Pesquisa Brasileira em Odontopediatria e Clínica Integrada 2020; 20:e0024
https://doi.org/10.1590/pboci.2020.157
ISSN 1519-0501 / eISSN 1983-4632

ORIGINAL ARTICLE

Clinical Evaluation of Ghana Shyam's TEFF (Telescopically Expanding Fixed Functional) Space Maintainer Versus Conventional Band and Loop Space Maintainer

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Academic Editor: Alessandro Leite Cavalcanti

Received: 17 February 2020 / Accepted: 09 June 2020 / Published: 11 August 2020

How to cite this article: Raviteja NVK, Prasad MG. Clinical evaluation of Ghana Shyam's TEFF (telescopically expanding fixed functional) space maintainer versus conventional band and loop space maintainer. Pesqui Bras Odontopediatria Clín Integr. 2020; 20:e0024. https://doi.org/10.1590/pboci.2020.157

Abstract

Objective: To compare the clinical efficacy of Ghana Shyam's TEFF space maintainer with band and loop space maintainer. **Material and Methods:** This split-mouth randomized clinical trial was conducted on 20 children (7-9 years), requiring bilateral/contralateral space maintenance therapy. After consent, all the selected children received both space maintainers and were followed up periodically every six months up to two years for clinical assessment according to the evaluation protocol. Instructions and motivation were given to the children. OHI (S) index was recorded before cementation of appliances. The following aspects were analyzed: 1) efficiency and function; 2) dislodgement due to cement loss; 3) breakage at soldered parts; 4) carious or gingival inflammation affecting abutment teeth; 5) distortion of band; 6) being embedded in gingival tissues / gingival slopping; and 7) initial and final S-OHIS scores. Statistical analysis was done using Fisher exact test for survival time and Chi-square test for chewing efficiency. **Results:** At 24th-month follow-up, 14 Ghana Shyam's TEFF space maintainers and 16 band and loop space maintainers were found to be intact. **Conclusion:** As both space maintainers demonstrated similar mean survival time Ghana Shyam's TEFF space maintainer with the added advantage of being functional can be recommended as an effective alternative to band and loop in premature loss of primary molar clinical situations.

Keywords: Orthodontics, Preventive; Space Maintenance, Orthodontic; Growth; Tooth Loss.

Introduction

Primary teeth are determining factors in the development of occlusion. The effects of the premature loss of primary teeth include decreased arch length, crowding, crossbite in the first permanent molar area, reduced masticatory function and accumulation of plaque material and food debris, which will often result in increased dental caries activity and gingival inflammation [1]. Previous authors reported the occurrence of 55.7% of malocclusion, which was due to premature loss of the deciduous teeth [2]. To prevent arch length changes, the best space maintainer is a well-maintained primary tooth and every effort should be made to retain primary molars until they are naturally exfoliated [3]. If nature's best space maintainer is lost prematurely, then appliance selection depends on factors associated with each case regarding the child age, child cooperation as well as the parents' desire of having fixed or removable replacement.

Removable space maintainers are worn by patients at their will, may break, they may swallow, get lost, may not have the desired effect if not worn enough and usually restrict the growth of the jaw involved [4]. Among preferable alternative fixed space maintainers, band and loop space maintainer is one of the most frequently used appliance and it was found to have survival times significantly greater than bilateral space maintainers such as the mandibular arch and Nance appliance [3]. It was previously reported that the band and loop space maintainers lasted the longest with a mean survival time of 13 months [5].

However, band and loop space maintainers have certain drawbacks, such as being non-functional, not preventing the supra-eruption of opposing tooth and prone to gingival slopping. It has been shown that the premature loss of the primary second molars could lead to changes in molar relations horizontally [6]. Less frequently used band and bar space maintainer, which is partly functional, restricts growth as both abutment teeth are banded and joined together by soldered stainless steel wire. To overcome these drawbacks, Ghana Shyam's TEFF (Telescopically Expanding Fixed Functional) space maintainer permits the growth of the involved jaw telescopically with similar indications as band and loop space maintainer has been designed.

Ghana Shyam's TEFF space maintainer utilizes economical components for its fabrication and consists of modified ridge-lap pontic, which aids in mastication, prevents supra-eruption of opposing tooth and provides better aesthetics. Therefore, our study aimed to compare the clinical performance and survival of Ghana Shyam's TEFF space maintainer with band and loop space maintainer.

Material and Methods

Study Design and Sample

This split-mouth randomized clinical trial was carried out in the Outpatient Department of Pediatric and Preventive Dentistry. A total of twenty children, including both sexes and aged between 7-9 years with good general health and sound abutment teeth requiring bilateral/contralateral space maintenance therapy, were taken up. Radiographically, the presence of succedaneous tooth with more than 1 mm of bone coverage and less than 1/3rd of root completion was taken into consideration for inclusion. Children with dental abnormalities (crossbite, open bite, and deep bite) and medical conditions that would contraindicate space maintainer therapy were excluded. The sample size was calculated based on the level of precision at ±5, the level of confidence at 95% and the desired level of confidence interval was taken as 95%.

All 20 children received a conventional band and loop space maintainer in one quadrant and Ghana Shyam's TEFF space maintainer on the other (Figure 1A). Instructions and motivation were given to the children. OHI (S) index was recorded before cementation of appliances. Patients were followed up periodically every six months up to two years to observe the eruption pattern radiographically and to assess the appliance

clinically for its function and efficacy along with the OHI (S) index. The children were also instructed to report if an appliance was lost and/or dislodged.

Fabrication of Band and Loop Space Maintainer

Band adaptation was done on the abutment tooth, alginate impressions were taken, bands were transferred and casts were poured. A loop was made with 19-gauge wire and was soldered to the buccal and lingual/palatal surfaces of the band. The band and loop maintainer was tried intraorally to confirm its position, then cemented using type I glass ionomer cement (GC Fuji I® Glass Ionomer Luting Cement, GC Corp., Bunkyo-ku, Japan) (Figure 1A).

Fabrication of the Ghana Shyam's TEFF Space Maintainer

Following the band adaptations, alginate impressions were taken, bands were transferred and casts were poured. To fabricate the U-shaped molar tube, a readily available 18-gauge disposable syringe needle was taken; the hub of the needle was cut away with a carborundum disc (Figure 1B). The needle was then bent into U-shape with the help of pliers and adapted according to the mesio proximal contour of the permanent first molar band. A 21-gauge orthodontic stainless steel wire was then bent into a U-shaped wire loop and was inserted into the already fabricated U-shaped tube. The U-shaped tube was soldered to the band on the mesial surface of permanent first molar (Figure 1B). The length of the U-shaped wire loop, which is placed into the soldered U-shaped molar tube, can be adjusted according to the space available over the working cast and after length adjustment, it was soldered to the band on the distal surface of deciduous first molar. Modified ridge-lap designed acrylic pontic was placed over the soldered U-shaped molar tube and acrylized (Figures 1C and 1D). Then the appliance was tried intraorally to confirm its position, followed by the appliance's cementation using type I Glass Ionomer Cement (GC Fuji I® Glass Ionomer Luting Cement, GC Corp., Bunkyo-ku, Japan) (Figures 1A and 1E)

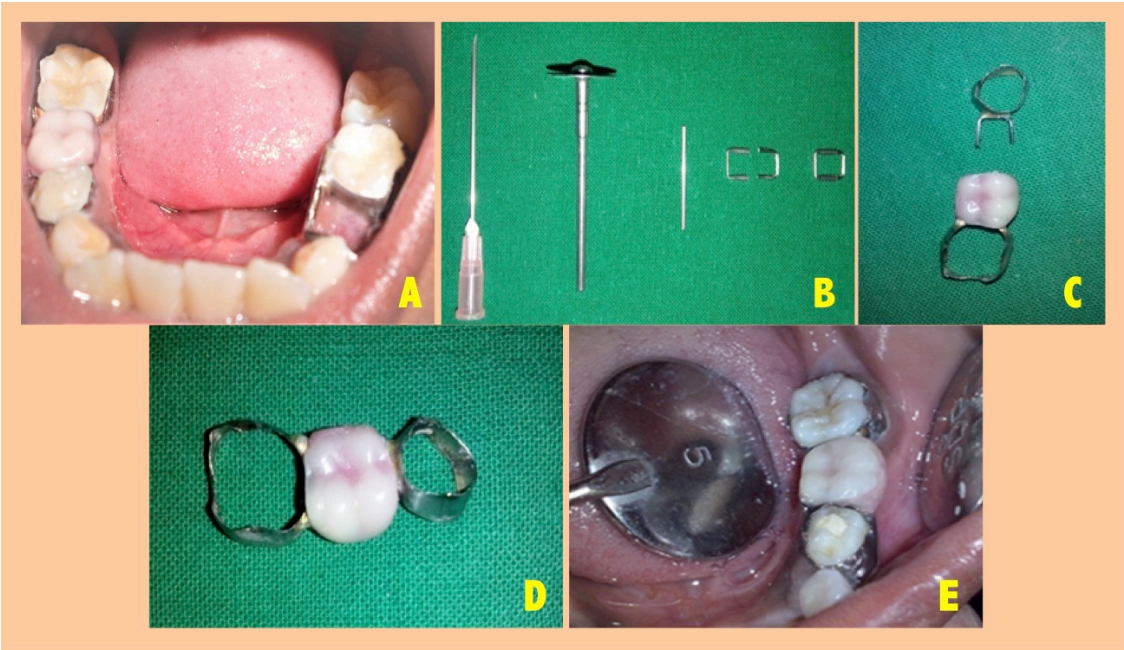

Figure 1. A: Ghana Shyam's TEFF and band and loop space maintainers. B: Ghana Shyam's TEFF space maintainer components. C: Ghana Shyam's TEFF after pontic acrylization. D: Ghana Shyam's TEFF before cementation. E: Ghana Shyam's TEFF after cementation.

Evaluation Protocol Used for Ghana Shyam's TEFF and Band and Loop Space Maintainers

The following aspects were analyzed: 1) Efficiency and function (chewing efficiency on that side); 2) Dislodgement due to cement loss; 3) Breakage at soldered parts; 4) Carious or gingival inflammation affecting abutment teeth; 5) Distortion of band (solder breakage from split bands); 6) Being embedded in gingival tissues / gingival slopping; and 7) Initial and final S-OHIS scores.

Data Analysis

The variables that might have affected the survival time of both space maintainers were tested using Fisher exact test. Chi-square tests were applied to compare the space maintainers concerning chewing efficiency and reasons for the appliance loss. Wilcoxon matched-pairs test was used to compare the simplified oral hygiene index scores. The level of significance was set at a p-value of less than or equal to 0.05.

Ethical Aspects

The study was approved by the Institutional Ethical Committee (Protocol/ IRB/54/2012-15) and written informed consent was obtained from the parents/guardians of the selected children.

Results

In the present study, all the space maintainers maintained the mesio-distal diameter of the prematurely lost tooth. The clinical success rate of both space maintainers was 75 %, while 25 % of the space maintainers needed to be replaced because of either cement loss or breakage at soldered parts. Among the 20 Ghana Shyam's TEFF space maintainers 14 were intact until 24th month-review, whereas, among 20 band and loop space maintainers, 16 were intact at 24th-month follow-up (p-value 0.3582). A non-significant difference was observed between both space maintainers after 6 months, 12 months, 18 months and 24 months (Table 1).

Table 1. Comparison of survival of Ghana Shyam's TEFF space maintainer with band and loop space maintainer at 6 months, 12 months, 18 months and 24-month interval.

Intervals	Band and Loop Space Maintainers		Ghana Shyam's TEFF Space Maintainers		Total		p-value[1]
	N	%	N	%	N	%	
6 Months							1.0000
Loss	0	0.0	0	0.0	0	0.0	
Present	20	100.0	20	100.0	40	100.0	
12 Months							0.2436
Loss	0	0.0	2	10.0	2	5.0	
Present	20	100.0	18	90.0	38	95.0	
18 Months							0.3582
Loss	4	20.0	6	30.0	10	25.0	
Present	16	80.0	14	70.0	30	75.0	
24 Months							0.3582
Loss	4	20.0	6	30.0	10	25.0	
Present	16	80.0	14	70.0	30	75.0	
Total	20	100.0	20	100.0	40	100.0	

[1]Fisher exact test.

Among all space maintainers, five space maintainers were lost due to cement loss and five space maintainers were lost due to Breakage at soldered parts. Concerning band and loop space maintainers, two were lost due to cement loss and two were lost owing to breakage at soldered parts. For Ghana Shyam's TEFF

space maintainers, three were lost due to cement loss and three were lost because of breakage at soldered parts (Table 2).

Table 2. Comparison of Ghana Shyam's TEFF space maintainer with band and loop space maintainer concerning reasons for appliance loss.

Reasons for Loss of Appliance	Band and Loop Space Maintainers		Ghana Shyam's TEFF Space Maintainers		Total		p-value
	N	%	N	%	N	%	
Present	16	80.0	14	65.0	30	75.0	0.890
Breakage at Soldered Parts	2	10.0	3	15.0	5	12.5	
Cement Loss	2	10.0	3	15.0	5	12.5	
Total	20	100.0	20	100.0	40	100.0	

A significant difference was observed (p=0.001) when the chewing efficiency was compared between both space maintainers (Table 3).

Table 3. Comparison of Ghana Shyam's TEFF space maintainer and band and loop space maintainer concerning chewing efficiency.

Satisfaction	Ghana Shyam's TEFF		Band and Loop		p-value
	N	%	N	%	
Yes	17	85.0	0	0.0	0.001
No	3	15.0	20	100.0	
Total	20	100.0	20	100.0	

When the initial and final debris and calculus index scores were compared a non-significant difference was observed (p=0.005 and p=0.033) (Table 4). None of the appliances displayed gingival slopping and carious or gingival inflammation affecting abutment teeth was also not found.

Table 4. Comparison of debris index and calculus scores by Wilcoxon matched-pairs test.

Indices	Time Interval	Mean	Standard Deviation	Z-value	p-value
Debris Index	Initial	0.52	0.23	2.8031	0.005
	Final	0.62	0.27		
Calculus Index	Initial	0.55	0.23	2.1325	0.033
	Final	0.71	0.30		

Discussion

Space maintenance in the primary and mixed dentitions is a principal factor in preventive orthodontics and continues to play an important role in pediatric dental practice [7]. Among all fixed space maintainers, band and loop is a gold standard appliance which has been used and tested over a long time with good success rates [8,9] However, because of its cantilever design, it has a chief disadvantage of being non-functional and will not prevent the continued eruption of opposing teeth [10].

Primary dentitions exhibiting anterior interdental and primate spacing frequently undergo characteristic physiological growth changes in their progression through the mixed dentition [11]. Previous authors reported that in general, from 5 to 10 years of age, the length of the maxillary and mandibular dental arches in the second primary molar region increased approximately by 1.5 mm [12]. To accommodate these growth changes Ghana Shyam's TEFF space maintainer was designed, which is fixed and functional appliance that permits jaw growth telescopically in the segment involved.

The results of the present study showed an overall failure rate of 25% for 24 months. At 6th month follow-up, 100% success was observed with both Ghana Shyam's TEFF and band and loop space maintainers. This result may have been because of more cautious nature of the patients in the immediate post appliance placement period. It is also possible that the parents were more vigilant and were more compliant with post-treatment instructions during this period.

In the present study at the 12th-month follow-up, 95% success was observed with Ghana Shyam's TEFF and a 100% success rate was observed for band and loop space maintainers. In both 18th and 24th month reviews, 70% success was observed with the Ghana Shyam's TEFF and 80% for the band and loop space maintainers.

The reasons for the failure of the space maintainers were cement loss and breakage at soldered parts. Glass ionomer cements are more widely accepted for cementation [8,9,13,14] as they have the advantage of adhering to both enamel and metal [15], release/uptake of fluoride [13] and the same has been used in the present study. In the current study, 12.5% of both space maintainers were lost due to cement loss. Although re-cementation of the appliance was carried out, these patients were excluded from further evaluation in the study.

Cement loss was initially seen in the 12th-month of evaluation, which may have been due to the non-application of a rubber dam during cementation. This was consistent with previous findings [13,14,16]. Although GIC has low oral solubility, cement loss could be due to difficulty in achieving complete isolation during cementation, especially in young patients. In comparison to resins and reinforced glass ionomer cements, the conventional glass ionomers have low flexural strength. Also, the mechanical bonding between the band material and the luting cement is less strong than the combined mechanical and chemical of glass ionomer to tooth enamel [17]. According to previous authors, cases of failure due to cement loss were attributed to poor band fit [14]. In the present study cement loss for band and loop maintainers was marginally low compared to Ghana Shyam's TEFF space maintainer, which can be attributed to presence of two bands in Ghana Shyam's TEFF space maintainer.

Approximately 12.50% of both space maintainers in the present study showed breakage of the wire loop at the 12th -month evaluation. Failure could have been due to the poor quality of construction, such as an incomplete solder joint, overheating of the wire during soldering, thinning of wire by polishing and failure of encasing the wire in the solder [16]. The breakage of band and loop maintainers in this study was relatively low compared with Ghana Shyam's TEFF space maintainers, which may be due to the presence of two solder joints in the Ghana Shyam's TEFF space maintainer. However, this difference was not statistically significant.

Other factors, which are possibly responsible for the failure of space maintainers, are; younger patients might have exhibited a lesser cooperation level; children playing/fiddling with the space maintainers, which leads to distortion of the wire; increased intake of sticky foods; lesser crown length available for banding and anatomy of the primary molars that precluded a tight fit band placement [18]. Other causes of failure, such as broken bands, soft tissue lesions, interference with the eruption, caries affecting abutment teeth, were not observed in the present study.

The present study also evaluated the masticatory efficacy and 85% of children reported good masticatory efficiency towards the side where Ghana Shyam's TEFF was cemented, which is because of the functional component that is an acrylic tooth that aided in mastication. Ghana Shyam's TEFF space maintainer has additional advantages as the components used for fabrication of this appliance are readily available, more economical and relatively high patient acceptance owing to its pontic design. But, the inherent

disadvantage associated with the Ghana Shyam's TEFF space maintainer is that it can obstruct the succedaneous tooth's eruption if the child fails to report for periodic checkups.

The major disadvantage of the bands is the possibility of creating an environment suitable for plaque accumulation on enamel surfaces adjacent to band margins [18]. The present investigation also showed an increase in the calculus and debris scores. Vigorous efforts in plaque removal are essential so that band-related decalcification or caries does not occur. The pediatric dentist should check the appliance periodically to see whether cement has washed out. Annual removal and re-cementation, followed by a topical application of a fluoride solution, are also recommended.

Further, all efforts should be made to provide space maintainers of excellent quality, including proper soldering techniques and optimal cementation procedures. All types of space maintainers should be under close observation with regular follow-up. Appliances must be monitored, adjusted, and possibly replaced over time. The present study found differences in survival times and failure rates among the two types of space maintainers tested; hence, future studies with a longer follow-up period and an increased sample size are recommended.

Conclusion

At the end of the 24th -month review, a non-significant difference was observed with 70% survival of Ghana Shyam's TEFF and 80% survival of band and loop space maintainers. Among 40 space maintainers, five were lost owing to cement loss and five were lost because of breakage at soldered parts. A significant difference was observed when the chewing efficiency was compared between both space maintainers. Whereas, a non-significant difference was observed when the initial and final debris and calculus index scores were compared.

Authors' Contributions

NVKR	0000-0002-5385-9893	Methodology, Investigation, Formal Analysis, Writing – Original Draft Preparation and Writing – Review and Editing.
MGP	0000-0001-9280-402X	Conceptualization, Methodology, Investigation, Formal Analysis, Writing – Original Draft Preparation and Writing – Review and Editing.

All authors declare that they contributed to critical review of intellectual content and approval of the final version to be published.

Financial Support

None.

Conflict of Interest

The authors declare no conflicts of interest.

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