

Evaluation of Posterior Fixed Functional Space Maintainers Made of Fiber Reinforced Composite

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Abstract

Aim of the study: Evaluation of posterior fixed functional space maintainers made of fiber reinforced composite in terms of clinical performance, patient satisfaction and effect on oral health. **Methods:** (I) *In vitro* study: Mean flexural strength values were determined for composite resin bars reinforced with one and two fiber bundles compared to unreinforced composite bars. (II) *In vivo* study: A randomized controlled split mouth clinical trial was carried out to evaluate fixed functional fiber reinforced composite space maintainer compared to band and loop space maintainer in fifteen children with premature bilateral loss of the first primary molar. **Results:** There was a statistically significant difference in flexural strength between the fiber-reinforced composite groups and the composite resin control group. Mean flexural strength for composite specimens reinforced with two fiber bundles was much higher than the normal occlusal forces. Combination of clinical performance and effect on oral health, the overall clinical success rate of fiber reinforced composite space maintainers was 93.3% while it was 80% for the band and loop. Parents and patients reported higher satisfaction with fiber reinforced composite space maintainers. **Conclusion:** Fiber reinforced composite space maintainers can be recommended as superior alternative to band and loop space maintainers in terms of clinical performance, effect on oral health and patients' satisfaction.

Key Words: Fiber reinforced composite, Chair-side, Direct, Functional, Esthetic space maintainer

Introduction

Premature loss of primary teeth continues to be a common problem, resulting in disruption of arch integrity and adversely affecting the proper alignment of permanent successors. Immediate provision of a space maintainer (SM) is the safest way to eliminate or reduce some of these difficulties [1]. Among the various types of SMs, band and loop (B&L) is the most commonly used fixed SM. However, its failure rate ranged from 13% to 73% of the cases [2].

Fabrication of SMs with fiber reinforced composite (FRC) possesses the advantages of being easily manipulated and directly chair-side applied. Moreover, they are fixed, minimally invasive, aesthetic, readily repaired, reversible, biocompatible, and of relatively lower treatment costs. However, their longevity is still a controversial issue [3].

Aim of the study

The current study was conducted to evaluate fixed functional space maintainers made of FRC, compared to the conventional B&L SMs, in terms of clinical performance, patient satisfaction and effect on oral health.

Materials and Methods

The current study included *in vivo* and *in vitro* parts.

In vitro study

The objective was evaluation of the reinforcing effects of glass fibers on composite resin beams and determination of fiber volume required to replace a missing primary molar. Equal sized rectangular bar shaped specimens with dimensions similar to that of the clinical situation (16*5*4 mm) were prepared, using Teflon split mold (Figure 1), for testing. Three groups of five specimens were prepared; group (1) was composite resin bars without fiber incorporation

served as control, group (2) was FRC bars reinforced with only one fiber bundle and group (3) was FRC bars each containing two fiber bundles.

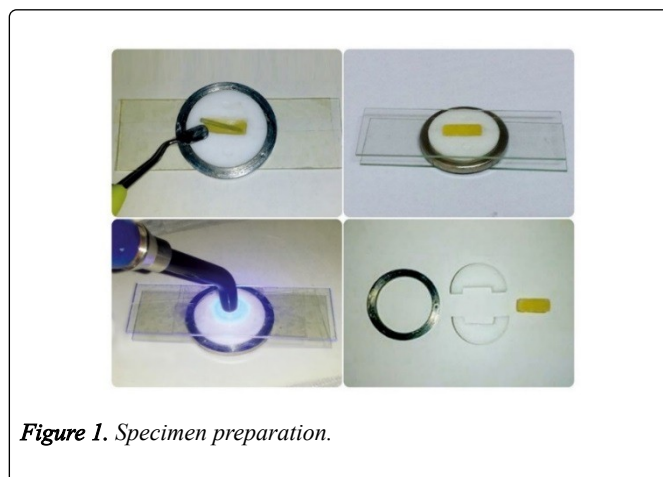


Figure 1. Specimen preparation.

Mean flexural strength values (σ_f) in mega Pascal (MPa) were determined in a 3-point bend test using an Instron Universal Testing Machine (Instron, Corporation, Canton, MA, USA) with a crosshead speed of 1 mm/min and the load-deflection curves were recorded with a Bluehill Lite computer software.

In vivo study

A randomized controlled split mouth clinical trial was designed to evaluate FRC SM compared to B&L SM in children, 5-7 years old, with premature bilateral loss of the first primary molar. 15 children were randomly selected and FRC SM was randomly allocated to one side and consequently the other side received B&L SM (in the upper or lower jaw).

All patients and their parents were informed in an easy detailed manner about the treatment procedures, expected

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outcome, as well as other treatment options. From all children/parents who accepted participation in the study, child verbal assent was obtained and the parents signed the consent of ethical committee of Faculty of Dentistry/Minia University.

Treatment procedures

Before constructing the space maintainers, a thorough assessment was executed. Oral prophylaxis, treatment of affected teeth and application preventive measures were carried out.

Fabrication of B&L SM was done [4,5] using preformed stainless steel band to fit the tooth distal to the space. Cementation was done using glass ionomer cement (GC Fuji I®, GC DENTAL PRODUCTS CORPOR., Japan).

Fabrication of FRC SM was performed according to the clinical guide of the manufacturer of the fibers used (everStick® C&B, GC Corporation, Japan). Moisture control was established using rubber dam and suction. For building the fiber framework, 2 everStick® C&B fiber bundles were used. Bonded fiber frame was covered with a layer of 1–2 mm of composite (G-aenial Posterior, GC DENTAL PRODUCTS CORPOR., Japan). Light-curing the fiber frame extended for 20 seconds. Layering the pontic was done using composite resin and the pontic design was self-cleaning (hygienic). Finally, finishing and polishing the fixed appliance was done.

All patients were instructed about following oral hygiene measures, caring for the space maintainers (*Figure 2*) and returning promptly to the pediatric dentist as soon as conveniently possible in case of any complaint. Parents and children were informed about recall at 1st, 3rd, 6th, and 12th months for evaluation of space maintainers and to continue periodic recall till appliance would eventually be removed. At baseline, oral health was assessed. Assessments at 1st, 3rd, 6th, and 12th months follow up period were accomplished for clinical performance and effect of SMs on oral health, while satisfaction of patient and parent was evaluated 12 months after the fabrication of SMs.



Figure 2. B&L and FRC SMs.

FRC SMs were evaluated for debonding at the enamel-composite interface, delamination at the fiber-composite interface, and fracture of the fiber frame while B&L SMs were evaluated for cement loss, distortion, and Loop fracture. SM was considered failed if any of the above mentioned events occurred.

Evaluation of oral health comprised detection of new carious lesions in the abutment teeth - around SM - according to the International Caries Detection and Assessment System II (ICDAS II) [6] and evaluation of the gingival health surrounding the appliances using the Gingival Index (GI) described by Löe and Silness [7].

A 5-point Likert-type [8] scale was used to evaluate parents' and patients' satisfaction. Parents were asked to rate color, shape, durability, overall satisfaction, if their child ever complained of any discomfort related to the space maintainer. Moreover, children were asked to rate their overall satisfaction and complaints. The format of a typical five-level Likert scale was collapsed for statistical reasons to dissatisfied, neutral responses and satisfied.

Results

In vitro study

Mean flexural strength (M Pa) was 97.817 ± 6.003 for the control group (composite resin only) while increased to 132.234 ± 11.354 for the 1 fiber reinforced composite group, and scored 184.089 ± 9.130 for group 3 composite specimens reinforced with 2 fibers. The differences between the three groups were statistically significant ($P < 0.05$).

In vivo study

FRC SMs had a higher clinical performance success rate than B&L SMs, however, the difference was not statistically significant ($P > 0.05$) (*Table 1*).

Table 1. Clinical performance and success rate of B&L and FRC SMs.

Type	Clinical performance	Number	Success rate
B&L SMs	- Cement loss	2	86.70%
	- Distortion	0	
	- Loop fracture	0	
FRC SMs	- Delamination between Fiber/Composite	1	93.30%
	- Debonding between Enamel/Composite	0	
	- Fracture of fiber frame	0	

Regarding the effect on oral health, no new carious lesions were detected in both types of space maintainers during the follow up period with a success rate of 100%. Gingival tissues surrounding FRC SMs showed no signs of inflammation throughout the follow up period in all cases reporting 100% success rate while one case showed mild gingivitis (score 1) around band and loop space maintainer. However, there was no statistical difference between both types of SMs regarding their effect on oral health ($P > 0.05$).

Combination of clinical performance and effect on oral health, the overall clinical success rate of FRC SMs was 93.3% while it was 80% for the B&L SMs. The difference was not statistically significant ($P = 0.2$).

Parents reported higher satisfaction with FRC SMs than B&L SMs regarding all the items of the questionnaire. Answers of children's questionnaires were also in favor of FRC SMs. Differences in parental satisfaction regarding color and shape of SMs were statistically significant ($P=0.005$ and 0.001 respectively). Also, difference in children's satisfaction was statistically significant ($P=0.007$) (Figure 3).

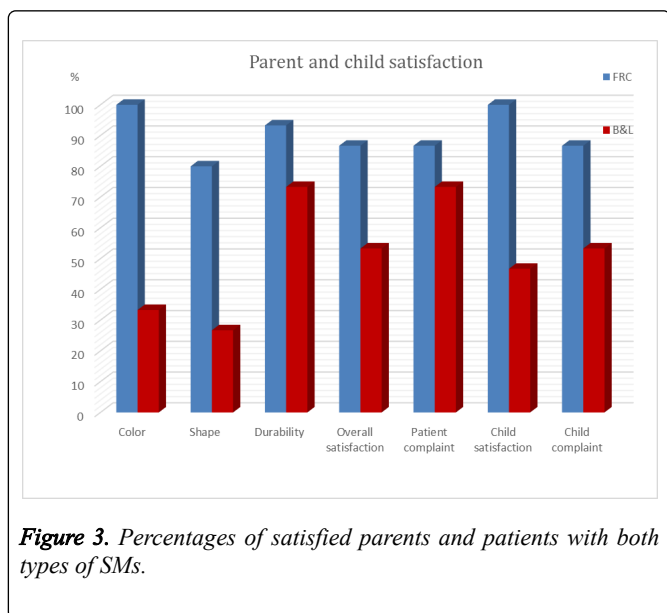


Figure 3. Percentages of satisfied parents and patients with both types of SMs.

Discussion

Characteristics of FRC in addition to the limitations of the conventional band and loop space maintainers suggested the evaluation of a new design of fixed functional FRC space maintainer as an alternative to the stainless steel band and loop.

Before clinical application, an *in vitro* study, measuring the mean flexural strength values for FRC resin bars compared to an unreinforced composite control group, was designed to determine the number of fiber bundles required to replace a missing primary molar since it wasn't suggested by the manufacturers or the dental literature.

Flexural strength was selected for *in vitro* measurements as it is a meaningful mechanical property for brittle materials; composite resin, to predict their clinical performance. The three-point bending test is a simple method - both in specimen fabrication and load application - to determine flexural strength [9].

Specimens of composite or composite and fibers were prepared in split mold held together by a metal frame to produce equal sized specimens and to bring them out easily. Composite was condensed into the split mold against a microscope glass slab to provide flat specimens with uniform surface [10].

Although a standard three-point bending test has been published by the International Standards Organization (ISO 4049, 2009) [11] describing the preparation of a test specimen for bending tests on composite beams, dimensions of specimen in this study were similar to the clinical situation as they can lead to flexural strength values similar to the ones obtained with standardized specimen, with the advantage of

demanding less amount of material and being less time consuming [12].

Glass fibers were chosen for composite reinforcement for both the *in vitro* and *in vivo* studies as they are considered the fibers of choice in dental applications due to the good esthetic and superior mechanical properties as well as their ability to chemically bond to dental composite resin materials. Moreover, the selected type of glass fibers was contained within a bi-phase matrix consisting of dimethacrylate and poly methyl methacrylate polymers. The PMMA matrix was highly viscous compared to the dimethacrylate system, hence improving both handling and bonding properties of fibers [13].

Fibers were oriented in a longitudinal direction to resist predominant oral stresses. Also, fibers were placed at the tensile side of the bar as it is the most efficient location for reinforcement [14].

The results of the current study showed that there was a statistically significant difference in flexural strength between the FRC groups and the composite resin control group. This result was similar to those reported in the review article of van Heumen et al. [14]. The current study revealed that the mean flexural strength of the specimens reinforced with one fiber was around the normal occlusal forces; 354.01 ± 134.04 newton, reported by Takaki et al. [15], while the mean flexural strength of the group reinforced with 2 fiber bundles was much higher suggesting the use of 2 glass fiber bundles to reinforce the composite for primary molar replacement.

Practically, occlusal forces have various directions rather than the one direction load applied in this test. This limitation brought out the need for a long-term clinical trial to determine the real performance of the FRC SM [14].

The *in vivo* study was designed to compare posterior fixed functional SMs made of FRC with B&L SMs in terms of clinical performance, patient satisfaction and effect on oral health.

The tested FRC SMs were designed as functional adhesive bridges, based on the clinical success of FRC posterior fixed partial dentures in adults [16], aiming to enhance function and esthetics. In addition, it was logic to search for new posterior appliances as space loss is more apparent in posterior region than in anterior one. B&L SMs were selected as control since they are most commonly used SMs in case of premature loss of a primary molar [2].

The study design was a randomized controlled split mouth clinical trial. This study design represented the optimal reliable study design since RCT has long been considered the gold standard for conducting evidence-based clinical research because they minimize bias. In addition, split-mouth design removes much of the inter-subject variability and has been the principal research tool in clinical trials to compare the periodontal health with different treatment modalities and to determine patient preferences [17].

For standardization, patients with symmetrical prematurely lost first primary molars indicated for space maintenance were chosen to be included in the split mouth study. The age group of 5-7 years was selected as in this age; the first permanent

molars had not yet fully erupted and hence could not be banded. Additionally, not all mandibular permanent incisors erupted [4].

FRC SM was randomly allocated to one side in an alternating pattern and consequently the other side received B&L SM to overcome the reported statistically significant higher survival rate for SMs cemented on the left side of the oral cavity compared with those on the right side [2].

Fabrication of B&L SM was done using the preferred prefabricated bands. Glass ionomer cement was used for cementation of bands as it adheres to both enamel and metal and also provides fluoride release [3]. FRC SMs comprised two glass fiber bundles (according to the results of the *in vitro* study) in a longitudinal direction at the tensile side, to get the best possible mechanical behavior [14].

Professional dental prophylaxis was implemented since proper etching requires clean enamel surface [18]. Four handed dentistry allowed for effective patient and time management [19]. Isolating the teeth to achieve a contaminant-free working area was done with rubber dam and high-volume suction to guarantee the long-term survival of composite resin [20].

The enamel etching time was 45 to 60 seconds as studies showed that optimal bond strength to aprismatic enamel is achieved by increasing the time of acid etching rather than removal of the surface layer of enamel whose thickness is impossible to define [21]. Light curing unit was placed too close to the composite resin to get the optimal composite microhardness [22]. Hygienic pontic design was followed as it is more amenable to oral hygiene [23]. Also, it allows detection of permanent successor eruption.

After construction of both types of SMs, all patients were followed up for 12 months. Assessment of the clinical performance was carried out according to the failure criteria established in previous studies [3,5,24,25].

Oral health was evaluated in terms of gingival health and detection of caries adjacent to the appliance. The gingival index was used for evaluating gingival health as it is a simple and accurate method in epidemiological and clinical research [26]. Also, ICDAS II was used for caries detection as it can record early noncavitated enamel carious lesions and become recommended internationally for dental health surveys [27].

Assessment of patient satisfaction towards FRC and B&L SMs was executed as patient acceptability is now considered a key part of the health care quality improvement initiative. Satisfied patients tend to show better compliance with prescribed treatments [28]. Garg et al. evaluated patient acceptability with the help of a Wong-Bakers pain assessment scale [24]. However, as most patient satisfaction studies, Likert-type scale that is a simple tool with adequate reliability and validity was used in the current study [28].

The results of the current study revealed that FRC SMs had a higher clinical performance success rate (93.3%) than B&L SMs (86.7%), the difference was not statistically significant. B&L SMs success rate was very close to that of Setia et al. who used also prefabricated bands [5]. In the current study, the only recorded mode of failure was cement loss that

occurred in 2 cases which is reported as the main reason of failure of B&L SMs. FRC SMs success rate surpassed the results of Tunc et al., Garg et al. and Setia et al. who used different fiber type. Also, it was higher than that of Subramaniam et al. who used the same fiber type. This may be due to used number of fiber bundles, etching method, bonding agent, veneering composite and adherence to the manufacturer instructions [3,5,24,25].

Regarding the effect on oral health, no new carious lesions were detected in both types of space maintainers during the follow up period with a success rate of 100%. These results came in conformity with the results of Subramaniam et al., Tunc et al. and Setia et al. [5]. Also, FRC SMs showed 100% success rate regarding the gingival health surrounding the appliances while it was 93.3% for B&L SMs. The difference was not statistically significant. These results are at par to those of Subramaniam et al. and Tunc et al. and on the contrary to the results of Setia et al. whose finding wasn't statistically significant [3,5,24,25].

The favorable effect on oral health of both types of SMs may be attributed to thorough instructions and adherence to the oral hygiene measures. In addition to the fluoride releasing capacity of glass ionomer used for luting B&L SMs as well as, flushing of the FRC with the abutment tooth eliminating food retentive areas and the hygienic pontic design.

Combination of clinical performance and effect on oral health, the overall clinical success rate of FRC SMs was 93.3% while it was 80% for the B&L SMs. Although the difference was not statistically significant, it suggests the use of FRC SM as an interesting alternative to the conventional band and loop.

Parents and children reported higher satisfaction with FRC SMs than B&L SMs regarding all the items of the questionnaire. Differences regarding color, shape and children's satisfaction were statistically significant. These results go in accordance with the results of Garg et al. [24] and may be attributed to FRC properties which meet patient's esthetic expectations [29]. Additionally, in the current study, the FRC SMs not only possessed the natural color but also the form of the missing tooth.

Conclusion

The current study suggested the use of 2 glass fiber bundles to reinforce the composite resin for replacing a primary molar.

FRC space maintainers can be recommended as superior alternative to B&L SMs in terms of clinical performance, effect on oral health and parents' and children's satisfaction.

However, further *in vivo* and *in vitro* studies are required to develop the best design of FRC SM and evaluate those indirectly fabricated to get the simplest application method.

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