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Precision in Practice-Clinical Performance and Acceptance of 3D Band and Loop Space Maintainer: A Randomised Control Trail

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Abstract: ***Aim: To evaluate the efficacy, longevity, gingival health, and patient acceptance of a 3D-printed PEEK band and loop space maintainer compared to the conventional stainless-steel band and loop space maintainer. Materials and Methods: Fifteen children aged 4 to 8 years, each requiring bilateral space maintenance due to early loss of primary first molars, participated in this randomized controlled trial. Each child received a conventional stainless-steel space maintainer on one side and a 3D-printed PEEK space maintainer on the other. The appliances were assessed over a six-month period for, gingival health, and patient acceptance. Results: The 3D-printed PEEK group consistently demonstrated better gingival health scores and higher patient acceptance throughout the follow-up period. Conclusion: Over the six-month evaluation period, 3D-printed PEEK space maintainers demonstrated superior gingival health outcomes and higher patient acceptance than conventional stainless-steel band and loop appliances.***

Keywords: Polyetheretherketone (PEEK), Three-dimensional space maintainer, Band and Loop space maintainer

1. Introduction

Primary teeth have an important role in directing the eruption of permanent teeth. Premature loss of primary teeth can lead to unwanted tooth movement resulting in loss of space in the arch leading to impaction of succedaneous teeth, which can cause malocclusion. It can also affect children's phonation, causing speech distortion. Psychosocial problems can also arise from premature tooth loss in children. [1] So maintenance of space is of pivotal importance and space maintainers are given.

To maintain space, band and loop have been used for both unilateral and bilateral space maintenance. Although band and loop space maintainer is considered as conventional and gold standard still it has few limitations and drawbacks such as non-functional, does not prevent supra eruption of opposing tooth, causes impingement of the loop in the soft tissue, fracture of solder or band, does not help in mastication, decalcification of the abutment tooth and has less longevity in oral cavity. Among these disintegration of cement and solder fracture are the two common causes of failures. [2]

With rapidly emerging technological advances, there is a paradigm shift towards digital dentistry providing the best and minimally invasive, novel treatment options to the patients to choose from. One such evolving concept is 3D space maintainer in the form of Digitainers /Digital space maintainers.[3]

Digital workflow enables precision-engineered 3D space maintainers which are accurate in their reproducibility of finer details as in hard tissue and soft tissue, enabling maximum accuracy and negligible human error, simplifying laboratory operations, with lowest likelihood of malfunction or breakage. [3,4]The 3D Space maintainer is printed as one unit minimizing the breakage, thus reducing failure of the appliance with higher level of precision.

Among the various material available cobalt-chromium, stainless-steel, nickel alloy and titanium metals are the metal incorporated options and metal free materials like plastics, polymers and zirconia-based materials have also been studied so far.[5]As conventional band and loop space maintainer is fully made of stainless steel some studies has shown allergic reactions and more plaque accumulation and poor gingival health and not pleasing to look.[6]

In order to overcome these drawbacks, more aesthetically pleasing and metal-free space maintainers have been developed, leading to the introduction of the CAD-CAM PEEK band and loop space maintainer. [7]

Polyetheretherketone (PEEK) is a thermoplastic, non-toxic material used as alternative with excellent mechanical properties, biocompatibility, and resistance to wear, corrosion, and high temperatures, better resilience to fractures and has shown low plaque affinity. [8,9]

Therefore, there is a need for a better space maintainer that fulfils the overall requirement with better patient acceptance. Hence our study focuses on evaluation of the clinical effectiveness of 3D band and loop space maintainer and its comparison with conventional band-and-loop space maintainer.

2. Materials and Methodology

A total of 15 children satisfying the inclusion and exclusion criteria from the Outpatient Department of Pedodontics and Preventive Dentistry, KVG Dental College, Sullia, were selected after obtaining parental consent. Inclusion criteria comprised clinical cases of bilateral loss of primary first molars within 6 months of tooth loss, with radiographic

confirmation of absence of periapical or pulpal pathology in the abutment tooth, presence of succedaneous tooth bud, and more than 1 mm of bone coverage over the succedaneous tooth germ or less than one-third root formation of the permanent tooth. Exclusion criteria included medically or physically compromised patients, uncooperative children or those under 3 years of age, patients with enamel developmental disturbances, poor oral hygiene or gingival conditions such as drug-induced gingival hyperplasia, space closure less than 7 mm, crowded or spaced arches, bone coverage less than 1 mm, succedaneous tooth with two-thirds root formation completed, allergy to stainless steel, and abutment teeth with pulp pathology.

Oral prophylaxis was performed for all participants, followed by putty impressions with silicone elastomers to obtain study and working casts.

In Group I (experimental), working casts were scanned using an Artec Leo 3D scanner, digitally designed via CAD, and 3D-printed in PEEK to fabricate band and loop space maintainers. In Group II (control), conventional stainless-steel band and loop space maintainers were fabricated intraorally, impressions were made, casts prepared, loops bent from 0.9 mm stainless steel wire, soldered, and polished. Appliances in both groups were checked for gingival clearance and occlusal interference, then cemented—Group I with self-adhesive resin cement and Group II with resin-modified glass ionomer cement. Oral hygiene and appliance maintenance instructions were given to children and parents. Follow-up visits at 1, 3, and 6 months assessed gingival health (Löe and Silness Index), subject acceptance (Facial Image Scale), appliance longevity, space maintenance (clinically and radiographically), and complications leading to failure.

3. Result

The study design was split-mouth design with coin-flip randomization was employed to compare the 3D-printed band and loop space maintainer (experimental group) with the conventional stainless-steel band and loop (control group). The primary outcomes assessed were gingival health and patient acceptance.

Regarding the gingival health, Within-group analysis showed that gingival scores in the experimental group did not change significantly across timepoints ($p = 0.059$), whereas the control group demonstrated a statistically significant increase in gingival inflammation over time ($p < 0.001$) (Table 1)

Between-group comparisons revealed no significant differences at baseline (p = N/A). At T1, gingival health was better in the experimental group though not statistically significant ($p = 0.134$). By T3 and T6, the differences widened in favour of the experimental group, with p-values approaching significance ($p = 0.062–0.063$) (Table 2).

Patient acceptance scores favoured the experimental group across all intervals, indicating lower discomfort. At baseline, mean scores were 1.27 ± 0.46 for the experimental group and 1.80 ± 1.08 for the control ($p = 0.090$). The trend of better acceptance continued through T1 to T6, with the greatest difference observed at T3 (1.17 ± 0.39 vs. 1.80 ± 1.08, $p = 0.066$). Although none of the differences were statistically significant, results suggested a consistent trend toward better tolerance with the 3D space maintainer (Table 3).

Table 1: Comparison of Gingival Health Over Time Within the Group

Group	Timepoint	Mean ± SD	ANOVA p-value
Experimental	T1	0.15 ± 0.38	0.059
	T3	0.33 ± 0.49	
	T6	0.45 ± 0.69	
Control	T1	0.47 ± 0.64	<0.001
	T3	0.87 ± 0.83	
	T6	1.13 ± 0.99	

Table 2: Comparison of Gingival Health Between Experimental and Control Groups at Each Interval

Timepoint	Group	Mean ± SD	p-value
T1	Experimental	0.15 ± 0.38	0.134
	Control	0.47 ± 0.64	
T3	Experimental	0.33 ± 0.49	0.062
	Control	0.87 ± 0.83	
T6	Experimental	0.45 ± 0.69	0.063
	Control	1.13 ± 0.99	

Table 3: Patient Acceptance of Space Maintainers Over Time

Timepoint	Experimental (Mean ± SD)	Control (Mean ± SD)	p-value
Baseline	1.27 ± 0.46	1.80 ± 1.08	0.09
T1	1.50 ± 0.94	1.87 ± 1.06	0.335
T3	1.17 ± 0.39	1.80 ± 1.08	0.066
T6	1.18 ± 0.40	1.80 ± 1.08	0.085

Figure 1: Conventional Stainless-Steel Space Maintainer and 3D-Printed PEEK Space Maintainer

Figure 2: IOPA of 3D-Printed PEEK Space Maintainer

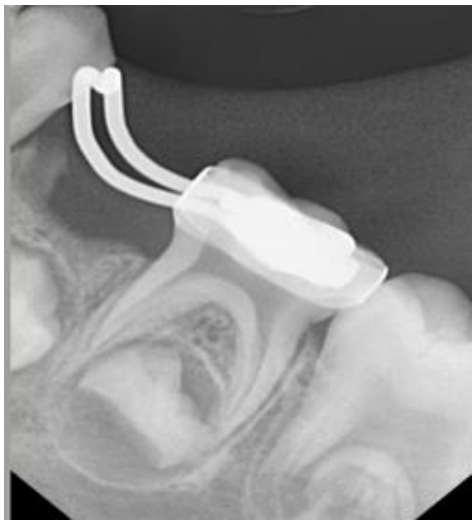

Figure 3: IOPA of Conventional Stainless-Steel Space Maintainer

4. Discussion

Children are highly prone for caries and some non-restorable tooth are inevitably extracted ahead of time, this can create space and adjacent tooth including the opposite tooth or teeth supra erupt along with space loss the other untoward after effects include malocclusion, habits, speech problems. So, it becomes mandatory to give space maintainer immediately after early loss. Till date for unilateral loss of first and second deciduous molars, band and loop has been the gold standard however the multiple disadvantage of the appliance has led to many alterations in its design and materials.

One of such innovation is the digital impression technique and space maintainer fabrication with new materials like PEEK. In the recent technology digitalized 3D printing offers several advantages like precise control over the dimensions and geometry of the manufactured appliance, allowing for high levels of customization to meet the needs of each individual patient along with faster production times.[10]

The selection of PEEK for our study was due to its exceptional biocompatibility, low affinity for plaque accumulation, has a number of colour constituents, one of them is white which has a close resemblance to tooth colour and also offering the possibility of customized 3D printing in as single unified structure with smooth surface eliminating the need for solder joints thereby reducing the risk of breakage, gingival inflammation.

Gingival health outcomes consistently favoured the 3D group, with lower mean Gingival Index scores at T1 (0.15 ± 0.38 vs. 0.47 ± 0.64, p = 0.134), T3 (0.33 ± 0.49 vs. 0.87 ± 0.83, p = 0.062), and T6 (0.45 ± 0.69 vs. 1.13 ± 0.99, p = 0.063), with p-values at T3 and T6 approaching significance, suggesting reduced gingival inflammation. in the 3D band and loop space maintainer group which can be attributed due to the high biocompatibility and polished surface likely minimize plaque accumulation, soft tissue irritation and also due to the customized design of 3D maintainers, achieved through digital workflows, ensures precise adaptation to the gingival margin, avoiding impingement that could exacerbate inflammation, unlike manually fabricated loops, which may have sharp edges or suboptimal contours.[2,11]

The elimination of solder in alternative designs removes these plaque-retentive sites, facilitating easier removal of plaque and debris, which helps reduce gingival irritation and inflammation and supports better overall gingival health.[12]This is attributed to the findings in accordance to Tyagi et al[13] Jain et al. (2022), who highlighted that 3D-printed dental devices offer better marginal adaptation, which can reduce plaque retention and thereby improve gingival health.[14]

The perception of child patient towards the new space maintainer we assessed the patient acceptances via the facial image scale (lower score indicating greater comfort) and found in T1, p = 0.335, T3, p = 0.066), and T6, p = 0.085), with T3 approaching significance, was seen consistently higher in the 3D group as children are more likely to tolerate devices that feel less intrusive. The 3D maintainers lightweight, smooth texture and precise fit, enabled by digital design, likely reduce discomfort compared to the heavier, potentially abrasive stainless steel.[3,15,16]

Manual fabrication variability in the control group may result in inconsistent loop contours or band fit, contributing to higher discomfort scores and greater variability.[2] This was in accordance with Dawood et al (2015) -[17] where they mentioned in digital customization 3D printed appliance leads to greater anatomical accuracy which can significantly enhance comfort and compliance in paediatric patients.

In contrast, children in the conventional band and loop group expressed dissatisfaction, particularly with the process of band selection. These findings were consistent with Nayak et al. (2004) Mittal et al. (2018), noted that repeated band adaptation and impression procedures are difficult for children who are uncooperative or have a strong gag reflex, resulting in lower acceptance of this method.[18,19]

This study highlights the growing relevance of digital dentistry and material science in paediatric practice.

According to the high success rates and patient comfort of CAD/CAM 3D space maintainer it could be suggested to be a treatment option for single unit space maintainer. The CAD/CAM 3D 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 3D 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.

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 3D space maintainer is useful in uncooperative patients and patients seeking for aesthetics but still needs further studies of other types of space maintainers and paediatric orthodontic appliances.

5. Conclusion

Within the limitations of the present study, it can be concluded that the 3D space maintainer demonstrated high clinical success rates over the six-month follow-up period, comparable to conventional band and loop space maintainers. The use of 3D Space maintainer did not adversely influence plaque accumulation or gingival health. The patients showed better comfort and acceptance with the 3D space maintainer compared to the conventional appliance, suggesting it as a promising alternative in paediatric space management.

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