly and Walker, 1990).

2.4.2 The distal shoe appliances (DS)

Distal shoe space maintainers are indicated when a primary second molar is lost before the eruption of the adjacent permanent first molar. Construction is similar to the band and loop, with an additional metal “shoe” (guide plane) soldered to the distal gingival end of the loop. The guide plane extends about one millimeter below the mesial marginal ridge of the erupting molar as an intra-alveolar extension (Hicks, 1973; Brill, 2002). Distal shoes are not routinely used, partly
due to difficulty in accurate construction and insertion. A radiograph is required to confirm the position of the intra-alveolar extension prior to cementation as inaccurate placement of the distal shoe appliance may damage the developing permanent dental follicle (Kirshenblatt and Kulkarni, 2011). As the adjacent molar erupts, the distal shoe appliance needs to be adjusted by trimming the intra-alveolar extension so that it will resemble a band and loop appliance. The distal shoe appliance is likely contraindicated for those patients lacking cooperation for radiographs due to the added requirement of radiographic verification of proper placement. The “shoe” piercing the gingiva also poses a possible route of infection. Hence, distal shoes are contraindicated in patients who require antibiotic prophylaxis against subacute bacterial endocarditis or in those who are immunocompromised (e.g., uncontrolled diabetes, transplant patients, children receiving or undergoing radiation therapy and/or chemotherapy).

Long-term success of distal shoes is unclear because few long-term studies have been done. However, Brill investigated the success rate of chair-side fabricated distal shoe appliances and found that 88 percent survived over a period of six years (Brill, 2002).
2.4.3 The lingual holding arch (LHA)

A lingual holding arch is indicated in cases where there are multiple mandibular posterior teeth missing. Since permanent mandibular incisors usually erupt lingual to their primary counterparts, lingual arches are usually not placed until all incisors have erupted to prevent their entrapment. Bands are fitted on the permanent first molars; the lingual arch (made of heavy gauge wire: 0.9 mm thick) is soldered to the molar bands or is removable, and attached onto lingual “attachments” on the bands. The LHA has to be passive to prevent undesirable tooth movement (i.e. should be in light contact with the cingula of incisors and 1 to 1.5mm off the soft tissue) (Kennedy, 1978). Occasionally, distal spurs are placed to prevent distal migration of anterior teeth (Bijoor and Kohli, 2005). If a band becomes loose, the chance of caries developing under the loose band is high; thus the appliance needs to be recemented periodically (Moore and Kennedy, 2006) (Figure 3).

Figure 3: Caries developing on lower left first molar. The tooth was previously the abutment for a lingual arch, which became loose with time.
Lingual arches are commonly used in orthodontics as a way to resolve mild mandibular crowding either by utilization of leeway space (Gianelly, 1994) or after disking of mandibular incisors (Dugoni et al., 1995). In the latter case, it has been found that lingual arches could improve lower incisor post-orthodontic treatment stability (Dugoni et al., 1995).

2.4.3.1 Effectiveness of lingual holding arches

There is a dearth of high-quality data on the effectiveness of lingual arches. In fact, Viglianisi (Viglianisi, 2010) conducted a systematic review on the effectiveness of lingual arches on mandibular arch preservation. Yet, of the 262 studies identified in the search, only two (Rebellato et al., 1997; Villalobos et al., 2000) met the final inclusion criteria.

Villalobos et al. (2000), in a retrospective, matched case-controlled clinical study (n=23, aged 10.4 years at the time of LHA insertion), demonstrated that the mandibular lingual arch proved useful to control the mesial movement of the molars and lingual tipping of the incisors. Pre-treatment and post-treatment cephalograms were used to measure molar positional changes over a 24-month period. The results were compared to controls matched by ethnic origin, age,
gender and mandibular plane inclination. Their results supported the use of a mandibular fixed lingual arch for preserving arch length by effectively controlling the mesial movement of the molars and lingual tipping of the incisors.

In a randomized controlled clinical trial, Rebellato et al. (1997) demonstrated that the mandibular lingual arch use was effective in reducing dental crowding during transition from the mixed to the permanent dentition. Sequential cephalometric radiographs were used to quantify the positional changes in the lower incisor and the lower first permanent molar between the control (with no LLHA) and the experimental (with LLHA) groups. In the treatment group, there was a backward tip of the molars and forward tip of the incisors. In the control group, there was a forward tip of molar and a backward tip of the incisors.

2.4.4 The Nance appliances (Nance)

H.N. Nance first described a Nance appliance in 1947 as a way to rotate, stabilize or prevent mesial drifting of molars. It is typically used in the case of premature loss of the primary maxillary second molars. Additionally, situations where the first premolars have been extracted and the lower second primary molars have exfoliated, a Nance appliance will stabilize the maxillary molars (McDonald, 2010). A Nance appliance is made by soldering a heavy gauge
wire (0.9mm) to previously fitted molar bands. It is stabilized anteriorly against the palatal tissue with an acrylic button. The acrylic button should be the size of a quarter coin and in contact with the anterior hard palate in the area of the rugae. The appliance should be frequently monitored to detect possible gingival irritation from the acrylic button.

2.4.5 The transpalatal arches (TPA)

Similar to Nance appliances, transpalatal arches are only used in the maxillary arch (Kupietzky and Tal, 2007). A TPA differs from a Nance in that there is a U-shaped loop positioned directly over the palatal vault but without contact to the palatal mucosa. It is usually indicated in cases where there is unilateral loss of a primary second molar, and aims to prevent mesio-palatal rotation and mesial tipping of the first permanent molar (Kupietzky and Tal, 2007). However, when there is bilateral loss of primary second molars, using the TPA may result in both first permanent molars tipping mesially.

In summary, a variety of different fixed space maintaining appliances have been developed to suit specific space control situations. However, due to the limited application of some appliances and patient-related difficulties in their fabrication, certain appliances are less problematic and tend to be more commonly used than
Early primary tooth loss is not always an indication for space maintenance. The decision to treat or observe is determined after careful consideration of numerous factors:

- the location of tooth loss;
- time elapsed since tooth loss;
- dental age of the patient;
- amount of bone covering the unerupted tooth;
- development of the unerupted tooth;
- sequence of eruption;
- presence/absence of permanent successors;
- extent of dental crowding (Durward, 2000);
- oral habits.

If arch length deficiency is suspected, a thorough space analysis must be done to determine if a space maintainer is indicated. The most important factors from the above list are discussed in the section below.
2.5.1 Specific tooth lost

Space loss is greatest after loss of the second primary molar, followed by the canine, the first primary molar, and the incisor. The most severe consequences occur following the loss of the maxillary primary second molar as space loss in the maxilla occurs faster than in the mandible. (Hoffding and Kisling, 1978a; Kisling and Hoffding, 1979c; Ghafari, 1986; Durward, 2000; Northway, 2000)

2.5.2 Timing of tooth loss

As previously discussed, the earlier the age at which the primary tooth is lost, the greater the magnitude of space loss.

2.5.3 Time since tooth loss

Studies had found that the greatest amount of tooth displacement occurred within six months following the loss of teeth (Richardson, 1965; McDonald and Avery, 1994; Terlaje and Donly, 2001); in fact, a recent study by Macena et al. (2011) suggested that the greatest repercussion from premature loss of primary molars occurs within the first three months after extraction. Therefore, a space maintainer should be placed as soon as possible after the tooth loss. If greater than six months has elapsed and space loss has occurred, space analysis is required to determine if space regaining, space maintenance or no treatment is needed (Daly and Walker, 1990).
2.5.4 Dental age and amount of bone covering the unerupted tooth

There is a positive correlation between root formation and the initiation of active tooth eruption (Fanning, 1962; Gron, 1962; Moorrees et al., 1969). According to Gron (1962) and Moorrees (1969), canines emerge with about three-fourths of the root formed and premolars emerge with one-half to three-fourths of the root developed (Gron, 1962; Moorrees et al., 1969; Cheek et al., 2002). However, this eruption timing can be affected by the timing of the loss of its primary molar predecessor (Posen, 1965). The amount of bone covering the unerupted tooth is also helpful in determining the approximate time of eruption of its permanent successor. It has been estimated that a permanent tooth usually requires five to six months to move through one millimeter of bone (Pinkham, 1999).
2.5.5 **Sequence of eruption**

The most common eruption sequence in the human permanent dentition begins with the mandibular central incisors and mandibular first permanent molar and varies between arches as follows: (Proffit et al., 2007) (Figure 4)

\[
\begin{align*}
\text{Maxillary} & \quad 6 & 1 & 2 & 4 & 5 & 3 & 7 \\
\text{Mandibular} & \quad 6 & 1 & 2 & 3 & 4 & 5 & 7 
\end{align*}
\]

Figure 4: Schematic depiction of permanent teeth eruption sequence

If a mandibular primary second molar is lost and the mandibular second molar is erupting ahead of mandibular second premolar, then a space maintainer may be indicated to prevent space loss from the mesial movement of the mandibular first molars. Similarly, following the extraction of a primary first molar, if the permanent lateral incisor is actively erupting, its adjacent primary canine may be pushed distally, encroaching on the space needed for the permanent successor (Daly and Walker, 1990; Terlaje and Donly, 2001). Furthermore, space maintenance is warranted to hold space in cases where a delay in the eruption of permanent teeth into normal position is anticipated.
2.6 Survival analysis

Survival analysis allows one to “look at how long people are in one state followed by a discrete outcome...can handle situations in which the people enter the trial at different times and are followed for varying periods... allows us to compare two or more groups” (Norman and Streiner, 2000).

The reliability of a survival analysis depends on the size of the sample, the length of the study compared with median life, the proportion of data that is censored and the quality of information on censored data (Davies, 1987).

2.6.1 Outcome and survival of space maintaining appliances

To date, only a few studies have looked at the survival of space maintainers. Some looked at removable and fixed space maintainers together (Hill et al., 1975; Tulunoglu et al., 2005), some were prospective studies (Hill et al., 1975; Sasa et al., 2009), but most were done retrospectively (Baroni et al., 1994; Qudeimat and Fayle, 1998; Tulunoglu et al., 2005; Moore and Kennedy, 2006; Fathian et al., 2007). The reported failure rates of space maintainers ranged from 28 percent to 63 percent with a median survival of seven to 27 months (Baroni et al., 1994; Qudeimat and Fayle, 1998; Tulunoglu et al., 2005; Moore and Kennedy, 2006; Fathian et al., 2007; Sasa et al., 2009).
Baroni et al. (1994) evaluated the survival of space maintainers inserted in the pediatric dentistry department of a dental school from 1986 to 1991. All of the space maintainers were inserted by faculty members and cemented using polycarboxylate cements. Eighty-eight space maintainers (36 lingual arches, 33 band and loops and 19 Nance appliances) were placed either on first permanent molars or second primary molars. Patients were five to nine years old and were followed for a maximum of 53 months. The overall rate of failure was 30.5 percent with Nance appliances surviving the longest and lingual arches, the shortest. Cement loss and solder breakage were the top two causes of failures. Frequency of failures did not differ among appliances cemented on permanent or primary molars. The authors attributed the failures to mechanical stress in long-term spacer use. They recommended changing the appliance as the patient grew if the space maintainers were needed for the long term (up to seven or eight years). Many contributing variables and median survival times were not recorded.

Qudeimat and Fayle, in a retrospective study on space maintainers (n=301) that were fitted in a UK dental school found that the majority of their space maintainers failed (n=190, 63 percent) (Qudeimat and Fayle, 1998). Failure was defined as those that were “lost or removed due to inadequate pretreatment diagnosis, poor design, faulty construction, failure of cementation, failure due to
caries, abutment pathology, poor follow-up care or poor patient cooperation or attendance” (Qudeimat and Fayle, 1998). The reasons for failure were cement loss (36 percent), breakage (24 percent), design problems (10 percent) and “lost” (9 percent). The type of space maintainers that were under investigation included removable partial denture (n=82, 31 percent), band and loops (n=81, 27 percent), lower lingual holding arch (n=71, 24 percent), Nance appliance (n=30, 10 percent), fixed partial denture (n=20, 7 percent), distal shoe (n=6, 2 percent), and crown and loop (n=1, 0.3 percent). The age range of patients was 3.4 to 22.1 years (mean 8.8, SD = 13.3). The majority of the appliances were inserted by students (83 percent), whereas the rest were inserted by staff or not recorded. In terms of appliance survival, the median survival time (MST) was found to be seven months. Band and loops had the highest MST (13 months); lingual arches had the lowest MST (four months). Unilateral space maintainers lasted longer than bilateral space maintainers (MST of 13 months vs. 5 months). No differences in survival time were reported among gender, age, arch, operator, fixed versus removable or adequacy of pretreatment assessment on survival time. The high failure rate and low MST makes one question “should space maintainers be placed at all?” The high failure rate might have been influenced by how “failure” was defined for this study. As seen above, it is questionable whether failure due to poor patient cooperation or attendance would be a fair reason for appliance failure. The type of cement that was used was not reported. There was a large distribution of subjects by age and a variety of appliances (removable, fixed, fixed with intra-alveolar component). Given the large
variability between subjects and appliances, a larger sample would be needed to
discern if there were indeed any differences in the survival of the space
maintainers.

Rajab et al. reported a median survival time of 18 months for maxillary Nance
appliances and 14 months for mandibular lingual arches (Rajab, 2002).
Teaching staff placed 387 passive fixed and removable partial space maintainers
(bands and loops, lingual arches, Nance and removable partial dentures) in 358
patients aged three to nine years over a five-year period. Thirty-two out of 387
appliances (8 percent) were removable appliances. Lingual arches and Nance
appliances were all fitted on first permanent molars. The overall percentage of
failure was 30.7 percent. Again, the Nance appliances (n=69) had the longest
median survival time (24 months), while lingual arches (n=115) had the shortest
survival time (14 months). Survival of band and loops (n=171) was somewhat in
between (20 months). Space maintainers fitted on maxillary teeth had a slightly
longer survival time than those on mandibular teeth, but this difference was not
statistically significant. The authors attributed the difference to mechanical stress
and difficulties in maintaining a dry field during cementation of mandibular
appliances. Moreover, they did not find any significant difference based on
gender, age, type of dentition, year of placement of the appliance, and number of
space maintainers fitted simultaneously in the same patient. This finding
suggested that appliance factors seemed to be more important than patient
factors in the survival of space maintainers. For this study, breakage of solder joints (50 percent) was ranked as the most common cause of failure; it was most commonly found in lingual arches, followed by band and loops. The second most commonly recorded cause of space maintainer failure was cement loss (33 percent). One operator was involved in the diagnosis and insertion of the appliances and the same lab technician fabricated the space maintainers. A breakdown of the subjects by age was not reported. Almost half of the appliances were band and loops. It was unclear from the study method how those subjects were selected and whether all patients who received a space maintainer from that particular dentist during the study period were included in the study. Since removable retainers do not manifest the same mode of failure as fixed space retainers (i.e., cementation is not required for removable space maintainers), the results obtained from these types of appliances should not be pooled together.

Tulunoglu et al. evaluated the median survival time of fixed and removable space maintainers (Tulunoglu et al., 2005). This retrospective study included 633 patients (with 654 appliances) aged between four and 15 years old. The space maintainers were placed by senior dental students. Over half of the space maintainers were lost at follow-up, 13 percent failed, 32 percent were successful while three percent were still in use at the end of the study. The overall median survival time was 6.51 months. Most commonly, failures occurred at the
soldered joints. The second most common cause of failure was tissue irritation from space maintainers. This study found no statistically significant difference between the median survival time values of different space maintainer types, age groups or gender types. Therefore, the authors suggested that appliance construction and cementation might be more important than the aforementioned factors. Despite the large sample size, the high number of drop-outs (53 percent) and low percentage of fixed space maintainers (32 percent, n= 207) made it difficult to make an accurate statement about the survival of fixed space maintainers. The median survival time was disturbingly low; one may attribute that to the “dental student factor”.

Moore and Kennedy (2006) reviewed 482 bilateral fixed space maintainers placed by orthodontists in a private practice between January 1, 1996 and December 31, 2003. The average patient age at appliance insertion was 10.9 years. The space maintainers were used for orthodontic reasons: either to retain the leeway space or used in conjunction with premolar serial extractions in the mixed dentition. The appliance was considered successful if it was still in use at the time of chart review or it was deemed clinically successful by the clinician. A 72 percent success rate was reported. The main cause of failure was cement loss (60 percent). No statistical differences were noted between survival and type of appliances. The mean pooled survival times were 20 months for lingual arches and 23 months for Nance appliances. Thirty-nine percent of the failed
appliances were not recemented or remade. When inserted in patients in the late-mixed dentition stage, the appliances were expected to last between 15 to 30 months, since by 12 years of age second molars would have erupted and phase II orthodontics could commence. A lingual arch that lasts 20 months and a Nance appliance that survives 23 months will suffice in serving their purposes.

Fathian et al. (2007), in a similarly designed project, studied the survival of space maintainers placed by pediatric dentists in the same private practice between January 1, 1997, and December 31, 2003. The mean age at insertion for band and loops was six years and for bilateral appliances was eight years. Thirty-two percent of the appliances failed. The most common cause was cement loss (60 percent). No statistically significant differences were found based on types of appliances, gender of subject, and types of failures. Interesting to note was that band and loops exhibited more cement loss than other appliances. The mean pooled survival times were between 26 and 27 months, longer than Moore’s study. Two-thirds of failed appliances were recemented or remade.

Sasa et al. (2009) conducted a prospective study on the longevity of band and loop space maintainers luted with glass ionomer cement. Forty children aged 3.4 to 7.3 years (mean age 5 year 5 months) each received one band and loop space maintainer. The same pediatric dentist carried out all diagnosis, band selection, impression taking and appliance cementation using GI cement
(Ketac™-Cem-Maxicap)™. Forty percent of the band and loop space maintainers were successful during the study period; 82 percent of failures were due to cement loss. The overall median survival time was 19.9 months. Failure due to solder breakage was relatively low (nine percent). Of interest, the B&Ls fitted on the left side lasted significantly longer than those fitted in the right side. The authors attributed the observed difference to the handedness of the operator and mastication preference of the child. Again, low sample size and availability of data on confounding variables limits conclusions from this study.

Tunc et al. (2012) have recently published a prospective study on the survival of three different types of fixed space maintainers – laboratory fabricated band and loop (B&Ls), direct bonded (DB) and fiber-reinforced composite (FRC). A total of 30 four to ten year olds (mean age = 6.9 years) were selected if they had premature loss of a primary molar due to caries and/or failed pulp therapy, had teeth present mesial and distal to extraction site and in Angle class I occlusion and normal primary molar relation. These patients were randomly assigned to receive one of three types of fixed space maintainers. Patients were recalled once every three months for one year or until appliance failure. Laboratory fabricated B&Ls demonstrated the longest survival (11.20 months) at the one-year follow-up. One year after appliance insertion, 90 percent of laboratory fabricated B&Ls survived, compared to 40 percent of DBs and 20 percent of FRCs. Age, patient gender, dental arch and side of the jaw were not significantly
related with appliance success (P>0.05). Despite the small sample size, a statistically significant difference in survival was found among appliance types.

Overall, previous studies have not demonstrated a statistically significant difference in appliance success by appliance type or patient gender (Moore and Kennedy, 2006; Fathian et al., 2007). With respect to appliance survival, some studies (Baroni et al., 1994; Qudeimat and Fayle, 1998; Rajab, 2002; Moore and Kennedy, 2006) found a statistically significant relationship between appliance type and survival; others (Tulunoglu et al., 2005; Fathian et al., 2007) did not. Regarding appliance survival in relation to dental arch (maxillary versus mandibular), patient age, gender and operator seniority, no significant differences were found in majority of the studies (Qudeimat and Fayle, 1998; Tulunoglu et al., 2005; Sasa et al., 2009). In contrast, the research done by Baroni et al. and Moore and Kennedy (Baroni et al., 1994; Moore and Kennedy, 2006) suggested that maxillary appliances survived longer in the mouth than mandibular appliances.

This lack of association indicates two possibilities: there was truly no statistically significant difference between success and survival when either appliance or patient factors were considered; or there was insufficient power to show such a difference statistically. The variability in the results on the appliance outcome and survival may simply be a reflection of the differences in study designs and
differences in cementation techniques, but may also stem from having an inadequate power.

2.6.2 Factors affecting accuracy of a survival analysis

Factors that affect the reliability of results obtained from survival analysis include the sample size, the length of the study compared with the median life of the appliances, the proportion of data that is censored and the quality of information on the censored data (Cutler and Ederer, 1958; Mathoulin-Pelissier et al., 2008). If a true difference in appliance survival exists, then a large sample size makes it more possible to demonstrate such a difference, even when it is small. The length of the study has to be longer than the median life of the appliances; otherwise, the survival analysis has to rely heavily on censoring. A survival analysis with a large proportion of censored data will overestimate the survival of the appliances.

2.7 Factors associated with space maintainer survival

Operator factors (students versus experienced dentists), patient factors (age and gender) and appliance types have been studied for their effects on survival time. Qudeimat et al. found no association between operator and patient factors with survival time. Rajab et al. did not observe any significant effect of gender, age,
type of dentition, year of appliance placement and number of appliances placed in the same patient on survival of space maintainers. Again, the study by Tulunoglu et al. did not see statistically significant effects of gender, age, location of appliance and the type of the space maintainer on appliance longevity. Finally, another study that investigated the survival of maxillary expansion appliances also did not see an association between the child’s gender, treatment compliance, presence of unilateral posterior crossbite, caries risk, oral hygiene, appointment-keeping and cement type (Beebe et al., 2008).

Many of the above-mentioned factors (age, gender, caries risk, type of appliances) cannot be changed. For example, the choice of appliances is mainly based on the presenting case – the appliance is chosen because of particular patient needs, not because one appliance would last longer than another. Some factors, however, can be modified: the type of cement, quality of the appliances (solder joint, gauge of wire) and fit of the appliances. Appliance quality is controlled by the laboratory. The factors that can be controlled by clinicians are the type of cement used, methods of insertion and the fit of the bands to the tooth.

2.7.1 Cement loss: a factor in space maintainer failure

As discussed previously, factors that have been identified to be related to space maintainer failure are: cement loss, solder breakage, split bands, eruption
interference, soft tissue pathology and loss of the appliance. Although some studies have identified solder joint breakage as a common cause of failure (Baroni et al., 1994; Rajab, 2002; Tulunoglu et al., 2005), cement loss is the most commonly reported cause of space maintainer failures (Baroni et al., 1994; Qudeimat and Fayle, 1998; Tulunoglu et al., 2005; Moore and Kennedy, 2006; Fathian et al., 2007; Sasa et al., 2009). Moore et al. had pointed out that cement loss is most likely due to poor band fit (Moore and Kennedy, 2006).

2.7.2 Types of dental luting cements used for space maintainers

Today’s dentist has a great selection of luting agents from which to choose. These range from water-based luting agents (zinc phosphate, zinc polycarboxylate, glass ionomer, or reinforced zinc oxide-eugenol) or a resin system with or without an adhesive (Rosenstiel et al., 1998).

Glass ionomer luting cement (GIC) is a popular choice among clinicians for band cementation (Dincer and Erdinc, 2002). There are three main types of glass ionomer cements: resin-modified glass ionomer cement, a modified composite or a conventional glass ionomer cement. Glass ionomer has the following properties: adherence to enamel and metal, release and uptake of fluoride and inhibition of microbial activity (Rosenstiel et al., 1998). GICs are, however, susceptible to moisture contamination during the setting reaction (Rosenstiel et
Some researchers advocated leaving a band of excess glass ionomer cement for ten minutes after crown cementation to prevent significant erosion in a wet field (Curtis et al., 1993). Resin-modified GICs (RMGICs) are a hybrid of their resin composite and glass ionomer parent groups and often have a tri-cure mechanism setting: an acid-base reaction, a light-cured polymerization reaction and a self-cure polymerization reaction. The modified composites are fundamentally a resin-matrix composite that has some glass ionomer filler particles. Setting is via free radical polymerization and an acid-base reaction is not involved.

An in-vitro study done by Millett, et al. found a significant difference between cement groups in how bonding fails. Bond failure for bands cemented with conventional GIC, RMGIC or the modified composite was mainly at the enamel/cement interface. The mean survival time of bands cemented with either the RMGICs or with the modified composite was significantly longer than for those cemented with conventional GIC (Millett et al., 2003). However, in a recent Cochrane review regarding adhesives used for fixed orthodontic bands to molar teeth, no conclusion could be drawn about what was the most effective adhesive for attaching orthodontic bands to molar teeth (Millett et al., 2007).
3 Rationale

Several review articles have discussed the “pros and cons” of space maintainers (Daly and Walker, 1990; Brothwell, 1997; Ngan et al., 1999; Durward, 2000; Terlaje and Donly, 2001; Bijoor and Kohli, 2005; Choonara, 2005). A recent review article written by Laing et al. found it difficult to recommend either for or against the use of space maintainers, based on the quality of evidence available (Laing et al., 2009). They further concluded that practitioners should prescribe space maintainers on an individual needs basis, weighing the pros and cons of their use. Investigators hope that this research will enhance our knowledge of space maintainer survival and help identify factors that may improve survival of space maintainers.
4 Hypotheses

1. There are no significant differences in the success of fixed space maintainers related to patient, appliance or provider factors.

2. There are no significant differences in the survival of fixed space maintainers related to patient, appliance or provider factors.
5 Methods

A retrospective chart review was conducted to address the research question. Similar to the methods of Moore and Kennedy (2006) and Fathian et al. (2007), data was collected from patient records of a private pediatric-orthodontic group practice in Vancouver, Canada.

Ethical approval for this research study was obtained from The University of British Columbia’s Clinical Research Ethics Board and University of North Carolina Institutional Review Board for the provision of statistical support.

5.1 Collection of data

5.1.1 Sample size

As previously mentioned in Section 2.6.2, the lack of a statistically significant difference may be a mere reflection of insufficient power in the study. Therefore, in order to detect any true differences that were not evident in previous studies, a large enough sample is required. A power calculation may be done if the variables are continuous. Since length of treatment is the only continuous variable in this study and the remaining variables are categorical, a power calculation is not beneficial. Since the sample sizes from previous studies ranged from 40 to 482 (Baroni et al., 1994; Moore and Kennedy, 2006; Fathian et al., 2007; Sasa et al., 2009), a sample size of 1000 fixed space maintainers was arbitrarily selected as it is substantially larger than any reported in previous
studies. By reviewing all lab prescriptions issued from January 1, 2000 to December 31, 2003, it was determined that a sample size of about 1000 would be achieved.

5.1.2 Study duration and follow-up period

Previous studies have found the MST for successful space maintainers to be in the range of seven months (Qudeimat and Fayle, 1998; Rajab, 2002; Tulunoglu et al., 2005) to 27 months (Fathian et al., 2007). Since reliability of a survival analysis hinges on the length of the study compared with MST (Davies, 1987), a long follow-up time is desirable. An end point on July 31, 2011 was more than adequate to allow one to observe the outcome of every single space maintainer inserted prior to December 31, 2003.

Potential subjects (n=1218) were identified by reviewing lab prescriptions for all space maintainers placed between January 1, 2000 and December 31, 2003. Charts were hand-searched and reviewed to confirm that the appliance met the selection criteria (Section 5.1.4). If not, the appliance was excluded from the study. With much effort, all but 59 charts were located.
5.1.3 Inclusion criteria

All included subjects were patients of record of one of four dental specialists (two pediatric and two orthodontic specialists) at three of the practice sites. Each subject had received at least one fixed space maintainer (a band and loop, Nance or lingual holding arch) from year 2000 to 2003 and had a complete chart record available.
5.1.4 Exclusion criteria

If the subject also had an active appliance (e.g. headgear or edgewise appliances) during the use of the space maintainer, the subject was excluded. No distal shoe appliances were studied due to the additional problems associated with this type of appliance. Because of its cantilever design into soft tissues, the distal shoe is more fragile (Pinkham, 1999) than a B&L, and hence more prone to failures.

5.1.5 Subject information

Subject birthdate, appliance insertion and removal dates, recementation or repair dates were recorded. Indications for the space maintainer were also documented. When an appliance failed and was still needed, it was either recemented, repaired or remade. When failure occurred, the recemented appliance was considered a new appliance. As such, the entry was noted as repair, recemented or new. When the appliance was intact but was loose, it was recemented with minimal modification to the existing appliance. A repair was ordered when the appliance could not be fitted/cemented without laboratory involvement. When the appliance was beyond repair or lost completely, a new impression was taken and a new appliance was made. For any of the three scenarios (recement, repair, remake), the appliance re-entered the study as a new entry. In addition, dentist, office site and type of cement were noted.
Patient factors, if charted, such as oral hygiene status, caries risk as well as patient cooperation at the time of appliance insertion, were noted if available.

Caries was assessed by the number of carious lesions documented in the previous 12 months prior to the time of appliance insertion. High caries risk was defined as ‘more than one’ new carious lesion, medium risk as ‘one’ new carious lesion, and low risk as ‘no’ new lesions within the past 12 months. By customary practice, the certified dental assistant would assess each patient’s oral hygiene using a score based on percentage of plaque that was present. However, some gave a ‘letter’ grade while others gave a ‘percentage’ grade. Therefore, an arbitrary OH score of “good”, “fair” or “poor” was assigned based on this percentage or letter grade (Table 1).

Table 1: Oral hygiene score

<table>
<thead>
<tr>
<th>OH score</th>
<th>Ability to keep teeth clean</th>
<th>Letter Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good</td>
<td>80-100</td>
<td>A, B</td>
</tr>
<tr>
<td>Fair</td>
<td>60-80</td>
<td>C</td>
</tr>
<tr>
<td>Poor</td>
<td>&lt;60</td>
<td>D, F</td>
</tr>
</tbody>
</table>

All information was de-identified and entered into a database using Excel (Microsoft Corp, Redmond, Wash).
5.1.6  **Definition of a success**

An appliance was deemed successful if it was in the mouth at the time of chart review or if it was removed by the orthodontist or pediatric dentist after serving its purpose. In other words, the appliance was without identifiable problem before the eruption of permanent teeth (Pediatric) or before the patient was ready to move from phase I treatment to phase II treatment (Orthodontic).

5.1.7  **Definition of a failure**

An appliance was deemed a ‘failure’ if it was removed before its serviceable lifetime due to cement loss, solder breakage, split bands, eruption interference, bent wire, development of soft tissue problems, complete loss of appliance, inappropriate use by the patient, or for reasons not specified. An appliance was also judged a failure but the decision was made not to recement or remake the appliance if it came out or was removed prior to the planned “end-date”.

5.1.8  **Appliance end-point**

In order to have a well-defined outcome e.g. eliminate errors from recall or reporting from parents, the decision was made to use the last documented date (chart record or radiograph) that the appliance was in the mouth to indicate appliance “end-date” if failure was not witnessed by the dental staff.
5.2 Fabrication and insertion of space maintainers

Space maintainers were fabricated in the following manner. If necessary, the first visit involved placement of separators to enhance band fitting between the tooth to be banded and adjacent teeth. In the second visit, the separators were removed, bands were fitted and an alginate impression was taken and separators were replaced after band fitting by an orthodontic module certified dental assistant. The space maintainers were then fabricated in the same in-house orthodontic laboratory by technicians using 0.9mm round stainless steel wire soldered to the lingual side of the molar bands. Prior to insertion, the separators were removed, the tooth was polished, the appliance was trial fitted and cemented by the dentist. Depending on the dentist involved, one of three types of glass ionomer cement was used (Fuji II, GC America, Alsip, IL; Ketac Cement Espe, Seefeld, Germany, and Band-Lok, Reliance Orthodontic Products Inc., Itasca, IL, USA). When inserted by an orthodontist, the interior of all bands was micro-etched with aluminum oxide prior to cementation.

5.3 Follow-up visits after space maintainer insertion

In general, patients were examined every six to nine months to clinically assess the appliance for integrity and evidence of cementation failure.
5.4 Statistical methods

5.4.1 Test of independence

Because multiple space maintainers were placed in 22 percent of the subjects, there was concern about considering space maintainers as independent sample units within the same subject. However, because the covariation of the responses in that subset of children approximated zero (0.03), it was confirmed that the logistic regression analysis and all other analyses could be done using “space maintainer” as the unit of analysis.

5.4.2 Survival analysis

Survival analysis was used in this study to assess the durability of space maintainers. There are different methods to summarize the data obtained for a survival analysis. One way is to look at only those subjects for whom we have complete data since we know their exact outcome. For this method, mean survival is used to represent the survival of the group. Another method is the use of “survival rate” to determine what proportion of appliances survive after a cut-off date. These methods assume a constant risk over time. Alternatively, the life-table (survival) technique, using either the actuarial approach or the Kaplan-Meier approach, makes use of the censoring technique. Kaplan-Meier test is a
statistical model used to estimate the length of time taken to reach a certain endpoint, such as appliance failure. Censoring is a key analytical problem in survival analyses and refers to situations where the exact survival time is not known due to insufficient information (Norman and Streiner, 2008).

The median survival time (MST) is defined as the time between a predefined starting event and a terminal event – when the space maintainer is no longer present in the mouth (be it removed by the clinician in the successful group or lost due to appliance failure in the failure group). In our study, median survival referred to the time for one-half of the appliances to survive. Therefore, by definition, half the appliances survived longer than the median survival. It was calculated as the shortest survival time for which the survivor function is less than or equal to 0.5 (Norman and Streiner, 2008).

The comparison between the different types of space maintainers was done using the Mantel-Cox Log-Rank Test (Log-rank test), a nonparametric test designed to compare the observed number of events with the number expected, under the assumption that the null hypothesis of no group differences is true (Norman and Streiner, 2000).
This study followed subjects and reported up to the actual end point of the space maintainers (appliance insertion between January 1, 2000 and December 31, 2003; chart review completed in June 2011). Therefore, at the time of chart review, the exact time of appliance outcome was available, with the exception of those that were lost to follow-up. To clarify the difference between success and failure, the dataset was divided into two sub-datasets: success dataset (N=564) and failure dataset (N=322); to estimate median time of wear for successes and failures Kaplan-Meier test was used; and to compare the times among the four types of space maintainers within each outcome category the Mantel-Cox Log-rank (Log-rank) test was used.
6 Results

![Diagram showing the results overview]

Figure 6: Overview of results

6.1 Subject and appliance information (Table 2)

There were 692 subjects in the data set (Table 2). Five hundred and thirty-nine subjects had only one space maintainer and 153 subjects had more than one. After excluding appliances with active components, insufficient information or loss to follow-up from the original sample of 1218 appliances, a final sample of 886 appliances was obtained. Bilateral appliances were most common.
Table 2: Distribution of appliances, age at insertion and gender of study subjects, n=692

<table>
<thead>
<tr>
<th>Appliance</th>
<th>Age at insertion, years Mean (SD)</th>
<th>Gender n (%)</th>
<th>Subjects with specific appliance n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>M</td>
<td>F</td>
</tr>
<tr>
<td>Md. lingual arch</td>
<td>10 (2)</td>
<td>168 (48)</td>
<td>182 (52)</td>
</tr>
<tr>
<td>Nance</td>
<td>10 (2)</td>
<td>110 (50)</td>
<td>109 (50)</td>
</tr>
<tr>
<td>Maxillary B&amp;L</td>
<td>7 (2)</td>
<td>24 (38)</td>
<td>39 (62)</td>
</tr>
<tr>
<td>Mandibular B&amp;L</td>
<td>7 (2)</td>
<td>36 (62)</td>
<td>22 (38)</td>
</tr>
<tr>
<td>All</td>
<td>9 (2)</td>
<td>338 (49)</td>
<td>352 (51)</td>
</tr>
</tbody>
</table>

Those patients who received bilateral appliances were on average three years older than those who received the unilateral appliances (Table 2). In the group with bilateral appliances, both genders were equally represented.

Lingual arch was the most commonly prescribed space maintainer (51 percent), followed by Nance appliance (32 percent). Only a small percentage of subjects had laboratory fabricated B&Ls (17 percent). The majority of bilateral space maintainers (99 percent) were retained by bands on permanent first molars; only one percent of bilateral appliances were retained on primary second molars.
6.2 Explanatory variables

The purpose of the research study was to investigate the association between appliance, patient and provider factors and survival of space maintainers. The explanatory variables selected for multivariate analysis included type of appliance, age at insertion, gender, specialty/indication for treatment, caries status, and type of cement (Table 3). The relationship between these variables and appliance success was examined using logistic regression analysis. Oral hygiene and patient cooperation at the time of appliance insertion were noted when available; however, no analysis was possible because of the large amount of missing information.
Table 3: Descriptive statistics for explanatory variables: Freq (Valid Pct) for categorical variables and Mean(SD) for continuous variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total subjects (n=692)</th>
<th>Appliance Type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>LHA (n=352)</td>
</tr>
<tr>
<td>Specialty</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orthodontic</td>
<td>322 (47%)</td>
<td>188 (53%)</td>
</tr>
<tr>
<td>Pediatric</td>
<td>370 (53%)</td>
<td>164 (47%)</td>
</tr>
<tr>
<td>Caries risk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>207 (30%)</td>
<td>115 (33%)</td>
</tr>
<tr>
<td>Medium</td>
<td>108 (16%)</td>
<td>70 (20%)</td>
</tr>
<tr>
<td>High</td>
<td>319 (46%)</td>
<td>133 (38%)</td>
</tr>
<tr>
<td>Cement Type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ketac</td>
<td>354 (51%)</td>
<td>159 (45%)</td>
</tr>
<tr>
<td>Band-Lok</td>
<td>187 (27%)</td>
<td>114 (32%)</td>
</tr>
<tr>
<td>Fuji II</td>
<td>117 (17%)</td>
<td>63 (18%)</td>
</tr>
<tr>
<td>Indications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leeway space management</td>
<td>336 (49%)</td>
<td>196 (56%)</td>
</tr>
<tr>
<td>Prevent space loss</td>
<td>353 (51%)</td>
<td>154 (44%)</td>
</tr>
<tr>
<td>Age @ insertion, years</td>
<td>9.3 (2.2)</td>
<td>9.8 (2.0)</td>
</tr>
<tr>
<td>Age @ end of treatment, years</td>
<td>11.4 (2.4)</td>
<td>11.8 (2.2)</td>
</tr>
<tr>
<td>Median survival time (MST), months</td>
<td>25 (15)</td>
<td>24 (14)</td>
</tr>
</tbody>
</table>
6.2.1 Appliance type and specialty

Patients from orthodontist and pediatric dentists were equally represented (Table 3). Bilateral appliances were the most common type of space maintainers for both specialties.

6.2.2 Caries risk

Almost half of the subjects who received laboratory space maintainers were deemed high caries risk (Table 3). The majority of the subjects in the unilateral group (B&Ls) were at high risk of developing dental caries, whereas the majority of the subjects in the bilateral group were low-medium risk of developing caries.

6.2.3 Type of cement

Three types of glass ionomer cement were used as luting agents for the appliances, and their use was “dentist-specific” (Fuji II, GC America, Alsip, Ill; Ketac Cement Espe, Seefeld, Germany, and Band-Lok, Reliance Orthodontic Products Inc., Itasca, IL, USA). Fuji II is a resin modified glass ionomer; Ketac Cement is a traditional glass ionomer and Band-Lok is a polyacid-modified composite (Aguiar et al., 2013). Pediatric dentists in this group practice consistently used Ketac Cement for their band cementation, but the orthodontists used Band-Lok or Fuji II. Almost half of the subjects had their space maintainers cemented with Ketac.
6.2.4 Rationale for space maintainer use

The rationale for space maintainer use fell into two broad categories. The first was preservation of leeway space and arch length in management of dental crowding or space preservation for future prosthetic replacement in cases where secondary teeth are absent (i.e., an "orthodontic" rationale). The second one was for the prevention of space loss usually as a result of untimely loss of a tooth due to advanced caries (i.e., a "pediatric" rationale). Forty-nine percent of subjects had space maintainers for “orthodontic management” and the remainder for “pediatric management”.

Of the orthodontic group, the majority (97 percent) had bilateral space maintainers; only three percent (n=2) had lower B&L. These two subjects had congenitally missing mandibular premolars; hence, B&Ls were placed in preparation for future prosthetic placement (Table 3).
6.3 Outcomes

The distribution of the 886 appliances in the study by type of appliance is presented in Table 4.

Table 4: Outcomes for all space maintainers (n=886)

<table>
<thead>
<tr>
<th></th>
<th>Placed</th>
<th>Success</th>
<th>Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Md lingual arch</td>
<td>460 (52%)</td>
<td>282 (61%)</td>
<td>178 (39%)</td>
</tr>
<tr>
<td>Nance</td>
<td>253 (29%)</td>
<td>176 (70%)</td>
<td>77 (30%)</td>
</tr>
<tr>
<td>Md B&amp;L</td>
<td>82 (9%)</td>
<td>44 (54%)</td>
<td>38 (46%)</td>
</tr>
<tr>
<td>Mx B&amp;L</td>
<td>91 (10%)</td>
<td>62 (68%)</td>
<td>29 (32%)</td>
</tr>
<tr>
<td>Total</td>
<td>886 (100%)</td>
<td>564 (64%)</td>
<td>322 (36%)</td>
</tr>
</tbody>
</table>

Sixty-four percent of all space maintainers were successful. The Nance was most likely to be successful (70 percent), followed by maxillary band and loops (68 percent), and mandibular lingual arch (61 percent). Mandibular band and loops were least successful (54 percent). Of the 322 space maintainers that failed, the “fate” of the appliances was documented for 269 appliances: 83 appliances were no longer needed, 135 were recemented, and 51 were remade.
6.4 Explanatory variables and outcomes (Table 5 and 6)

Explanatory variables, such as cement type, practice site, practitioner of record, caries risk and specialty type were all analyzed, but only the age at insertion, gender and specialty type were found to have a relationship to appliance outcome that was significant or approached significance. After controlling for the effect of all explanatory variables, analysis demonstrated that the age and gender of the patient were significantly related to success (Table 5).

Table 5: Logistic regression: likelihood of appliance success explained by demographic variables (n=886); * p<0.05

<table>
<thead>
<tr>
<th></th>
<th>OR</th>
<th>95% CI lower limit</th>
<th>95% CI upper limit</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age @ insertion</td>
<td>1.6</td>
<td>1.4</td>
<td>1.9</td>
<td>&lt;0.0001 *</td>
</tr>
<tr>
<td>Gender (F:M)</td>
<td>1.7</td>
<td>1.1</td>
<td>2.3</td>
<td>0.003 *</td>
</tr>
<tr>
<td>Pediatric Dentist vs. Orthodontist</td>
<td>0.6</td>
<td>0.4</td>
<td>1.0</td>
<td>0.07</td>
</tr>
</tbody>
</table>

The likelihood of success increased 1.6 times for each one-year increase in the child’s age at insertion. Females were 1.7 times more likely to have a successful outcome than males. The type of specialty care was not significantly associated with success (Table 5), but the association approached significance, p = 0.07.
Pairwise comparisons of appliance success by appliance types were done. Those comparisons with clinical meaning are listed in Table 6. A band and loop appliance (B&L) placed in the lower arch was three times more likely to be successful than a lingual holding arch (Table 6). A B&L appliance placed in the maxilla was 6.1 times more likely to succeed than a Nance appliance. Therefore, when all explanatory factors were considered, unilateral space maintainers were more successful than bilateral space maintainers placed in the same arch. Unilateral space maintainers demonstrated a statistically significant difference in outcome between arches, with maxillary B&L exhibiting higher success rates. By contrast, a relationship between "arch of placement" and appliance success was not observed for Nance and LLHA.
6.5 Survival analysis

6.5.1 Successful group

Sixty-four percent of all space maintaining appliances succeeded based on the Kaplan-Meier analysis. The overall median survival time (MST) to success was 25.4 months [95 percent Confidence Interval (CI): 24.1-26.8].

The Log-rank test was used to compare the MST among the types of space maintainers. Successful mandibular B&Ls had the highest median survival time: 38 months (Table 7 and Figure 7). Nance and lingual arches behaved similarly to each other; both survived just over two years. Maxillary B&Ls had the lowest survival time, 22 months. The survival time was found to be significantly different among the types of appliances (p=0.001). The lengthy mean survival time of mandibular B&Ls compared to the other appliances was likely the “factor” that explained the significant difference in median survival time amongst the appliances (Figure 7).
Table 7: Log-rank test for median time to success (MST) between space maintainers (n=564) (* p=0.0012; ** Confidence interval)

<table>
<thead>
<tr>
<th>Appliance</th>
<th>Time to Success (months)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MST (95% CI**)</td>
</tr>
<tr>
<td>Lingual Arch</td>
<td>24.6 (23.3-26.7)</td>
</tr>
<tr>
<td>Nance</td>
<td>26.0 (24.3-29.4)</td>
</tr>
<tr>
<td>Band &amp; Loop Upper</td>
<td>22.0 (15.5-24.0)</td>
</tr>
<tr>
<td>Band &amp; Loop Lower</td>
<td>38.3 (28.9-43.4)</td>
</tr>
</tbody>
</table>

Figure 7: Survival analysis for successful appliances by type (Median Survival Time in months) n=564
6.5.2 Failure group

In the “failure” group, the MST to failure was 13.2 months (95 percent CI: 11.4-14.8). Mandibular B&Ls failed in nine months, the other three appliances failed at 12 to 14 months (Table 8). Failure times were not statistically different (p=0.24) (Figure 8).

Table 8: Survival analysis: Log Rank Test for Time to Failure for different space maintainers (n=322) (* p = 0.2407; CI: Confidence Interval)

<table>
<thead>
<tr>
<th>Appliance</th>
<th>Time to Failure (months)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median (95% CI)</td>
</tr>
<tr>
<td>Lingual Arch</td>
<td>14.2 (11.2 - 16.4)</td>
</tr>
<tr>
<td>Nance</td>
<td>12.6 (10.7 - 17.7)</td>
</tr>
<tr>
<td>Band &amp; Loop Upper</td>
<td>13.4 (8.7 - 15.2)</td>
</tr>
<tr>
<td>Band &amp; Loop Lower</td>
<td>8.9 (6.3 - 12.8)</td>
</tr>
</tbody>
</table>
6.6 Reason for appliance failure

Cement loss was the most common cause of failure (39 percent). Other causes of failures included solder breakage, band split, eruption interference, soft tissue lesions, complete loss, inappropriate use and reasons not specified.
7 Discussion

In summary, 64 percent of all space maintainers were successful. Success was related to the age at insertion, gender of the patient and type of space maintainer. A better outcome could be expected when the appliance was placed in an older child. A space maintainer placed in a girl had a better chance of success than in a boy of the same age. Unilateral appliances had better success than bilateral appliances in the same arch and maxillary B&Ls were more likely to succeed than mandibular B&Ls (Table 6). The main reason for failure was cement loss.

In the successful group, the median survival time was significantly related to the type of appliance, which was in turn related to the clinical need for that particular appliance. Mandibular B&Ls had the longest MST (38 months), followed by Nance and LLHAs and maxillary B&Ls (22-26 months). However, in the failure group, no differences in MST were found between different appliances.

7.1 Outcomes

Few clinical procedures in dentistry are 100 percent successful. It has previously been reported that 10-58 percent of fixed laboratory space maintainers failed; that is they did not survive the time required for clinical success (Baroni et al., 1994; Moore and Kennedy, 2006; Fathian et al., 2007; Sasa et al., 2009; Tunc et al., 2012). In our study, 36 percent of the space maintainers failed, a proportion
that fell within the previously reported range of failures. At one year follow-up, a failure rate of ten percent was reported by Tunc et al. (2012). At the other extreme, over a 40-month follow-up of 30 patients treated in a hospital-dental center, a failure rate of 58 percent in B&Ls was reported (Sasa et al., 2009). These appliances were all inserted by the same clinician. Authors attributed the high failure to the young mean subject age, of five year five months. In our study, the failure rate was slightly higher than the 28 percent reported by Moore and Kennedy (2006) and the 31 percent reported by Baroni et al. (1994). However, the study by Moore and Kennedy exclusively examined space maintainers from an orthodontic practice, where typically patients are older, more compliant and motivated to follow instructions – i.e., wanting to have a better ‘smile’. Baroni et al. (1994) followed patients for a shorter amount of time (mean = 24 months SD = 13 months); polycarboxylate cement was used as the band luting agent. The failure rate of the present study closely approximated the 32 percent reported by Fathian et al. (2007). This is not surprising as the samples for our study and that of Fathian et al. (2007) were drawn from the same private practice.

Given that cement failure is still the main reason for appliance failure, good patient cooperation, both during the strategic insertion step and beyond remains essential. Majority of space maintainer failures in previous studies have been attributed to cement loss (Table 9). Since cement type was not found to be related to appliance failure in our study, the success of cement may be more a
function of band fit (Moore and Kennedy, 2006) and the amount of moisture present during cementation (Rosenstiel et al., 1998) than cement type. Maintaining a relatively dry field can be challenging, especially in a child patient who salivates profusely or has trouble sitting still during appliance cementation.

The observed clinical success rate of space maintainers was 64 percent in the present study. However, eighty-three of the “failed” space maintainers were not replaced because they were no longer required in the mouth. The difficulty in ascribing “success” comes when the decision is made not to recement a ‘failed’ appliance yet the appliance has served its clinical purpose. At the time of study design, the decision was made to treat all cases that exhibited failures as “Failures” even if the clinician decided to leave the appliance out. If the percentage of patients whose failed appliances were no longer needed were re-allocated to the successful group, the success rate would rise to an enviable 73 percent.
Table 9: Failure Rates Comparison

<table>
<thead>
<tr>
<th></th>
<th>Baroni et al. (Baroni et al., 1994)</th>
<th>Moore et al. (Moore and Kennedy, 2006)</th>
<th>Fathian et al. (Fathian et al., 2007)</th>
<th>SaSa et al. (Sasa et al., 2009)</th>
<th>Tunc et al. (Tunc et al., 2012)</th>
<th>Present study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure rate</td>
<td>30.5%</td>
<td>28%</td>
<td>32%</td>
<td>57.5%</td>
<td>10%</td>
<td>36%</td>
</tr>
<tr>
<td>Main cause of failure</td>
<td>Solder breakage</td>
<td>Cement loss</td>
<td>Cement loss</td>
<td>Cement loss</td>
<td>Cement loss</td>
<td>Cement loss</td>
</tr>
<tr>
<td>Cement used*</td>
<td>Polycarboxylate cement</td>
<td>RMGIC or polyacid modified composite</td>
<td>GIC</td>
<td>GIC</td>
<td>GIC</td>
<td>GIC, RMGIC or polyacid modified composite</td>
</tr>
</tbody>
</table>

* GIC – glass ionomer cement; RMGIC – resin-modified glass ionomer cement

This study is the first to report a statistically significant association between age, gender and appliance success (Table 5). Even though the samples were drawn from the same private practice, Moore and Kennedy (2006) and Fathian et al. (2007) did not find a statistically significant difference in appliance success when age and gender were considered. The sample size in the present study was robust enough to show differences that may not have been observed with a smaller sample.
7.2 Explanatory factors and appliance outcome

7.2.1 Age of child at insertion

Several interesting findings were noted in this study. First of all, the age at appliance insertion in the pediatric group ranged from six to ten years old, higher than expected since pediatric dentists “specialize” in preschool children younger than 6 years. The maturity of the pediatric patients may be partly explained by several factors. The exclusion of pre-fabricated space maintainers biased the sample toward older children. Pre-fabricated space maintainers were customarily inserted under general anesthesia because the child was too young to cooperate for dental treatment. The procedures (i.e., band fitting, impression-making) necessary for the fabrication of laboratory-made space maintainers require a child patient to have attained a certain level of cognition and adequate level of compliance during appliance cementation. Moreover, the sample was disproportionately over-represented by bilateral appliances (lingual arch and Nance), more commonly placed in older children after the complete eruption of permanent molars and incisors, which occurs around eight to nine years of age.

Secondarily, this study is the first to demonstrate a relationship between appliance success and age at insertion – for example, an appliance inserted in a younger child is more likely to fail than one inserted in an older child. A space maintainer placed in the early mixed dentition is required to last longer than one placed in the late mixed dentition (Moore and Kennedy, 2006) and such an
appliance may be expected to experience a higher failure rate (Beebe et al., 2008). For example, a lingual arch inserted after early loss of tooth 85 is required to be serviceable until eruption of second premolar (usually erupts around age 12). In this situation, a lingual arch inserted at the age of eight is expected to last four years, contrast to the two years of life expectancy in one inserted at ten years of age. Thus, appliances placed in younger children have more “exposure” time to fail.

7.2.2 Gender

Similar to age, no previous study has demonstrated a relationship between appliance success and patient gender (Baroni et al., 1994; Qudeimat and Fayle, 1998; Rajab, 2002; Tulunoglu et al., 2005; Moore and Kennedy, 2006; Fathian et al., 2007; Sasa et al., 2009). Space maintainers placed in girls were 1.7 times more likely to succeed than boys. Since permanent teeth in boys generally erupt later than in girls (Wedl et al., 2004; Almonaitiene et al., 2010), a space maintainer placed in a boy is expected to last longer than one placed in a girl of the same age. The longer the appliance must survive in the mouth, the longer it is subjected to the challenges of the oral environment and repeated occlusal stress. Thus, failure is more likely (Beebe et al., 2008). Therefore, it is not surprising that space maintainers placed in girls were more likely to succeed than in boys of the same age. Girls had their appliances removed earlier as
permanent bicuspids erupted; thus appliances had less chance of failure.

7.2.3 Type of specialty care

The present study suggested that space maintainers inserted in a pediatric practice were less likely to succeed compared to an orthodontic practice. This finding is consistent with what one would expect given the different patient characteristics and practice protocols of pediatric and orthodontic specialists. For example, since age was an important determinant in appliance success, one would expect to see a higher failure rate in appliances placed in pediatric patients, who are generally younger than orthodontic patients. Further, children are referred to the pediatric dentists because they are too “behaviourally challenged” to be managed in the general practice. Placing a bilateral space maintainer in this group of children will be more challenging to accomplish with a less predictable result. However, caution in interpreting the difference between specialty groups must be noted because the difference did not achieve statistical significance (P=0.07).

7.2.4 Appliance type and outcome

None of the previous space maintainer studies (Baroni et al., 1994; Qudeimat and Fayle, 1998; Rajab, 2002; Tulunoglu et al., 2005; Moore and Kennedy, 2006;
Fathian et al., 2007) reported a statistically significant correlation between appliance success and type of appliances. This study, however, was able to demonstrate such a relationship. Maxillary band and loops were more likely to succeed than their mandibular counterparts. This result is consistent with clinical practice: maxillary placed B&Ls are not subjected to the same stress from the tongue as mandibular band and loops and it is generally easier to maintain a dry field in the maxilla than in the mandible. However, such a difference between dental arches was not noted with Nance and lingual holding arches; thus, other factors may have influenced the outcomes of bilateral appliances. For example, the higher mean age at insertion for the bilateral appliances could have dampened the effects of any arch-related factors on the critical tasks of fitting bands, making good impressions and cementing the appliance. Additionally, since mandibular teeth are in direct view for the operator, it is easier to fit and adapt bands onto the mandibular teeth. Any combination of these factors may have differentially improved the success for the lingual arches compared to the Nance appliances in the sample to the point that previously noted arch differences were not observed.

Logistic regression demonstrated that unilateral space maintainers had a higher success rate than bilateral space maintainers in the same arch. A reason for this may be the ease of cementing one band at a time and maintaining a dry field. Additionally, the band in an unilateral appliance is not subjected to the same
leverage (Moore and Kennedy, 2006) from the archwire spanning two bands in a bilateral appliance.

7.3 Survival time

7.3.1 Time to success

We defined an appliance to be successful if it was still in place at the time of review or had been removed by the clinician after being judged clinically successful. In other words, in the successful group, it was purely a clinical decision that determined time to success. Thus, a clinician likely removed the lingual arch after 24 months because the permanent successors had erupted, not because problems i.e., cement loss had been encountered. In this study, the age at insertion for bilateral appliances and the MST to success fell somewhere between that in Moore’s and Fathian’s (Moore and Kennedy, 2006; Fathian et al., 2007) (Table 10). Because of our large sample size, the MST to success had a small standard deviation (Table 10).

A statistically significant difference for median survival time to success was associated with appliance type. Likely that difference in MST was mainly due to the long median survival time of the mandibular B&L group (38 months). The long MST to success in mandibular B&Ls was not reported in Fathian et al. study (2007). In fact, they reported a slightly higher, but not statistically significant,
MST to success for the maxillary B&Ls. In our study, two of the 38 successful mandibular B&Ls were placed in preparation for future implant placement due to the congenital absence of mandibular premolars. Since one would need to wait until growth is complete prior to implant placement, the survival time for those two cases would have been lengthy. The MST of these two “outlier” cases may have artificially inflated the MST of mandibular B&Ls. However, it is more likely that the lengthier median survival time to success of mandibular B&Ls is a reflection of the differences in eruption time between maxillary and mandibular first premolars as maxillary first premolars generally erupt before mandibular first premolars. A mandibular B&L needs to be in place for a prolonged period of time.

Table 10: MST to success comparison (NS = non-significant)

<table>
<thead>
<tr>
<th>Appliances</th>
<th>Success+/- (SD) (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Rajab, 2002) (Moore and Kennedy, 2006) (Fathian et al., 2007) (Sasa et al., 2009) Present study</td>
</tr>
<tr>
<td>Lingual arch</td>
<td>14 21.9±10.5 31.3±13.4 -- 24.6±1.3</td>
</tr>
<tr>
<td>Nance</td>
<td>24 25.3±11.3 29.9±14.1 -- 26.0±1.7</td>
</tr>
<tr>
<td>B&amp;Ls Upper</td>
<td>20 -- 31.1±17.9 38.0 22.0±6.5</td>
</tr>
<tr>
<td>B&amp;Ls Lower</td>
<td>-- 30.3±14.1 38.3±9.4</td>
</tr>
<tr>
<td>Pooled</td>
<td>-- 23.9±10.8 30.8±14.5 -- 25.4±1.3</td>
</tr>
<tr>
<td>Significance</td>
<td>P&lt; 0.005 P=0.011 NS -- P=0.001</td>
</tr>
<tr>
<td>between appliance type</td>
<td></td>
</tr>
</tbody>
</table>
Table 11: MST to success and mean age at insertion

<table>
<thead>
<tr>
<th></th>
<th>(Moore and Kennedy, 2006)</th>
<th>(Fathian et al., 2007)</th>
<th>Present study</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LLHA</td>
<td>Nance</td>
<td>LLHA</td>
</tr>
<tr>
<td>Age @ insertion</td>
<td>11 yr.</td>
<td>11 yr.</td>
<td>8 yr.</td>
</tr>
<tr>
<td>MST to success</td>
<td>21.9 mo.</td>
<td>25.3 mo.</td>
<td>31.3 mo.</td>
</tr>
</tbody>
</table>

7.3.2 Time to failure

Median time to failure for failed appliances did not significantly differ between appliances which is consistent with other studies (Table 12). The shortest time to failure was six months (Table 12). Therefore, the recall interval for any space maintainer should be set no longer than six months. If a space maintainer were to fail, failure would most likely occur after twelve months following insertion. This information should form part of the informed consent discussion when space maintainer appliances are processed.
Table 12: MST to failure comparison (NS = non-significant)

<table>
<thead>
<tr>
<th>Appliances</th>
<th>Failure +/- (SD) (Moore and Kennedy, 2006)</th>
<th>Failure +/- (SD) (Fathian et al., 2007)</th>
<th>Present study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lingual arch</td>
<td>14±9.9</td>
<td>16.6±10.8</td>
<td>14.2±3.0</td>
</tr>
<tr>
<td>Nance</td>
<td>13.3±10.7</td>
<td>16.0±11.4</td>
<td>12.6±1.9</td>
</tr>
<tr>
<td>B&amp;Ls Upper</td>
<td>--</td>
<td>18.4±13.4</td>
<td>13.4±8.7</td>
</tr>
<tr>
<td>B&amp;Ls Lower</td>
<td>--</td>
<td>20.9±13.3</td>
<td>8.9±2.6</td>
</tr>
<tr>
<td>Pooled</td>
<td>13.7±10.2</td>
<td>17.6±12.0</td>
<td>13.2±1.8</td>
</tr>
<tr>
<td>Significance between appliance type</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
</tbody>
</table>

7.3.3 Accuracy of survival analysis used in this study

Several assumptions (Norman and Streiner, 2000) are generally required when performing survival analysis:

- An identifiable and readily available starting point;
- A well defined end point;
- Loss to follow-up unrelated to the outcome;
- No secular trend over the study period.

For this study, the first assumption is easily met as for every case there is an identifiable starting point. The second point is defined as the time either when the appliance is removed from the mouth by the clinician as deemed clinically successful, or when the appliance failed. To eliminate possible ambiguity from
recall or reporting from parents, the decision was made to use the last documented date (chart record or radiograph) that the appliance was in the mouth if a failure was not witnessed by the dental staff. According to the chart record, the majority of the cases were lost to follow-up simply because patient left the practice after treatment was completed.

The last point was also satisfactorily met since there had been no change in the methods used by the clinicians over the time period in question in either the appliance selection or insertion technique for each space maintainer, nor those used by the lab technicians in how they fabricate the space maintainers.

This study meets all four criteria needed to support an accurate survival analysis. Furthermore, the large sample size, extensive follow-up period and the absence of censoring make the results from this survival analysis even more compelling.

### 7.4 Clinical implications

Properly done space maintainers are successful in the majority of the cases. If a failure were to occur, it will most likely occur by 12 months. This information should be included as part of the informed consent obtained from parents at the time of treatment consultation so that parents understand the implications in
space maintainer use. Since the shortest median survival time in the failure group was at six months, it follows that the appropriate first recall period should be at six months. Since age and gender appear to play an important role in appliance success, it is reasonable to advise parents to be extra vigilant if the appliance is placed in a young boy.

7.5 Study strengths

This study is the first of its kind to follow and report up to the actual end point of the space maintainers since previous studies had used censoring i.e. some cases were not followed to appliance end-point in the estimation of survival time in space maintainers. It is also the first of its kind to include a large sample size (n>1000) originating from a private specialty practice. Since a power analysis could not be done, we had to depend on getting a large sample, sufficiently robust to demonstrate any statistically significant differences in appliance success and survival that may not have been possible with a smaller sample. Having an in-house laboratory for fabrication of all of its space maintainers ensured that all space maintainers were constructed in a similar fashion. All but six percent (n=59) of the original sample were included in the study.

A practice-based research study such as this project offer several advantages. Participation in a practice-based research study improves one’s accountability
and responsibility (Curro et al., 2011). It offers practitioners who were involved in study an opportunity to assess their own work. For example, the clinicians who were involved in the fabrication of those space maintainers can learn from this study and look for ways to improve the outcome of their work. To the dental providers in-large and the profession of Dentistry, a practice-based research study of this kind strengthens the knowledge base and provides a foundation of knowledge which will be useful for future clinical recommendation. Information gained from practice-based research provides a good representation of what it is like in the “real-world” and helps “identify problems that arise in daily practice” (Westfall et al., 2007). A practice-based research study requires meticulous and consistent record keeping, a challenge to accomplish where multiple providers are involved. Since confounders such as practitioner’s practice preference cannot be controlled with a practice-based research study, the result may only be applicable to other practices with similar practice protocols and patient profiles.

7.6 Study limitations

The randomized controlled trial remains the ‘gold standard’ in research design. However, this type of design cannot be applied to the purposes of this study, as one cannot simply ‘randomly’ assign any type of space maintainer to any child. A particular space maintainer is selected by the practitioner for use in a particular patient because of what the practitioner feels is best based on accepted “clinical
A prospective cohort study would be the next choice as it enables investigators to design the data collection to minimize inconsistencies in record keeping. However, significant expense and labor are required to follow a large number of patients for a long period of time. A prospective study is likely the best method to consider for future research to investigate the long term effectiveness of different space maintainers or to determine, for example, if caries risk does indeed affect appliance outcome.

A major challenge faced by the investigators in this study was inconsistencies in record keeping. The original intent was to investigate the relationship of a variety of patient factors to space maintainer survival. Due to inconsistencies in charting, data was insufficient to analyze the contribution of factors such as oral hygiene status and patient cooperation at the time of insertion. Perhaps such factors could be managed in a well-designed prospective study.

Lastly, there is an under-representation of unilateral appliances in the pediatric sample. One would have expected to see more unilateral space maintainers made in a pediatric practice. However, in this study, this finding was not observed. In this practice, pre-fabricated band and loops were commonly used, especially in the young ones who had treatment under general anesthesia.
7.7 Future research

Using a prospective study design, many of the problems encountered with this retrospective study may have been avoided. Even more importantly, due to the existing scarcity of evidence pertaining to the effectiveness of the different types of space maintainers, prospective studies will provide the best level of evidence for practice. For example, to study the relationship between maxillary unilateral or bilateral appliances and appliance success, one can consider randomly assigning patients with bilateral premature loss of maxillary primary molars to one of two groups: one to receive two B&Ls or one to receive a single Nance appliance. In this manner, one can overcome the problem that arises from confounding by indications. Further, this particular specialist practice where the study was conducted used a large number of pre-fabricated B&Ls, one may consider selecting a practice where only lab-fabricated B&Ls were placed. However, given the extensive body of clinical research already done on the topic of space maintenance, the need for further study of this topic is worthy of serious reflection.
8 Conclusion

In this practice-based research study, appliance type, patient gender and age at insertion were associated with success of laboratory fabricated fixed, passive space maintainers. The majority of fixed space maintainers lasted their anticipated lifetime. Thirty-six percent of appliances failed, with cement loss being the major factor contributing to their failure. Failed space maintainers had a median survival time that ranged from 6-17 months. Hence, the first recall after space maintainer insertion should be set at six months. When relevant clinical explanatory factors were included in the analysis, unilateral space maintainers had a significantly greater chance of success than bilateral appliances in the same arch.
References


Richardson M (1965). The relationship between the relative amount of space present in the deciduous dental arch and the rate and degree of space closure to the extraction of deciduous molar. *Dental Practitioner and Dental Record* 16:111-118.


