



Clinical Evaluation of Band and loop Versus PEEK Space Maintainers

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ABSTRACT: Objectives: Evaluate two different designs of CAD/CAM space maintainers made from PEEK versus band and loop considering efficacy, failure rate of space maintainers.

Material and methods: This study was designed as a controlled clinical trial. Thirty-six children with an age range of 4-7 years with extracted lower first primary molar, were recruited from the pediatric dental clinic, Faculty of Dentistry, Mansoura University. Every type of space maintainer was assigned to 12 children of the total. The 3 groups are: Group I (band and loop space maintainer), Group II (PEEK ridge crest space maintainer) Group III (PEEK ridge off space maintainer). Patients were recalled at 1, 3, 6, 9 months. All data obtained were subjected to statistical analysis.

Results: The band and loop showed more significant linear and rotational changes than two PEEK groups. The most common type of failure in band and loop was loss of retention which showed significant decrease in retention of bands in compare to two PEEK groups. PEEK ridge crest group has the least failure rate 0% while the band and loop group has the highest failure rate between all 3 groups 33.33%.

Conclusion: PEEK CAD/CAM space maintainers could be considered as valuable alternatives to conventional band and loop space maintainers with superior clinical performance in 9 months follow up.

KEYWORDS: PEEK material, CAD/ CAM space maintainer, band and loop.

I. INTRODUCTION

Among all the fixed space maintainer used in pediatric dentistry, band and loop space maintainers are the most prevalent. These appliances undoubtedly are simple in construction and modification, strong, durable and stable but they have disadvantages such as cement loss and de-retention of appliance, metal allergy, solder

breakage and inability to prevent the rotation and tipping movement of abutment teeth. Due to these varied disadvantages, attempts have been made to utilize newer material in the fabrication of space maintainer.^(1, 2)

Advances evolved in the field of dentistry have introduced digital space maintainer. Digital space maintainer is space maintainer made by CAD CAM or 3d print technology with modern biocompatible material such as PEEK material. PEEK material which is biocompatible material, has no metal allergy or cytotoxicity. PEEK material has variety of colors, which one of them is white that's near toothcolor so improving appearance. These digital space maintainers can be fabricated in different designs by using exocad software. These allow to test new designs of space maintainers which are less bulky and less interfering with tongue.⁽³⁾

PEEK material can be employed to solve the drawbacks of traditional removable space maintainers, which exhibit shrinkage and tiny cracks over time. CAD-CAM guided fabrication of PEEK space maintainers may replace traditional self-cure and heated cured space maintainers to offer efficient and aesthetically pleasing space maintainers.⁽⁴⁾ A similar use in terms of fixed space maintainers in the case of early loss of primary molars has been explored, with good patient compliance and a beneficial physical outcome.

Therefore, this study aimed to evaluate failure rate and efficacy in this new types of PEEK CAD/CAM space maintainers versus conventional band and loop space maintainers.

II. MATERIAL AND METHODS

Thirty-six (36) children with an age range of 4-7 years were selected from pediatric dental clinic, Faculty of Dentistry, Mansoura University. Sample size calculation was based on success rate of space maintainers between different intervention groups retrieved from previous research (Tuncet al.,



2012)⁽⁵⁾. Using G power program version 3.1.9.4 to calculate sample size based on expected difference of 70%, using 2-tailed test, α error =0.05 and power = 90.0%, the total calculated sample size will be 10 in each group and by adding 20% to compensate possible drop out then total sample size will be 12 in each of studied groups.

Inclusion criteria

1. The extraction space is of only one missing lower first deciduous molar with teeth present on mesial and distal side of extraction space
2. Absence of any pathological evidence on the eruption track of the permanent tooth.
3. Extraction of the first primary molar is not exceeding 3 months.
4. Absence of abnormal dental occlusion conditions such as crossbite, open bite, deep bite.
5. Radiographically, presence of permanent successor with bony crypt upon the tooth germ.

Ethical considerations:

This study was designed as a controlled clinical trial. The study was approved from Ethical Committee of Faculty of Dentistry, Mansoura University. Agreement for participation in the study gained from the parents in a written consent form

Patient grouping: The selected patients (36 extraction site) were divided into 3 groups each has (12 extraction site). This was done randomly by envelope randomization. The three groups are: Group I: conventional band and loop (controlgroup) Group II: band and single loop from PEEK (loop on crest of ridge) Group III: band and single loop from PEEK (loop off the ridge).

• **Technique of construction of conventional band and loop space maintainer (group I):**

The band were tried on the abutment tooth (second primary molar) until one can seated properly on abutment tooth by fine finger pressure. After the selected band was fitted to abutment tooth, a rubber base impression was taken for the whole arch using stock tray. The loop was modelled from wire 0.7 rounded stainless-steel wire. The wire was shaped into a loop and contoured to be fitted to band and alveolar ridge using angle's pliers and then the loop was fitted to band in correct position. After that the loop soldered to band using solder and flux with flame. Finishing and polishing were done using white stone and rubber wheel and then cementation was

done to abutment tooth using GC Fuji I radiopaque glass ionomer luting cement.

• **Technique of construction of band and single loop (on crest of ridge) space maintainer from PEEK (Group II):**

Construction of digital space maintainer from PEEK were done through 3 main steps (data capture, space maintainer design, milling of space maintainer).

Data capture: a rubber-based impression was taken for the whole arch of child mouth. Then this rubber-based impression poured with extra hard stone to obtain a working cast. Optical scanner of CAD CAM machine transferred this stone model into digital model on software of CAD CAM machine.

Space maintainer design: By using various tools of software (exoCad), the digital space maintainer was designed on 3d digital model. This digital space maintainer consists of band of PEEK around abutment tooth with thickness from 1mm to 1.5 mm and single loop extend from the band to anterior abutment (primary canine) following the crest of the ridge with thickness from 1 to 1.5 mm and width of the loop 2mm. The end of the loop resembling letter "C" that's extended from distal one third of labial surface to distal one third of lingual surface of primary canine. By using tools of software program (exCad) cement gap was controlled to 80 μ m.

Space maintainer milling: After the design has been finished, Computer aided manufacturing (CAM) was used to mill the space maintainer from PEEK disk by using Subtractive process.

• **Technique of construction of band and single loop (loop off ridge) space maintainer from PEEK (Group III):**

The technique of construction and cementation was similar to technique of construction and cementation of group II except the design of the loop of space maintainer. The loop design was out of crest of the ridge on buccal aspect of the ridge and extended from the band around abutment (2nd primary molar) to anterior abutment (primary canine). The end of loop was resembling letter 'C' that's extend from linguo-distal line angle of the deciduous canine to cover the distal one-third of labial surface.

Patient evaluation

Patients were recalled at 1, 3, 6 and 9 months. The following date were recorded:



a. Evaluation of failure rate of space maintainers related to material behavior:

Based on previous clinical comparative studies, a space maintainer was classified as having failed when it presented with any of the following:

1. Loss of retention of space maintainers at band cement interface.
2. Mechanical failure of space maintainers that's include Fracture or distortion at any part of space maintainers (fracture at band, loop or area of junction of band and loop) and (distortion of loop that's means bending of the loop to the extent that the device was in contact with the soft tissue).

b. Evaluation of the efficacy of space maintainers using modified Swaine and Wright method:

At each recall, alginate impression was taken for each patient and then poured immediately was stone to make a cast. By using optical scanner of CAD/CAM machine the stone cast was transferred into digital one. The measurements were calculated on these digital models of the initial study before applying space maintainers and then at the end of the follow up period.

In the absence of lower first deciduous molar:

1. Mesiobuccal and mesiolingual cusp tips of lower 2nd primary molar, and the cusp tip of lower primary canine form three points which was joined to form a triangle with the corresponding sides as A1, B1, and C1. The line that connects the mesiobuccal and mesiolingual cusp tips of the 2nd primary molar constituted the base side of the triangle.
2. The line that connects the mesiobuccal cusp tip of the 2nd primary molar and the cusp tip of the canine formed the second side (B1) of the triangle.
3. The line that connects the mesiolingual cusp tip of the 2nd primary molar and the cusp tip of the canine formed the third side (C1) of the triangle. (Figure 29)

- The measurements recorded under these criteria were applied in square root formula:

$$([B1 \times B1 + C1 \times C1 - A1 \times A1/2]/2)$$

Thus, the **linear** changes were obtained.

- To find out whether there any **rotation** occurred in abutment teeth, the apex angle of the triangle was taken into consideration. This angle was calculated with the degree formula: $([\text{ACOS}(B1 \times B1 + C1 \times C1 - A1 \times A1)] / [2 \times B1 \times C1])$.

- **Statistical Analysis:** Statistical analysis was performed using a commercially available

software program (SPSS Chicago, IL, USA). Numerical data were described as mean and standard deviation or as median and range as appropriate according to the normality of the data using tests of normality (Shapiro-Wilk test). Numerical data were described as mean and standard deviation. Chi-square test was used for comparison of all binary outcome data at different time's points. Student t-test was used to compare the mean age in two groups'-test (ANOVA) was used for normally distributed quantitative variables, to compare more than two groups. The level of significance was set at $P < 0.05$. All tests were two-tailed.

III. RESULTS:

1. Efficiency measurements results:

- **Comparison of space maintainer linear measurements regarding the follow-up periods:**

The enrolled space maintainers among the three studied groups were compared regarding linear measurements at baseline and after 9 months, using a two-way **ANOVA test and paired t-test**. The statistical analysis results of the linear measurements, which shows mean values and standard deviation (mean \pm SD) for linear measurements among the three studied groups were summarized and represented in (**Table1**).

- Two-way ANOVA results: Factor – A (follow-up periods): The two-way ANOVA results revealed that the difference between the sample averages of all groups regarding the follow-up periods is not big enough to be statistically significant ($p=0.7666$).

Factor – B (type of space maintainer):The two-way ANOVA results revealed that the difference between the sample averages of all groups regarding the type of space maintainer is not big enough to be statistically significant ($p=0.2339$).

Interaction AB:The two-way ANOVA results revealed that the difference between the sample averages of all groups regarding the interaction between the follow-up periods and the type of space maintainer is not big enough to be statistically significant ($p=0.9433$).

- Paired (dependent) t-test results:

The results of comparison space maintainers' linear measurements at baseline and after 9 months of the control group showed that the sample difference between the averages is big enough to be statistically significant ($p= 0.013$).



Moreover, the results of comparison space maintainers' linear measurements at baseline and after 9 months of the PEEK/ Ridge crest group showed that the sample difference between the averages is not big enough to be statistically significant ($p= 0.623$).

Furthermore, the results of comparison space maintainers' linear measurements at baseline and after 9 months of the PEEK/ Ridge off group showed that the sample difference between the averages is not big enough to be statistically significant ($p= 0.170$).

Table (1): Comparison of space maintainer linear measurements regarding the follow-up periods.

Variable	Baseline	9 months	t-value	p-value
Control (G 1)	12.88±1.22	12.65±1.13	2.9	0.013*
PEEK/ Ridge crest (G2)	13.33±1.55	13.36±1.44	0.5	0.623 Ns
PEEK/ Ridge off (G 3)	13.39±1.28	13.30±1.37	1.5	0.170 Ns

• **Comparison of space maintainer rotation measurements regarding the follow-up periods:**

The enrolled space maintainers among the three studied groups were compared regarding rotation measurements at baseline and after 9 months, using a two-way ANOVA test and paired t-test. The statistical analysis results of the rotation measurements, which shows mean values and standard deviation (mean ± SD) for rotation measurements among the three studied groups were summarized and represented in (Table2).

• Two-way ANOVA results:

Factor – A (follow-up periods): The two-way ANOVA results revealed that the difference between the sample averages of all groups regarding the follow-up periods is not big enough to be statistically significant ($p=0.7423$).

Factor – B (type of space maintainer): The two-way ANOVA results revealed that the difference between the sample averages of all groups regarding the type of space maintainer is big enough to be statistically significant ($p=0.0390$).

Interaction AB: The two-way ANOVA results revealed that the difference between the sample averages of all groups regarding the interaction between the follow-up periods and the type of space maintainer is not big enough to be statistically significant ($p=0.9743$).

• B. Paired (dependent) t-test results:

The results of comparison space maintainers' rotation measurements at baseline and after 9 months of the control group and two PEEK group showed that the sample difference between the averages is not big enough to be statistically significant.

Table (2): Comparison of space maintainer rotation measurements regarding the follow-up periods.

Variable	Baseline	9 months	t-value	p-value
Control (G 1)	18.39±2.51	18.71±2.72	1.6	0.146 Ns
PEEK/ Ridge crest (G2)	16.76±1.75	16.78±1.80	0.08	0.937 Ns
PEEK/ Ridge off (G 3)	17.72±2.54	17.95±2.72	2.2	0.0527 Ns

*; Significant. Ns; Non-significant.

2. Comparison of failure rate regarding the type of space maintainer at different follow-up periods:

After 1 month: all study groups showed no failure. The results revealed that after 1 month, there was no significant difference between all 3 groups.

After 3 months: all study groups showed no failure except control group showed only one case of loss of retention with failure rate 8.33%. The results revealed that after 3 months, there was no statistically significant difference between all 3 groups.

After 6 months:The results regarding failure due to loss of retention revealed that after 6 months, there was significant increase in failure rate in band and loop group in compared to 2 PEEK groups. The results regarding mechanical failure due to Fracture of any part of space maintainer or bending in loop and become in contact with soft tissue revealed that after 6 months, there was no significant difference between all 3 groups.

After 9 months:The results regarding failure due to loss of retention revealed that after 9 months, there was statistically significant increase in failure



rate in band and loop group in compared to PEEK/ ridge crest group and PEEK/ ridge off group. The results regarding mechanical failure due to Fracture of any part of space maintainer and bending in loop and become in contact with soft tissue revealed that after 9 months, there was no significant difference between all 3 groups.

IV. DISCUSSION

In the present research results, regarding space maintainers linear measurements along 9 months follow up period, band and loop group showed significant decrease in mean of linear measurements while PEEK/ Ridge crest group and PEEK/ Ridge off group showed non-significant decrease in mean of linear measurements, which means band and loop group showed more linear changes than PEEK/ Ridge crest group and PEEK/ Ridge off group. This is in agreement with Mittal S et al in (2018)⁽⁶⁾ who found that band and loop showed more linear changes that's might be due to contact point of band and loop on unattached abutment tooth which loses the proper contact leads to tipping of abutment teeth.

Also, there is no significant difference was observed between PEEK/ Ridge crest group and PEEK/ Ridge off group, regarding the linear measurements. That's due to this two-group made from the same material (PEEK) and by the same technology (CAD CAM) but with different designs. Also, two designs of PEEK space maintainers showed perfect surface adaptation to both abutments which lead to firm contact with both abutments not like contact point that's present in band and loop, so the two PEEK groups prevent tipping of anterior abutment, so they have less linear changes than the control group.

Regarding rotation measurements, there is no significant difference between all groups, but still band and loop group has more rotational changes followed by PEEK/ Ridge off group and then PEEK/ Ridge crest group. The rotational changes in band and loop space maintainer is in accordance with Mittal S et al in (2018)⁽⁶⁾ who reported that no significant difference regarding rotational changes between band and loop and fiber reinforced composite space maintainer but still band and loop had more rotational changes than fiber reinforced composite space maintainers and It was noted that as band and loop space maintainers have the potential to submerge into the gingivoalveolar tissues which lead to tipping and rotating in the abutment teeth.

There was no statistically significant difference between the three groups regarding mechanical failure, but there was a significant

difference regarding loss of retention between the band and loop and the two peek groups. This is agreement with Garg et.al in (2014)⁽⁷⁾, Moore et.al in (2006)⁽⁸⁾ and Subramaniam et.al in (2008)⁽⁹⁾ who found that the most common cause of failure of band and loop space maintainers was loss of retention at band cement interface. The mechanical bonding between the band material and the luting cement is less strong than the combined mechanical and chemical adhesion of glass ionomer to tooth enamel. According to these studies, cases of failure classified as being due to loss of retention are likely to be due to poor band fit.

Fathian et.al in (2007)⁽¹⁰⁾ who reported that patient's young age was an important factor responsible for failure of retention of band and loop space maintainer. As young patients exhibited a lesser cooperation level, increased sticky food intake, lesser crown length available for banding, and anatomy of the primary molars that precluded a tight fit band placement.

Despite all efforts to produce a tight-fitting band for the band and loop space maintainer, it still has a significant cement gap, which allows for cement to dissolve through increased contact with saliva in the oral cavity. On the other hand, it was entirely different in the two PEEK groups because the bands in those groups were made digitally using CAD/CAM technology and had control cement gaps of 80 μm , allowing for producing a band of PEEK that was extremely tightly fitted to abutment tooth.

In two PEEK groups, bands of PEEK were treated with sandblasting using aluminum oxide (grit size 110 μm) under pressure of 2 to 3 bars to increase the surface area for cementation and by using Viso-link adhesive system made micro mechanical retention between luting cement and PEEK surface. All of that enhanced PEEK band /luting cement retention.

Regarding mechanical failure due to fracture any part of space maintainer, band and loop had 2 case which occur at band-loop junction with failure rate 16.7% after 9 months of follow up. That's agreement with Subramaniam et.al in (2008)⁽⁹⁾ and Setia et.al in (2014)⁽¹¹⁾ who reported that mechanical failure could have been due to the poor quality of construction which might be due to incomplete solder joint, overheating of the wire during soldering, thinning of wire by polishing, and failure to encase the wire in the solder.

PEEK/ Ridge off group had 2 case of fracture to any part of space maintainer which occur at middle of loop with failure rate 16.7% while PEEK/ Ridge crest group was reported no mechanical failure along follow up period.



However, the two PEEK groups were produced from the same material (PEEK) and by the same technology (CAD CAM), they had two different designs. So that's might be due to in PEEK/ Ridge crest group, loop was shorter in length and not accessible to child hand but, in PEEK/ Ridge off group, loop was longer and accessible to child hand as it presented buccally to ridge.

V. CONCLUSION

- 1) PEEK CAD/CAM space maintainers could be considered as valuable alternatives to conventional band and loop space maintainers with superior clinical performance in 9 months follow up period.
- 2) Further studies are needed to assess the efficacy of PEEK CAD/CAM space maintainers with other different designs and for longer follow up periods.

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