Comparison between removable devices in palatal expansion: a randomised open label clinical trial

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Abstract

Background Posterior crossbite is a very frequent malocclusion in the Caucasian population and is most often associated with hypoplasia or retrusion of the upper jaw. Treatment involves palatal expansion with the use of fixed or removable orthodontic devices. The aim of the present study is to compare two different devices used in expansion: the Eptamed Equilibrator elastodontic device (series 00) with the Schwartz plate, which is traditionally used in palatal expansion.

Materials and methods 70 children (30 boys and 40 girls, average age: 11 ± 1 years) were recruited and divided into a test group and a control group. The test group underwent palatal expansion with the elastodontic device, the control group with the Schwartz plate. Controls were carried out at 6 months and 12 months after the start of treatment. The distance between the cusps of the first upper premolars was taken as the reference or the width between the second deciduous molars. For statistical analysis, the t-test or Wilcoxon signed-rank test for continuous variables and chi-square test or Kruskal-Wallis test for categorical variables were used.

Results Statistical analysis showed no statistically significant difference in the expansion with the two different devices.

Conclusions The Eptamed Equilibrator device allows palatal expansion like that achieved with traditional expansion devices, but with greater comfort and greater compliance for patients.

Trial registration "Comparison between removable devices in palatal expansion: a randomised open label clinical trial", ID number: NCT05848882. Date of the first registration: 08/ 05/2023 https://clinicaltrials.gov/study/NCT05848882?cond=NCT05848882&rank=1

KEYWORDS Posterior Cross-bite, elastodontic device, Schwartz Plate, palatal expansion.

Introduction

The cross-bite is a transverse disharmony, where there is an incorrect relationship between one or more teeth of the maxillary arch with those of the mandibular one. In particular, a posterior crossbite occurs when the top back teeth bite inside the bottom back teeth [Ugolini et al., 2021]. Posterior cross-bite has a prevalence between 7% and 23% [Lo Giudice et al., 2023], it depends on ethnic differences, number of samples studied, age of patients and their dentition. For example, cross-bite cases occur more in the Caucasian population than in the African and Asian population. Moreover, this type of malocclusion, in most cases (50%-90%), continues to persist at the time of the permutation from deciduous teething to the permanent one. Only for a small slice of the child population, the cross-bite self-resolves [Ugolini et al., 2021]. In general, the posterior cross-bite can affect the jaw bones both bilaterally and unilaterally. Patients who have a unilateral cross-bite may manifest an asymmetry in the activity of the masticatory muscles. They will have a contralateral and irregular chewing cycle on the cross-bite side; infact, due to this condition, patients may have a reduction in chewing strength on that side [Tsanidis et al., 2015]. Moreover, several studies have reported a certain tendency of patients with unilateral cross-bite to have temporomandibular disorders, joint clicks and blockages of the jaw [McNamara and Turp, 1997]. For these reasons, it is important to act with early therapies that can avoid or at least slow down the problems described. Assuming that most cases of cross-bite are associated with a maxillary hypoplasia or its asymmetry, the treatment of choice is indeed a palatal expansion [Villani et al., 2023]. The expansion of the palate is proposed to the patient usually in mixed teething and can be carried out with different devices both fixed and removable. It increases the size of the dental arch by acting on the median palatine suture, at the same time it applies a buccal rotary force on the maxillary alveolar shelves [Garret et al., 2008]. This type of therapy can act not only on a purely dental-alveolar level, but also has many positive effects on the systemic level. The use of these devices improves obstructive sleep apnea, in patients with adenoiditis or tonsillitis, reducing the size of adenoids and tonsils [Yoon et al., 2022]. Moreover, with the expansion of the palate it is possible to act also on oral respiratory subjects. The treatment involves an expansion not only of the palate, but also an increase in the size of the nasal passages, so there will be a reduction in air resistance. All this will facilitate nasal physiological breathing [Sakai et al., 2021]. Finally, in a case-control study of Tecco et al. [2005]

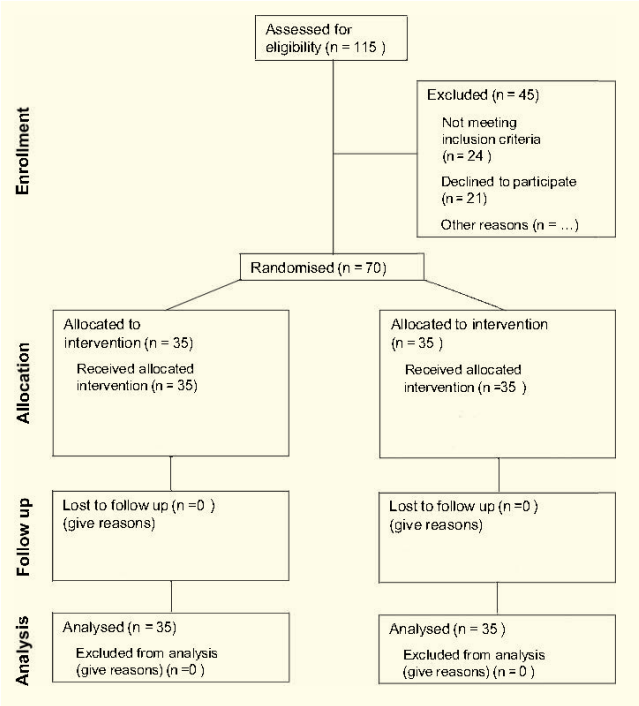

FIG.1
Flow diagram of the progress through the phases of the parallel randomised trial of two groups.

the treatment with palatal expander had positive effects also in the body posture of oral respiratory patients (case group), with an improvement of the craniocervical angle and no significant results in the control group.Nowadays in clinical practice there is a wide availability of different devices and therapeutic modalities that can be offered to patients who manifest cross-bite. The Schwartz plate is widely used among them. This is a removable device that is used in cases where palatal or mandibular expansion is needed. The device consists of a resin plate that goes over the lingual surface of the teeth in the mandible, or the palatal surface on the upper jaw. A median expansion screw is incorporated into the resin, and retention is provided primarily by Adams hooks placed on deciduous or permanent molars. In addition to Schwartz's appliance, many other fixed or removable devices can be used in the treatment of cross-bites, for example the elastodontic device. It is an elastic removable appliance made of silicone of different size depending on the dimensions of the small patient's mouth. The elastodontic device is preformed but is individualised according to the individual patient's arch form In this regard, an open label clinical trial was conducted where children with cross-bite were recruited to perform treatment with the elastodontic appliances and with Schwartz plate. The main objective of this study is in fact to consider the possibility of using a new method of treatment of cross bites with elastodontic devices, of which little is known. Infact, such devices are very useful in the field of interceptive orthodontics. They are advantageous devices for the treatment of dental crowds and malocclusions, thanks to their ease of use and the greater comfort guaranteed to the patient [Ortu et al., 2021].

Methods

This research was conducted in accordance with the basic principles of the Declaration of Helsinki. Before the study was begun, the protocol was approved by the Internal Review Board of the University of L'Aquila, Italy (57/2021-22). The clinical trial has been registered on website: clinicaltrials.gov, ID number: NCT05848882, on 08/05/2023, according to the CONSORT statement of the updated guidelines for reporting randomised clinical trials. It was a parallel group randomised clinical trial, monocentric study with a 1:1 allocation ratio. As described by the flow diagram below (Fig. 1), required by CONSORT 2010 guidelines, 115 patients aged between 9 and 15 years were clinically examined at some dental studies affiliated with the University of L'Aquila in March 2023. The same clinician (EO) performed all examinations. Examinations included the acquisition of dental panoramic radiographs according to European guidelines on radiation protection in dental radiology, extraoral and intraoral photographs, and intraoral scannings of both dental arches. Based on these data, the orthodontist created a treatment plan specific to each patient, following the index of orthodontic treatment needs described by Brook and Shaw [1989].

The following exclusion criteria were applied:
- IOTN (INDEX OF ORTHODONTIC TREATMENT NEED) index>4;
- presence of epilepsy;
- systemic disease;
- TMD, or periodontal disease;
- lack of written informed consent from a parent or legal guardian.

Inclusion criteria were:
- skeletal class I relationship,
- molar class I relationship;
- complete eruption of upper first premolars;
- presence of unilateral or bilateral cross bite (falling within grade 3 IOTN index).

Forty-five patients were excluded from the study either because they did not meet the eligibility criteria or because they had not given consent to participation in it. Ultimately, 70 patients (30 males and 40 females, mean age: 11 ± 1 years) were enrolled in the study. The subjects were randomly divided into test and control groups, through computer generated software (https://www.sealedenvelope.com/) and was stratified with a 1:1 allocation using random block size of 4,6,8. The test group (35 patients, 15 males and 20 females, mean age: 11.29 years) was treated with the elastodontic device, in particular an orange Eptamed Equilibrator (series 00), the remaining half was treated with the Schwartz plate (35 patients, 15 males and 20 females, mean age: 11.14 years).

To evaluate the two different orthodontic appliances for the palatal expansion, the cusps of the upper first premolars or the distance between cusps of second deciduous molars subtracted 3 millimeters were taken as repere points and the distance between them was measured to compare the treatment results in the two different groups. The orthodontist (EO) checked patients in every 30 days to evaluate eventual modifications for optimise the execution of the device. The elastodontic device and the Schwartz plate were to be carried only during the night, the activation of the Eptamed Equilibrator (series 00) was through the chewing of the device by the patient (Fig.2 A). Activation of the Schwartz plate took place in the dental study by the clinician (EO) every month with an activation equal to 2/4 turn (Fig.2 B). In addition, all

dental scannings were taken with an intraoral scanner (I-Tero) and examined pre-treatment (T0), six months after the onset of therapy (T1) and 1 year after the treatment (T2) to assess the distance between the cusps examined teeth (Fig.3). For statistical analysis, the t-test or Wilcoxon signed-rank test for continuous variables and chi-square test or Kruskal-Wallis test for categorical variables were used.

Results

Data were collected using an electronic spreadsheet, and we employed both parametric and non-parametric methods to investigate differences between elastodontic and Schwartz devices. Continuous data underwent testing using either the t-test or Wilcoxon signed-rank test, while categorical data were assessed using the chi-squared test or Kruskal-Wallis test. Our tables present the results from parametric analyses, whereas non-parametric findings are depicted in plots. Within the narrative, we provided information on means and standard deviations (SD), whereas figures display means and standard errors (SE). We established statistical significance at a predetermined threshold of $p < 0.05$ and a confidence interval of 95%. All statistical analyses and visualisations were generated using R software version 4.0.2.

As shown in Table 1, baseline demographic and clinical characteristics of the two groups were not statistically different. There is no statistical difference in the values of the groups related to sex or age at all stages. To determine whether any differences between the distance of upper first premolars before and after treatment between the two groups were related to sex and physiologic growth, that value was evaluated with non-parametric Kruskal-Wallis test for conservativeness. Thus, results depended only on the type of device used. The two devices appeared to be equally effective. There were no statistically significant differences between the expansions that resulted from the Schwartz Plate and the Eptamed devices at T0 [Eptamed series 00, mean: 28.16 (95% CI 27.6 to 28.7); Schwartz plate, mean: 28.53 (95% CI 27.9 to 29.1)], T1 [Eptamed series 00, mean: 30 (95% CI 29.5 to 30.5); Schwartz plate, mean: 30.24 (95% CI 29.7 to 30.8)] and T2 [Eptamed series 00, mean: 30.53 (95% CI 29.9 to 31.1); Schwartz plate, mean: 30.01 (95% CI 29.5 to 30.5)]. The two devices were similarly effective as shown in Table 1 and Figure 4. In Table 1 are shown the results (mean and SD) of the t-test or Wilcoxon signed-rank test for continous variables and chi-square test or Kruskal-Wallis test for categorical variables for the two groups.

The values of the distance between upper first premolars at T0, T1 and T2 are expressed in mm. There is no statistically difference in the values of the groups related to sex or age at all stages. The figure compares the values of the distances between the upper first premolars using the Schwartz plate and the elastodontic device before treatment (T0), after 6 months (T1) and after 12 months (T2). The two groups presented similar results, which were not statistically significant. None of the patients examined had treatment-related side effects during the evaluation period.

Discussion

Cross-bite is one of the most frequent malocclusions in the Caucasian population, in most cases, it is associated with a lack of development of the upper jaw. In subjects affected by cross-bite, therapy must be timely to avoid in the future

FIG. 2 Examples of the two devices used in the study. A: Eptamed Device B: Schwartz plate

respiratory, phonatory and postural problems. The treatment of choice of transverse discrepancies is palatal expansion. It can be carried out with the use of different types of fixed or removable devices [Caruso et al., 2023; Manzo et al., 2022]. According to our hypothesis elastodontic devices can be a valid alternative in the treatment in question. Elastodontics is a branch of interceptive orthodontics that is based on the use of removable preformed silicone devices of different sizes and hardness. These devices are capable of both dental and orthopedic action. They can act preventively on early malocclusions, in particular Class II malocclusion division I [Migliaccio et al., 2014; Inchingolo et al., 2022], cases of tongue malposition and respiratory problems [Fleming et al., 2017]. Furthermore, these devices can also be used to prevent or eliminate bad habits in the young patient, and they guarantee the correct eruption of the teeth [Marra et al., 2022]. However, there are several studies that have evaluated the use of such devices in cases of dental crowding, overjet and overbite [Ortu et al., 2021; Fichera et al., 2021], there is still very little scientific evidence about the use of elastodontia in the treatment of cross-palate discrepancies; the aim of this study is to fill this gap.

Only in a study by Lo Giudice et al. [2023] the use of elastodontic devices in the treatment of cross-bite is proposed. He compared a group of 25 subjects with posterior cross-bites treated for a year with elastodontic devices, and a control group of 14 untreated subjects. To evaluate the results of palatal expansion, digital models were analysed to evaluate inter-canine, inter-molar and hemilateral measurements. The degree of asymmetry of the palate was also analysed with a 3D visualisation of the models. If at T0 the indices considered were not statistically significant different between the two groups, after one year of treatment the subjects with elastodontic devices showed an increase in all the parameters

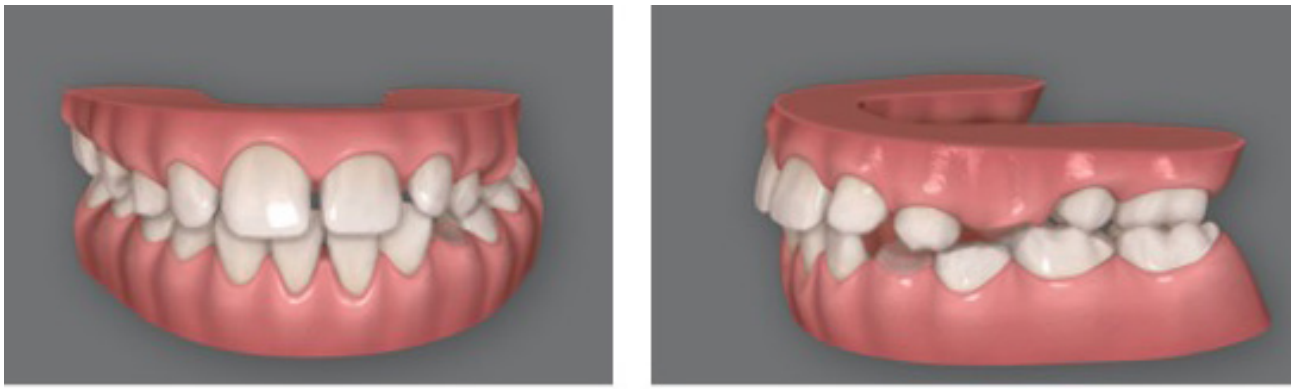

FIG. 3 Intraoral scanning superimposition of a patients before the start of the therapy

	Eptamed series 00	SCHWARTZ PLATE	p
n	35	35	
Race = C (%)	33 (94.3)	35 (100.0)	0.473
Sex= Males (%)	15 (42.9)	15 (42.9)	1
Age (mean (SD))	11.29 (1.53)	11.14 (1.57)	0.701
Distance between upper first premolars at T0 (mean (SD))	28.16 (1.75)	28.53 (1.80)	0.38
Distance between upper first premolars at T1_6 months (mean (SD))	30.00 (1.63)	30.24 (1.56)	0.526
Distance between upper first premolars at T2_12 months (mean (SD))	30.53 (1.79)	30.01 (1.55)	0.203
Treatment= SCHWARTZ PLATE (%)	0 (0.0)	35 (100.0)	<0.001

TABLE 1 Results (mean and SD) of the t-test for continous variables and chi-square test for categorical variables (gender) for the two groups.

evaluated, compared to the control group. There was an increase of the maxillary intercanine and intermolar distance and a reduction of the palatal asymmetry. The results obtained from this study allow us to consider elastodontic devices capable and effective in the treatment of crossbite compared to non-treatment. On the other hand, the use of Schwartz plate in dento-alveolar palatal expansion is widely known, and several studies have compared it with the use of fixed expansion devices. Erdinç et al. [1999], for example, compared posterior cross-bite treatment in three different groups: 14 patients treated with quad-helix, 13 treated with Schwartz plate and 10 patients not treated. Each patient was requested a dental cast and lateral and frontal cephalometric radiographs. Although Schwartz plate required a longer-lasting treatment (1.2 years) compared to quad-helix devices (0.6 years), the results were similar with an improvement of cross-bite in both groups. Godoy et al. [2011] compared a traditional fixed appliance, quad-helix device, with a removable plate expansion (Schwartz plate) for the treatment of cross-bite in growing patients. 99 patients were divided in three groups: quad-helix, expansion plate and patients not treated. While the length of treatment and the costs were higher in the expansion group than in the quad-helix group, the success rates were similar for the quad-helix and the expansion plate groups. Moreover, the most common complications that can occur during palatal expansion, such as appliance breakage, were less frequent during treatment with Schwartz's appliance than with Quad-helix. Furthermore, in a randomised clinical trial [Petrén et al., 2011], it was seen that subjects treated with Quad-helix and those treated with an expansion plate (Schwartz plate) achieved the same results both during treatment and at the 3-year follow-up. The purpose of our study is that elastodontic devices can also be considered valuable tools for the treatment of transverse discrepancies, as well as traditional expansion plates. Although, to the best of our knowledge, this is the first study in the literature that investigated the effects of a palatal expansion carried out with elastodontic devices and compares them with the Schwartz plate. In this study it was considered the distance between the cusps of the first upper premolars as a point of reference to assess the extent of expansion. This measure was compared between the two groups at T0, before treatment, after 6 months from the start of treatment, T1, and at T2, after 12 months. The following study showed no statistically significant difference following the use of Eptamed device and the Schwartz plate for the treatment of cross-bite discrepancies, regardless of age and gender. The distance between the cusps of the upper first premolars was similar in both groups in T1 (Eptamed, 30.00 mm, Schwartz plate, 30.24 mm) and in T2 too (Eptamed, 30.53 mm, Schwartz plate, 30.01 mm). Both devices were found to be effective for the treatment of cross-bite. The absence of a statistically significant difference between subjects treated with Eptamed and those treated with Schwartz plate, confirms the fact that

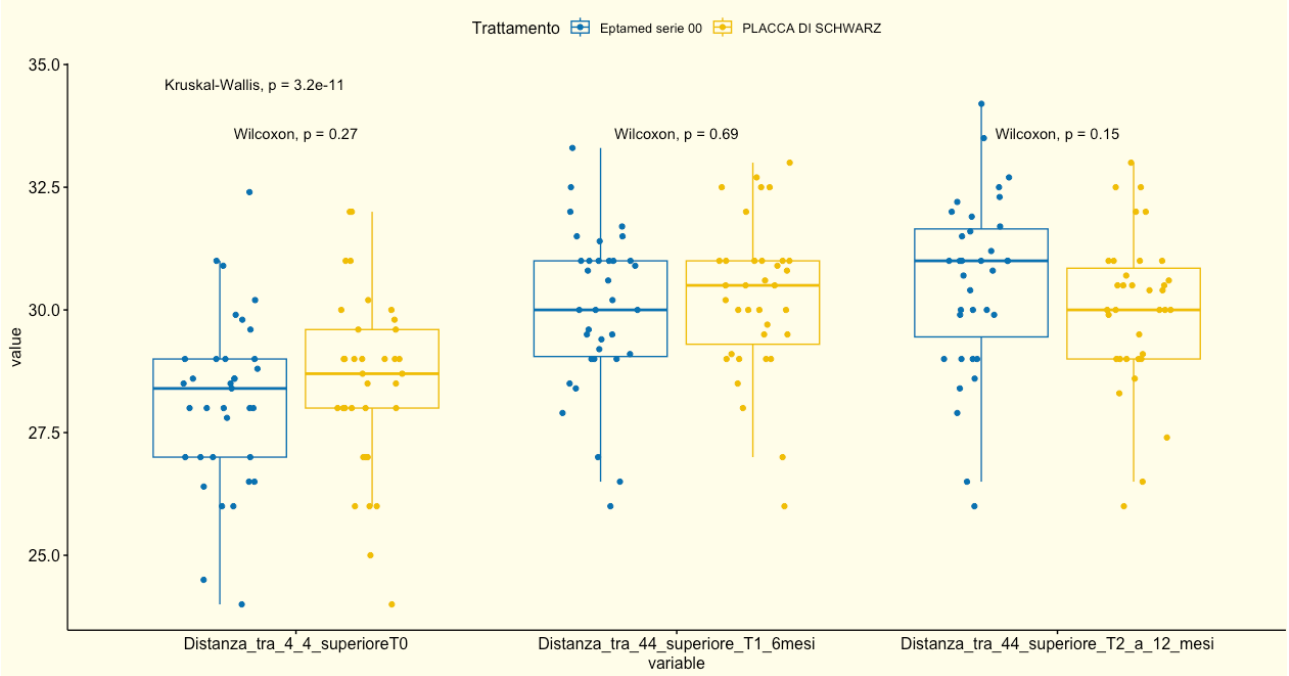

FIG. 4 Results of the non-parametric variables using the Kruskal-Wallis test.

elastodontics can achieve the same results as traditional therapies, and can be a valuable palatal expansion technique to propose to patients. The use of elastodontic devices is much more appreciated by patients. First, they are removable devices that can be worn even at night, do not have hooks or metal wires, but are simple silicone products, so they are comfortable to wear. Moreover, a study by Ortu et al. [2020] also found that, following electromyographic and kinesiographic examination, the use of elastodontic devices allows greater relaxation of the masticatory muscles, with less risk of developing temporomandibular disorders during orthodontic treatment. All this guarantees greater adherence to therapy with lower costs for both the operator and the patient. Concluding in clinical practice, elastodontic devices are also effective in various types of orthodontic treatments including crossbite. However, the above study has several limitations, primarily the samples considered are undersized. Therefore, further studies with a larger number of participants would be necessary. Also, it would be interesting to compare the elastodontic device with other palatal expansion devices other than the Schwartz plate. Therefore, it turns out to be indispensable to continue the research in this regard, delving deeper into the subject matter with a larger number of participants so that the limitations just stated can be overcome.

Conclusion

Orthodontic treatment of a posterior crossbite achieves the same results when done with an elastodontic device as compared to a Schwartz plate. The distance between the cusps of the upper first premolars is the same in both groups. The use of such devices could be a viable, effective, low-cost and much more comfortable therapeutic alternative for the patient. However, more studies are needed to deepen the lack of knowledge of this technique.

Declarations

Ethics approval and consent to participate

This research was conducted in accordance with the basic principles of the Declaration of Helsinki. Before the study was begun, the protocol was approved by the Internal Review Board of the University of L'Aquila, Italy (57/2021-22). Written informed consent was obtained from all parents or legal guardians of the subjects involved in the study.

Consent for publication

Written informed consent for the publication of the study was obtained from all participants.

Availability of data and material

All data generated or analysed during this study will be available on reasonable request to the corresponding author (and its supplementary information files).

Competing interest

The authors declare no competing interest.

Funding

Not applicable.

Authors' contributions

EO, RG and AM contributed to conception and design of study. EO, AC and SC were involved in acquisition of data. MS contributed to analysis and/or interpretation of data. EO and SDN were involved in drafting the manuscript. EO and AM revised the manuscript critically for important intellectual content. All authors read and approved the final manuscript. The authors wish to thanks the Orthosystem Dental Laboratory of Rome for their collaboration.

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