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Original Article

Digital Versus Traditional: An *In Vivo* Study of 3D-Printed and Conventional Band and Loop Space Maintainers

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Abstract

Introduction: The preservation of space within the dental arch following the premature loss of primary teeth is a critical aspect of pediatric dentistry. Space maintainers help preserve the arch integrity and provide guidance for proper tooth development. Band and loop space maintainer remains one of the most commonly employed due to its simplicity, adaptability, and clinical effectiveness. Conventional band and loop space maintainer poses challenges such as prolonged chairside time, plaque accumulation, and patient discomfort. The advent of 3D printing technology offers a promising alternative by improving precision, customization, and reducing chair time.

Aim: The aim of the study was to compare the clinical effectiveness of conventional band and loop space maintainer and 3D-printed band and loop space maintainer.

Material and Methods: The study was conducted on 42 children aged 4–9 years who required band and loop space maintainers. They were randomly divided into two groups; Group A – Conventional space maintainers, and Group B – 3D-printed space maintainers. Clinical assessments of dental and gingival health, plaque accumulation, and failure rate were done at 3, 6, 9, and 12 months. Data were analyzed using the Statistical Package for the Social Sciences 23.0, with statistical significance set at $P < 0.05$.

Results: The 3D-printed space maintainers demonstrated a more stable Decayed Missing and Filled Teeth (DMFT)/dmft score, while the conventional maintainers showed an increase in dental caries, which, however, was statistically insignificant. Plaque score and gingival inflammation were significantly higher in the conventional group. Although the difference in failure rates was not statistically significant, the conventional space maintainer showed higher failure due to issues like cement loss and solder breakage.

Conclusion: 3D-printed band and loop space maintainers demonstrated superior clinical effectiveness compared to conventional maintainers, as evidenced by reduced gingival inflammation, lower plaque accumulation, and fewer failure.

Key words: 3D printing, Band and loop, Early tooth loss, Gingival index, Space maintainers

INTRODUCTION

The preservation of space within the dental arch following the premature loss of primary teeth is an essential aspect of pediatric dentistry. Early loss of primary teeth, due to caries, trauma, or developmental anomalies, can disrupt the normal eruption sequence of permanent teeth, leading to malocclusions, crowding, and altered arch forms.[1,2] Space maintainers are employed to preserve arch integrity and ensure proper dental development. Among these, the conventional band and loop space maintainer is commonly used for its functional simplicity and cost-effectiveness.

Fabrication of conventional band and loop space maintainers has relied on a manual time-consuming process. This includes taking physical impressions, preparing

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dental casts, selecting or customizing stainless steel bands, and manually soldering loops. While these maintainers have demonstrated clinical reliability over decades, the fabrication process is prone to variability depending on the operator's skill, and often requires substantial chairside adjustments to achieve proper fit.[3] Moreover, conventional space maintainers are associated with certain limitations, such as bulkier designs, patient discomfort, and the potential for plaque accumulation around bands if not carefully cleaned.[4]

Recent advancements in digital dentistry and additive manufacturing technologies have introduced transformative changes in the fabrication of dental appliances. Among these, 3D printing, also known as additive manufacturing, has emerged as a promising alternative to conventional techniques. The workflow involves digital scanning of the patient's dentition, computer-aided design of the space maintainer, and layer-by-layer fabrication using a 3D printer. This technology eliminates the need for physical impressions and traditional casting, providing enhanced precision, reproducibility, and speed in the fabrication process.[5,6] In addition, 3D-printed appliances can be customized with a level of accuracy that is difficult to achieve with traditional methods, leading to improved patient comfort and satisfaction.[7]

Preliminary studies on 3D-printed maintainers suggest several advantages, including better fit, reduced chairside adjustments, and improved patient compliance.[8] There has been a growing adoption of 3D-printed band and loop space maintainers, but question remain regarding their long-term clinical effectiveness compared to conventional space maintainer.

This randomized controlled study aimed to compare the clinical effectiveness of the conventional band and loop space maintainer and the 3D-printed band and loop space maintainer

MATERIAL AND METHODS

This study included healthy children aged 4–9 requiring a band and loop space maintainer. Ethical approval was obtained for the study, and the accompanying parents or guardians received a comprehensive explanation of the study objectives, methodology, and associated risks and benefits. Subsequently, written consent was obtained from the parents or guardians.

Inclusion Criteria

This study included healthy children between age of 4 and 9 years, provided their permanent successor were at Nolla's developmental stages one through seven, presenting with unilateral premature loss of primary molars due to dental caries, trauma, and other pathological conditions, or bilateral loss of primary molars before the eruption of permanent incisor.

Exclusion Criteria

Children who presented with significant arch length discrepancy (>4 mm)[9] or severe crowding, ongoing orthodontic treatment, history of dental trauma causing occlusal disturbance, ankylosis, or premature loss of multiple teeth, and known allergies or hypersensitivity to any material used in the fabrication or cementation of the space maintainer were excluded from the study.

Sample Size Calculation

Sample size estimation was done using G Power software (version 3.0). Sample size was estimated for *t*-test. A minimum total sample size of 42 was found to be sufficient for an alpha of 0.05, power of 80%, 0.80 as effect size (large effect size). The sample size was further divided as 21 in two study groups.

Randomization

The simple random sampling method used in this study ensured that all eligible participants had an equal chance of being assigned to either treatment group. A simple randomization was carried using the lottery method. For randomization, 42 identical slips of paper were prepared, with 21 slips labeled "Group A" (Conventional Space Maintainer) and 21 slips labelled "Group B" (3D-Printed Space Maintainer). These slips were thoroughly mixed in an opaque container to prevent any selection bias. Each participant, or their accompanying guardian, was asked to draw one slip from the container, thereby determining their group allocation [Figure 1].

Methodology

Children in group A were given a conventional band and loop space maintainer. Band material was fitted and spot-welded on the teeth. Impression was taken of the upper and lower arch using alginate impression material, and a study model was procured. A loop was soldered to the band and spans the edentulous space to contact the abutment tooth. The band and loop space maintainer were then cemented onto the patient's teeth using GIC (type1) [Figure 2]. Children in Group B were given band and loop space maintainer fabricated using 3D printing technology. Singlestep rubber base impression was made using addition silicon and was poured to make a cast. The retrieved cast was sent to the 3D printing laboratory for scanning and printing a metal-based space maintainer. Designing of the band and loop was done on this model similar to that of conventional space maintainer

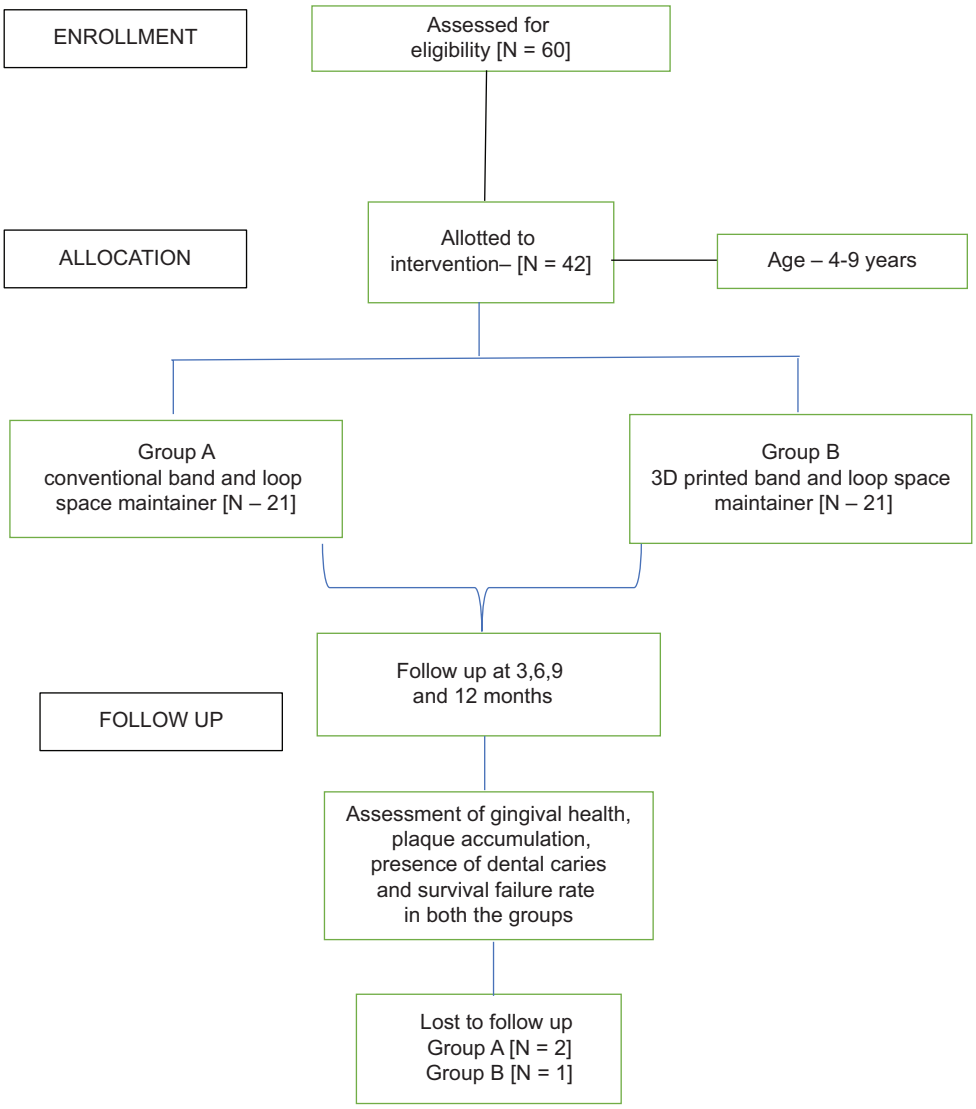

Figure 1: Consort flow diagram for the clinical trial

Figure 2: Conventional band and loop space maintainer

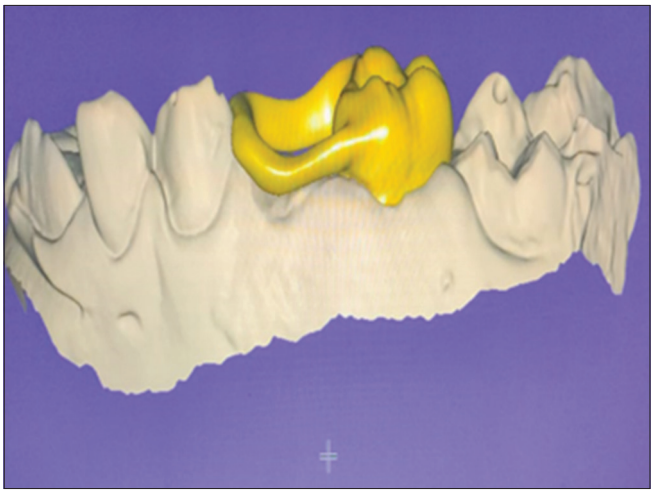

Figure 3: Designing of 3D printed band and loop space maintainer

[Figure 3]. 3D-printed band and loop space maintainer was printed using a titanium-based powdered metal material (Ti64 Gd23; LPW Technology Ltd., Cheshire, UK) material and then cemented using GIC (type 2) [Figure 4].

Figure 4: 3D printed band and loop space maintainer

The following parameters were clinically assessed at 3, 6, 9, and 12 months;

- Clinical evaluation of gingival health: Gingival health of abutment teeth was evaluated using the criteria established by Löe and Silness in 1963.[10] Plaque accumulation on abutment teeth was evaluated using criteria established by Silness and Löe in 1964[11]
- Clinical evaluation of the presence of dental caries: Dental caries was evaluated using the DMFT/dmft index[12,13]
- Assessment of failure of space maintainer: Space maintainer in both groups were considered a failure if there was loss of cement, failure of soldering leading to breakage at the loop and band interface, distortion of the loop or the band, loop fracture, breaking of the band and lost to follow-up.

Statistical Analysis

The data for the present study were entered in the Microsoft Excel 2007 and analyzed using the Statistical Package for the Social Sciences statistical software 23.0 Version. The descriptive statistics included mean, standard deviation frequency, and percentage. The level of the significance was fixed at 5%. The intergroup comparison for the continuous variables was done using the Mann–Whitney U test, and for the continuous variables Chi-square test was used. The intragroup comparison between the different time intervals was done using the Wilcoxon Signed-Rank Test (within-group). The Shapiro–Wilk test was used to investigate the distribution of the data, and Levene's test to explore the homogeneity of the variables.

RESULTS

At baseline, both Group A (conventional band and loop space maintainer) and Group B (3D-printed band and loop space maintainer) demonstrated comparable clinical parameters, with no statistically significant differences in DMFT/dmft scores, plaque index, or gingival status ($P > 0.05$).

Intergroup Comparison

Over a 12-month period, the intergroup difference in DMFT/dmft score remained statistically insignificant ($P = 1.000$) [Table 1]. In contrast, significant differences were observed in plaque accumulation and gingival health over time. Group A showed a marked decline in oral hygiene, with the percentage of subjects maintaining a "Good" plaque index dropping from 95.23% at baseline to 43.75% at 12 months, and a rise in "Fair" and "Poor" categories ($P = 0.001$). Group B also experienced a decline but maintained comparatively better plaque scores, with 50% of subjects still in the "Good" category at 12 months [Table 1]. Gingival health followed a similar trend: Group A showed increasing inflammation, with moderate to severe gingivitis seen in 62.5% of cases by 12 months, compared to 45.45% in Group B ($P = 0.001$) [Table 1]. These findings suggest that while caries progression was not statistically significant, 3D-printed space maintainers offered superior outcomes in terms of plaque control and gingival health.

Intragroup Comparison

On intragroup comparison, over the 12-month follow-up period, Group A exhibited a statistically insignificant increase in DMFT/dmft scores, rising from 0.904 ± 0.300 to 1.095 ± 0.889, whereas Group B maintained a relatively stable mean score of 0.952 ± 0.497, indicating better caries prevention [Table 2].

Group A showed a significant deterioration in plaque control over 12 months ($P = 0.001$): the proportion with mild plaque fell from 95.23% at baseline to 43.75% at 12 months, while moderate/severe increased from 4.77% (plus one severe case at baseline) to 56.25% (moderate 43.75%, severe 12.5%). Group B showed better overall plaque control with no severe cases throughout follow-up; however, mild plaque decreased from 100% at baseline to 50% at 12 months, with a corresponding rise in moderate plaque from 0% to 50% ($P = 0.001$) [Table 2].

Gingival health also followed a similar trend, with Group A showing a significant deterioration in gingival status over 12 months ($P = 0.001$). Mild scores declined from 95.2% at baseline to 43.75%, while moderate increased from 4.8% to 50%, and severe cases emerged by 9 months (0% → 6.25% at 12 months). Group B maintained better gingival status with no severe cases throughout; however, mild scores declined from 95.2% at baseline to 55.55% at 12 months, with a corresponding rise in moderate scores from 4.8% to 45.45% ($P = 0.001$) [Table 2].

Table 1: Intergroup comparison of DMFT/dmft index, plaque index, and gingival status between both the groups at different time intervals

Time	Group	DMFT/ dmft Score (Mean±Standard deviation)	*P*-value (DMFT/ dmft)	Plaque index (Good/Fair/Poor) (%)	*P*-value (Plaque)	Gingival status (Mild/ Moderate/Severe) (%)	*P*-value (Gingival)
Baseline	Group A	0.904±0.300	1.000	Good: 20 (95.23), Fair: 1 (4.77)	1.000	Mild: 20 (95.20), Moderate: 1 (4.80)	1.000
	Group B	0.912±0.384	(Non-Sig)	Good: 21 (100)	(Non-Sig)	Mild: 20 (95.20), Moderate: 1 (4.80)	(Non-Sig)
3	Group A	0.904±0.300	1.000	Good: 16 (80), Fair: 4 (20)	0.001	Mild: 14 (70), Moderate: 6 (30)	0.001
Months	Group B	0.912±0.384	(Non-Sig)	Good: 17 (89.47), Fair: 2 (10.53)	(Sig)	Mild: 17 (89.47), Moderate: 2 (10.53)	(Sig)
6	Group A	0.952±0.384	1.000	Good: 12 (63.15), Fair: 7 (36.85)	0.001	Mild: 12 (63.15), Moderate: 7 (36.75)	0.001
Months	Group B	0.952±0.497	(Non-Sig)	Good: 15 (78.95), Fair: 4 (21.05)	(Sig)	Mild: 15 (78.95), Moderate: 4 (21.05)	(Sig)
9	Group A	1.047±0.384	0.876	Good: 10 (58.82), Fair: 6	0.001	Mild: 9 (52.94), Moderate: 7 (41.18),	0.001
Months			(Non-Sig)	(35.29), Poor: 1 (5.89)	(Sig)	Severe: 1 (5.88)	(Sig)
	Group B	0.952±0.497		Good: 13 (72.22), Fair: 5 (27.78)		Mild: 12 (66.66), Moderate: 6 (33.33)	
12	Group A	1.095±0.889	0.372	Good: 7 (43.75), Fair: 7 (43.75),	0.001	Mild: 7 (43.75), Moderate: 8 (50),	0.001
Months			(Non-Sig)	Poor: 2 (12.50)	(Sig)	Severe: 1 (6.25)	(Sig)
	Group B	0.952±0.497		Good: 9 (50), Fair: 9 (50)		Mild: 10 (55.55), Moderate: 8 (45.45)	

DMFT: Decayed missing and filled teeth

Table 2: Intragroup comparison of DMFT/dmft index, plaque index, and gingival status between both the groups at different time intervals

Time	Group	DMFT/dmft score (Mean±Standard deviation)	*P*-value (DMFT/dmft)	Plaque index (Good) (%)	*P*-value (Plaque)	Gingival status (Mild) (%)	*P*-value (Gingival)
Group A	Baseline vs. 3	0.904±0.300	1.000	20 (95.23)	0.001 (Sig)	20 (95.20)	0.001 (Sig)
	Months	0.904±0.300	(Non-sig)	16 (80)		14 (70)	
	Baseline vs. 6	0.904±0.300	1.000	20 (95.23)		20 (95.20)	
	Months	0.952±0.384	(Non-sig)	12 (63.15)		12 (63.15)	
	Baseline vs. 9	0.904±0.300	0.876	20 (95.23)		20 (95.20)	
	Months	1.047±0.384	(Non-sig)	10 (58.82)		9 (52.94)	
	Baseline vs. 12	0.904±0.300	0.372	20 (95.23)		20 (95.20)	
	Months	1.095±0.889	(Non-sig)	7 (43.75)		7 (43.75)	
Group B	Baseline vs. 3	0.912±0.384	1.000	21 (100)	0.001 (Sig)	20 (95.20)	0.001 (Sig)
	Months	0.912±0.384	(Non-sig)	17 (89.47)		17 (89.47)	
	Baseline vs. 6	0.912±0.384	1.000	21 (100)		20 (95.20)	
	Months	0.952±0.497	(Non-sig)	15 (78.95)		15 (78.95)	
	Baseline vs. 9	0.912±0.384	0.876	21 (100)		20 (95.20)	
	Months	0.952±0.497	(Non-sig)	13 (72.22)		12 (66.66)	
	Baseline vs. 12	0.912±0.384	0.372	21 (100)		20 (95.20)	
	Months	0.952±0.497	(Non-sig)	9 (50)		10 (55.55)	

DMFT: Decayed missing and filled teeth

Failure Rate

Regarding failure rates, Group A had a higher failure incidence (23.81%) compared to Group B (14.28%). In Group A, failures were primarily due to dislodgement (9.52%), loss to follow-up (9.52%), and band breakage (4.76%). In Group B, failures were due to cement loss (4.76%), dislodgement (4.76%), and loss to follow-up (4.76%). The intergroup difference in failure rates was not statistically significant ($P = 0.431$) [Table 3].

DISCUSSION

The premature loss of primary teeth is a critical concern in pediatric dentistry, as it disrupts the natural exfoliation and eruption sequence, often resulting in malocclusion, crowding, and altered arch integrity.[14] The placement of space maintainers plays a crucial role in preserving the dental arch space and facilitating the normal eruption of permanent teeth. Traditionally, conventional band and loop space maintainers have been a suitable option for clinicians. However, with technological advancements, particularly in digital dentistry and additive manufacturing, 3D-printed space maintainers have emerged as promising alternatives offering several clinical advantages.

In the present randomized controlled trial, the clinical effectiveness of conventional versus 3D-printed band and loop space maintainers was compared across various parameters, including plaque accumulation, gingival health, caries development (DMFT/dmft index), and survival-failure ratio. The study included children who required space maintenance following premature loss of primary

Table 3: Comparative evaluation of failure rate between conventional and 3D-printed band and loop space maintainer

Groups	Factors for failure							Total (%)	*P*-value
	Loss of cement (%)	Failure of soldering (%)	Distortion (%)	Loop fracture (%)	Dislodgement (%)	Lost to follow-up (%)	Band breakage (%)		
Group A	0 (0%)	0 (0)	0 (0)	0 (0)	2 (9.52)	2 (9.52)	1 (4.76)	05 (23.81)	0.431
Group B	1 (4.76)	0 (0)	0 (0)	0 (0)	1 (4.76)	1 (4.76)	0 (0)	03 (14.28)	(Non-Sig)

molars only if the adjacent permanent successors were in Nolla's developmental stage one to seven.[15,16]

The survival rate is a vital determinant of a space maintainer's long-term success. At the end of a 12-month follow-up period, the survival rate for conventional space maintainers was found to be 78%, whereas the 3D-printed maintainers demonstrated a higher survival rate of 85%. The comparatively lower success in the conventional group can be attributed to dislodgement, band breakage, and solder failure, all of which stem from the inherent weaknesses of manually fabricated devices. Previous studies, such as those conducted by Tunc *et al.*,[17] Mittal *et al.*[18] and Setia *et al.*[19] reported higher success rates of 90%, 86.7%, and 84.6%, respectively. However, other studies, such as Thakur *et al.*[20] and Cengiz *et al.*[8] reported significantly lower survival rates of 3D-printed space maintainer underscoring the variability influenced by clinical technique, material quality, and patient-related factors. In contrast, failures in the 3D-printed group were primarily due to loss of cement or dislodgement, but lacked structural breakdowns such as solder failure. These findings are consistent with a study done by Thakur *et al.*,[20] where dislodgement and mechanical breakage have been identified as primary modes of failure in conventional appliances. This absence of mechanical failure reinforces the structural integrity and precision of 3D-printed devices. The improved fit and adaptability offered by digital design allow for better interaction with oral tissues, reducing the likelihood of functional dislodgement and enhancing appliance longevity. The absence of soldered joints in 3D-printed space maintainers reduces weak points that commonly cause failure in conventional appliances.

DMFT/dmft scores remained relatively stable in the 3D-printed group throughout the study. Meanwhile, the conventional group showed a slight increase in caries incidence, possibly due to higher plaque retention around band margins. These findings support those of Zhu J,[21] who noted that although 3D-printed appliances offer enhanced customization and comfort, their direct impact on preventing dental caries is minimal when oral hygiene practices and diet are not adequately managed.

Plaque accumulation is a strong predictor of caries development and gingival deterioration. The study found that participants using 3D-printed maintainers had significantly lower plaque scores over the evaluation period compared to those with conventional appliances. This can again be attributed to the smoother surface texture and better design precision inherent in the digital workflow. In contrast, the manual fabrication of conventional maintainers often results in irregularities that trap food and plaque. Interestingly, a gradual worsening of plaque scores was observed in both groups over time, reflecting the general difficulty of maintaining optimal oral hygiene among pediatric patients. However, the deterioration was more prominent in the conventional group. The findings are in contrast to the findings of Cengiz *et al.*[8] where the plaque scores of the patients with conventional band and loop space maintainers were statistically not different from the patients with 3D space maintainers at baseline and 6 months' time intervals, and there was improvement in the plaque scores during the follow-up time with the regular use of 3D-printed space maintainers.

Gingival health is another key marker for evaluating the biocompatibility and design efficiency of dental appliances. In this study, 3D-printed space maintainers consistently exhibited better gingival scores at all-time intervals. No participants in this group experienced severe gingival inflammation. In contrast, the conventional group showed a higher incidence of moderate and severe gingival scores. These findings corroborate those of Barve *et al.*,[22] who reported that conventional maintainers often promote plaque retention and mechanical irritation, leading to inflammation and potential gingival recession. Thakur *et al.*[19] also reported that a higher proportion of patients with moderate gingival inflammation were observed in the conventional space maintainer group compared to those with 3D-printed space maintainers. The superior performance of 3D-printed appliances in this aspect can be credited to smoother surfaces, more

accurate marginal adaptation, and reduced bulk, which facilitate easier oral hygiene maintenance and less tissue trauma.

Despite its strength, the study had certain limitations. Patient compliance and oral hygiene maintenance may have affected the outcomes, particularly with regard to plaque accumulation and gingival inflammation. Despite providing oral hygiene instructions, variations in patient adherence could have influenced the gingival and plaque index scores. In addition, the study did not conduct a cost-benefit analysis comparing the economic feasibility of 3D-printed versus conventional space maintainers. A larger sample size would provide more statistically robust conclusions and improve the generalizability of the results. Future studies with extended follow-up periods are required

The integration of digital technology in pediatric dentistry represents a pivotal shift toward more precise, personalized, and patient-friendly care. As 3D printing continues to evolve, it holds the potential to redefine conventional treatment protocols, not by replacing traditional methods, but by complementing them where appropriate and feasible.

Clinical Significance of the Study

This study provides valuable clinical insights into the comparative effectiveness of 3D-printed versus conventional band and loop space maintainers in pediatric dentistry. The findings demonstrate that 3D-printed space maintainers offer notable advantages in terms of improved gingival health, reduced plaque accumulation, and better overall oral hygiene maintenance over a 12-month follow-up period. Their precise fit and smooth surface reduce areas prone to biofilm retention and soft-tissue irritation, which are common drawbacks associated with conventionally fabricated devices.

From a clinical perspective, the higher survival rate of 3D-printed appliances with fewer mechanical failures, such as band breakage or solder failure, suggests enhanced durability and reduced need for emergency repairs or replacements. In addition, the digital workflow used in fabricating these appliances potentially minimizes chairside adjustment time.

Thus, incorporating 3D printing technology in the fabrication of space maintainers represents a meaningful advancement in pediatric dental care, offering improved clinical outcomes, and enhanced treatment efficiency.

CONCLUSION

The result of the study indicates that 3D-printed band and loop space maintainers demonstrate superior clinical effectiveness compared to conventional ones, with better gingival health, reduced plaque accumulation, and higher appliance survival rates. These findings support the adoption of 3D printing technology in pediatric space maintenance, highlighting its potential to improve treatment efficiency and long-term success in clinical practice. Integrating 3D printing into routine practice can enhance treatment outcomes and streamline appliance fabrication in space management.

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