

# EFFECTIVENESS OF CAD/CAM PEEK FABRICATED SPACE MAINTAINER IN CHILDREN: A RANDOMIZED CONTROLLED CLINICAL TRIAL

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## ABSTRACT

**INTRODUCTION:** Space maintainers are appliances used in maintaining space and guiding unerupted permanent successor into the arch in the proper position. With today's technological advances, attempts have been made to implement new materials in manufacturing.

**OBJECTIVES:** To study the clinical effectiveness and the patient's comfort of CAD/CAM PEEK space maintainer and compare it to the conventional band and loop space maintainer.

**MATERIALS AND METHODS:** A Two parallel arms randomized controlled clinical trial where 20 children with an age range 5-7 years indicated for space maintainer were selected and were randomly allocated into 2 groups: Experimental group (CAD/CAM PEEK space maintainer), Control group (Metal Band & Loop space maintainer). Space maintainers were checked for occlusal interference and gingival clearance. Oral hygiene and appliance maintenance instructions were explained to both children and parents. Patients were recalled at the 1, 3, and 6 months for clinical follow-up. The patient's comfort was assessed after insertion of the space maintainers.

**RESULTS:** Evaluation was evaluated at 1,3 and 6 months. Fisher's Exact test, and Mann-Whitney U test were used to compare groups. Friedman test was used to assess changes in gingival status across time. The significance level was set at a *P* value of 0.05. There weren't any statistically significant differences between the two groups regarding the clinical effectiveness, plaque deposition and gingival health. (*P*=1.00), (*P*=0.052) respectively. Only one case failed of the study group. There was a statistical significance difference regarding the patient's comfort (*P*=0.001). The experimental group had greater patient's comfort than the control group.

**CONCLUSIONS:** The CAD/CAM PEEK space maintainer showed a high clinical success rates with a greater patient's comfort during the 6-month follow-up period in comparison to the band and loop space maintainer.

**KEYWORDS:** CAD/CAM, PEEK, Space maintainer

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## INTRODUCTION

Primary teeth play a vital role in the growth and development of the dentition. Premature loss of posterior teeth can result in rotating, crowding, tipping, impaction of permanent teeth, and a reduction in the arch length that is required to align the underlying permanent teeth. Unilateral loss of primary first molars or canine could cause mesial migration of the posterior segment of the arch and central line deviation (1).

Appropriate space management can spare a child from esthetic and functional displacement and save the parents from a lot of

financial expenses in successive orthodontic treatment (2). The safest method is to place an effective and durable space maintainer to maintain the mesiodistal relationships in the dental arch (3). Space loss usually happens within the first three to six months following tooth loss, so it is recommended to insert a space maintainer in a month following tooth loss (4, 5).

The most frequently used fixed appliances in children is band and loop space maintainers (6). As it is easy to construct, effective, applicable and adapts easily to accommodate the transitional dentition and is

still known as the gold standard (7). However, it has some disadvantages as cement loss, solder failure, being embedded in gingival tissues, caries surrounding the band, and tipping or rotation of the neighboring teeth (3). In the last few years, adhesive technology has been utilized replacement of the conventional space maintainer by direct bonded space maintainers. It started with an orthodontic stainless-steel wire used as a loop and attached directly to the tooth using composite resin (8) and the fiber-reinforced composite resin (FRCR) space maintainers as (Ribbond®) (9) and (Everstick) (10). The bonded space maintainer is somehow better than the conventional banded space maintainer. It eliminates the urge for laboratory procedures and it decreases the possibility of plaque accumulations which aids in preserving the health of the soft and hard tissues in the oral cavity (8). However, failures observed in FRCR space maintainers were mainly as a result of enamel-composite interface debonding, then fiber-composite interface debonding and fiber frame fracture (11, 12).

Although, band and loop space maintainers are routinely used in dentistry. They have many disadvantages that have led to developing more aesthetically pleasing and metal-free space maintainers that head to the introduction of the CAD-CAM PEEK band and loop space maintainer (13).

The Polyetheretherketone (PEEK) was commercialized since 1978. It is a semi-crystalline polymer and consists of repeated units of three phenyl rings, one keto group and two ester groups (14). PEEK has excellent mechanical properties that are maintained at a high temperature. It is a radiolucent rigid material with distinct combinations of properties that consists of remarkable chemical, wear, electrical and temperature resistance, in addition to dimensional stability and resistance to hydrolysis. PEEK is non-toxic, biocompatible and has low plaque affinity (15). PEEK was identified as a material in numerous dental applications as dental implant, endocrown, temporary abutment for implant-supported prosthesis, removable partial dentures, fixed dental prostheses prosthesis frameworks, maxillofacial prostheses and orthodontic wires and retainers (16).

Digital pediatric dentistry's space maintainers have obtained a tremendous step regarding customized appliances. Devices make the techniques for digital fabrication more trustworthy, long-lasting and eliminate manual manufacturing phases that take a long time (17). Recently, the usage of CAD-CAM

technologies in pediatric dentistry has enormously succeeded (18). The main advantages are improved patient compliance and comfort towards the treatments. Since conventional impressions are considered an unpleasant experience by some children, the switch to digital impression procedures may have a long-term positive impact on patient perceptions of dental procedures (19). There is lack of comparative studies in the literature comparing the efficacy of conventional banded type of band and loop with newly available bonded types of space maintainers (11). Few published case studies demonstrate short and long-term efficacy of digital applications in pediatric patients (17, 20).

Therefore, this study was conducted to evaluate clinically the success of CAD/CAM PEEK space maintainer in comparison to the conventional metal band and loop space maintainers and the patient's comfort. The null hypothesis was that there are no differences in the clinical and the patient's comfort between CAD/CAM PEEK and metal band and loop space maintainer

## METHODOLOGY

The study design was a two parallel arms randomized controlled clinical trial that was established and reported according to the CONSORT guidelines (21). Ethical approval was achieved from the Research Ethics Committee, Faculty of Dentistry, Alexandria University prior the start of the research under the code IRB NO 00010556-IORG0008839.

The PICOT question was: do children having unilateral premature loss of mandibular first primary molars (population; P) having a CAD/CAM PEEK space maintainer (intervention; I) in comparison to conventional metal band and loop (control; C) show better clinical success and patient comfort (outcome; O) after 6 months follow up (time; T).

The study took place at the Department of Pediatric Dentistry at Faculty of Dentistry, Alexandria University. The CAD/CAM unit was at the "Dental Aesthetics Private Center" and the laboratory work was done at "Digident Private Center". Alexandria, Egypt.

### Sample Size Estimation

The sample size was based on a 5% alpha error, 80% power, and survival rate of 4.2% and 60% for the test and control, respectively (22). The required sample size was calculated to be 8 children per group increased to 10 children to compensate for the potential loss of cases of 20%. (<http://powerandsamplesize.com/Calculators/Compare-2-Proportions/2-Sample-Equality0>).

Inclusion criteria: children aged 5-7 years old having unilateral extracted mandibular primary first molars, sound abutment teeth, flush/mesial step terminal plane relationship of second primary molars and angle's class I molar relationship of first permanent molars if erupted. Exclusion criteria: multiple premature loss and carious buccal and lingual surfaces of abutment teeth. Before intervention the study objectives, parents and children were both given an explanation of the study's potential advantages, risks and methodologies. Informed consent was signed by parent/caregiver of children before participation in the study. Every chosen child was examined and a brief medical and dental history was obtained. Intraoral photography and periapical radiographs were taken. Oral prophylaxis and restorative treatments were performed. Patients were motivated to maintain adequate oral hygiene, instructed to avoid sticky food and to attend regular follow-up periods for maintenance of the appliance (23).

Randomization, Allocation Concealment and Grouping: Subjects following the inclusion criteria were allocated at random by a computer-generated list of random numbers to one of the two arms. Allocation was performed by a trial independent individual and the allocation ratio was equal. Allocation was in blocks of four. Each child was represented by a code (the serial of participant in the study) and the group name. The group and child's name were sealed in sequentially numbered opaque envelopes kept by an assistant and the code of the child was written on the envelope. At the visit of application of the intervention, the name of the child was matched against the code, the envelope was retrieved, unsealed and the group was identified. All participants were randomly allocated and divided into 2 equal groups: Group I: consisted of 10 children assigned for CAD/CAM PEEK space maintainer (Study Group) and Group II: consisted of 10 children assigned for conventional metal band and loop (Control Group).

Intraexaminer reliability was done for the survival rate (success/failure) by re-examining 6 children twice a week apart under the supervision of the second author. Kappa was calculated to be 0.73 indicating a substantial agreement.

#### Intervention

The CAD/CAM PEEK space maintainer (Group I) (24). The "Cerec Connect 5.0.2 Software" of the intraoral scanner "Primescan" (DentsplySirona, Germany) was activated. The personal data of the patient were entered (name and age). To create the virtual

digital models, the mandibular edentulous area for the space maintainer was selected and the intraoral scanning for the mandibular arch and the maxillary arch were taken. The intercuspation of the buccal bite was registered and scanned. The virtual models via Connect Portal were uploaded and sent to the lab as the processed data were exported in connect format (colored images). In the lab the case was uploaded from "Inlab 19 Software to Removable Partial denture (RPD) module Software."

The design of space maintainer framework was defined on the abutments and edentulous area refined with smooth form tool RPD module Software. Then the design of the space maintainer was sent for milling according to BioHPP PEEK (Bredent, Germany) material used. A clasp was designed around the mandibular second primary molar and a major connector designed on the edentulous area with relief of 1 mm from gingiva. The BioHPP PEEK disc was inserted in the MCX5 milling machine (DentsplySirona, Germany). After milling, the PEEK material was micropolished from buccal surfaces using polishing burs (Bredent kit) and microsandblasted from fitting surface of abutments' arms to be ready for adhesive bonding.

After lab construction: the patient was recalled in the clinic and the space maintainer was tried in and the bite was checked and gingival relief was checked. The abutment tooth was acid etched under partial isolation and cemented with the resin cement "Multilink R Speed" (Ivoclar Vivadent AG, Liechtenstein) and cured for 20 seconds (25). (Fig. 1)

The conventional band and loop space maintainers (Group II): was constructed according to the approach stated by Graber and Finn (26). Parents and children were given instructions on oral hygiene and appliance maintenance. Patients were recalled if the appliance became loose, dislocated, or was damaged. During evaluation periods, if failures occurred the space maintainers were removed and were either repaired or replaced and excluded from the study (22).

#### Outcome Assessment

The space maintainers were evaluated clinically after 1 month, 3 months and 6 months.

The CAD/CAM PEEK space maintainers were evaluated using the following criteria (27):

Debonding at the Enamel-Resin interface.

Debonding at the Resin-PEEK interface.

Fracture of the PEEK frame.

Loss of space.

Caries or decalcification.

Gingival inflammation.

The band and loop space maintainer were evaluated using following criteria (28).

Distortions.

Cement wash-out.

Loop's Fractures.

Loss of space.

Caries or decalcification.

Gingival inflammations.

Survival Rate of the space maintainers (11)

The survival rate was evaluated:

a. Successful (S) (If there is no failure in the previous criteria).

b. Failed (F) (If there is at least one failure in the previous criteria).

c. Lost to follow-up (LF).

Gingival Health (12)

The following measurements were evaluated just before space maintainer was inserted (baseline; T0) and at the 1 month (T1), 3 months (T2) and 6 months (T3) of treatment.

(a) Plaque deposition of the abutment tooth was evaluated according to Silness and Loe plaque index (29) by a sterile periodontal probe and recorded for each follow up period.

(b) Gingival inflammation of the abutment tooth evaluated by a sterile periodontal probe according to Loe and Silness gingival index (30) and recorded.

Patient comfort assessment (26)

The patient was asked to choose the appropriate figure representing his comfort regarding the treatment by visual analogue scale (six-point facial Wong-Baker Scale) after completing the treatment and inserting of the space maintainer. (Fig. 2)

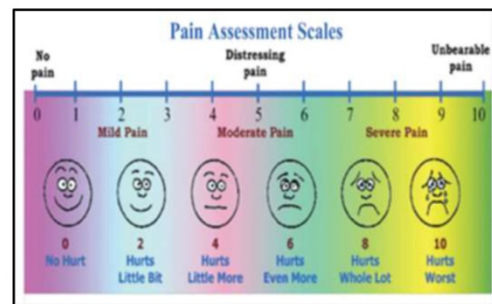
Statistical analysis

Normality was checked using Shapiro Wilk test, box plots and descriptives. Data were not normally distributed and presented using mainly Median, Inter Quartile Range (IQR) and Minimum and Maximum values in addition to Mean, Standard deviation (SD).

Success and failure rates were compared using Fisher's Exact test. Groups were compared regarding all quantitative variables using Mann Whitney U test. Changes in plaque and gingival indices across time intervals were compared using Friedman test followed by post hoc test when the results were significant. Significance level was set at P value of 0.05. All tests were two tailed. Data were analyzed using Statistical Package for the Social Sciences (SPSS) for windows version 23. Armonk, NY: IBM Corp.



**Figure (1):** CAD/CAM PEEK Space Maintainer



**Figure (2):** Wong-Baker FACES Rating Scale.

## RESULTS

A CONSORT diagram showing the study protocol up to the 6-month follow-up is presented. (Fig. 3)

The children ages ranged from 5-7 years with mean age =  $5.7 \pm 0.48$  for experimental group and mean age =  $5.7 \pm 0.42$  for control group. There was no statistically significant differences ( $P=0.000$ ). In each group (7 males, 3 females) with no statistically significant differences ( $P=0.000$ ), this shows that the two groups were matching.

Regarding, the survival rate of the space maintainers. Group I showed 100% success at 1, 3 month and 90% after 6 months where one case failed because of enamel-resin interface debonding. Whereas group II showed a success rate of 100% at the follow-up periods 1,3 and 6 months. When comparing the two groups there was no statistically significant differences. ( $P=1.00$ ). (Table 1)

Regarding the gingival health, in group I the plaque and gingival indices scores were (mean =  $2.30 \pm 0.48$ ) (mean =  $2.31 \pm 0.49$ ) respectively at baseline and decreased throughout the follow-up periods with scores (mean =  $1.50 \pm 0.53$ ) (mean =  $1.51 \pm 0.52$ ) respectively at 6 months with a statistically significant difference ( $P=0.009$ ). In group II the plaque and gingival indices scores were (mean =  $2.80 \pm 0.42$ ) (mean =  $2.82 \pm 0.41$ ) respectively at baseline and decreased throughout the follow-up periods with scores (mean =  $1.70 \pm 0.48$ ) (mean =  $1.72 \pm 0.49$ ) at 6 months with a statistically significant difference

( $P=0.042$ ). There was an improvement in the gingival health throughout the follow-up periods. However, there were no statistically significant differences between the two groups regarding the gingival health. ( $P=0.052$ ). (Fig. 4,5)

Regarding the patient's comfort there was a statistically significant difference among the two groups. ( $P=0.0001$ ) All the patients in Group I had better comfort to the CAD/CAM PEEK space maintainer with scores 0 that indicate no pain, whereas in Group II they had less patient comfort to the band and loop with mean scores =  $3.8 \pm 1.47$  that indicate mild to moderate pain. (Table 2)

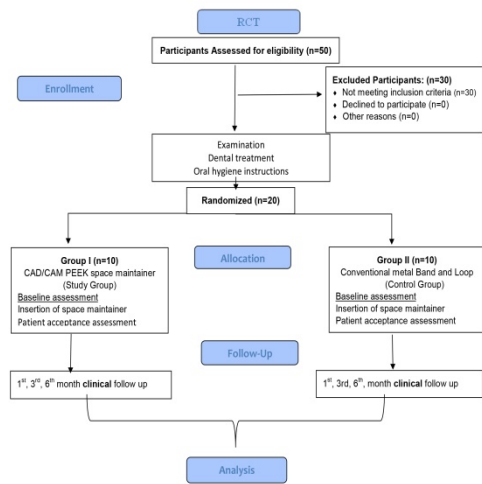


Figure (3): Flow chart of the treatment groups

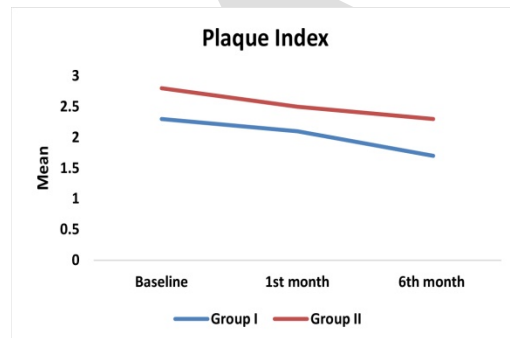


Figure (4): Plaque index between group I and group II at baseline, 1,3 month and 6 month

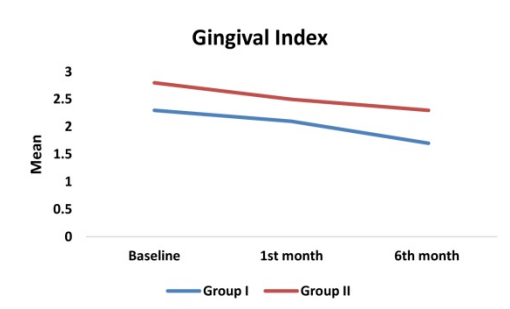


Figure (5): Gingival index between group I and group II at baseline, 1,3 month and 6 month

Table (1): Survival of the space maintainers between the CAD/CAM PEEK and the band and loop type groups

Survival rate	Group I (CAD/CAM PEEK) (n=10)	Group II (Band and Loop) (n=10)
	n (%)	
Success	7 (70%)	6 (60%)
Failure	3 (30%)	4 (40%)
X <sup>2</sup>	0.220	
P-value	1.00	

\*Statistically significant difference at  $P$ -value  $\leq 0.05$

X<sup>2</sup>: Fisher's Exact test

Table (2): Patient's acceptance between the CAD/CAM PEEK and the band and loop type groups

	Group I (CAD/CAM PEEK) (n=10)	Group II (Band and Loop) (n=10)	U test (P-value)
Mean (SD)	0 (0)	3.80 (1.47)	0.000 (<0.0001*)
Median (IQR)	0 (0)	4.00 (3)	
Min - Max	0 - 0	2 - 6	

\*Statistically significant difference at  $P$ -value  $\leq 0.05$

U test: Mann Whitney U test

### DISCUSSION

From the findings of the current study the CAD/CAM PEEK space maintainer was clinically successful with no effect on the gingival health comparable to the band and loop space maintainer; however it showed a better acceptance by the patients.

In the present study clinical assessment of the success and failure of the CAD/CAM PEEK space maintainer and the conventional metal Band and Loop was based upon certain criteria described by Setia et al 2014 (11). The null hypothesis in the current study was accepted regarding the clinical success and gingival health where no differences between the CAD/CAM PEEK and metal band and loop groups at all the follow up visits. On the other hand, the null hypothesis was rejected regarding the patient comfort. The CAD/CAM PEEK group had a greater patient's comfort than the conventional metal band and loop.



The case that failed after 6 months in group I was due to enamel–resin interface debonding in CAD/CAM PEEK space maintainer can be attributed to its placement on primary tooth, the presence of prismless enamel which has poor bond strength with resins that had negative effect on the resin retentions. The outcomes of this study were in agreement with the studies done by Kargul et al. 2003 (9), Kirzioglu and Ozay 2004 (27) and Subramaniam et al 2008., (22) who reported that debonding at the enamel composite interface was the primary reason for the failure of bonded space maintainers. In addition, Saravanakumar et al 2013(31) assessed the clinical success of FRCR space maintainers for 18 months and observed that the mean survival time to be 12 months. The Ribbond® bondable reinforcement ribbon space maintainers can be recommended as a suitable space maintainer only for a short period. It was noted that success rate relies on operator experiences, choosing the appropriate patients and the isolation. Similarly, Budanur et al 2015 (32) noticed that the failures were because enamel-composite interface debonding within six months in the non-resin impregnated FRC and the resin-impregnated (PRE-PREG) FRC space maintainers. The problem was solved by rebonding and repairing. Moreover, Mittal et al 2018 (12) noted that failures were at the enamel composite was due to manipulation of the young children with the fiber framework.

Band and loop space maintainer showed 100% success during the 6 months. In contrast, the results of Moore and Kennedy 2006 (33) who described that cement loss to be the most frequent reason for a fixed space maintainer to fail. Glass ionomer cement has a low oral solubility, yet cement loss may occur because complete isolation during cementation can be challenging, particularly in younger patients. Failures as a result of solder breakage (loop fracture) may be because of subpar construction, such as an imperfect solder junction, scorching the wire during soldering, an inability to completely wrap the wire in the solder residue of flux, or excessive wire thinness during polishing. This was in line with the findings of Garg et al 2014 (25) who discovered that failures in metal SSC band and loop were most frequently caused by cement loss, band gingival slippage, loop fracture (solder breakage), and distortion of band.

In the current study the results regarding the plaque deposition and the gingival health were higher in band and loop than the CAD/CAM PEEK space maintainers but with no statistically significant differences. The plaque deposition decreased and the gingival health improved by time in both groups with a statistically significant difference. The results of

the present study were in contrast to Setia et al 2014 (11) who showed that the conventional band and loop had better gingival health than the Ribbond space maintainers. While the Super splint space maintainers observed poorest gingival health among all groups.

The current results also resemble the assumptions of Hosseinipour et al 2019 (34) who revealed that applying fixed space maintainers changed bleeding on probing and the gingival index in these teeth. Also, fixed space maintainers increased probing pocket depth in the distolingual area of these teeth. In addition, Özüdoğru and Tosun 2021 (35) found that patients with fixed and removable space maintainers have higher plaque and periodontal index scores. Given the elevated risk of teeth decay and periodontal diseases, it is essential to observe these patients carefully. Children should be encouraged to practice good oral hygiene. Therefore, space maintainers' treatments must be cautiously tailored to the patient's condition, considering the assumed survival time.

Using a Wong-Bakers Scale, the patient's comfort level with the treatment was evaluated. This scale has good psychometric features and is quick, affordable and simple to use. It is also widely acceptable. Parents and kids of all ages prefer it over all other facial pain scales (36).

The findings of the current study revealed that, patient's comfort was greater in the CAD/CAM PEEK space maintainer group with no pain as compared to that of the band and loop space maintainers where they had mild to moderate pain. As in the CAD/CAM PEEK group the children enjoyed the intraoral scanning, the clinical procedure was easier and was esthetically acceptable. On the other hand, the band and loop group disliked the band selection and the conventional impression taking. The results are in line with the study done by Nayak et al. 2004 (7) which inferred that band and loop require minimum two appointments with more laboratory time and difficulty in impression taking in especially young and uncooperative children. As stated by Yeluri and Munshi 2012 (37) FRCR space maintainer are clinically and esthetically acceptable and perhaps a convenient choice to the conventional band and loop appliances.

Moreover, Mittal et al 2018 (12) noted that in the conventional band and loop space maintainers' patients' repetitive band adaptation procedure and impression taking were difficult in young and uncooperative children or those with severe gag reflex led to its poor acceptability. Moreover, Tyagi et al 2021 (38) who found that the patients' satisfactions were more toward bonded space

maintainers. The reason could be assigned to the lack of impression making and band adaptation.

Digital impressions are capable of increasing efficiency, patient and clinician comfortability and reducing time of the procedure. Digital impressions are routinely applied in other areas of dentistry, and extending their application to pediatric dentistry may be of value to both patients and providers (19).

The present results are similar to Yuzbasioglu et al 2014 (39) and Yilmaz and Aydin (40) 2019 who compared the two impression techniques concerning the treatment comfort and patient preferences. The digital impression technique was more preferable to the patients than the conventional technique. In addition, Vij and Reddy 2020 (37) used digital impressions to construct space maintainer in case reports.

In the future, the digital dentistry will be exploring more materials that will be used to acquire several advanced appliances. As the digital age arrives and the benefits come, more "clinicians" may start using digital in their daily practice (17). According to the high success rates and patient comfort of CAD/CAM PEEK space maintainer it could be suggested to be a treatment option for single unit space maintainer. The CAD/CAM PEEK technique has extended advantages as its ease of scanning and fabrication, clinical success and could be a suitable treatment option for anxious children with fear of impression taking, however the CAD/CAM PEEK requires very accurate and precise diagnosis by conducting a proper history from the patient and good case selection and accurate clinical examinations and proper follow up. One of the limitations of this study that the parent satisfaction towards the novel treatment modality needed to be evaluated and the high cost of the equipment and the material. It was observed that it took shorter time of the intraoral scanning and the lab construction.

It is suggested that, in future studies, the cost effectiveness of both treatment groups and the clinical success for longer follow up periods and on extended number of patients. The CAD/CAM PEEK space maintainer is useful in uncooperative patients and patients seeking for esthetics but still needs further studies of other types of space maintainers and pediatric orthodontic appliances.

## CONCLUSION

Within the limitations of the current study, it can be concluded that, The CAD/CAM PEEK space maintainer showed high clinical success rates during the 6

month follow up period similar to the band and loop space maintainers.

The CAD/CAM PEEK space maintainer did not affect the dental plaque deposition and the gingival health.

The patients showed better comfort to the CAD/CAM PEEK space maintainer compared to the band and loop space maintainers.

## CONFLICT OF INTEREST

There was no conflict of interest in the following study.

## FUNDING STATEMENT

No institutional funding was provided.

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