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Children's satisfaction and survival rate of fiber-reinforced space maintainer versus band and loop space maintainer in children with premature loss of maxillary primary first molar: A randomized clinical trial

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Abstract---Background: Band and loop space maintainer (BLSM) are well tolerated and long-lasting appliances, but it comes with several drawbacks, including longer lab times, more frequent cement loss dislodgements, longer visits, and the inability to avoid the rotation or tilting of neighboring teeth. These limitations motivate the search for alternative appliance such as fiber-reinforced space maintainers. Aim of the study: Evaluation of children's satisfaction and survival rate of fiber-reinforced space maintainer versus band and loop space maintainer in children with premature loss of maxillary primary 1st molar. Materials and Methods: Thirty patients, randomly divided into two groups (n=15). BLSM group: which included (15) patients who receive band and loop space maintainer. FRSM group: which included (15) patients who were received fiber-reinforced space maintainer. The patients were evaluated for satisfaction based on Likert -type scale and survival rate. Results: The FRSM group showed a higher satisfaction score than BLSM group. For survival rate the fiber-reinforced space maintainers showed a greater success rate than band and loop space maintainers. Conclusions: The FRSM can be used as an alternative to BLSM regarding clinical performance and patient's satisfaction in children with premature loss of maxillary 1st primary molars.

Keywords---band, loop space maintainer, fiber-reinforced space maintainer, patient satisfaction, survival rate, primary teeth.

Introduction

One of the most common reasons of malocclusion in patients in the deciduous or in mixed dentition phases is space loss, following early loss of deciduous teeth. Space maintenance is an essential section of pedodontics and is one of the primary preventive and interceptive orthodontic procedures that is used to reduce the incidence of malocclusion. [1] Therefore, a space-maintaining device that works well could reduce the frequency of occlusal discrepancies. [2] Depending on the dental developmental stage, dental arch, number of teeth, position, and primary tooth type involved, several types of space maintainers can be employed [3]. The band and loop space maintainer (BLSM) is the most often utilized appliance out of all those that are available. [4] According to **Qudeimat** and **Fayle** [5], the BLSM is affordable, simple to construct, adaptable, and needs minimal chairside time. However, it comes with several drawbacks, including longer lab times, more frequent cement loss dislodgements, longer visits, and the inability to prevent rotation or tilting of neighboring teeth. A prefabricated BLSM was introduced to address these drawbacks of BLSM. However, the only benefit it had over BLSM was that the additional appointments needed for placement were not necessary [6], but in contrast the cost was higher. To overcome the drawbacks of BLSM, a fiber-reinforced composite resin space maintainer (FRSM) was recently developed. The FRSM are physically similar to standard BLSM in terms of strength and are more aesthetically pleasing, less time-consuming, less bulky, and take up less space in the oral cavity [7-9]. The present study aimed to evaluate children's satisfaction and survival rate of fiber-reinforced space maintainer versus band and loop space maintainer in children with premature loss of maxillary primary 1st molar.

Subjects and Methods

Study Design

Randomized controlled clinical trial.

Study setting

The current clinical trial was conducted on a total of 30 patients who were selected from the outpatient clinics of Departments of orthodontics and pedodontics, Faculty of Dental Medicine (Boys), Al-Azhar University, Cairo, Egypt.

Inclusion criteria

- Patients with age ranges from 5-8 years.
- Patients with early loss of primary maxillary 1st molar.
- Presence of class I occlusion and normal primary molar Relations.

Exclusion criteria

- Medically compromised patients.
- Non cooperative patients.
- Patients with bone thickness less than 1mm overlying the successor tooth.

Sample size calculation

Based on a previous study [10] and Using G power statistical power analysis program (version 3.1.9.4) for sample size determination, A sample size (n=14 for each space maintainer) was sufficient to detect a large effect size (ρ) = 0.67 and d=1.33 respectively, with an actual power (1-β error) of 0.8 (80%) and a significance level (α error) 0.05 (5%) for two-sided hypothesis test.

Randomization and group allocation

It was done by giving a number to each patient and then they were allocated using online website (http://www.graphpad.com/quickcalcs/index).

Grouping

The selected patients were allocated randomly into 2 groups:

- BLSM group [control group]: which included (15) patients who receive band and loop space maintainer.
- FRSM group [test group]: which included (15) patients who were received fiber-reinforced space maintainer

Intervention
Pre-operative evaluation

Intraoral periapical radiographs were taken in the areas of tooth loss to evaluate the following: Absence of periapical pathology, presence of succedaneous tooth bud, presence of more than 1 mm bone overlying the succedaneous tooth germ and/or less than one-third of the root of the permanent tooth formed.

Construction of space maintainer
Construction of band and loop space maintainer

After selection of proper band size and fitting to the abutment, a full arch impression was taken with alginate impression material. Then, the band was removed with band remover and placed and stabilized in the impression in the correct position; next a working model was prepared from dental stone with the band in its place. The loop was made of 0.9mm stainless steel wire; it was designed to approximate the gingival contour of the extraction space to avoid occlusal interferences and extends from the middle of the band from its either side to reach the distal surface of the anterior abutment tooth just below the contact (Figure 1). Cementation was done using glass ionomer cement (Gc Fuji I®, Gc Dental Products Corpor., Japan).

Construction of fiber-reinforced space maintainer

Isolation was done using rubber dam and suction (Figure 2). Both the abutment teeth (primary canine and second primary molar) were cleaned and air dried then etched. After etching (Scotchbond™, 3M-ESPE, USA) for 15 seconds bonding agent (Adper™, Single Bond, 3M-ESPE, USA) was applied and light cured for 20 s. A thin layer of flowable composite (Filtek Z 350 XT, 3M-ESPE, USA) was applied to the buccal surfaces of abutment tooth and required length of fiber (Ribbond, Inc., Seattle, WA, USA) was placed on this composite, extending from the buccal aspect of the primary second molar to proximal surface of the primary canine.

The ends of the fiber were adapted to tooth surface with a plastic instrument. Preliminary curing for 40 s was done individually at each end of the fiber framework. At the end additional layer of flowable composite was applied over the area where the fiber adapted to the tooth surface and over the fiber and then was light cured for 40 seconds. Lastly, finishing and polishing the whole appliance was done. (Figure 3). Oral hygiene and home care instructions were given for each patient or guardians. Also, the parents instructed to return promptly in case of the appliance was dislodged, fractured, or even loosened.

(a) (b)

Figure 1. Band and loop space maintainer after final cementation (BLSM group)

A B

Figure 2. Rubber dam placement before fabrication of fiber-reinforced space maintainer (FRSM group)

(a) (b)

Figure 3. Fiber- reinforced space maintainer after final adjustment. (FRSM group)

Evaluation
Children satisfaction

At the end of the study patients reported their level of satisfaction by answering questions based on a 5-point Likert scale, which focused on four areas: the color of the space maintainer, discomfort with eating, discomfort with tooth brushing, and general satisfaction with the appliance. The questions used in this study were translated into arabic before giving to the patients.

The questions used were as the following:

Q1- Do you satisfied with the color of the space maintainer?
1= Very Unsatisfied.
2= Unsatisfied.
3= Neutral.
4= Satisfied.
5= Very Satisfied.

Q2-Do you feel discomfort with eating after placement of space maintainer?
1= Sever Discomfort.
2= Moderate Discomfort.
3= Mild Discomfort.
4= little Discomfort.
5= No Discomfort.

Q3-Do you feel discomfort with tooth brushing after placement of space maintainer?
1= Sever Discomfort.
2= Moderate Discomfort.
3= Mild Discomfort.
4= little Discomfort.
5= No Discomfort.

Q4- Generally are you satisfied with this appliance?
1= Very Unsatisfied.
2= Unsatisfied.
3= Neutral.
4= Satisfied.
5= Very Satisfied.

Evaluation of survival rate of space maintainers

Recalling patients was at 1,3, and 6 months for clinical evaluation of the space maintainer. For band and loop space maintainer the device was considered failed if (Dislodged, broken band or loop, Loos of cement, wire Impinged into the soft tissue, or Severe inflammation surrounding band). For the fiber-reinforced space maintainer, it was considered failed in case of: Fracture of any part of the space maintainer or debonding at the enamel composite interface.

Statistical analysis

Data management and statistical analysis were performed using the Statistical Package for Social Sciences (SPSS) version 18. Numerical data were summarized using mean, standard deviation and median and range. Data were explored for normality by checking the data distribution and using Kolmogorov-Smirnov and Shapiro-Wilk tests. Comparisons between groups with respect to non-parametric numeric variables were compared by Mann Whitney U test. Categorial qualitative data were expressed as number and percentage and were compared using Chi square test. All p-values are two-sided. P-values ≤0.05 were considered significant.

Results

Children satisfaction. (table 1)

Q1- Color satisfaction:

Patient's satisfaction toward the color was greater in group 2 as, (6.7%) were neutral, (26.7%) were satisfied, while (66.7%) were very satisfied compared to Group 1 where (13.3%) were very unsatisfied, (46.7%) were unsatisfied, and (40.0%) were neutral, and the difference was found to be statistically significant (p=0.000).

Q2- Discomfort with eating:

In group (1); (13.3%) of patients were sever discomfort,(53.3%) were moderate discomfort, (20.0%) were mild discomfort, and (13.3%) were little discomfort. While in group (2) (6.7%) of patients were sever discomfort, (26.7%) were moderate discomfort, (53.3%) were mild discomfort, and (13.3%) were little discomfort. The difference between the two groups was not statistically significant (p=0.286).

Q3- Discomfort with tooth brushing:

In group (1); (6.7%) of patients were sever discomfort, (20%) were moderate discomfort, (53.3%) were mild discomfort, and (20%) were little discomfort. While in group (2) (0%) of patients were sever discomfort, (13.3%) were moderate discomfort, (66.7%) were mild discomfort, and (20%) were little discomfort. The difference between the two groups was not statistically significant (p=0.70).

Q4- Satisfaction with the appliance:

Patient's general satisfaction toward the space maintainer was greater in group 2 as (13.3%) were neutral, (40.0%) were satisfied, and (46.7%) were very satisfied compared to group (1) in which (6.7%) were very unsatisfied, (20.0%) were unsatisfied, (53.3%) were neutral, (20.0%) were satisfied. The difference between the two groups was found to be statistically significant (p=0.004).

Survival rate

At one month and 3 months, survival rate in both groups respectively was 100% and 93.3% (p=1). At 6 months, the survival rate in group 1was 73.3% in comparison to 80% in group 2, with no significant difference between groups (p=0.67). Table (2)

Failure reason

In Group 1 (band and loop), cement dislodgment was the reason of failure in 75% of cases, while solder dislodgment was the reason in 25%. In Group 2 (FRSM), Composite debonding was the reason of failure in 66.7% of cases, while fracture of fiber was the reason in 33.3%. Table (3).

Table 1

Qualitative descriptive statistics of Children satisfaction response and comparison between group (chi square test)

Score		Q1		Q2		Q3		Q4	
		BLSM group	**FRSM group**	**BLSM group**	**FRSM group**	**BLSM group**	**FRSM group**	**BLSM group**	**FRSM group**
1	**Count (%)**	2 (13.3%)	0 (0.0%)	2(13.3%)	1 (6.7%)	1 (6.7%)	0(0.0%)	1 (6.7%)	0 (0.0%)
2	**Count (%)**	7 (46.7%)	0 (0.0%)	8(53.3%)	4(26.7%)	3(20.0%)	2(13.3%)	3(20.0%)	0 (0.0%)
3	**Count (%)**	6 (40.0%)	1 (6.7%)	3(20.0%)	8(53.3%)	8(53.3%)	10(66.7%)	8(53.3%)	2(13.3%)
4	**Count (%)**	0 (0.0%)	4 (26.7%)	2(13.3%)	2(13.3%)	3(20.0%)	3(20.0%)	3(20.0%)	6(40.0%)
5	**Count (%)**	0 (0.0%)	10(66.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0 (0.0%)	0 (0.0%)	7(46.7%)
P value		0.000*		0.268 NS		0.70 NS		0.004*	

Q= questions. BLSM= Band and Loop Space Maintainer. FRSM= Fiber-Reinforced Space Maintainer Significance level p≤0.05, *= Significant, NS=Non-Significant.

Table 2

Qualitative descriptive statistics of survival rate and comparison between group (chi square test)

Score			1M		3M		6M	
			BLSM group	**FRSM group**	**BLSM group**	**FRSM group**	**BLSM group**	**FRSM group**
	Success	**Count (%)**	15 (100%)	15 (100%)	14 (93.3%)	14 (93.3%)	11 (73.3%)	12 (80%)
	Failure	**Count (%)**	0	0	1 (6.7%)	1 (6.7%)	4 (26.7%)	3 (20%)
Total			15	15	15	15	15	15
P value			1 NS		1 NS		0.67 NS	

M=Month, BLSM= Band and Loop Space Maintainer, FRSM= Fiber-Reinforced Space Maintainer, P= Probability, NS= Non-Significant, Significance level p ≤ 0.05

Table 3

Descriptive statistics of failure reason in both groups

Reason		Failed cases	
		BLSM Group	**FRSM Group**
Cement Dislodgment	**Count (%)**	3 (75%)	0 (.0%)
Solder dislodgment	**Count (%)**	1 (25%)	0 (.0%)
Composite debonding	**Count (%)**	0 (.0%)	2 (66.7%)
Fracture of fiber	**Count (%)**	0 (.0%)	1 (33.3%)
Total cases		4	3

BLSM= Band and Loop Space Maintainer. FRSM= Fiber-Reinforced Space Maintainer

Discussion

Numerous events occur as the occlusion develops from the primary dentition through the mixed dentition into the permanent dentition. These events are essential in the development of a functional, aesthetic, and stable occlusion. If this sequence is disrupted, it will eventually affect the final occlusion in the permanent dentition.[11,12] Primary teeth basically act as natural space maintainers for the permanent dentition. This is an additional function apart from its primary role in speech, chewing, appearance and prevention of bad oral habits. The exfoliation of these teeth is a physiological process although if there is premature loss of these teeth, several malocclusions such as crowding, impaction of the succedaneous tooth are predisposed to occur. [13] It also causes loss of arch length, shift in midline, tilting of adjacent teeth into the edentulous space and supra eruption of opposing tooth. Hence, maintenance of this space may eliminate or reduce these consequences. [14]

Space maintainers preserves this space and helps in guiding the erupting tooth into its proper position in the dental arch thus minimizing the need for orthodontic correction in the future [15]. Band and loop space maintainer (BLSM) are well tolerated and long-lasting appliances, but it comes with several drawbacks as mentioned before. These limitations motivate the search for alternative appliance such as fiber-reinforced space maintainers. The present study evaluated children's satisfaction and survival rate of fiber-reinforced space maintainer versus band and loop space maintainer. The area with loss of maxillary primary 1st molar, was chosen to allow easy fabrication and isolation specially for FRSM which require complete and perfect isolation to ensure the good success rate particularly with the use of rubber dam which provides optimum isolation.

Assessment of patient satisfaction towards FRSM and BLSM space maintainers was chosen as patient acceptability is now considered a key part for improvement of health care quality as the satisfied patients tend to show better compliance with prescribed treatment procedures. [16,17] Likert-type scale has been used in the current study because it is a simple tool, with adequate reliability and validity for assessment of patient satisfaction. [16] In the present study, FRSM group showed a higher satisfaction score than BLSM group. Kamal et al., [18] Evaluated posterior fixed functional space maintainer in terms of its clinical performance, patient satisfaction and effect on oral health. They found that FRSM showed higher satisfaction than BLSM concerning color and shape which is in accordance with our results and with the results of Garg et al. [17] This could be attributed to properties of FRC which fulfill patient's esthetic hopes. [19]

At 6 months, the survival rate in FRSM group was to 80%, a non-statistically higher than BLSM group (73.3%). The overall failure rates after six months, were (20 %) for FRCSM while in BLSM group was (26.6%). Saravanakumar et al., [20] conducted a clinically study to evaluate the long-term effect of FRCR space maintainer made with Ribbond® bondable reinforcement ribbon in children over a period of 18 months, and the mean survival time of

space maintainer were found to be 12 months (minimum 1 and maximum 18 months), which is in agreement with our results. Also, a study by Kargul et al [21] showed success of glass fiber-reinforced composite resin space maintainers and concluded that it function well during a mid-term evaluation. also, Simsek et al [22] evaluated the clinical performance of simple fixed space maintainers bonded by using a flowable composite resin for 12 to 18 months and they concluded 95% success rate.

This may be attributed to the properties of fiber-reinforced materials specially (Ribbond) which is mainly consists of bondable and reinforced polyethylene fibers with high strength and elasticity that makes them resistant to stretch and distortion with a high resistance to traction making them easily adapted and contoured following the dental arch tomography and tooth morphology. In contrast to our results Kirzioglu et al [23] showed 27% success of 40 FRSM at 6 months and 13% at 12 months and concluded that it can be accepted as successful appliances only for short periods, but in this study another material was used which is basically a glass reinforced fiber material which may differ from the material used in current study. Also, Tunc et al., [24] provided a comparative evaluation of the survival times and failure rates of different types of fixed space maintainers. They concluded that BLSM showed superior performance in terms of both survival time and success rates versus direct bonded and fiber-reinforced composite space maintainers, with mean survival time for FRSM was (6.70 months) which is approximately comparable to our study's results.

Conclusions

Fiber-reinforced composite space maintainers can substitute the traditional band and loop space maintainer with proper clinical performance and patient's satisfaction in children with premature loss of maxillary 1st primary molars. Further clinical studies on fiber-reinforced composite space maintainers might be recommended to assess its clinical performance with a large sample size, different designs and its effect on oral health.

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