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EFFECTIVENESS OF COMBINED DESIGN NANCE/TRANSPALATAL ARCH APPLIANCE IN MAINTAINING ARCH DIMENSIONS AFTER PREMATURE EXTRACTION OF PRIMARY MOLARS (A RANDOMIZED CONTROLLED CLINICAL TRIAL)

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ABSTRACT

INTRODUCTION: A combination of Nance and transpalatal arch space maintainers has previously been studied in treatment of Angle's class II cases. However, this appliance hasn't been the subject of any trials as a space maintainer.

AIM: To evaluate the effectiveness of the combined Nance/transpalatal arch (N-TPA) appliance compared to Nance space maintainer in maintaining arch dimensions after bilateral premature loss of maxillary primary molars.

MATERIAL AND METHODS: Thirty children with bilateral premature loss of maxillary primary molars were randomly allocated into two groups (n=15). The test group received the N-TPA appliance, and the control group received the Nance appliance. Baseline measurements including arch circumference, intermolar width and arch depth were recorded. Participants were followed up to 9 months for re-evaluation.

RESULTS: No statistical significance was found when comparing arch circumference, intermolar width and arch depth. Intra-group comparison of arch depth in the N-TPA group showed a statistical significance at 9 months. Comparison of difference in arch depth measurements from baseline to follow-up time points showed a statistical significance at 6 and 9 months.

CONCLUSION: Both appliances provided acceptable space maintenance regarding arch circumference and arch width. Statistical significance was found when comparing arch depth measurements, however, further research is necessary to confirm clinical significance.

KEYWORDS: Nance space maintainer, Nance/transpalatal arch, space maintainers, space maintenance.

LIST OF ABBREVIATIONS: SM: space maintainer; FPM: first permanent molar; TPA: transpalatal arch; N: Nance; N-TPA: combined Nance/transpalatal arch

RUNNING TITTLE: Nance/Transpalatal arch appliance for maintaining arch dimensions

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INTRODUCTION

Primary teeth contribute to a significant role in the growth, development, and speech of a child. Moreover, one of their main functions is to maintain the space for permanent teeth until their eruption, resulting in the development of normal occlusion.(1)

Exfoliation of primary teeth is a normal physiologic process that guides the eruption of underlying permanent teeth. However, their premature extraction, can disrupt the stability of the dental arch due to the tendency of the first permanent molars (FPMs) to drift mesially.(2,3)

A space maintainer (SM) is used to maintain the space created by the lost primary tooth/teeth until the eruption of their successors. Depending on the number of teeth missing, the jaw involved, dental age, and the child's compliance, many types of appliances can be utilized to maintain space.(4) The most commonly used SMs in the maxillary arch are the Nance and transpalatal arch or bar (TPA) appliances.(5-7)

Nance SM is indicated for both unilateral and bilateral loss of maxillary primary molars. The appliance maintains space by receiving anchorage from the palatal vault, which resists mesial

movement of the banded FPMs, and hence is better suited for patients with a deeper palatal vault.(7,8)
However, a limitation of the Nance appliance is that in order to perform its function correctly, it must be constructed so that it touches the palatal mucosa. Additionally, excessive anchoring stresses on the appliance may cause it to become embedded in the palatal mucosa, making it unsanitary and difficult to remove. This makes it mandatory to maintain regular follow-ups every 6 months for removal, cleaning, and re-cementation. (7,9,10) To avoid this drawback, the acrylic button could be constructed with a minimal space from the palatal mucosa. As a result, no matter how small the gap is, it can allow for some space loss to occur. Furthermore, despite its ability to resist mesial movement of the banded molars, the Nance appliance lacks a design element that prevents the FPM from rotating around their palatal roots. (3,8)
The TPA resists mesial migration of maxillary FPMs only in cases of unilateral premature loss of primary molars. By bringing the FPMs' roots into contact with cortical bone, the TPA mainly prevents them from rotating around the palatal root. However, when the appliance is used in cases with bilateral premature extraction, mesial migration and rotation of the FPMs could occur.(5,6,8)

Both the Nance and the TPA appliances have therefore some limitations in their design. To overcome these limitations and to benefit from both their advantages, the combined Nance/Transpalatal arch (N-TPA) appliance has previously been introduced as an anchorage device by orthodontists during orthodontic treatment of Class II malocclusion patients. They concluded that this combined design was an effective method of anchorage during distalization of the anterior segment.(11-12) Nevertheless, this appliance has not been previously tested as a SM in the mixed dentition of pediatric patients. Therefore, this study is the first to address the use of N-TPA appliance as a SM in children with mixed dentition, and to evaluate its effectiveness compared to the conventional Nance SM in maintaining the arch dimensions after bilateral premature extraction of primary molars.

The null hypothesis of the study is that there is no difference in maintaining the arch dimensions between the Nance and combined Nance/transpalatal arch appliances.

MATERIAL AND METHODS

Ethical approval

The ethical approval for this research protocol was obtained from the Research Ethics Committee at the Faculty of Dentistry, Alexandria University, Alexandria, Egypt. The study protocol was approved on 30/11/2020 by the Institutional Review Boards (IRB) of Research Ethics Committee, Faculty of Dentistry, Alexandria University, Egypt (IRB NO 00010556-IORG 0008839) with the identifier: 0110-11/2020 and was registered retrospectively in ClinicalTrials.gov with the identifier: NCT05514145. Following explanation of the risks and benefits of the study, the parents were asked to sign a consent approval that they were aware of the nature of the study and willing to let their children join any of the two studied groups. Parents were also assured about data confidentiality and their right to withdraw at any time (Helsinki declaration guidelines).(13)

Sample size calculation

The minimal sample size was calculated based on a previous study aimed to investigate dental-arch space problems arising as a result of premature loss of primary maxillary first molar.(14) Based on their results, adopting a power of 80% to detect a standardized effect size in the arch circumference (d=1.087) (large-sized standardized effect size), and level of significance 5% (α=0.05), the minimum required sample size was found to be 15 patients per group (number of groups=2) (Total sample size=30 patients)(15) and is the minimum required sample size. The sample size was calculated using GPower version 3.1.9.2.(15,16)

Study Design

This study is a randomized, parallel, controlled clinical trial, with a 1:1 allocation ratio, setup and reported according to the CONSORT guidelines.(17)

The PICOT question was: Do children aged 8-9 years with bilateral prematurely extracted maxillary primary molars (P; Patient) receiving a combined Nance/TPA appliance (I; Intervention) in comparison to those receiving a Nance space maintainer (C; Comparison) show any difference in arch dimensions' changes (O; Outcome) at 9 months follow-up (T; Time)?

Sample selection

Screening visit:

One experienced pediatric dentist recruited the sample of this study by examining children attending the outpatient clinic Pediatric Dental Department at Faculty of Dentistry, Alexandria University, Egypt. Generally healthy children (ASA 1)(18), aged 8-9 years with bilateral prematurely extracted maxillary primary molars within a period not more than one month were selected. The patients were familiarized with the clinic, and all the procedures were explained to them using the tell-show-do method.(19) A panoramic x-ray was taken and alginate (Cavex CA37; Cavex Holland BV, Haarlem, Netherlands) primary impressions for both arches were made for each patient. Diagnostic casts were immediately poured with type IV dental stone and were used for arch length analysis. Patients who met the inclusion criteria were then included in the study.

Inclusion criteria:

Fully erupted maxillary permanent first molars.
Angle's class I occlusion.

Adequate space for premolar eruption according to Moyer's arch length analysis.(20)
Fair to good oral hygiene according to Silness and Loe plaque index.(21)
No history of allergy to polymethyl methacrylate.
Exclusion criteria:
Children with congenitally absent permanent successors.
Children with successors not covered by bone.
Children with successors with two-thirds or more of their roots formed.(22)
All parents of the children included in this study signed a consent form.
Baseline measurements:
On the study casts the baseline measurements were taken using a brass wire and digital caliper with 0.02 mm accuracy as follows:
Primary outcome
Arch circumference measurement: the arch was measured from the mesial midpoint of the permanent first molar on one side through the cusp tip of the canine and the incisal edges of the incisors to the mesial midpoint of the permanent first molar on the other side.(14)

Intermolar width measurement: the distance between the central fossa on the occlusal surface of bilateral first permanent molars.(23)

Arch depth measurement: the perpendicular distance from the contact point of the central incisors to the intermolar width line.(14)

Intra examiner reliability

Intra examiner reliability for the main researcher was assured regarding measurement of arch circumference, intermolar width and arch depth. This was done by the researcher examining 10 cases of each group on a minimum of two successive examination settings. Statistical measurements were done using Intraclass correlation (ICC).(24) The Intraclass Correlation coefficient yielded a score of 0.996 for arch circumference, 0.983 for arch width and 0.993 for arch depth which ensured excellent agreement.

Randomization and blinding

A permuted block randomization technique was used by the main researcher to create the allocation sequence with a changeable block size.(25) Using sealed, opaque envelopes, the allocation sequence and code were hidden from the person assigning participants to the intervention arms and the investigators.(26) Children complying with the inclusion criteria were randomly and equally (1:1) assigned into two groups according to the SM used:
Test group - Group N-TPA (n=15): received combined Nance/transpalatal arch appliance.
Control group - Group N- (n=15) received Nance appliance.
Blinding was employed throughout the statistical analysis so that the statistician was unaware of which group the data belonged to. Participants were also blinded and were not told which space maintainer design they would receive.

First Intervention visit

The same pediatric dentist who recruited the participants performed all the clinical procedures. Within 2-3 days of the screening visit, participants returned for the intervention visit. Bands for the maxillary FPMs were selected using Ormco™ standard high-retention first molar band kit (Ormco™; California, USA). The selected bands were the smallest tight-fitting bands with the occlusal end just below the proximal ridges and the gingival end 1mm below the gingival margin. For the manufacturing of the appliances, a secondary alginate (Cavex CA37; Cavex Holland BV, Haarlem, Netherlands) impression was made and the selected bands were secured in the impression using stapler pins then immediately poured using dental stone type IV.(27)

Space maintainers fabrication

Group N-TPA (Test group)
Combined Nance/transpalatal arch appliance was designed using 0.9 mm wire. In the design the wire was welded palatally to the posterior molar band and extends anteriorly to the acrylic button resting on the rugae area. Another wire was then welded to the posterior molar bands and extends horizontally across the palate between them with an omega loop midway across its length. The omega loop faced mesially. (Figure 1)
Group N (Control group)
Nance SM was designed using 0.9 mm wire. In the design the wire is welded palatally to the posterior molar bands and extends anteriorly to the acrylic button resting on the rugae area. (Figure 2)

The same technician fabricated all appliances for the participants.

Second Intervention visit: Appliance insertion

Participants returned for appliance insertion within 2-3 days from the intervention visit. Tell-Show-Do was used to introduce the appliance to the child.(19) The appliances were first tried on to ensure proper fit. As previously stated, the bands must be correctly seated in position, the wire should not irritate the palatal mucosa, and there should be no blanching around the acrylic button. If blanching was noticed, the wire was modified so that the button was passively resting on the rugae.
The appliances were then cemented in place using glass ionomer cement (Medicem, Promedica Dental Material GmbH, Neumuenster, Germany), and oral hygiene instructions for the appliances were given to the participants.

Follow-up visits:

All participants were followed up after 3, 6 and 9 months. The appliances were removed using a band remover (Leone S.p.A; Florence, Italy) and an alginate (Cavex CA37; Cavex Holland BV, Haarlem, Netherlands) impressions of the upper

arches were made and immediately poured using dental stone type IV.

The banded molars were examined for any signs of decay at each follow-up and, if necessary, treated. The rugae area was carefully examined for inflammation. If inflammation was observed, the device was removed, mouthwash was prescribed, and the appliance was re-cemented after 5 days.

Patient acceptance of the space-maintainers was measured using a "faces scale" modified from the Maunuksela et al(28) scale which represents satisfaction, indifference, or dissatisfaction. The patient's response was then noted in the patient's sheet. (Figure 3)

Fluoride varnish (Fluorodose® varnish, Safco Dental Supply LLC, Chicago, IL, USA) was applied to all teeth and given 2 minutes to dry. Finally, using glass ionomer cement (Medicem, Promedica Dental Material GmbH, Neumuenster, Germany), the appliances were re-cemented in place, and patients were given oral hygiene instructions.

All measurements were then repeated on the dental casts after each follow-up visit.

Outcome assessment

Objectively changes in arch dimensions after insertion of either Nance or Nance/transpalatal arch (N-TPA) appliances were measured on study casts using a brass wire and digital caliper with 0.02 mm accuracy after 3- , 6- and 9-months follow-up.

Primary outcome

Changes in arch circumference after 9-months follow-up.

Secondary outcome

Changes in arch circumference after 3- and 6-months follow-up.

Changes in arch width after 3-, 6- and 9-months follow-up.

Changes in arch depth after 3, 6- and 9-months follow-up.

Subjectively patient acceptance of either Nance or Nance/transpalatal arch (N-TPA) appliances was measured at the 3, 6- and 9-months follow-up using a "faces scale" modified from the Maunuksela et al(28) scale which represents satisfaction, indifference, or dissatisfaction.

Statistical analysis

Normality was checked using the Shapiro Wilk test, box plots, and descriptive statistics. Arch circumference, width, and depth were normally distributed and presented using Mean and Standard deviation while Median, Inter Quartile Range (IQR) were used for differences in all parameters from baseline. Comparisons between the groups were done using the independent t-test and repeated measures ANOVA was applied for within-group comparison followed by a post hoc test with Bonferroni correction when results are significant. Differences in all parameters were compared using the Mann-Whitney U test. Pearson Chi-Square was applied to assess differences in patient satisfaction and complications between groups. The significance level was set at a P value of 0.05. All tests were two-tailed. Data were analyzed using SPSS for windows version 23.

Figure (1): A case from group N-TPA showing the appliance immediately after insertion and after 9 months follow-up. (a) N-TPA appliance intra-oral immediately after insertion (b) N-TPA appliance intra-oral after 9 months follow-up.

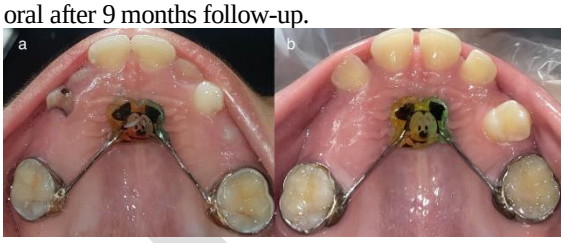

Figure (2): A case from group N showing the appliance immediately after insertion and after 9 months follow-up. (a) Nance appliance intra-oral immediately after insertion (b) Nance appliance intra-oral after 9 months follow-up.

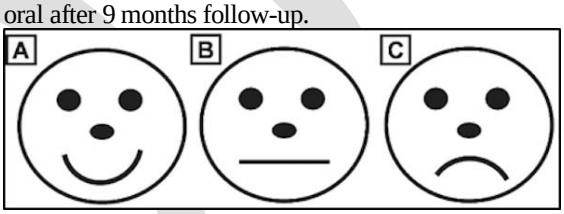

Figure (3): Faces scale modified from the Maunuksela et al(28) scale showing the 3 schematic faces representing: (A) satisfaction; (B) indifference; and (C) dissatisfaction, respectively.

RESULTS

A CONSORT diagram showing the study protocol up to the 9–months follow–up is presented in (Figure 4). Participants were recruited at the outpatient clinic of the Pediatric Dental Department at Alexandria University in Egypt starting January 2021 and was completed in May 2021. Two participants declined to participate, and three participants did not meet the inclusion criteria. Thirty participants (15 boys (50%) and 15 girls (50%) with a mean age of 8.4 ± 0.51 years participated in this study. Participants were then followed up for a period of 9 months until June 2022. Each child had received either Nance (n=15) or N-TPA SM (n=15). No significant differences were found between the test group (group N-TPA) and control group (group N) regarding both age (p=1.00), and gender (p=0.715) (Table 1).

Arch circumference

No statistical significance was found in the mean arch circumference measurements at baseline (p=0.821), 3-months (p=0.957), 6-months (p=0.701) and 9-months follow-up (p=0.534) between both groups.(Table 2)

Intra-group comparison using repeated measures One-way analysis of variance (ANOVA)

showed no statistical significance in either group during the 9 months follow-up period: group N (p=0.712) and group N-TPA (p=0.057)

Inter-molar width measurements

No statistical significance was found when both groups were compared at baseline (p=0.152), 3-months (p=0.115), 6-months (p=0.065) and 9-months (0.053). (Table 3)

Intra-group comparison using One-way analysis of variance in both groups showed no statistical significance in either group during the 9 months follow-up period: group N (p=0.343) and group N-TPA (p=0.051).

Arch depth

There was no statistically significant difference between the two groups at baseline (p=0.975), 3-months (p=0.827), 6-months (p=0.294) and 9-months (p=0.184) follow-up. (Table 4)

The intra-group comparison using repeated measures One-way analysis of variance (ANOVA) in group N showed no statistical significance (p=0.513, Baseline =30.0 mm ±2.4and 9 months = 29.9 mm ± 2.7).

The intra-group comparison using repeated measures One-way analysis of variance (ANOVA) in group N-TPA showed a statistically significant difference over the 9 months follow-up period (p<0.0001, Baseline =30.0 mm ± 1.6 and 9 months = 31.0 mm ± 1.7).

Intra-group analysis using post-hoc test in the group N-TPA showed a statistically significant difference when comparing the baseline with 6- and 9-months follow-ups and when comparing the 3- and 9-months follow-ups (p ≤0.05). No statistically significant difference was found when comparing baseline and 3-months follow-up, 3- and 6-months follow-up and 6- and 9-months follow-up (p > 0.05).

Comparison of difference in arch depth between the group N and the group N-TPA from baseline to follow-up time points showed no statistically significant difference at 3-months (p=0.297) but was statistically significant at both 6- and 9- months follow-ups (p ≤0.05) (Table 5).

Appliance acceptance

Both appliances during the 3, 6-, and 9 months follow-up had an overall acceptance of 93.3% (Figure 5). There was no significant difference between both groups (p ≥0.05).

Complications

During the 9-month follow-up period some complications were noted including inflammation related to the acrylic button and fracture of the appliances. Comparison of complications among the study groups showed no statistically significant difference (P=3.467). Group N resulted in 26.7 % of participants with soft tissue inflammation related to the acrylic button while in group N-TPA 6.7% of the participants were affected. Only one participant in group N experienced a space maintainer fracture that required repair. No fractures of the space maintainer were encountered in group N-TPA. (Figure 6)

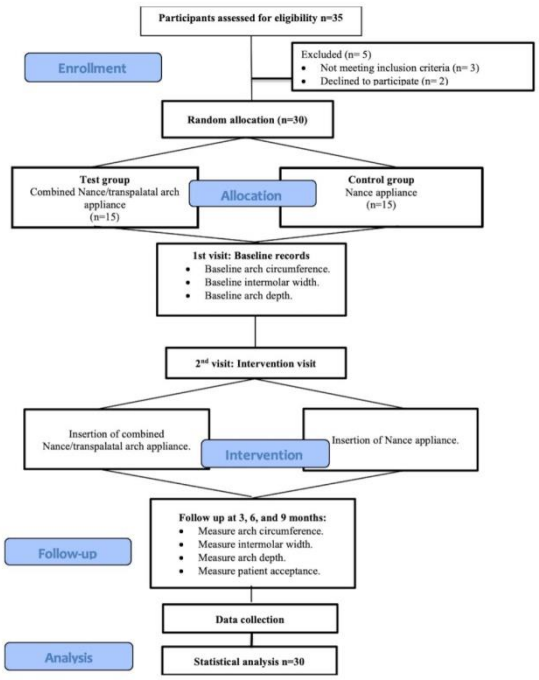

Figure (4): Comparison of patient satisfaction between the Nance appliance and Nance/transpalatal arch appliance.

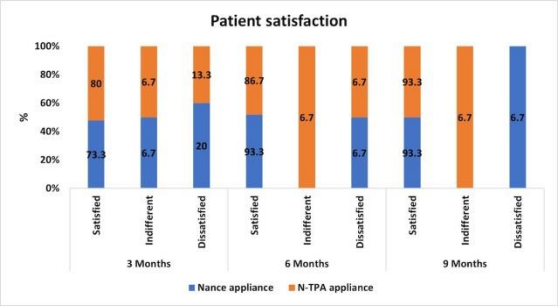

Figure (5): Complications among the study groups.

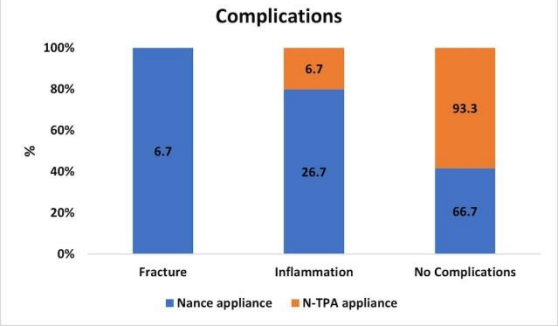

Figure (6): Complications among the study groups.

Table 1: Comparison of demographic variables between the Nance appliance and Nance/transpalatal arch appliance.

	Nance appliance Control group (n=15)	**N-TPA appliance Test group (n=15)**

Age in years: Mean ±SD		8.4 ± 0.5	8.4 ± 0.5
Gender: n (%)	Males	8 (53.3%)	7 (46.7%)
	Females	7 (46.7%)	8 (53.3%)

Table 2: Comparison of arch circumference between the Nance appliance and Nance/transpalatal arch appliance.

	Nance appliance Control group (n=15)	**N-TPA appliance Test group (n=15)**	**Test (p value)**
	Mean ±SD		
Baseline	81.9 ± 5.6	82.3 ± 4.8	0.229 (0.821)
3 months	82.1 ± 5.5	82.2 ± 4.8	0.054 (0.957)
6 months	82.1 ± 4.9	82.7 ± 4.3	0.388 (0.701)
9 months	82.1 ± 4.7	83.0 ± 4.1	0.630 (0.534)
Test§ (p value)	0.194 (0.712)	4.094 (0.057)	

T tests were used to compare means; SD: standard deviation.
§ Repeated measure ANOVA was used for within-group comparison.

Table 3: Comparison of intermolar width between the Nance appliance and Nance/transpalatal arch appliance**.**

	Nance appliance Control group (n=15)	**N-TPA appliance Test group (n=15)**	**Test (P value)**
	Mean ±SD		
Baseline	43.6 ±1.4	44.8 ± 2.8	1.473 (0.152)
3 months	43.6 ± 1.4	44.9 ± 2.8	1.627 (0.115)
6 months	43.8 ± 1.3	45.3 ± 2.7	1.923 (0.065)
9 months	43.7 ± 1.3	45.3 ± 2.6	2.023 (0.053)
Test§ (Pvalue)	1.055 (0.343)	4.090 (0.051)	

T tests were used to compare means; SD: standard deviation.
§ Repeated measure ANOVA was used for within-group comparison**.**

Table 4: Comparison of arch depth between the Nance appliance and Nance/transpalatal arch appliance.

	Nance appliance Control group (n=15)	**N-TPA appliance Test group (n=15)**	**Test (P value)**
	Mean ±SD		
Baseline	30.0 ±2.4	30.0 ± 1.6	0.031 (0.975)
3 months	30.0 ± 2.4	30.2 ± 1.7	0.221 (0.827)
6 months	29.9 ± 2.6	30.7 ± 1.6	1.069 (0.294)
9 months	29.9 ± 2.7	31.0 ± 1.7	1.363 (0.184)
Test§ (P value)	0.778 (0.513)	**8.812 (<0.0001*)**	
Post hoc test	-	P1=0.744 **P2=0.049*** **P3=0.049*** P4=0.071 **P5=0.050*** P6=0.230	

T tests were used to compare means; SD: standard deviation.
§ Repeated measure ANOVA was used with Bonferroni post hoc corrections for pairwise comparisons.
*Statistically significant at p value ≤ 0.05.
P1: comparison between baseline and 3 months, P2: comparison between baseline and 6 months, P3: comparison between baseline and 9 months, P4: comparison between 3 months and 6 months, P5: comparison between 3 months and 9 months, P6: comparison between 6 months and 9 months.

Table 5: Comparison of difference in arch depth from baseline to follow-up time points.

Follow-up time (Mean ± SD) (Median (IQR)	**Nance appliance Control group (n=15)**	**N-TPA appliance Test group (n=15)**	**MWU test (P value)**
3 months	0.01 ± 0.16	0.20 ± 0.47	1.042 (0.297)
	0.00 (0.03)	0.12 (0.31)	
6 months	-0.12 ± 0.40	0.74 ± 0.93	**3.321 (<0.0001*)**
	0.02 (0.45)	0.61 (0.88)	
9 months	-0.16 ± 0.81	0.98 ± 1.23	**2.904 (0.004*)**
	0.02 (0.83)	0.92 (1.08)	

MWU, Mann–Whitney U test; IQR, inter quartile range.
*Statistically significant at p value ≤ 0.05.

DISCUSSION

This study aimed to evaluate the effectiveness of N-tpa appliance compared to the conventional Nance SM in maintaining the arch dimensions after bilateral premature extraction of primary molars. Thirty children were randomly allocated into two groups (n=15). The test group received the N-TPA appliance, and the control group received the Nance appliance. Baseline measurements including arch circumference, intermolar width and arch depth were recorded. Participants were followed up to 9 months for re-evaluation. Patient satisfaction was measured at each follow-up visit and any complications were recorded. Following statistical analysis, the null hypothesis was rejected for arch circumference and width but accepted for arch depth. A statistically significant difference was found between both groups regarding arch depth measurement.

Space closure after premature loss of primary molars takes place within the first six months after extraction, hence, a SM is essential to maintain arch dimensions.(5) Gandhi et al (29) even reported that space loss has its greatest effects during the first 3 months following premature extraction of primary molars. Bhujel et al(30) concluded that the need for orthodontic treatment following premature extraction of primary molars increases with the number of molars extracted. Space loss in the maxillary arch occurs due to both mesial drift and mesio-palatal rotation of FPMs. It is therefore necessary to insert a SM in the maxillary arch capable of preventing both mesial drift and mesio-palatal rotation of FPMs as soon as possible following the premature loss of maxillary primary molars.(31,32)

The combination of both Nance and TPA appliances has been studied by orthodontists for anchorage during the distalization of the anterior section in class II cases.(11-12) However, this appliance hasn't been the subject of any trials as a SM in the mixed dentition. This led to the belief that this design could be useful in pediatric patients as a SM for bilateral premature primary molar loss aiming to prevent both rotation and mesial migration of the FPMs.

The study sample included participants with an age range of 8-9 years to ensure the complete eruption of the FPMs and allow for correct band placement and proper retention of the appliances. To avoid cases with accelerated eruption of the premolars, a panoramic x-ray confirmed that less than two-thirds of the roots were completed, and the successors were covered by bone. (22) Furthermore, according to Cieślińska K et al(33), during the intraosseous stage, the tooth moves at a rate of 1–10 μm per day which approximately will take 1 mm of bone to resorb in 4 to 5 months. Hence, bone covering over the crown of unerupted successors together with the determined stage of root development indicated the need for a space maintainer.

The three parameters arch circumference, arch depth and intermolar width were used to measure changes in the position of the FPM. The findings showed a slight increase in the arch circumference and intermolar width in both groups over the 9 months follow-up period. Although the results when compared were not statistically significant, this increase can be contributed to the normal growth of the arches that takes place in this period of “growth spurt”.(34,35) These findings were in agreement with the findings of Rajbhoj et al(35)and Bishara SE et al (35) who both observed a significant increase in intermolar width and arch circumference during normal occlusal development at the age of eight. However, the results may not have been clinically significant due to the shorter follow-up time and smaller sample size.

A statistically significant increase of 1 mm in arch depth was found within the N-TPA group. This was consistent with the results found by Ross-Powell RE and Harris EF (36) who found a substantial increase in arch depth (an increase of approximately 3 mm) as the permanent incisors emerged. In another study by Thilander B(37) an increase was observed up to 13 years of age in both jaws, mainly between 7 and 13 years (maxilla: 5 mm, mandible: 3 mm), due to eruption of the permanent incisors in a proclined position. In the present study the same was not true for control group N where the arch depth decreased over the 9 months follow-up period. This decrease could indicate mesial movement or rotation of the FPM.

The difference in arch depth measurements between the two groups can be justified by the different actions of the two appliances. The increase in the arch depth in the N-TPA group showed that it allowed normal developmental changes to occur without compromising the arch depth by preventing both the mesial drift and rotation of the FPM while maintaining arch dimensions. On the contrary, the decrease in arch depth measurements in control group N indicates that some space loss had occurred during the follow-up time.This loss of space could be attributed to the rotation of the FPM around the palatal roots which was obvious clinically in the follow-up visits. Thus, the Nance appliance prevented the mesial drift without preventing the rotation of the FPM around the palatal root and accordingly led to some loss in arch dimensions.

Comparison of the difference in arch depth between both groups from baseline to follow-up time points were found to be statistically significant at the 6 months and 9 months’ follow-up times. This finding was in agreement with other studies

stating that space closure takes place within the first six months after premature primary molar extraction.(29) The statistical significance found between both groups regarding arch depth could be explained by a space loss occurring in the Nance group during the first 6 months. This space loss occurring as early as 6 months post-extraction, however small, may indicate the need for a space maintainer as soon as premature extraction of primary molars has occurred.(38)

Children's satisfaction with the appliances was assessed using the modified Maunuksela et al scale.(28) This faces scales has been considered the simplest tool to measure the degree of pain or discomfort in young children because it requires little attention, and gives them a range of expressions from smiling to crying to choose from.(39) There was no difference in child satisfaction in both groups and the overall acceptance of both appliances was 93.3%, thus adding the TPA to the Nance design did not affect the appliance acceptance.

Upon observation during the follow-up time, a higher percentage of patients were found with soft tissue lesions related to the acrylic button in control group N. Although comparison of complications among the study groups showed no statistically significant difference, group N showed a higher number of participants with soft tissue inflammation related to the acrylic button compared to the group N-TPA. A previous study by Stivaros N et al(40) with a larger sample size found results with a significant number of participants with soft tissue lesions related to the acrylic button in the Nance SM. However, in the present study a lower number in the group N-TPA could be attributed to less mesial forces transmitted from the FPMs to the soft tissue due to the presence of the transpalatal arch which may have provided a better anchorage of the FPMs.

Statistical analysis of the findings favors the N-TPA appliance over the Nance appliance. However, given the multitude of parameters implicated in determining the clinical significance of space loss, comprehensive assessment of the various characteristics of each patient including number and type of teeth extracted should characterize management decisions in individual cases. For example, cases in which maintaining all space in the maxilla is necessary could benefit from receiving an N-TPA appliance over a Nance appliance.

Limitations to this study include the small sample size (n=30) as well as the short follow-up time; however, due to the absence of literature on the design being effective as a space maintainer, care was taken not to increase the number of patients nor the follow-up time unless the design proved successful. Another limitation is the absence of an economic analysis comparing the difference in cost between both appliances in relation to their clinical efficiency.

Since a limited amount of research was found regarding the comparison of clinical efficiency of the two different space maintainer designs, the findings of this study could be useful as a pilot study for future research on this topic to allow for generalizability of the results and aid in clinical management of individual cases.

CONCLUSION

Both combined Nance/transpalatal arch and Nance appliances provided acceptable bilateral space maintenance regarding arch circumference and arch width.

Statistical significance was found when comparing arch depth measurements, however, further research is necessary to confirm clinical significance.

Both combined Nance/transpalatal arch and Nance appliances were equally acceptable designs for children.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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REFERENCES

1. Bijoor RR, Kohli K. Contemporary space maintenance for the pediatric patient. New York State Dental Journal. 2005;1:32-5.
2. Rönnerman A, Thilander B. A longitudinal study on the effect of unilateral extraction of primary molars. Scand J Dent Res. 1977;85:362-72.
3. Green J. Mind the gap: Overview of space maintaining appliances. Dental Nursing. 2015;11:24-7.
4. Qudeimat MA, Fayle SA. The longevity of space maintainers: a retrospective study. Pediatr Dent. 1998;20:267-72.
5. Terlaje RD, Donly KJ. Treatment planning for space maintenance in the primary and mixed dentition. ASDC J Dent Child 2001;68:109-14.
6. Singh PH, Naorem H, Devi TC, Debbarma N. Modern concepts of space maintainers and space regainers: a review article. Eur J Pharm Med Res. 2020;7:176.
7. Laing E, Ashley P, Naini FB, Gill DS. Space maintenance. Int J Paediatr Dent. 2009;19:155-62.
8. Kupietzky A, Tal E. The transpalatal arch: an alternative to the Nance appliance for space maintenance. Pediatr Dent. 2007;29:235-8.
9. Baroni C, Franchini A, Rimondini L. Survival of different types of space maintainers. Pediatr Dent. 1994;16:360-1.

10. Luca MM, Dinu Ș, Nikolajevic-Stoican N, Boia S, Boia ER, Dragoș B, Popa M. Space control in mixed dentition-space maintainers. Jurnalul Pediatrului. 2020;1:68.
11. Ubilla-Mazzini W, Moreira-Campuzano T, Mazzini-Torres F. Efficacy of Maximun Anchoring Using Transpalanance and Double ATP in Cases Requiring First Superior Premolar Extractions: A Comparative Analysis. Odovtos-Int J Dent Sc. 2019;21:119-26.
12. Ubilla-Mazzini W, Mazzini-Torres F, Moreira-Campuzano T. Orthodontic management of dentofacial discrepancies in skeletal Class II patients. Contemp Clin Dent. 2018;9:474-7.
13. General Assembly of the World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. J Am Dent Assoc. 2014;81:14-8.
14. Lin YT, Lin WH, Lin YT. Immediate and six-month space changes after premature loss of a primary maxillary first molar. J Am Dent Assoc. 2007;138:362-8.
15. Charan J, Biswas T. How to calculate sample size for different study designs in medical research? Indian J Psychol Med. 2013;35:121-6.
16. Faul F, Erdfelder E, Lang AG, Buchner A. G* Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behav Res Methods. 2007;39:175-91.
17. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ. 2010; 340:c869
18. Doyle DJ, Garmon EH. American Society of Anesthesiologists classification (ASA class). StatPearls Publishing LLC. 2019.
19. American Academy of Pediatric Dentistry. The Reference Manual of Pediatric Dentistry. 2020; 266-279.
20. Moyer RE. Handbook of orthodontics. 4th ed. Chicago: Year Book Medical Publishers; 1998;235-23.
21. Silness J, Loe H. Periodontal disease in pregnancy. II. Correlation between oral hygiene and periodontal condition. Acta Odontol Scand. 1964;22:121-35.
22. Grøn AM. Prediction of tooth emergence. J Dent Res. 1962;41:573-85.
23. Lux CJ, Conradt C, Burden D, Komposch G. Dental arch widths and mandibular-maxillary base widths in Class II malocclusions between early mixed and permanent dentitions. Angle Orthod. 2003;73:674-85.
24. Cicchetti DV. Guidelines, criteria, and rules of thumb for evaluating nor- med and standardized assessment instruments in psychology. Psychol Assess. 1994;6:284.
25. Schulz KF, Grimes DA. Allocation concealment in randomised trials: defending against deciphering. The Lancet. 2002;359:614-8.
26. Schulz KF, Grimes DA. Generation of allocation sequences in randomised trials: chance, not choice. The Lancet. 2002;359:515-9.
27. Prabhawati PI, Sangeetha P. Clinical Aid in Pediatric Dentistry: Techniques of Band Stabilisation in Impression.2016;3:7-11.
28. Maunuksela EL, Olkkola KT, Korpela R. Measurement of pain in children with self-reporting and behavioral assessment. Clin Pharmacol Ther. 1987;42:137–41.
29. Gandhi JM, Gurunathan D. Short-and long-term dental arch spatial changes following premature loss of primary molars: A systematic review. J Indian Soc Pedod Prev Dent. 2022;40:239-45.
30. Bhujel, N., Duggal, M.S., Saini, P. et al. The effect of premature extraction of primary teeth on the subsequent need for orthodontic treatment. Eur Arch Paediatr Dent. 2016;17, 423-34.
31. Chauhan SP, Sharma DS, Jain ML. Initial stresses induced in permanent maxillary first molar in mixed dentition under normal masticatory forces: A finite element study. JOCPD. 2016;40:334-40.
32. Gibas-Stanek M, Loster BW. The effect of premature extraction of primary molars on spatial conditions and formation of malocclusion–a systematic review. Journal of Stomatology. 2018;71:420-31.
33. Cieślińska K, Zaborowicz K, Buchwald Z, Biedziak B. Eruption pattern of permanent canines and premolars in Polish children. IJERPH. 2022;19:8464.
34. Rajbhoj AA, Parchake P, Begnoni G, Willems G, de Llano-Pérula MC. Dental changes in humans with untreated normal occlusion throughout lifetime: A systematic scoping review. Am J Orthod Dentofac Orthop. 2021;160:340-62.
35. Bishara SE, Jakobsen JR, Treder J, Nowak A. Arch length changes from 6 weeks to 45 years. The Angle Orthodontist. 1998;68:69-74.
36. Ross-Powell RE, Harris EF. Growth of the anterior dental arch in black American children: a longitudinal study from 3 to 18 years of age. Am J Orthod Dentofac Orthop. 2000;118:649-57.
37. Thilander B. Dentoalveolar development in subjects with normal occlusion. A longitudinal study between the ages of 5 and 31 years. Eur J Orthod. 2009;31:109-20.
38. Alnahwi HH, Donly KJ, Contreras CI. Space loss following premature loss of primary second molars. General Dentistry. 2015;63:e1-4.
39. Hain RD. Pain scales in children: a review. Palliative Medicine. 1997;11:341-50.

40. Stivaros N, Lowe C, Dandy N, Doherty B, Mandall NA. A randomized clinical trial to compare the Goshgarian and Nance palatal arch. Eur J Orthod. 2010;32:171-6.