CHILDREN'S SATISFACTION WITH TWO TYPES OF SPACE MAINTAINERS USED IN MAXILLARY ARCH: A RANDOMIZED CLINICAL TRIAL

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Abstract

Objectives: The current study aimed to evaluate children's satisfaction with Transpalatal arch and Nance holding arch space maintainers. **Subjects and methods:** A sample of 20 children with missed upper second primary molars aged between 6 and 9 years from both genders were allocated and randomly divided into two groups (n = 10). Group I included children treated with a Transpalatal arch space maintainer, while group II included children treated with a Nance holding arch space maintainer. A questionnaire was done after 6 months from the beginning of treatment to assess the children's satisfaction. **Results:** No significant difference was found regarding the children's satisfaction between the Transpalatal arch and the Nance space maintainer. **Conclusion:** The level of patient satisfaction for the two types of space maintainers is good with no significant difference between both of them.

Keywords: Children satisfaction, Transpalatal arch, Nance holding arch, Space maintainer.

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INTRODUCTION

The primary dentition is crucial and very important during childhood's growth period as it guides the eruption of permanent teeth and is also important for speaking, chewing, appearance, and the prevention of bad oral habits (1).

Early loss of primary molars is mostly caused by tooth decay, dental trauma, periodontal affection, and early root resorption, and it can deteriorate and affect pronunciation and chewing functions (2).

The early loss of primary molars and especially the primary second molars has a great effect on the dental arch, and this is considered one of the most complicated problems regarding space problems during the primary dentition stage. (3)

Early loss of primary molars requires immediate intervention using space maintainers to preserve the dental arch's integrity and to maintain normal occlusion. However, most space loss and changes were reported within the first three weeks after tooth loss (4).

A lot of space maintainer's types are available, and they differ according to many factors, such as the site and amount of space loss (5). However, the most common types used in the maxillary arch are bands and loops, crowns and loops, Nance appliances, and Transpalatal arches (TPA).

Treatment planning might be affected according to the children's satisfaction with the dental treatment (6). Moreover, patient satisfaction is very important tool which is usually used as an indicator for measuring the quality of health care, as the best possible health care can be measured by assessing the satisfaction of patients (7).

As the patient is considered the primary source of data recording, it's important to assess the patient's opinions regarding the treatment, which is also very important for patient cooperation (8, 9). So patient cooperation, which has a great effect on patient satisfaction, and because clinical outcomes are dependent on patient cooperation, it can be said that, without satisfied patients, health care may not be effective (10).

From the previous point, we can consider that patient satisfaction is considered one of the most important factors in assessing the quality of treatment. In this regard, this study is directed at assessing the children's satisfaction with the Transpalatal arch and Nance space maintainers.

SUBJECTS AND METHODS

Study Design:

Randomized clinical trial.

Randomization: randomization was done through a computerized simple online generated randomization plan using online software found at the website: http://www.graphpad.com/quickcalcs/randomize2/.

Study Setting and Population:

Twenty children with missed upper primary second molars were selected from patients attending the Outpatient Clinic in the Department of Pedodontics and Oral Health, Faculty of Dental Medicine (Boys), Al-Azhar University, Cairo, Egypt.

Sample Size:

From a previous study (11) the expected difference in intermolar width between the studied groups was 3±2.28mm. Using power of 80% and a 5% significance level,

we will need to study 10 in each group. Sample size calculation was achieved using PS: Power and Sample Size Calculation software Version 3.1.2 (Vanderbilt University, Nashville, Tennessee, USA). The study will be carried out on 20 children; ten for each group.

Grouping:

After subject selection and obtaining signed informed consent, the involved children were randomly divided into two groups (n = 10). Group I was the TPA group, which received the Transpalatal arch space maintainer, and Group II was the Nance group, which received the Nance holding arch space maintainer.

Eligibility criteria: (12, 13)

Inclusion criteria:

1. Age: 6-9 years old.
2. Mixed dentition.
3. Unilateral premature loss of maxillary second deciduous molar.

Exclusion Criteria:

1. Patient with any craniofacial anomalies.
2. Previous use of any space maintainer.

Patient and parent Consent:

All the enrolled children, accompanied by their parents, were informed in detail about the procedure used in this study. Then, each parent was asked to sign an informed consent, including details of the treatment and the procedures.

Interventions

After clinical examination of the patients, stainless steel bands were selected to be placed on the maxillary first permanent molar using a band seater (5). Alginate impression material was used for taking the impression. Then the bands were removed from the patient's mouth, washed, disinfected, dried and transferred to the correct position inside the impression. The impression was sent to the dental lab for pouring, making study models and fabrication of the space maintainer.

Appliance design:

1.Transpalatal arch:

A stainless steel wire (0.9 mm) was used to construct the arch, which crosses the palate to solder with the molar bands on both sides. (14)

2.Nance holding arch appliance:

The same was done for the Nance appliance, except that the palatal wire was connected anteriorly to an acrylic portion positioned in the highest part of the palate, resting on the mucosa. (14)

The space maintainers were tried inside the mouth to ensure fitting as it was on the cast before cementation with glass ionomer cement (5). The excess cement was removed from the occlusal and cervical margins of the band with a sharp probe after setting of the cement.

After a 6-month follow-up period (15), the children were asked with their parents to complete the printed questionnaire about patient satisfaction with the space maintainer they had used. The questionnaire was initially prepared in English, then translated to Arabic, and then translated again to English to ensure its accuracy (11).

The questionnaire consisted of two sections. The first was designed to record demographic data, while the second section was to evaluate the children's satisfaction, and it consisted of four questions (11). Fig (1)

The clarity, relevance, comprehensiveness, and applicability of the questionnaire were evaluated by five staff experts from the Department of Pedodontics and Oral Health, Faculty of Dental Medicine, Al Azhar University, and according to their comments, some modifications were made as follows:

A content validity index (CVI) was calculated for each question, denoted as ne

/N (ne - representing the number of members who marked the question as relevant/very relevant, N – representing the total number of committee members).

Questions that scored CVI ≤0.6 were excluded from the questionnaire (n = 5).

Content Validity Index (ACVI) was calculated for the entire questionnaire as sum CVI/n (sum CVI - representing the sum of all CVI indexes for all questions included in the questionnaire, and n - representing the number of questions included in the questionnaire), to ensure that ACVI = 0.8 after final inclusion of questions.

Questionnaire

Name: .....

Gender: .....

Age: .....

Type of space maintainer: .....

Address: .....

Mobile: .....

	Question	Yes	No
Q1	Has the space maintainer caused any pain in your mouth?		
Q2	Does the space maintainer interfere with your speech?		
Q3	Does the space maintainer interfere with your eating?		
Q4	Are you comfortable with the space maintainer in your mouth?		

Fig 1: Questionnaire used in this study

STATISTICAL ANALYSIS

Data management and statistical analysis were performed using the Statistical Package for Social Sciences (SPSS) version 20. Qualitative data were summarized as frequency (number of responses) and percentage. A chi-square test was used for comparison between groups. All p-values are two-sided. P-values ≤0.05 were considered significant.

RESULTS

Eighteen children completed the study, but only two children were excluded during the study, the first one was in group I, who was excluded from the study due to several missed appointments during follow-up, and the second was in group II, who was excluded due to a breakage of the appliance.

Q1: Has the space maintainer caused any pain in your mouth?

In the TPA group and the Nance group, 77.8% of the patients responded (no) and 22.2% responded (yes), with no difference between groups (p=1).

Q2: Has the space maintainer interfere with your speech?

In the TPA group, 77.8% of the patients responded (no) and 22.2% responded (yes), while in the Nance group, 66.7% of the patients responded (no) and 33.3% responded (yes). The difference between groups was not statistically significant (p = 0.599). Overall, 72.2% of the patients responded (no) and 27.8% responded (yes).

Q3: Does the space maintainer interfere with your eating?

In the TPA group, 77.8% of the patients responded (no) and 22.2% responded (yes), while in the Nance group, 66.7% of the patients responded (no) and 33.3% responded

(yes). The difference between groups was not statistically significant (p = 0.599). Overall, 72.2% of the patients responded (no) and 27.8% responded (yes).

The previous results are summarized in the following table and figure [Table 1 and Fig. 2]

Table 1: Descriptive statistics of responses to the questionnaire and comparisons between groups

			Groups		Total	Significance of difference between groups	
			TPA	Nance		X^2	P value
Q1	No	Count	7	7	14	0.00	1 ns
		%	77.8%	77.8%	77.8%		
	Yes	Count	2	2	4		
		%	22.2%	22.2%	22.2%		
Q2	No	Count	7	6	13	0.277	0.599 ns
		%	77.8%	66.7%	72.2%		
	Yes	Count	2	3	5		
		%	22.2%	33.3%	27.8%		
Q3	No	Count	7	6	13	0.277	0.599 ns
		%	77.8%	66.7%	72.2%		
	Yes	Count	2	3	5		
		%	22.2%	33.3%	27.8%		
Q4	No	Count	2	2	4	0.00	1 ns
		%	22.2%	22.2%	22.2%		
	Yes	Count	7	7	14		
		%	77.8%	77.8%	77.8%		

Q1: Has the space maintainer caused any pain in your mouth? Q2: Has the space maintainer interfere with your speech?
Q3: Does the space maintainer interfere with your eating?
Q4: Are you comfortable with the space maintainer in your mouth? Significance level $p \leq 0.05$, ns=non-significant

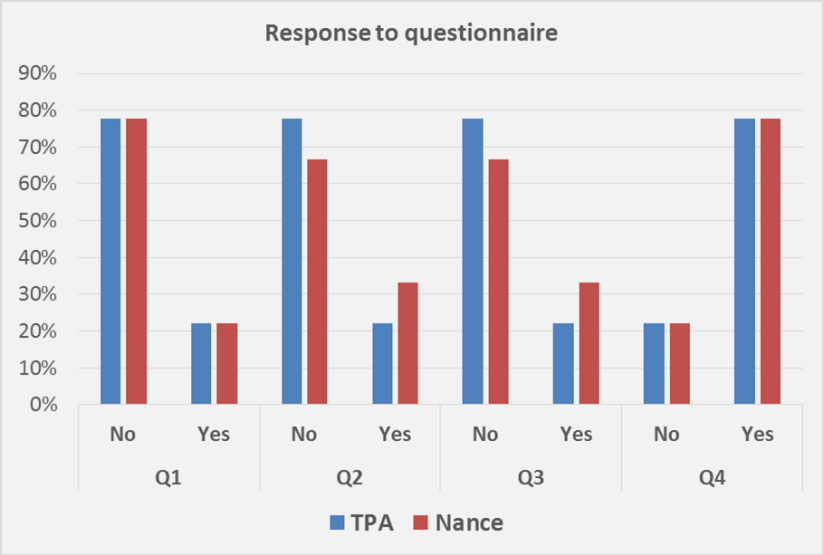

Fig. 2: Bar chart illustrating percentages of responses to the questionnaire

DISCUSSION

Preservation of the primary teeth in a healthy state is considered the best choice to maintain the space for the upcoming permanent teeth, and once early tooth loss occurs, space maintainers should be placed (16). In this study, TPA was used because it's one of the most common appliances used to prevent space loss in the maxillary molar area and also to provide anchorage in its simplest and most modest form. It can also be used for up-righting molar rotation, stabilization of transverse dimensions during orthodontic treatment, and maintenance of leeway spaces during the mixed dentition (17).

This study also used the Nance appliance, which simply resembles the design of the lingual arch used for the lower arch but differs in that the acrylic portion

doesn't contact the anterior teeth but approximates the anterior palate. The palatal portion contains an acrylic portion that contacts the palatal tissue, which provides resistance to forward mesial drift of the posterior teeth (18).

The children in this study were in the mixed dentition period, as they were expected to be more cooperative, as that also came in agreement with other previous studies (13).

In this study, the assessment tool was a simple questionnaire that contained simple questions to assess the children's satisfaction wih the appliances, questionnaire was done for this study because it is an efficient tool for assessment and also because it's easy to complete either by the patients or the operators and can be finished within a short period of time. Also, the items included in this questionnaire were designed to be simple and could be easily understood, scored and analyzed. (19)

This study showed no significant difference in child satisfaction between the TPA and Nance appliances. This comes in agreement with a previous study (18) that compared the use of TPA and Nance appliances, and the results were found to be that the TPA can be as effective as the Nance for space maintenance.

The data recorded from the questionnaire showed that the pain and discomfort related to the usage of TPA and Nance were comparable. This disagreed with another study (20) that found that the main disadvantage of Nance appliances is discomfort and tissue irritation.

Another previous study (21) disagreed with this study, which found that there was a statistically significant difference in discomfort between the two groups, with the Nance palatal arch reported to be more uncomfortable compared with the TPA.

CONCLUSIONS

The level of patient satisfaction for the two types of space maintainers is good with no significant difference between both of them.

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