REVIEW ARTICLE

Clinical Effectiveness of Fiber-reinforced Composite Space Maintainer and Band and Loop Space Maintainer in a Pediatric Patient: A Systematic Review and Meta-analysis

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Abstract

Background: Objectives: This systematic review aimed to evaluate the clinical effectiveness of fiber-reinforced composite space maintainer (FRCSM) and band and loop space maintainer (BLSM) in a pediatric patient.

Materials and methods: Eligibility criteria: Randomized controlled trials (RCTs) were conducted on 3–12-year-old children who received FRCSM and BLSM. **Information sources:** Literature search of electronic databases such as PubMed, Cochrane, and Google Scholar for the time period of 2000 to October 2020. **Risk of bias:** Cochrane collaboration's risk of bias tool was used to assess the risk of bias.

Results: Included studies: The search resulted in 147 published studies. After the removal of duplicate studies and full-text analysis, eight studies were selected. **Synthesis of results:** Fiber-reinforced composite restoration (FRCSM) was judged to be good for short-term space maintenance with good esthetics, less time-consuming, and good patient and parental acceptance. Meta-analysis was done for failure rate at 6 months and 12 months. After 6 months, the FRCSM group showed less failure, with a risk ratio of 0.83 (95% CI = 0.47–1.49; *Z* value = 0.61). However, after 12 months, the FRCSM group showed more failure, with a risk ratio of 1.30 (95% CI = 0.04–4.23; *Z* value = 0.44). **Description of the effect:** FRCSM performed better than BLSM for a short-term, i.e., around 6 months but after 12 months of space maintainer placement BLSM performed better than the FRCSM.

Discussion: Strengths and limitations of evidence: The strength of this systematic review is its complete adherence to the PRISMA statement 2009. This review attempted to evaluate the effectiveness of FRCSM when compared with BLSM which has not been evaluated before. Additionally, only RCTs were included in this review adding to its validity. This review also included a meta-analysis that compared the failure rate at the 6th and 12th month. The main shortcoming of this systematic review is the limited number of databases searched and the limited number of existing studies. **Interpretation:** Within the limitations of this review, it can be stated that the FRCSM is an effective space maintainer for short-term space maintenance. However, it is necessary to conduct more RCTs with larger sample size, preferably using a split-mouth design to improve the longevity of FRCSM. Additionally, it is also necessary to standardize the technique of fabrication of FRCSM since an existing study showed high heterogeneity in the technique of fabrication.

Other: Funding: None. **Registration:** The protocol of this systematic review was registered on PROSPERO (ID-CRD42020165831).

Keywords: Band and loop space maintainer, Fiber-reinforced composite space maintainer, Primary dentition, Space maintainer, Systematic review.

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Introduction

Rationale

Primary dentition plays a vital role in the growth and development of the child. It aids in speech, mastication, appearance, prevention of deleterious oral habits, and guiding permanent teeth during an eruption.[1] Premature loss of deciduous teeth leads to crowding, rotation, distal drifting of the tooth, and impaction of the permanent teeth.[2,3]

Primary teeth are considered to be the best space maintainer under normal physiological conditions.[4] However, in cases with premature loss of primary teeth, the best way to prevent future malocclusion would be to place an effective, affordable, and perdurable space maintainer. Space maintainers are applicable dental devices specifically designed to maintain or to create an additional space that was lost due to premature loss of primary teeth.[5]

Various types of space maintainers can be used which depend on the dental developmental stage, dental arch involved, the number of teeth involved, location, and type of primary teeth involved.[6] Among all the available appliances, band and loop space maintainer (BLSM) is the most commonly used.[4] Qudeimat and Fayle[7] stated that the BLSM is economical, easy to fabricate, adapts easily, and requires less chairside time. However, it has many disadvantages like increased laboratory time, frequent

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dislodgement due to cement loss, increased visits and does not prevent rotation or tipping of adjacent teeth. To overcome the disadvantages of BLSM, a prefabricated BLSM were introduced. However, the only advantage it had over BLSM is that subsequent appointment for placement is not required was costlier than the latter.[8]

Recently, a fiber-reinforced composite resin space maintainer (FRCSM) was introduced to overcome the disadvantages posed by BLSM. Fiber-reinforced composite resin space maintainers (FRCSM) are esthetic, less bulky, less time consuming, occupies less space in the oral cavity, well tolerated by the patient, does not require annual maintenance steps and physical strength is comparable to the conventional BLSM.[9–11]

There are only a few studies that attempted to compare the clinical performance of FRCSM and BLSM which were of the different follow-up period.[8,12,13] Some of these studies favored FRCSM over BLSM while others favored BLSM. Literature has reported a wide variation in the survival rate of metal-based and resin-based space maintainers. At present, the lack of adequate evidence precludes clinicians from recommending a single best-fixed space maintainer. Therefore, there is a need for a systematic review to critically appraise and summarize the results of clinical trials evaluating the effectiveness of FRCSM, since FRCSM could be a very good alternative to BLSM.

Objective

This systematic review was planned to evaluate the clinical effectiveness of FRCSM and BLSM in pediatric patients.

Materials and Methods

Protocol and Registration

The protocol of this systematic review was registered on PROSPERO (International Prospective Register of Systematic Reviews, National Institute for Health Research) with registration number-ID-CRD42020165831. This review follows the PRISMA statement 2009.

Eligibility Criteria

The eligibility criteria of the included studies were determined scientifically with the scope of evaluating the clinical effectiveness of fiber-reinforced composite space maintainer (FRCSM). They were as follows:

- Participant/population characteristics
- Studies were conducted on children in the age-group of 3–12 years.

Inclusion Criteria

Clinical Criteria

- Premature loss of primary first molar (unilateral or bilateral).
- Premature loss of primary second molar provided permanent first molar is erupted (unilateral or bilateral).

Radiographic Criteria

- Abutment tooth without any periapical pathology.
- Presence of succedaneous tooth or tooth bud.
- Succedaneous tooth with less than two-thirds of root formation.

Exclusion Criteria

- Patient with abnormal dental conditions such as crossbite, open bite, and deep bite.

Intervention

- Fiber-reinforced composite space maintainer.

Control Group

- Band and loop space maintainer.

Outcome

Studies Evaluating

- Durability.
- Survival rate/failure rate.
- Caries and gingival inflammation of abutment tooth.
- Time is taken to carry out the procedure.
- Patient acceptance and parental acceptance.

Study Design

- Randomized controlled trials (RCTs).

Information Sources

A systematic search of major electronic databases was performed to include publications in English in the time period of 2000 to October 2020.

Electronic searches were performed in the following search engines:

- PubMed.
- Cochrane Central Register of Clinical Trials (CENTRAL).
- Google Scholar.

Search

PubMed Search Strategy (Since 2000 to October 2020)

The keywords were selected based on Medical Subject Headings (MeSH) and non-MeSH terms. The main included keywords were:

- Intervention: Fiber-reinforced composite resins; ribbond; composite resins; resin, composite; glass fiber-reinforced composite resins.
- Outcome: Maintenance, orthodontic space; Maintenances, orthodontic space; Orthodontic space maintenance; Orthodontic space maintenances; Space maintenances, orthodontic; Space maintenance; Maintenance, space; Maintenances, space; Space maintenances.

Cochrane Central Register of Controlled Trials (CENTRAL) Search Strategy

- Intervention: Fiber-reinforced; composite resin; ribbond; composite resin
- Outcome: Space maintenance.

Search Term for Google Scholar

- Fiber-reinforced composite space maintainer.

Study Selection

Study selection and data collection were performed by two independent authors, i.e., Henpu Kamki (HK) and Hemraj Badhe (HB) and in case of any discrepancies, it was resolved by the third author, i.e., Ritesh Kalaskar (RK).

Data Collection Process

Data collection was performed using a customized data extraction form.

Data Items

Information related to the study including study design, method of randomization, description of population in terms of age and gender, sample size, details of inclusion and exclusion criteria in the study as well as the control group. The data were sorted based on the outcome and intervention. The primary outcomes for FRCSM were durability, failure rate/success rate, caries, and gingival inflammation of the abutment tooth. The primary outcome for BLSM were durability, failure rate, band slippage toward the gingival surface, caries, and gingival inflammation of abutment tooth. Secondary outcomes are a duration for fabricating appliance, patient and parental acceptance for both FRCSM and BLSM.

Risk of Bias in Individual Studies

The risk of bias in individual studies was evaluated by Cochrane collaboration's risk of bias tool.

Summary Measures

The primary outcome of this systematic review was to assess the effectiveness of FRCSM in terms of durability, failure rate/success rate, caries, and gingival inflammation of abutment teeth. The primary outcomes for BLSM were durability, failure rate, and band slippage toward the gingival surface, caries, and gingival inflammation of the abutment tooth. Secondary outcomes were duration for fabricating appliance, patient, and parental acceptance.

Synthesis of Results

The meta-analyses were applied with RevMan 5.3 (RevMan 5.3, The Nordic Cochrane Centre, Copenhagen). Heterogeneity was assessed by a *Q* test and quantified with I^2 statistics. Data were obtained from the included studies. Success/failure of the space maintainer was considered as the primary outcome. Comparisons between FRCSM vs BLSM were performed using the frequency of failure after 6 months and 12 months. For analysis, if the test showed substantial heterogeneity ($I^2 > 50\%$), a random-effects model was applied, or else ($I^2 \leq 50\%$), a fixed-effects model would be used.

Results

Study Selection

The initial search strategy yielded a total of 147 results including the studies obtained from Google Scholar. After duplication removal, articles were evaluated for their abstracts and full texts. Finally, after strict and careful application of the inclusion and exclusion criteria, eight articles were selected for the final systematic review (Flowchart 1).[8,12–18]

Risk of Bias within Studies

Risk of bias for randomized trials: Cochrane risk of bias tool for randomized controlled trials (Figs 1 and 2).

Results of Individual Studies

Results of individual studies are given in Tables 1 and 2.

Synthesis of Results

Comparison of Failure Rate after 6 Months

Seven studies[8,12–18] were included in the meta-analyses comparing the failure rate after 6 months among FRCSM (experimental) group and BLSM (control) group. After 6 months, the FRCSM group showed less failure, with a risk ratio of 0.83 (95% CI = 0.47–1.49; *Z* value = 0.61). This means that after 6 months, the risk of failure is 17% less among FRCSM as compared to BLSM. However, this difference in failure rate among the two groups was not statistically significant ($p = 0.54$) (Fig. 3).

Comparison of Failure Rate after 12 Months

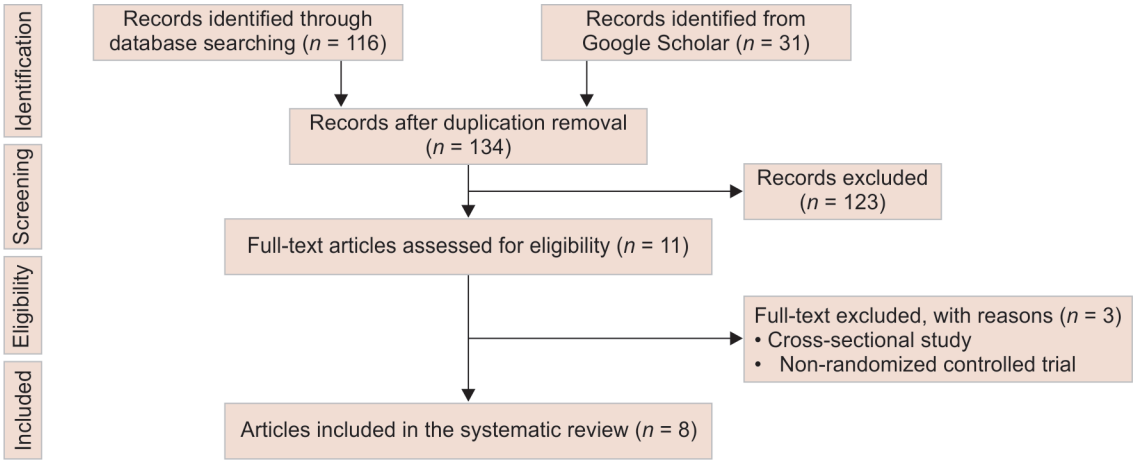
Four studies[8,15,17,18] were included in the meta-analyses comparing the failure rate after 12 months among FRCSM (experimental) group and the BLSM (control) group. After 12 months, the FRCSM group showed more failure, with a risk ratio of 1.30 (95% CI = 0.04–4.23; *Z* value = 0.44). This means that after 12 months, the risk of failure is 30% more among FRCSM when compared with BLSM. However, this difference in failure rate among the two groups was not statistically significant ($p = 0.66$) (Fig. 4).

Discussion

Summary of Evidence

At present, there is only one systematic review conducted by Ramakrishnan et al. assessing the survival rate of different fixed posterior space maintainers used in pediatric dentistry. They reported that there is a wide variation in the survival rate of metal-based and resin-based space maintainers and also variation existed within the metal-based space maintainers as well. Therefore, there is inadequate evidence to recommend any particular fixed space maintainer as the best due to the lack of well-designed studies.[19]

Flowchart 1: PRISMA flow diagram of the literature search and selection process



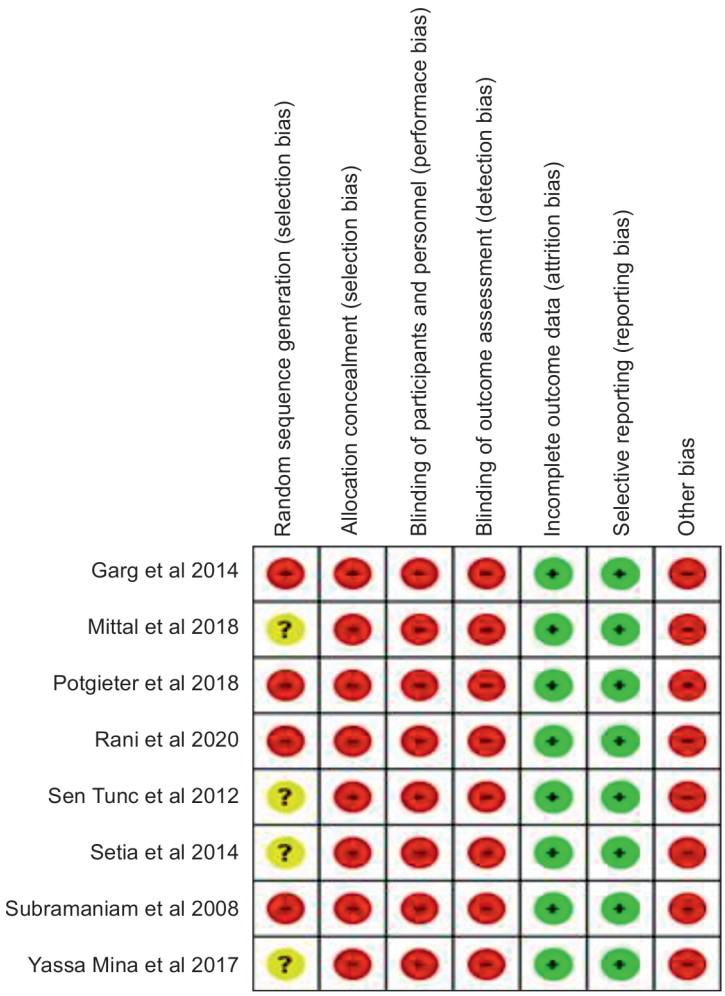


Fig. 1: Risk of bias summary (Cochrane Collaboration's tool)

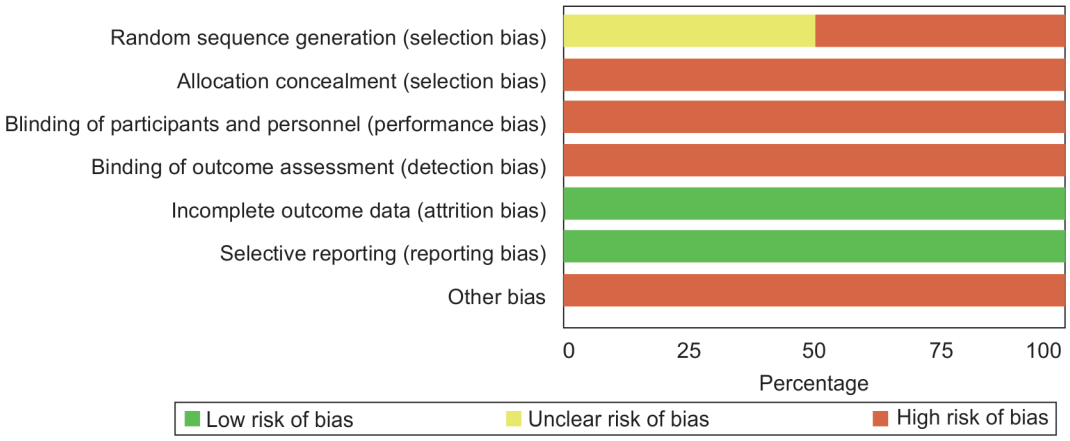


Fig. 2: Risk of bias graph (Cochrane Collaboration's tool)

Kargul et al.[20] evaluated glass fiber-reinforced composite resin (FRCSM) as a fixed space maintainer in children for 12 months and found that it functions well up to 5 months. A similar conclusion was also drawn by Saravanakumar et al.[21] that FRCSM (Ribbond®) can be accepted over conventional BLSM for an only short period.

Quality and Design of Included Studies

To assess the quality and design of included studies, risk of bias analysis of included studies was carried out using the Cochrane risk of bias tool. Overall, a high risk of bias was observed in all the included studies. High risk was mostly due to: (a) inability to blind participants and principal investigator because of the nature of the

Table 1: Population, intervention, control, outcome and study design of included studies

S. no.	*Study*	*Country*	*Population*	*Inclusion and exclusion criteria*	*Intervention*	*Control/ comparator group*	*Outcome*
1	Rani et al. (2020)	India	20 patients, aged 6–8 years	Inclusion criteria: Clinical criteria • Premature loss of primary first molars in two quadrants • Sound and healthy abutment teeth • Presence of Angle's Class I molar relationship and/or presence of flush terminal plane/ mesial step primary molar relationship • Absence of abnormal dental conditions such as open bite, crossbite, and deep bite Radiographic criteria: • Absence of periapical pathology • Presence of succedaneous tooth bud • Presence of >1 mm bone overlying the succedaneous tooth germ or less than one-third of the root of the permanent tooth formed Exclusion criteria: • Carious buccal and lingual surfaces of abutment teeth • Absence of teeth on the mesial and distal side of the edentulous area • Arch analysis conforming space loss	FRCSM	BLSM	FRCSM: • Debonding at the enamel-composite interface • Debonding at the fiber-composite interface • Fracture of the fiber frame • Caries and gingival inflammation BLSM: • Distortion • Cement loss • Fracture of the loop • Caries or gingival inflammation
2	Mittal et al. (2018)	India	45 patients, aged 6–9 years	Inclusion criteria: • Caries-free abutments teeth • Teeth present on mesial and distal side of extraction space • Absence of abnormal dental conditions such as crossbite, open bite, deep bite • Adequate bone overlying erupting successor on the radiographic examination. Exclusion criteria: • Absence of teeth on mesial and distal side of the edentulous area • Patient with a history of systemic diseases • Patient with furcal pathosis or cariously involved non-restorable abutment teeth.	FRCSM	BLSM	• Distortion/debonding at the enamel-composite interface • Cement loss/debonding at the fiber-composite interface • Fracture loop/fracture fiber framework • Caries

Contd…

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S. no.	*Study*	*Country*	*Population*	*Inclusion and exclusion criteria*	*Intervention*	*Control/ comparator group*	*Outcome*
3	Potgieter et al. (2018)	South Africa	20 patients, aged 4–9 years old	Inclusion criteria: • Premature loss of a deciduous first molar (>1 year before the expected exfoliation time) • Anchor teeth (second deciduous molars) with intact, undamaged buccal and lingual surfaces to bond to • Anchor teeth with more than half of the root length present Exclusion criteria: • Teeth with compromised structure in the intended bonding area (i.e., demineralized enamel, caries, fractures, iatrogenic damage, or existing restorations) • Occlusal discrepancies (i.e., a crossbite, an open bite, or a deep bite) • Inability to return for a monthly follow-up appointment	FRCSM	BLSM	• Debonding at the fiber-composite or the band-cement interface • Debonding at the enamel-composite or the cement-enamel interface • Fracture of fiber or metal framework • Bending of the fiber/metal loop to the extent that the device was in contact with the soft tissue
4	Yassa et al. (2017)	Egypt	15 patients, aged 5–7 years	Inclusion criteria: • Premature bilateral loss of the first primary molar.	FRCSM	BLSM	FRCSM: • Delamination between fiber/composite • Debonding between enamel/composite • Fracture of the fiber frame BLSM: • Cement loss • Distortion • Loop fracture
5	Garg et al. (2014)	India	30 patients, aged 5–8 years	Inclusion criteria: A. Clinical criteria • Premature loss of primary first molar in two quadrants. • Sound and healthy abutment teeth. • Presence of Angle's Class I molar relationship and/or presence of flush terminal/mesial step primary molar relationship. • Absence of abnormal dental conditions such as crossbite, open bite, and deep bite.	FRCSM	BLSM	FRCSM: • Debonding at the enamel-composite • Fracture of the fiber frame • Debonding at the fiber-composite BLSM: • Cement loss

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S. no.	Study	Country	Population	Inclusion and exclusion criteria	Intervention	Control/ comparator group	Outcome
				B. Radiographic criteria • Absence of periapical pathology. • Presence of succedaneous tooth bud. • Presence of >1 mm bone overlying the succedaneous tooth germ and/or less than one-third of the root of the permanent tooth formed. *Exclusion criteria:* • Carious buccal and lingual surfaces of abutment teeth. • Absence of teeth on mesial and distal side of edentulous area.			• Distortion of band • Slippage of band gingivally • Fracture of the loop
6	Setia et. al. (2014)	India	32 patients, aged 4–9 years [sample size = 15 each for both ribbond (FRCSM) and BLSM]	*Inclusion criteria:* • Patients in the age group of 4–9 years • Extraction sites with no space loss • Erupting permanent tooth having adequate bone covering • Fully erupted carious-free teeth • Patients with dmf ≤4 were included in the study.	Ribbond (FRCSM)	BLSM	• Survival rate • Caries • Gingival health
7	Tunc et al. (2012)	Turkey	30 patients, aged 4–10 years (mean age = 6.9 years old) Sample size = 10 each for both Ribbond (FRCSM) and BLSM	*Inclusion criteria:* *Clinical:* • Premature loss of a primary molar • Presence of teeth on the mesial and distal sides of the extraction space • Angle's Class I occlusion and normal primary molar relation. *Radiographic criteria:* • No root resorption of abutment teeth • Presence of a succedaneous tooth bud • Presence of the bone crypt over the succedaneous tooth bud • Succedaneous tooth root development • Absence of pathology on the eruption track of the succedaneous tooth.	Ribbond (FRCSM)	BLSM	FRCSM: • Debonding of fiber-composite interface • Debonding of enamel-composite interface • Fiber frame fracture • Caries or gingival inflammation BLSM: • Distortion • Cement loss • Loop fracture • Caries or gingival inflammation

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S. no.	*Study*	*Country*	*Population*	*Inclusion and exclusion criteria*	*Intervention*	*Control/ comparator group*	*Outcome*
8	Subramaniam et al. (2008)	India	30 patients (23 boys and 7 girls), aged 6–8 years	Inclusion criteria: *Clinical criteria:* • Premature loss of primary first molar in two quadrants • Non-carious buccal and lingual surface of abutment teeth • Presence of teeth on the mesial and distal side of edentulous area • Presence of Angel's Class I molar relationship and/or presence of flush terminal step primary molar relationship • Absence of abnormal dental conditions such as crossbite, open bite, and deep bite *Radiographic criteria:* • Absence of pathology • Presence of succedaneous tooth bud. • Presence of >1 mm bone overlying the succedaneous tooth germ and/or less than one-third of the root of the permanent tooth formed (Nolla's stage 7).	FRCSM	BLSM	FRCSM: • Debonding of enamel-composite interface • Debonding of fiber-composite interface • Fracture of the fiber frame • Caries or gingival inflammation Band and loop SMs • Distortion • Cement loss • Loop fracture • Caries or gingival inflammation

Table 2: Interpretation of results

S. no.	*Author*	*Interpretation of results*
1	Rani et al. (2020)	At 9 months, the overall success was 85% for FRCSM and 60% for BLSM. This difference was statistically significant.
2	Mittal et al. (2018)	At 12-month follow-up, overall success for group I (band and loop SMs) was 86.6%, for group II (Glass FRCSM) 80%, and for group III (Impregnated glass fibers) 73.3%. On overall comparative analysis, there was statistically no significant difference in retention between these three types of space maintainers on second molar.
3	Potgieter et al. (2018)	At 6-month follow-up, the overall failure rates were 50% for both BLSM and FRCSM.
4	Yassa et al. (2017)	At 12-month follow-up, the overall clinical success rate of FRCSM was 93.3 and 80% for BLSM. Although, the difference was not statistically significant.
5	Garg et al. (2014)	At 6-month follow-up, FRCSM exhibited higher success rate (63.3%) compared with BLSM (36.7%). This difference was statistically significant.
6	Setia et al. (2014)	At 18-month follow-up, BLSM and FRCSM had success rate of 73.3 and 45.4%. This difference was statistically significant.
7	Tunc et al. (2012)	The survival rate was higher for BLSM (11.2 months), followed by FRCSM (6.7 months), and overall failure rates during the 12-month evaluation period were 10% for BLSMs and 80% for FRCSMs. This difference was statistically significant.
8	Subramaniam et al. (2008)	At 12-month follow-up, the overall success rate was 55% for FRCSM and 33.3% for BLSM. This difference was not statistically significant.

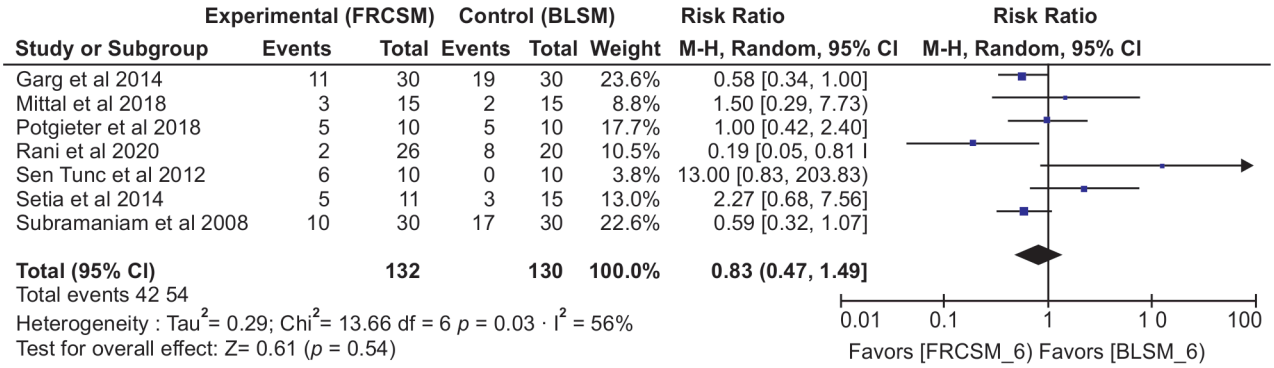

Fig. 3: Forest plot of included studies showing failure rate at 6 months

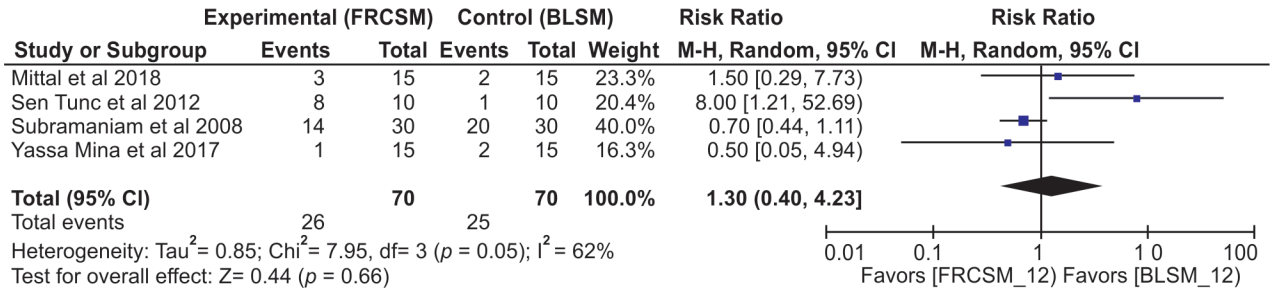

Fig. 4: Forest plot of included studies showing failure rate at 12 months

intervention, (b) allocation concealment was not done in any of the studies, (c) random sequence generation was not reported in four studies.[12–14,18] Moreover, the randomization method was not properly explained in four studies[8,15–17] which led us to categorize it as an unclear risk of bias. A low risk of bias was seen in attrition and reporting bias in all the included studies. Only one study[15] performed a split-mouth design which minimized the inter-subject variability.

Characteristics of the Studied Groups

In all the clinical trials, participants were in the age-group of 4–10 years. Inclusion and exclusion criteria were similar in all the studies, except for a study conducted by Yassa et al.[15] in which cases with only premature bilateral loss of the first primary molar were included. The follow-up period for space maintainers varied from 6 to 12 months. The sample size of included studies mostly ranged from 20–30. The criteria used for evaluating the effectiveness of

both SM were distortion/debonding at the enamel-composite interface, cement loss/debonding at the fiber-composite interface, fracture loop/fracture fiber framework, caries, and gingival inflammation.[8,12–18]

Assessment of Individual Space Maintainers

Fiber-reinforced Composite Space Maintainer

Fiber-reinforced composite space maintainer was reported to be superior over BLSM by two of the included studies.[12,13] One study[14] reported equal failure rate for both FRCSM and BLSM. Overall, all the studies reported higher parental and patient satisfaction with FRCSM. Although FRCSM fabrication takes less time than BLSM, fabrication of FRCSMs was reported to be technique sensitive in two studies.[8,14]

The majority of studies stated that failures observed in FRCSM were mostly due to debonding of an enamel-composite interface,[8,13–18] followed by debonding of fiber-composite interface and fracture of the fiber frame.[8,12–14,16–18] Additionally, an increased tendency for plaque accumulation at the gingival areas on the abutment teeth was observed in one study. This finding was ascribed to plaque retentive sites along with the fiber framework.[16]

The failure of FRCSM due to debonding of enamel-composite interface could be due to; (a) negative influence of prismless enamel on resin retention,[8,12–14,17,18,22,23] (b) tangential and compressive forces acting on the hanging fiber bridge,[16] (c) transmission of forces from fiber frame to bonding margins between tooth and ribbond on either side of the framework,[16] (d) improper surface preparation,[17] (e) disturbances during the adhesive setting process,[17] and (f) moisture contamination (reported in almost all the included studies). The aforementioned observations made by Tunc et al.[17] were in accordance with the studies conducted by Zachrisson et al.,[24] Soares et al.[25] It was also observed that the majority of dislodged space maintainers were found to be in the mandible which may be attributed to the excessive chewing forces in the mandible.[8]

The second possible reason for the failure of FRCSM was debonding of the fiber composite interface. This was ascribed to the overzealous finishing and wearing away of the thin layer of composite from the fiber frame during mastication.[12–14,16,18]

Another reason for failure was the fracture of the fiber frame of FRCSM itself. This might have resulted due to chewing of hard food by the patients as reported by four studies.[12–14,18] Three studies[13,14,18] reported that as time passes, supra eruption of the opposing tooth may impinge on the fiber frame causing increased concentration of mechanical stresses resulting in its subsequent fracture. Another plausible reason could be the transmission of forces from the fiber frame to bonding margins between the tooth and ribbond (FRCSM) on either side of the framework.[16] Another study reported that patients' habit of putting pencils inside their oral cavity could have possibly resulted in pulling out of the fiber framework.[8]

Furthermore, there was no uniformity observed in the fabrication techniques of FRCSM in the included studies. Numerous methods of fabrication were adopted by authors which included bonding on the buccal[8] or palatal surface,[17] fabrication as a hygienic pontic,[14] loop,[12–14] or as a saddle design.[16,18] In one study,[12] FRCSM was fabricated first in a study model and then it was bonded to the tooth. These variations in fabrication techniques might have affected the effectiveness of FRCSM. Therefore, during the placement of FRCSM, the mechanical stresses to which the appliance was subjected should be taken into consideration since it plays an important role in its long-term success than its design as stated by Baroni et al.[26]

Certain modifications could be adopted to improve the overall functioning of FRCSM. The bond strength on the functional side of the deciduous abutment tooth could be improved by adding mechanical retention by embedding the fiber and composite into a prepared groove. This could be advantageous but merits further exploration. One study had reported that two FRCSM devices that fractured, surprisingly retained contact with their non-abutment teeth, thereby fulfilling their space-maintaining purpose even though it was considered as a failure under failure criteria.[14] Therefore, FRCSM devices with half loop bonded to the non-functional side of the abutment tooth design could also be investigated.

Furthermore, differences in bonding agents, types of composite and operator skill, follow-up period might have contributed to the variation in these results since FRCSM-related techniques are not yet standardized.

Band and Loop Space Maintainer

Band and loop space maintainer exhibited higher survival rate in three of the included studies,[8,16,17] whereas one study reported a similar failure rate for both FRCSM and BLSM.[14] In this review, it was observed that the most common reason stated for the failure of the BLSM was majorly cement loss,[8,12,13,15–18] followed by slippage of band gingivally causing gingivitis[12–16] and fracture of the loop.[8,12–14,18] Distortion of the band was observed to have very less implication in failure of BLSM since it was reported in only two of the studies.[13,14]

Failure of BLSM due to cement loss might be due to various reasons, among which inadequate moisture control was the most commonly cited reason.[8,12–18] Inadequate moisture control can lead to cement loss in glass-ionomer cement even though it has low oral solubility.[12,13,18] Two studies[8,14] reported that along with inadequate isolation during cementation, cement loss could also be attributed to poor band fit. Potgieter et al.[14] specifically mentioned that GIC could have led to cement loss since the ideal cement to secure bands as suggested by Croll et al.[27] was zinc phosphate or polycarboxylate cement. But all the included studies used GIC for cementing the band since GIC has additional fluoride-releasing the property. Setia et al.[16] reported that though extreme care was exercised during appliance fabrication, still there might have been some failure at the band cement interface, leading to the failure of the space maintainer. The author further reported that the failure could have also been due to the non-adherence of the patient to the postoperative instructions.[16] On contrary to other included studies, Tunc et al.[17] reported only one case of cement loss. They reported that these findings could be due to differences in luting cement (GIC) and length of follow-up periods as compared to the previously conducted studies where zinc phosphate or polycarboxylate cement were used for band cementation.

The second possible reason for the failure of BLSM was due to distortion of wire. This failure could be due to bending of the loop with subsequent submerging of the wire beneath the gingiva as reported in one study. The author reported that bending of the loop may have occurred due to the intermittent functional loading on the space maintainer causing high compressive stresses on the tooth supporting the cantilever extension. This same observation was made by White et al.[28] in his study. Another reason reported by the author was the extension of the loop to the deciduous

canine with the absence of a rest which gave the cantilever wire a smaller contact area leading to instability of the loop.[14] Garg et al.[13] also reported that the reason for the distortion of wire might be because the solder wire loop lost proper contact with the non-attached abutment tooth, eventually submerging into the gingiva. This reason was also suggested by Croll[27] and Kara et al.[29] in their study. Also, distortion of wires might have occurred due to children fiddling with devices, as one child admitted to playing with the wire in one study.[14] This finding was in accordance with Sasa et al.[30]

Another reason for failure was the solder breakage (fracture of the loop). This failure may have occurred due to poor quality of construction which may either be due to an incomplete solder joint,[8] overheating of the wire during soldering, a remnant of flux on the wire, over thinning the wire during polishing, or failure to encase the wire in the solder.[12,14,18]

Meta-analysis

This meta-analysis combines data across studies to estimate failure rate with more precision than in a single study. The main limitation of this meta-analysis is the small number of included studies and small patient population, also the variation in the follow-up period, which could influence the results. More randomized trials would be required to increase the accuracy of the results. Meta-analysis was done for failure rate at 6 months and 12 months. It was observed that after 6 months FRCSM performed better than BLSM.[8,12–14,16–18] However, at the end of 12 months BLSM performed better than FRCSM.[8,15,17,18]

Strengths and Limitations

The strength of this systematic review is its complete adherence to PRISMA statement 2009. This review attempted to evaluate the effectiveness of FRCSM when compared with BLSM which has not been evaluated before. Additionally, this review only considered RCTs adding to its validity. This review also included a meta-analysis that compared the failure rate at the 6th and 12th month. The main shortcoming of this systematic review is the limited number of databases searched and the limited number of existing studies.

There is much need to conduct more RCTs with larger sample size and preferably split-mouth design since split-mouth design removes much of the inter-subject variability and can be used to check patient preferences. These studies should mainly focus on the bonding of FRCSM to the appropriate tooth surface to minimize the mechanical stresses subjected to it, in both maxillary and mandibular arch with an adequate long-term follow-up. Also, the patient should be instructed not to play with the space maintainer as this may result in inadvertent failure of the space maintainer.

Conclusion

The overall quality of evidence was judged as very low, due to the methodological limitations of the included studies. There is much-needed standardization of the fabrication technique of FRCSM for both maxillary and mandibular arch.

Therefore, it is necessary to conduct more well-designed RCTs which are focused on standardizing the fabrication technique of FRCSM to improve the effectiveness of FRCSM. The study population should consist of the patient where the split-mouth trial is possible since split-mouth design removes much of the inter-subject variability and can be used to check patient preferences. Also, these trials should be of long-term follow-up as it is important to evaluate the effectiveness and durability of FRCSM. Lastly, the patient should be strictly instructed not to play with the space maintainers, since it can result in inadvertent failure of the space maintainer.

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