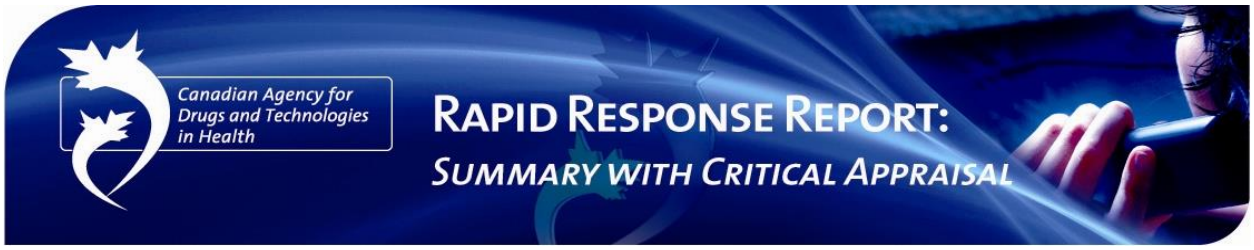

TITLE: Dental Space Maintainers for the Management of Premature Loss of Deciduous Molars: A Review of the Clinical Effectiveness, Cost-effectiveness and Guidelines

DATE: 20 October 2016

CONTEXT AND POLICY ISSUES

Premature loss of primary teeth in children may lead to changes to the permanent dentition including malocclusion and dental arch issues due to drifting teeth. Dental space maintainers (SMs) are commonly used to preserve alignment of the existing dental arch, and to preserve space for unerupted teeth. Broadly, there are two categories of SMs: fixed, which are cemented to one or more teeth, and removable, which are not cemented and can be taken out of the oral cavity. They can be constructed of different materials such as stainless steel wire, or glass fiber-reinforced composite resin (GFRCR). They can be placed on the mandibular or maxillary arch. Examples of SMs include band and loop, lingual arch, palatal arch, and crown-loop.

Given suggestions by dental associations for their use among children for primary teeth loss,[1] it is important to understand the clinical evidence and costs associated with SMs, as well as to look to evidence-based guidelines on appropriate use. Potential benefits include reduction of crowding, ectopic eruption, crossbite, excessive overbite and overjet, and poor molar relationship.[2] However, SMs can increase plaque accumulation, decrease periodontal health, and increase oral microflora.[3]

The purpose of this review is to examine the clinical effectiveness, cost-effectiveness, and guideline recommendations surrounding the types and use of SMs.

RESEARCH QUESTIONS

1. What is the clinical effectiveness of space maintainers in the management of premature loss of deciduous molars (primary teeth)?

2. What is the comparative clinical effectiveness of different types of space maintainers in the management of premature loss of deciduous molars (primary teeth)?

3. What is the comparative effectiveness of space maintainers placed by specialists versus general practitioners?

4. What is the cost-effectiveness of space maintainers for the management of premature loss of deciduous molars (primary teeth)?

5. What are the evidence-based guidelines regarding the use of space maintainers?

KEY FINDINGS

One quasi-randomized controlled trial, three controlled clinical trials, and four observational studies were reviewed on the clinical effectiveness of space maintainers (SMs) in the management of premature loss of primary teeth in children. No economic evaluations or evidence-based guidelines were retrieved on the topic.

Comparing patients with and without SMs, studies reported that patients with SMs had more frequent eruption difficulties, but no difference in space loss. Other studies compared different types of SMs including band and loop, lingual holding arch, and glass fiber-reinforced composite resin maintainers. Most types appeared to fare similarly in terms of gingival health and proportion of patients developing caries.

METHODS

Literature Search Methods

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, ECRI Institute, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit retrieval by publication type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2006 and September 21, 2016.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria	
Population	Pediatric patients (age 0-18) with primary or mixed dentition, with premature loss of deciduous molars (primary teeth)
Intervention	Dental space maintainers
Comparator	No space maintainer; different types of space maintainers
Outcomes	Clinical effectiveness (e.g. prevention of change in the arch length/space, prevention malocclusion (e.g. ectopic eruptions, rotations, crowding, spacing, crossbite, overbite, overjet, impactions, midline shifts), cost-effectiveness, guidelines (including indications, recommendations on type of space maintainer, and type of practitioner)
Study Designs	HTA/Systematic Reviews/Meta-Analyses Randomized Controlled Trials Economic Evaluations Non-Randomized Studies Guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, were duplicate publications, or were published prior to 2011. Guidelines were excluded if they were not evidence-based, or were superseded by more recent publications. Systematic reviews were excluded if only one database was searched, or if only one reviewer selected and assessed the studies.[4]

Critical Appraisal of Individual Studies

For critical appraisal of the included controlled trials and observational studies, the Downs and Black instrument was used.[5] Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study were described.

SUMMARY OF EVIDENCE

Quantity of Research Available

A total of 250 citations were identified in the literature search. Following screening of titles and abstracts, 229 citations were excluded and 21 potentially relevant reports from the electronic search were retrieved for full-text review. No additional citations were retrieved from the grey literature search. Of these potentially relevant articles, 13 publications were excluded: one enrolled an irrelevant population, three evaluated irrelevant outcomes, six were irrelevant study designs, and three did not include a comparator. Eight publications met the inclusion criteria and were included in this report. Appendix 1 describes the PRISMA flowchart of the study selection.

Additional references of potential interest are provided in Appendix 5.

Summary of Study Characteristics

A detailed description of individual study characteristics is provided in Appendix 2.

Study Design
One study was a quasi-randomized controlled trial (RCT),[6] three were controlled clinical trials (CCT),[7-9] and the remaining four were observational studies.[10-13] No evidence-based guidelines, systematic reviews, or economic evaluations were identified.

Owais et al. was classified as quasi-RCT because the investigators used alternation as a method of SM treatment assignment. Setia et al.,[7] Subramaniam et al.,[9] and Nidhi et al.[8] were classified as CCTs because the investigators "[did] not state explicitly that the trial was randomized, but randomization [could] not be ruled out".[4] Studies were classified as observational if the investigators did not explicitly report actively introducing a treatment. Specifically, the observational studies were cohort studies, of which one was retrospective,[11] one was prospective,[13] and two were unspecified.[10,12]

Setting
Three studies (38%) were from India,[7-9] one from Jordan (13%),[6] one from the United States (13%),[13] and three (38%) were unknown.[10-12] From the studies that reported settings, all were single centre studies except for Rubin et al., which enrolled participants from three centres.[13] The settings varied from an outpatient centre,[7] to a teaching hospital,[9] to private orthodontic practices.[13] None were reported to be from remote settings.

Patient Population
Patients were pediatric patients, with mean ages of 10 years or under, and ranges between two to 12 years of age. Ethnicity was not provided in any study, except one that recruited all Caucasian children.[12] Inclusion criteria generally required healthy patients with loss of primary teeth during mixed dentition,[6,11-13] and no congenitally missing teeth.[8-11] Two studies exclusively considered mandibular arches,[6,13] while others accepted mandibular and maxillary arches.[7,10,11]

Interventions and Comparators
The most common SM examined was band and loop (5 studies, 63%).[7-11] Four studies[6,11-13] examined lingual arch appliances, while three studies[7-9] examined glass fiber-reinforced composite resin (GFRCR) maintainers including Ribbond[7] and Super splint.[7]

Two studies compared use of SMs versus no dental SM.[11,12] Four studies compared different types of SMs to each other.[7-10] Two studies compared different types of SMs to each other as well as to no SM.[6,13] In terms of the placement of SMs, five studies had comparators placed in separate groups of patients, so that comparisons were made between patients.[6,10-13] Three studies had different SM comparators placed either in different quadrants of the mouth,[8,9] or in different extraction sites of the mouth,[7] so that comparisons were made within patients.

Outcomes
Several studies examined the presence of caries,[7-9] and gingival health, which was evaluated either as an index score,[10] or as the presence of gingival inflammation.[8,9] One study examined tooth eruption difficulty.[13] The remaining studies examined cephalometric measurements from radiographs including sagittal variation in incisors,[12] arch dimensions,[6] and space loss.[11]

Summary of Critical Appraisal

A summary of critical appraisal of individual studies can be found in Appendix 3.

The quality of evidence was generally low. Among the clinical trials, one used a quasi-random method of treatment assignment.[6] Three were unclear as to whether a random or non-random method of treatment assignment was used.[7-9] Not assigning treatments in a random manner introduces selection bias, whereby there may be imbalances in prognostic variables between treatment groups. The quasi-RCT and CCTs did not conceal allocation methods. Given the nature of orthodontic treatments, blinding was not possible. Biases from lack of blinding may have been minimized, however, since outcome measurements were objective. None of the clinical trials provided sample size calculations to ensure they were sufficiently powered to detect treatment effects. It is unclear if statistically non-significant results[6,7] were due to a lack of power or a true lack of effect.

Among the included studies, three addressed the issue of confounding.[8,9,13] Confounding occurs when the outcomes observed may not be a result of SM treatment, but rather a result of other factors such as patient compliance or the child's cooperativity. Two CCTs applied two different SMs to the same patients, so that patients acted as their own controls.[8,9] One observational study controlled for known confounders within the statistical model.[13]

Across all studies, the most common follow-up times were 12 months or less,[7-10] with the longest being 48 months.[11] Other studies followed patients to the end or after SM treatment,[6,13] or after eruption of permanent teeth,[12] but they did not report the actual follow-up time. Six of the eight studies enrolled fewer than 50 patients or extraction sites per comparator.[6-10,12]

Overall, reporting was poor across all studies. Five of the eight studies did not report details of recruitment.[6,8,10-12] Patient populations and settings were also poorly reported. Four studies reported gender.[9,10,12,13] One did not report age.[12] Other patient characteristics such as rurality were not described in any of the studies. In three studies, the country of origin and clinical setting were unknown.[10-12]

Summary of Findings

Detailed findings from each individual study can be found in Appendix 4.

1. *What is the clinical effectiveness of space maintainers in the management of premature loss of deciduous molars (primary teeth)?*

Four studies examined SM versus no SM as part of their comparisons.[6,11-13] There was no description of the care provided for patients who did not receive SMs. In one study, SMs (Schwarz appliance, lingual holding arch, or combination) were associated with greater odds of eruption difficulty after adjusting for confounding (odds ratio not reported; $P = 0.026$).[13] In terms of cephalometric measurements, Letti et al. found the position of the lower incisors changed more in patients with SMs (lingual arch) than patients without.[12] Specifically, patients with SMs had significantly different linear distances between the most prominent portion of the lower incisor crown and the NB line ($P = 0.002$), and had significantly different angles between the long axis of lower incisor and the NB line ($P = 0.000$). Owais et al. found the inclination of the lower incisors to the mandibular plane was increased in patients with SMs (lingual arch, 0.9 mm or 1.25 mm wire), and the differences were statistically significant compared to patients without SMs ($P \leq 0.01$ for 0.9 mm SM, and $P \leq 0.05$ for 1.25 mm SM).[6] Alnahwi et al. found no differences in space loss between patients with SM (any type) and without SM (no *P*-values reported).[11]

2. *What is the comparative clinical effectiveness of different types of space maintainers in the management of premature loss of deciduous molars?*

Six studies compared different types of SMs.[6-10,13] Patients did not develop caries throughout follow-up for most SM types: Setia et al.[7] reported no caries for four types of SMs (band and loop, band and custom loop, Ribbond, and Super splint) over nine months; Subramaniam et al.[9] reported none for two types of SMs (GFRCR, band and loop) over 12 months; and Nidhi et al.[8] reported none for GFRCR over five months, and one case (6.25%) for band and loop. Arikan et al.[10] found plaque deposition was similar across most time points up to nine months for band and loop SM compared to a removable SM ($P > 0.05$).

In terms of gingival health, Nidhi et al.[8] reported no inflammation for GFRCR over five months, and Subramaniam et al.[9] reported no inflammation for GFRCR and band and loop over 12 months. Setia et al.[7] noted no statistical differences in the proportion of patients with poor gingival health receiving one of four types of SMs (band and loop, band and custom loop, Ribbond, and Super splint) ($P = 0.949$). Arikan et al.[10] found bleeding index scores and changes in pocket depth scores differed between the band and loop SM, and removable SM over the nine months of follow-up ($P < 0.05$). However, the data were presented as multiple stratifications, and it was not possible to determine which SM was superior.

In terms of eruption difficulties, in one study, the lingual holding arch had the lowest proportion of patients with problems (4.7%), and the combination of Schwarz appliance and lingual holding arch had the highest (14.7%).[13] No statistical comparisons were made.

In terms of cephalometric measurements, Owais et al.[6] found no statistical differences between the lingual holding arch made of 0.9 mm wire and one made of 1.25 mm wire ($P > 0.05$).

3. *What is the comparative effectiveness of space maintainers placed by specialists versus general practitioners?*

No comparative data were available. Among included studies, there were no descriptions or summary statistics on whether SMs were placed by specialists or general practitioners.

4. *What is the cost-effectiveness of space maintainers for the management of premature loss of deciduous molars?*

No data were available.

5. *What are the evidence-based guidelines regarding the use of space maintainers?*

No data were available.

Limitations

This review identified a substantial literature gap in the management of premature loss of primary teeth in children using SMs. No RCTs, systematic reviews, economic evaluations, or evidence-based guidelines were retrieved. The robustness of the evidence outlined in this review is limited due to the poor quality and poor reporting. Given the variation in the types of SMs, the construction material, the placement of SMs, and the outcomes examined in the included studies, consensus on the potential effects of SMs cannot be drawn.

The extent to which the results could be applied externally is uncertain as a result of inadequate reporting. For one, patient populations were not clearly described and sample sizes were small. Among studies that described their settings, they were from single centres. None appeared to be on Canadian populations.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

One quasi-RCT, three CCTs and four observational studies were included and reviewed on the use of SMs in children with premature loss of primary teeth. Only clinical effectiveness was examined, including gingival health, presence of caries, plaque formation, eruption difficulties, cephalometric measurements, and space loss. Studies did not examine cost-effectiveness or guideline recommendations.

Overall, several methodological limitations and uncertain generalizability of the studies preclude robust conclusions about the use of SMs.

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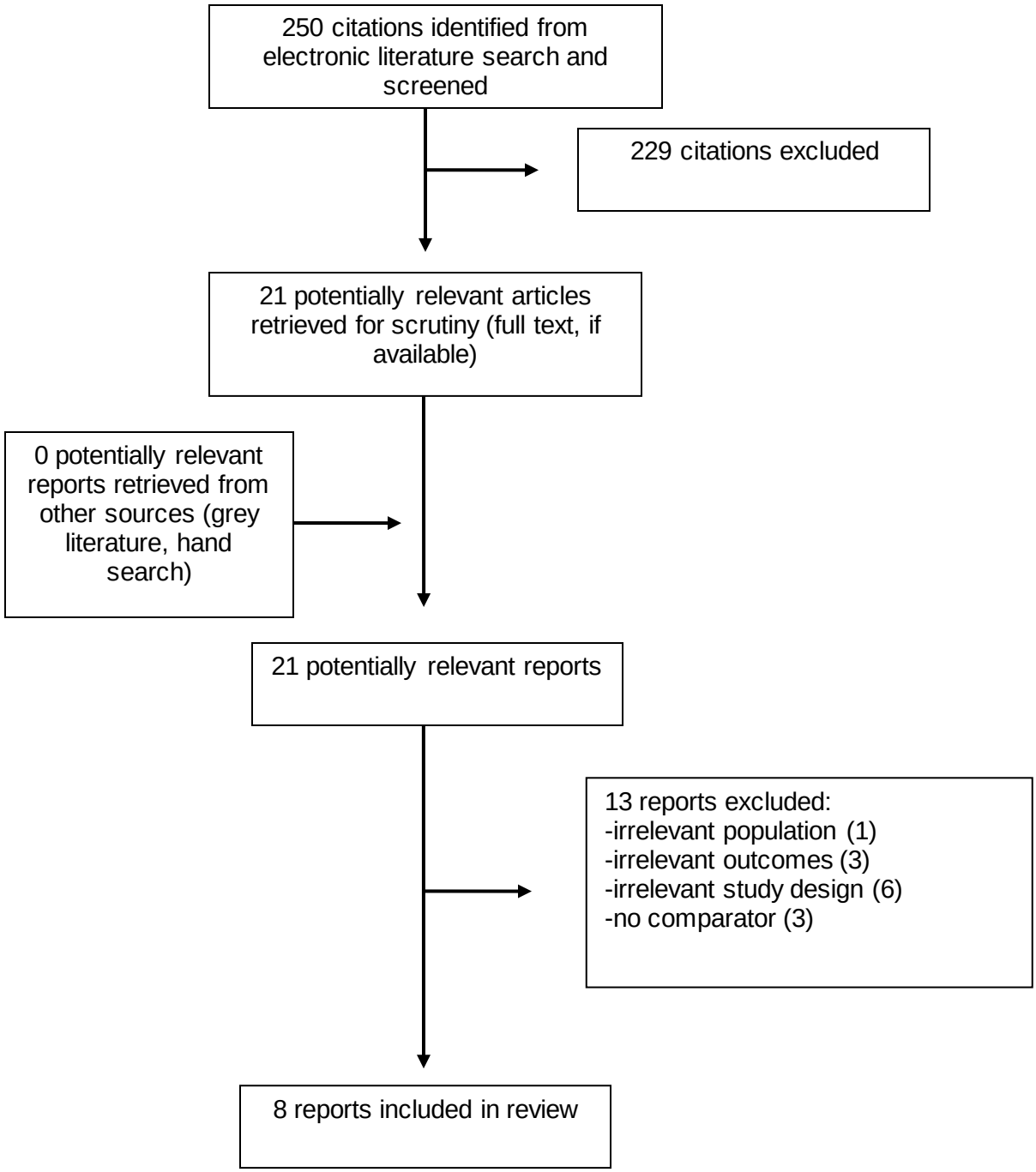
LIST OF ABBREVIATIONS

1.NB	Angle between long axis of lower incisor and NB line
1-NB	Linear distance mm between most prominent portion of the lower incisor crown and NB line
ANOVA	analysis of variance
CCT	controlled clinical trial
GFRCR	glass fiber-reinforced composite resin
IMPA	angle between long axis of lower incisor and base of mandible
LLHA	lower lingual holding arch
NR	not reported
RCT	randomized controlled trial
SE	standard error
SM	space maintainer
vs.	versus

APPENDIX 1: SELECTION OF INCLUDED STUDIES



APPENDIX 2: CHARACTERISTICS OF INCLUDED PUBLICATIONS

Table A1: Characteristics of Included Clinical Studies

First Author, Publication Year, Setting, Country	Study Design	Patient Characteristics	Type of space maintainer	Comparator(s)	Clinical Outcomes, Statistical Analysis
Setia[7] 2014, Outpatient centre, India	CCT: Extraction site as unit of assignment	32 children (range: 4 to 9 years; gender NR) who either required extraction of the primary first/second molar or having pre-extracted primary first or second molar in any of the arches; Patients could have single or multiple extraction sites in maxillary or mandibular arch (n= 60 samples)	Band and loop (n= 15 samples)	1. Prefabricated band with custom made loop (n= 15 samples) 2. Ribbond (n= 15 samples) 3. Super splint (n= 15 samples)	Caries (Y/N); Plaque deposition of the abutment tooth using Silness and Loe index (Good/ Fair/ Poor)[14] Chi-square, McNemar's test (paired data for same patients)
Nidhi[8] 2012, Single centre, India	CCT: Split-mouth trial	20 normal, healthy, and cooperative children (range: 4 to 9 years; gender NR) who had premature loss of a primary first molar in at least two quadrants	Glass fiber-reinforced composite resin (GFRCR) in one quadrant of mouth	Band-and-loop in the other quadrant of mouth	Caries or gingival inflammation Chi square test; Fisher's exact test
Owais[6] 2011, Single centre, Jordan	Quasi-RCT: Alternation used as method of treatment assignment; Parallel arms	67 children (mean age approximately 10 years; gender NR) with late mixed dentition; One or both mandibular primary second molars indicated for extraction	Lower lingual holding arch (LLHA) made with 0.9 mm stainless steel wire (n= 20)	1. LLHA made with 1.25 mm stainless steel wire (n= 24) 2. No treatment (n= 23)	Arch dimensions Analysis of variance with Bonferroni correction
Subramaniam[9] 2008,	CCT: Split-mouth trial	30 normal, healthy, and cooperative children (range: 6 to 8 years; 23% girls) who	Glass fiber-reinforced composite resin	Band and loop in the other quadrant of mouth (n= 30)	Caries or gingival inflammation

Table A1: Characteristics of Included Clinical Studies

First Author, Publication Year, Setting, Country	Study Design	Patient Characteristics	Type of space maintainer	Comparator(s)	Clinical Outcomes, Statistical Analysis
Teaching hospital, India		had premature loss of a primary first molar in at least two quadrants	(GFRCR) in one quadrant of mouth (n= 30)		Chi square test; Fisher's exact test

CCT = controlled clinical trial; GFRCR = glass fiber-reinforced composite resin; LLHA = lower lingual holding arch; RCT = randomized controlled trial

Table A2: Characteristics of Included Observational Studies					
First Author, Publication Year, Setting, Country	**Study Design**	**Patient Characteristics**	**Type of space maintainer**	**Comparator(s)**	**Clinical Outcomes, Statistical Analysis**
Alnahwi[11] 2015, NR	Cohort, retrospective	87 healthy children (range 2 to12 years; gender NR) in the primary or mixed dentition with no congenitally missing or supernumerary teeth; Patients could have maxillary or mandibular prematurely extracted primary second molars (n= 100 samples)	Space maintainer after primary second molar extraction (n= 36 samples) Note: Mix of appliances were used (band and loop, lower lingual holding arch, transpalatal arch, and Nance holding appliance) Note: Most appliances were placed in the first two months of extraction; 10 samples were placed one to two years after extraction	No space maintainer following the extraction of a primary second molar (n= 64 samples)	Space loss measured by bitewing and periapical radiographs: measurements were made from the mesial surface of the permanent first molar (or the distal surface of the primary second molar if the permanent first molar had not erupted) to the distal surface of the primary canine Student's t-test
Letti[12] 2013, NR	Cohort, unspecified	44 Caucasian children with mixed dentition (age NR; 59% girls)	Lingual arch appliance made with 0.9 mm stainless steel wire (n= 30)	No orthodontic/ orthopedic treatment (n= 14)	Sagittal variation on the lower incisors: 1. Angle between long axis of lower incisor and base of mandible (IMPA);

Table A2: Characteristics of Included Observational Studies					
First Author, Publication Year, Setting, Country	**Study Design**	**Patient Characteristics**	**Type of space maintainer**	**Comparator(s)**	**Clinical Outcomes, Statistical Analysis**
					2. Angle between long axis of lower incisor and line NB (1.NB) 3. Linear distance mm between most prominent portion of the lower incisor crown and line NB (1-NB) Student's t-test
Rubin[13] 2012, Three private orthodontic practices, United States	Cohort, prospective	Consecutively treated children (mean age about 9 years; 54% girls); Comparators were matched on age, but matching methods were NR	Schwarz appliance (n= 58)	1. Mandibular lingual holding arch (n= 85) 2. Combination of both appliances (Schwarz appliance used first then removed; mandibular lingual holding arch used near end of mixed dentition) (n=58) 3. Controls from another study (n= 100)	Eruption difficulty: root of the mandibular second molar was at least 75% formed, but the tooth remained unerupted Descriptive statistics; Logistic regression for predictors of eruption difficulty (controlling for age, angulation, retromolar space)

Table A2: Characteristics of Included Observational Studies					
First Author, Publication Year, Setting, Country	**Study Design**	**Patient Characteristics**	**Type of space maintainer**	**Comparator(s)**	**Clinical Outcomes, Statistical Analysis**
Arikan[10] 2007, NR	Cohort, unspecified	56 healthy children (mean age 8.2 years; range: 7 to 10 years; 43% girls) who had early loss of primary molars (maxillary or mandibular)	Band and loop (n= 26)	Removable appliance (n= 26)	Gingival index (Lobone); Plaque index (Silness and Loe index; Turesky)[14,15]; Bleeding index scores; Pocket depths ANOVA; Chi-square; Fisher's exact

1.NB = angle between long axis of lower incisor and line NB; 1-NB = linear distance mm between most prominent portion of the lower incisor crown and line NB; ANOVA = analysis of variance; GFRCR = glass fiber-reinforced composite resin; IMPA = angle between long axis of lower incisor and base of mandible; NR = not reported

APPENDIX 3: CRITICAL APPRAISAL OF INCLUDED PUBLICATIONS

Table A3: Strengths and Limitations of Controlled Trials and Observational Studies using Downs and Black[5]

First Author, Publication Year, Study Design, Comparators	Strengths	Limitations
Space maintainer (SM) vs. none:		
Alnahwi[11] 2015 Observational SM (mix of band and loop, lower lingual holding arch, transpalatal arch, and Nance holding appliance) vs. No SM	• Long follow-up period (up to 48 months) • Defined inclusion/ exclusion criteria • Defined outcomes	• Did not describe recruitment • Did not account for confounding • Grouped different appliances, which may have different treatment effects into one comparator; did not report the proportion of each SM type used • Included patients who had SM applied years after primary second molar extraction • Small sample size • Single centre
Letti[12] 2013 Observational Lingual arch appliance vs. No SM	• Used commonly accepted cephalometric analyses to measure outcomes	• Did not describe recruitment • Did not account for confounding • Reported a study error in the outcome measurements; measurements were taken again and no significant differences were found (Student's t test, p> 0.05) • Results did not support conclusions • Poor reporting overall • Single centre
Comparisons of different types of SM to each other:		
Setia[7] 2014 CCT Band and loop vs. Band and custom loop vs. Ribbond vs. Super splint	• Technique of each SM application described • Used commonly accepted index for measuring plaque deposition as an outcome	• Method of randomization not described although there was mention of SM "randomly placed" in extraction sites • No information on concealment of allocation • No power calculation • Small sample size • Single centre

Table A3: Strengths and Limitations of Controlled Trials and Observational Studies using Downs and Black[5]

First Author, Publication Year, Study Design, Comparators	Strengths	Limitations
Nidhi[8] 2012 CCT GFRCR vs. Band and loop (in different quadrants of mouth)	• Both SM appliances applied to each patient so that each patient acted as own control to address potential confounding • Procedure for SM application clearly described	• Did not describe recruitment • No indication that randomization occurred • Statistical analysis may not be appropriate (used Chi-square instead of McNemar's test); did not account for correlation • No power calculation • Small sample size • Single centre
Subramaniam[9] 2008 CCT GFRCR vs. Band and loop	• Both SM appliances applied to each patient so that each patient acted as own control to address potential confounding • Defined inclusion/ exclusion criteria • Defined outcomes	• No indication that randomization occurred • Did not describe recruitment • No information on concealment of allocation • No power calculation • Small sample size • Single centre
Arikan[10] 2007 Observational Fixed appliance (band and loop) vs. removable appliance	• Used commonly accepted indices for measuring plaque deposition and gingival health as outcomes • Defined most inclusion criteria	• Did not describe recruitment • Did not account for confounding • Small sample size; further stratified into smaller groups (verbal vs. written health education; test vs. control teeth); made statistical comparisons even with such small sample sizes • Single centre
Comparisons of different types of SM to each other as well as to No SM:		
Rubin[13] 2012 Observational Schwarz appliance vs. Lingual holding arch vs. Combination of two appliances vs. Control	• Prospective study • Defined inclusion/ exclusion criteria • Defined outcomes • Matched comparators based on age (although methods not described) • Provided power calculation • Statistical analysis controlled for some known confounders (i.e., age)	• Consecutively recruited patients, which may not provide a representative sample • Potential for residual confounding • Did not describe losses to follow-up • Final time point for outcome measurement and statistical analysis varied among patients ("after treatment

Table A3: Strengths and Limitations of Controlled Trials and Observational Studies using Downs and Black[5]

First Author, Publication Year, Study Design, Comparators	Strengths	Limitations
	• Same investigator checked reliability of measurements made; noted high intraclass correlation coefficients (≥ 0.95) • Large sample size • Multi-centre study	with the appliance and before fixed or orthodontic treatment in the permanent dentition" p. 147)
Owais[6] 2011 Quasi-RCT LLHA 0.9 mm wire vs. LLHA 1.25 mm wire vs. No SM	• Defined inclusion/ exclusion criteria • Defined outcomes • Assessed information bias: same examiner reassessed outcome measurements of 10 randomly chosen patients; coefficient of reliability was > 90% • Provided numbers lost to follow-up • Statistical analysis was appropriate; Bonferroni correction used for multiple comparison tests •	• No information on recruitment • Quasi-random method of treatment assignment (alternation using odd and even numbers) • No information on concealment of allocation • No power calculation • Small sample size • Single centre

CCT = controlled clinical trial; GFRCR = glass fiber-reinforced composite resin; LLHA = lower lingual holding arch; RCT = randomized controlled trial; SM = space maintainer; vs. = versus

APPENDIX 4: MAIN STUDY FINDINGS AND AUTHOR'S CONCLUSIONS

Table A4: Summary of Findings of Included Studies

First Author, Publication Year, Study Design, Comparators	Main Study Findings	Author's Conclusions
Space maintainer (SM) vs. none:		
Alnahwi[11] 2015 Observational SM (mix of band and loop, lower lingual holding arch, transpalatal arch, and Nance holding appliance) vs. No SM	Space loss at 12 months • > 3 mm space loss for both groups • At 6 months and 12 months: No difference in space loss between SM group and No SM group (No *P* value provided) Note: No statistical comparisons at 48 months	• "Space loss in the groups with SMs and without SMs was similar." (p. e4) • "Space loss after the first year was generally minimal. Therefore, a clinical decision to provide an SM after a year should be considered cautiously. This practice should be limited to cases in which it is crucial to maintain remaining space, such as in patients with crowding, a Class III molar relationship and premature primary mandibular second molar loss, or a Class II molar relationship and premature primary maxillary second molar loss." (p. e3)
Letti[12] 2013 Observational Lingual arch appliance vs. No SM	Change in IMPA from baseline after eruption of permanent canines and premolars • Lingual arch: 1.9° • No SM: -0.6° • *P* = 0.083 Change in 1.NB from baseline • Lingual arch: 2.7° • No SM: -0.8° • *P* = 0.002 Change in 1-NB from baseline • Lingual arch: 0.2 mm	• IMPA, 1.NB: "The use of the lingual arch prevented the tendency of lingual inclination … of lower incisors." (p. 33) Instead, projection was observed, which can be "clinically advantageous" (p. 33) and "facilitat[e] orthodontic [procedures] with gain of space…The lower incisors were projected after using the lingual arch to control the space on the transition from mixed dentition to permanent, however within acceptable standards." (p. 33) • 1-NB: "Lingual arch show[ed] efficiency on the maintenance of the lower arch

Table A4: Summary of Findings of Included Studies		
First Author, Publication Year, Study Design, Comparators	**Main Study Findings**	**Author's Conclusions**
	• No SM: 1.6 mm • *P* = 0.000	perimeter, that is, preventing the molar movement to mesial and the linguoversion of the incisors. [This may lead] to the reduction of mandibular crowding." (p.32)
Comparisons of different types of SM to each other:		
Setia[7] 2014 CCT Band and loop vs. Band and custom loop vs. Ribbond vs. Super splint	<u>Proportion with poor gingival health at 9 months</u> • Band and loop 36%, • Band and custom loop 27%, • Ribbond 40%, • Super splint 50% • All comparisons: *P* = 0.949 <u>Caries</u> • None developed in the four groups over 9 months of follow-up	• "Prefabricated band with custom made loop may be a viable alternative to conventional band and loop since it has somewhat more success rate and less plaque deposition." (p. 103) • Ribbond and Super splint "observed higher proportions of patients with poor gingival health as compared to [band and loop] and [band and custom loop], this might be attributed to plaque retentive sites along the fiber framework." (p. 103)
Nidhi[8] 2012 CCT GFRCR vs. Band and loop (in different quadrants of mouth)	<u>Caries or gingival inflammation</u> • At 3 months: None developed in either group in first and third months • At 5 months: None developed in GFRCR vs. 6.25% (n = 1 out of 16) in Band and loop	• "None of the failures because of caries or gingival inflammation were seen in GFRCR space maintainers. It may be because the fibers were coated with flowable composite and finished adequately to allow maintenance of oral hygiene." (p. 28) • "GFRCR space maintainers can be used as an alternative method to conventional band and loop space maintainers for short term space maintenance required due to premature primary tooth loss." (p. 29)

Table A4: Summary of Findings of Included Studies		
First Author, Publication Year, Study Design, Comparators	**Main Study Findings**	**Author's Conclusions**
Subramaniam[9] 2008 CCT GFRCR vs. Band and loop	Caries or gingival inflammation • None in either group over 12 months of follow-up	• "The GFRCR space maintainer seems to be a suitable alternative to the conventional fixed space maintainer." (p. S103)
Arikan[10] 2007 Observational Fixed appliance (band and loop) vs. removable appliance	Plaque index score • At baseline, 6 months and 9 months: no difference between groups ($P > 0.05$) • At 3 months: groups differed ($P < 0.05$) Bleeding index score • At baseline: no difference between groups ($P < 0.05$) • At 3 months, 6 months and 9 months: groups differed ($P < 0.05$) Difference in pocket depth scores since baseline • At 3 months, 6 months and 9 months: groups differed ($P < 0.05$)	• "Both fixed and removable SM cause an increase in plaque accumulation…Special concern should be given on oral and dental health of children who use fixed SM since they were found to cause an increase in bleeding index and pocket depth compared to the removable appliances." (p. 233)
Comparisons of different types of SM to each other as well as to No SM:		
Rubin[13] 2012 Observational Schwarz appliance vs. Lingual holding arch vs. Combination of two appliances vs. Control	Proportion of patients with eruption difficulty • Schwarz appliance: 7.8% • Lingual holding arch: 4.7 % • Combination: 14.7% • Control: 1% Logistic regression (odds ratios NR) • Schwarz vs. control: $P = 0.04$ • Lingual holding arch vs. control: $P = 0.42$	• "All treatment groups had a higher percentage of mandibular second molar eruption difficulty when compared with the control group." (p. 150) • "Schwartz appliance or the combined Schwarz and lingual holding arch in the mixed dentition was associated significantly with mandibular second molar eruption difficulty." (p. 151)

Table A4: Summary of Findings of Included Studies		
First Author, Publication Year, Study Design, Comparators	**Main Study Findings**	**Author's Conclusions**
	• Combination vs. control: *P* = 0.018 • Any appliance vs. control: *P* = 0.026	
Owais[6] 2011 Quasi-RCT LLHA 0.9 mm wire vs. LLHA 1.25 mm wire vs. No SM	<u>Change in lower incisor inclination to the mandibular plane (Li-Mand) at end of treatment since baseline</u> • LLHA 0.9 mm wire: 4.50° ± SE 0.77 • LLHA 1.25 mm wire: 3.36° ± SE 1.07 • No SM: -0.24° ± SE 0.82 • Difference between LLHA 0.9 mm wire vs. No SM: 4.74° (*P* ≤ 0.01) • Difference between LLHA 1.25 mm wire vs. No SM: 3.60° (*P* ≤ 0.05) • Difference between LLHA 0.9 mm wire vs. LLHA 1.25 mm wire: 1.14° (p> 0.05) <u>Change in distance of the lower incisor edge to the A-Pogonion (Li-A-Pog); Lower molar angulation to mandibular plane (LM1-Mand); Arch length; Arch depth; Intercanine width; Intermolar width; Primary second premolar extraction space</u> • No statistically significant difference between groups (Table 3, p.40)	• "Lower incisor inclination to the mandibular plane was increased in [LLHA 0.9 mm wire] and [LLHA 1.25 mm wire]… Significant differences were found when…compared with the controls." (p. 40) • "The LLHA used in both treatment groups tended to cause proclination of Li-Mand and forward movement of the lower incisors relative to the A-Pog line (Li-A-Pog)." (p. 41) • "The LLHA used in both treatment groups preserved arch length throughout the study duration. There was arch length gain of 0.53 mm in [LLHA 0.9 mm wire] and arch length loss of 0.98 mm in [LLHA 1.25 mm wire]." (p. 41)

1.NB = angle between long axis of lower incisor and line NB; 1-NB = linear distance mm between most prominent portion of the lower incisor crown and line NB; CCT = controlled clinical trial; GFRCR = glass fiber-reinforced composite resin; IMPA = angle between long axis of lower incisor and base of mandible; NR = not reported; RCT = randomized controlled trial; SE = standard error; SM= space maintainer; vs. = versus

APPENDIX 5: ADDITIONAL REFERENCES OF POTENTIAL INTEREST

Cost-effectiveness analysis (not specific to pediatrics):

Antonarakis GS, Prevezanos P, Gavric J, Christou P. Agenesis of maxillary lateral incisor and tooth replacement: cost-effectiveness of different treatment alternatives. Int J Prosthodont. 2014 May-Jun;27(3):257-63.