

*Research Article***Clinical Performance of CAD /CAM Fixed Functional Space Maintainer Made of Poly Ether Ether Ketone (PEEK)**Essawy kareem¹, Yasser Fathi Gomaa², Nagwa Mohmmad Ali Khattab³¹ Department of Pediatric Dentistry and Dental Puplic Health , Faculty of Dentistry, Minia University² Department of Dental Materials, Faculty of Dentistry, Minia University³ Departmentr of Pediatric Dentistry and Dental Puplic Health, Faculty of Dentistry, Ain Shams University**Abstract**

Aim of the study: The current study was conducted to evaluate the clinical performance of PEEK polymeric material used as a Computer-aided design or computer-aided manufacturing (CAD /CAM) posterior fixed functional space maintainer clinical performance. **Methods:** A randomized clinical trial was carried out to evaluate PEEK polymeric materials used as CAD/CAM posterior fixed functional space maintainers in terms of clinical performance in thirteen children with premature unilateral loss of the first primary molar were selected. Assessment was done according to the modified United States Public Health Service (USPHS) criteria at 3, 6 and 12 months. Data were statistically analyzed between different times at P<0.05 level of significance. **Results:** Analysis of data regarding success rate in PEEK at 3,6 and 12 months revealed that there were insignificant differences (p >0.05) regarding all study parameters: color match, anatomic contour, surface texture , marginal integrity, gross fracture indicating no change in PEEK SM during 12 months follow up. **Conclusion:** PEEK CAD/CAM space maintainers represent valuable alternatives to conventional space maintainer with superior clinical performance.

Key Words: CAD/CAM, PEEK, Functional, Esthetic space maintainer**Introduction**

Deciduous teeth have an important role in children's development, not only in terms of speech, mastication, and aesthetics, but also as a natural space maintainer, protecting the dental arch perimeter and preventing harmful oral habits.^[1]

As a result, primary dentition is well fitted to function as the best space maintainers for permanent teeth. However, because premature loss of primary teeth is prevalent in children, the most effective, long-lasting, and cost-effective strategy to avoid future malocclusions and impairment of function is to use a space maintainer.^[2,3] Many factors should be consider when decide to use a space maintainer as position of tooth lost, time since tooth loss, development of permanent successor, the alveolar bone covering permanent successor, oral habits, and oral hygiene.^[4]

The most commonly used fixed space maintainers are those made of a wire soldered

to a band or a stainless steel crown.^[5] However, these fixed appliances do not retrieve normal function. It was not the only drawback, as most parents and children are concerned about dental aesthetics. Pediatric dentists strive to achieve a balance of aesthetics and space.^[6,7]

CAD/CAM technology allows dentists to create dental restorations that are free of human error and produce exceptionally pleasing results. Ceramic blocks were used initially, but they have now been replaced by polymeric blocks, which are easier to produce and repair. Although CAD/CAM restorations have been a prominent treatment option for permanent teeth, there were few case reports on their use in primary teeth^[8].

The current study was conducted to evaluate CAD/CAM polymeric bridges made of PEEK as an interesting alternative to conventional space maintainers possessing the advantages of

being fixed, functional fulfill esthetic considerations.

Material and Methods

Ethical regulations:

The current trial was approved by Minia University's institutional ethical committee (permission number 334), and subjects were chosen randomly. Before the experiment, parents/legal guardians who chose to participate signed an informed consent form after clarifying all of the advantages, hazards, and alternatives to the treatment under evaluation. Patients who refused to accept the new treatment were given the regular treatment routine.

Study design: A randomized clinical split-mouth trial design was used in this study.

Randomization and allocation:

Independent investigator created a randomized sequence for the eligible subject. For everyone involved in the study, this sequence was disguised at all times. The allocation was done with the help of a printed letter that placed into an opaque envelope with a serial number on the exterior which included the child's ID, the date, and the material to be utilized. Thirty eligible children were included.

Eligibility criteria:

Inclusion Criteria:

- Children age from 4-7 years old
- Patients with unilateral recent premature loss of first primary molars.
- The successors of the lost primary molars were not expected to erupt within 6 months.
- No congenital absence of the successors.
- Presence of teeth on the mesial and distal side of edentulous area.
- Parents and children were accepting the new treatment modality.
- History, clinical examination and radiographs revealed absence of any pathological condition.

Exclusion Criteria:

- Children with poor oral hygiene.

- Children with poor compliance.
- Children with parafunctional oral habits.
- Severe crowding
- Space has already been lost.
- Abnormal occlusion.
- Children in whom there were inability for moisture control.
- Children with systemic disease.

Child assessment and preparation

Before constructing the appliances to a child who fulfilled the eligibility criteria above, a thorough assessment was reached through; history, clinical examination, radiographs, study casts and arch length analysis. Oral prophylaxis, dental restoration of all decayed teeth, application of professional preventive measures and counseling about measures to promote oral health were also carried out.

Tooth preparation was performed then physical impression was obtained using elastomeric impression material (Elite HD, Germany), a working cast was moulded using high strength dental stone, and the shade color of the teeth was chosen, then a 3D scanner was used to scan the working cast (Ineos x5 dentsply sirona). The design of the space maintainer was completed using Exocad Program (In lab dentsply sirona, Germany). Polymeric blocks of PEEK (poly ether ether ketone) were milled using CAD/CAM machine (dentsply sirona, Germany). The abutment tooth was isolated, etched, and air dried after trimming, finishing, and polishing the space maintainer. The bridge was cemented using luting Rely X Unicem resin cement (3M ESPE Dental products, St. Paul, USA) and the child's occlusion was evaluated for any premature contact (Figure 1). The legal guardians were urged to keep their children under control in order to avoid eating hard or sticky foods and to maintain proper dental hygiene. The parents were advised that the pontic will be excised by a dentist at the age of about 8-9 years to allow permanent successors to erupt.

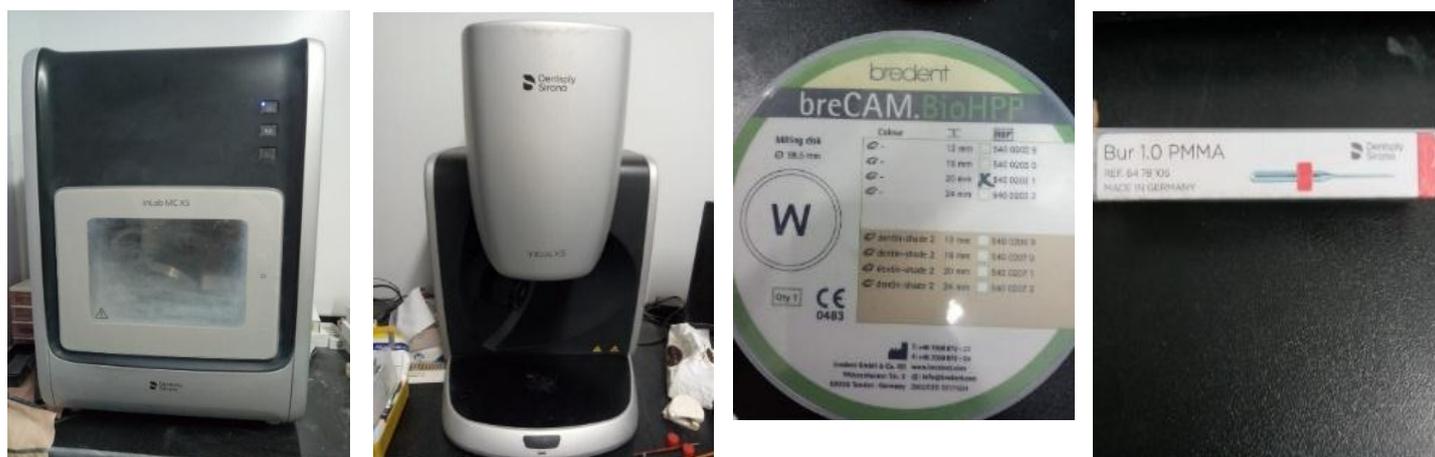


Figure (1): Scanning and milling work:(milling machine, extraoral scanner ,machine burs, PEEK blocks).

Evaluation of SMs:

The patient was recalled for the first time after 24 hours, followed by recall visits 3,6and 12 months. During evaluation and in case of failure of the appliance, the parents would freely decide to accept repair of the appliance or shifting to another regularly used method of institution where the experiment was admitted.

The clinical performance was evaluated during recall visits via a clinical examination of: (1) Color match, (2) Anatomic contour, (3) Marginal integrity, (4) Surface texture, and (5) Gross fracture by using the modified United States Public Health Service (USPHS) criteria for direct clinical evaluation of restoration.

The obtained data were coded, tabulated, and statistically analyzed using SPSS program (Statistical Package for Social Sciences)

software version 26.For parametric (normally distributed) quantitative data, descriptive statistics were calculated using the mean, standard deviation (SD), and minimum and maximum range, whereas for qualitative data, frequency and percentage were used. The significance level was set at (P value < 0.05).

Results

Of 36 children examined for eligibility, 30 children were enrolled in the present study. Six participants were excluded as 4 children didn't meet the eligibility criteria and 2 children's parents refused to participate in the study Data in table 1 represented the retention rate of CAD/CAM polymeric bridges made of PEEK at the follow-ups. At 3 months the retention rate of both space maintainers was 100%. At 6 and 12 months, only two cases (6.7%) were lost.

Table (1): Retention rate of CAD/CAM polymeric bridges made of PEEK at 3, 6, and 12 months

	3 months	6 months	12 months
	N (%)	N (%)	N (%)
Retained	30 (100)	28 (93.3)	2 (6.7)
Lost	30 (100)	2 (6.7)	2 (6.7)
p	N/A	0.56	0.5

Analysis of data regarding success rate in PEEK at 3, 6 and 12 months revealed that there were insignificant differences (p>0.05) regarding all study parameters: color match, anatomic contour, surface texture, marginal integrity, gross fracture indicating no change in

PEEK SM during 12 months follow up that make PEEK CAD/CAM space maintainers represent valuable alternatives to conventional space maintainer with superior clinical performance (Table 2 and Figure 2).

Table (2): United States Public Health Service (USPHS) criteria of the PEEK at 3, 6, and 12 months

	3 months	6 months	12 months
	N (%)	N (%)	N (%)
color match			
Alpha	0 (0)	0 (0)	0 (0)
Bravo	25 (83.3)	25 (83.3)	25 (83.3)
Charlie	5 (16.7))	5 (16.7))	5 (16.7))
anatomic contour			
Alpha	30 (100)	30 (100)	30 (100)
Bravo	0 (0)	0 (0)	0 (0)
Charlie	0 (0)	0 (0)	0 (0)
marginal integrity			
Alpha	10 (33.3)	10 (33.3)	10 (33.3)
Bravo	11 (36.7)	10 (33.3)	9 (30)
Charlie	9 (30)	10 (33.3)	11 (36.7)
surface texture			
Alpha	25 (83.3)	25 (83.3)	24 (80)
Bravo	4 (13.3)	3 (10)	4 (13.3)
Charlie	1 (3.4)	2 (6.7)	2 (6.7)
gross fracture			
Alpha	30 (100)	26 (86.6)	25 (83.3)
Bravo	0 (0)	2 (6.7)	3 (10)
Charlie	0 (0)	2 (6.7)	2 (6.7)

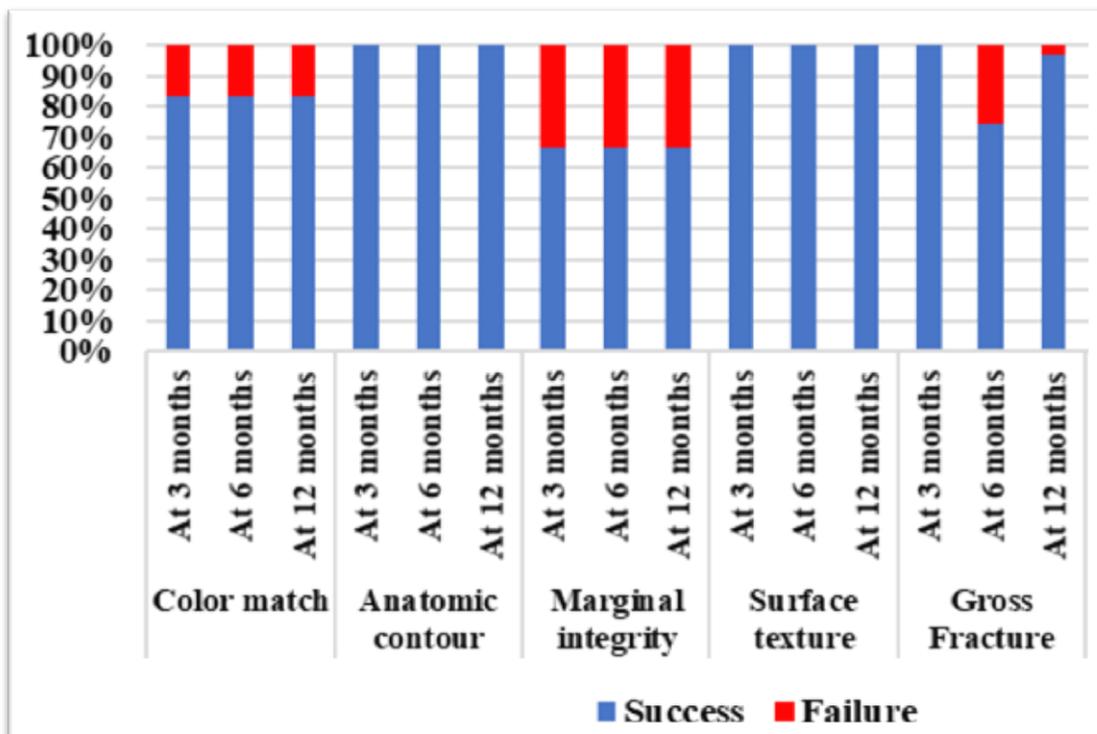


Figure (2): Clinical success rate for the space maintainer at 3,6,12 months follow up period

Discussion

Premature loss of primary teeth is still representing a common issue that if not properly managed would result in adverse effects regarding arch integrity and permanent teeth proper alignment^[9]. The prompt space maintainer construction is considered the ideal treatment option in indicated situations to prevent the deleterious effects of primary teeth premature loss^[10].

While band and loop conventional space maintainer is considered the most commonly used fixed type in cases of single tooth loss with certain disadvantages as non-functioning and bad esthetics^[11]. The use of CAD/CAM space maintainer had been reported as a valuable alternative to conventional one with superior esthetics^[12].

PEEK has been reported to be trialed as a suitable material for CAD/CAM bridges construction by some authors^[13]. Up to our knowledge there is no published clinical trial evaluate PEEK clinical performance when used as space maintainer constructing material thus the current study with randomized clinical design was conducted.

The selected subjects age was ranged from 4 to 7 as the first permanent molars had not yet fully erupted and hence could not be banded. Additionally, children did not have all their mandibular permanent incisors erupted for lingual arch construction^[14].

The modified USPHS criteria, an established method used in clinical investigation was selected in the current study to evaluate the space maintainers. The modified USPHS criteria are considered the most commonly used system for evaluating the most important criteria of direct restorations^[15, 16].

The results of the current study at 3,6 and 12 months revealed that there were insignificant differences ($p > 0.05$) in PEEK space maintainer regarding all study parameters: color match, anatomic contour, surface texture, marginal integrity, gross fracture. Thus, may be due to the higher strength, fatigue resistance, hardness, wears resistance and color stability for PEEK^[17, 18].

Regarding the comparison of the current study results with previous studies, there were no published clinical trials that allow comparison the tested materials as CAD/CAM space maintainer constructing materials.

Conclusion

PEEK CAD/CAM space maintainers represent valuable alternatives to conventional space maintainer with superior clinical performance in one year follow up period.

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