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Comparative Evaluation of Dentoalveolar Effects of Sawangi Flexiforce Expander as Against Quad Helix in Cleft Lip and Palate Patients of 7 to 12 Years in Central India Population: A Randomised Clinical Trial

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ABSTRACT

Introduction: Cleft Lip and Palate (CLP) is among the most prevalent congenital craniofacial anomalies, often accompanied by maxillary hypoplasia and transverse deficiency. Surgical scarring and disrupted maxillary development in CLP patients typically lead to posterior crossbites and constriction of the maxillary arch. Orthodontic maxillary expansion is a key early intervention. Although the Quad Helix (QH) is a commonly used slow expansion appliance, it has limitations related to molar tipping and control. The Sawangi Flexiforce Expander (SFE) is a newly developed appliance designed to provide more controlled and parallel expansion, and its dentoalveolar effects were evaluated in the present study.

Aim: To compare and evaluate the dentoalveolar effects of the SFE against the QH appliance in CLP patients aged 7 to 12 years in the Central India population.

Materials and Methods: A prospective randomised clinical trial was conducted at the Department of Orthodontics and Dentofacial Orthopaedics, Sharad Pawar Dental College, Wardha, Maharashtra, India from December 2023 to June 2024. A total of 30 patients aged 7-12 years with unilateral CLP and maxillary constriction were randomly allocated into two groups (n=15 each). Group I was treated with a QH, and group II received the SFE. Expansion was done according to standard protocols. The Cone Beam Computed Tomography (CBCT) scans were taken before (T0) and after complete expansion of the maxillary arch i.e. after 6 months (T1,) to assess inter-canine width, inter-molar width, molar tipping, and inter-molar angle. Demographic details such as age and gender were recorded. Data were analysed using the Independent Sample t-test with Statistical Package for Social Sciences (SPSS) version 27.0, and statistical significance was set at p-value <0.05.

Results: The SFE group (group II) showed significantly greater increases in inter-canine width (4.57 mm, p-value <0.0001) and inter-molar width (5.10 mm, p-value <0.001) compared to the QH group. Molar tipping was significantly lower in the group II (7.0°, p-value <0.001), indicating better control. The inter-molar angle was also significantly more favourable in group II (96.0°, p-value <0.001), reflecting more parallel and bodily expansion.

Conclusion: The SFE demonstrated superior and more controlled dentoalveolar expansion than the QH, making it a promising, a cost-effective appliance for CLP patients.

Keywords: Alveolar process, Cone beam computed tomography, Facial growth, Maxillary arch, Orthodontic appliances

INTRODUCTION

Cleft Lip and Palate (CLP) are considered the most common craniofacial anomalies in humans, which are characterised by complete or partial clefting of the lip and/or palate [1]. These malformations can involve the upper lip, alveolar ridge or palate and, in general, cause aesthetic, functional, and psychosocial impairments in different magnitudes, depending on their location and extent [2]. The defect arises during early embryonic development due to the failure of fusion between the medial nasal and maxillary processes, leading to orofacial clefts affecting the upper lip, alveolus, and/or primary palate. The development of CLP is associated with genetic and environmental factors [3]. It may be seen as an isolated birth defect, a non syndromic cleft or as a part of a syndrome with multiple congenital anomalies.

In general, patients with CLP who underwent lip and palate repair at early ages usually show severe deficiencies of maxillary growth, demonstrating maxillary dental arch constrictions and posterior crossbites [4]. Maxillary growth is hampered in all three dimensions. The most important cause of growth inhibition seems to be the iatrogenic effect of surgical intervention and the subsequent constriction induced by scar tissue [5]. However, some authors attribute such a deficiency to the developmental hypoplasia of both the alveolar and palatal soft and hard tissues, as well as to functional factors [6]. The maxillary growth deficiency affects the dental arches relationship on the vertical, sagittal, and transverse planes, frequently resulting in anterior and/or posterior crossbite occurring in the early dentition [7].

Orthodontic treatment of CLP patients during the deciduous and mixed dentition period has been recommended to create more favourable conditions for midfacial growth, normalise the inter-maxillary basal relationship, and prevent or eliminate functional disturbances [8]. The most common orthodontic interventions involve maxillary expansion to address transverse deficiencies, alignment and proclination of incisors to correct crowding, rotations, and anterior crossbites, as well as maxillary protraction to manage maxillary retrusion.

Maxillary Expansion is an essential treatment modality in CLP patients to correct dental and skeletal crossbites and to increase the transverse dimension of narrow maxillary arches. There are two modalities commonly used for maxillary expansion: Rapid Maxillary Expansion (RME) and Slow Maxillary Expansion (SME). Slow palatal expansion generates less resistance in the circummaxillary tissues and promotes better bone formation at the inter-maxillary suture, which may theoretically overcome or reduce the limitations associated with rapid palatal expansion [9]. Many appliances have been used for maxillary expansion in CLP patients, including the Hass Expander, Hyrax Expander, QH, Trihelix, etc.

A SFE is a novel appliance that can be used to achieve transverse expansion of the maxilla. It is fabricated using stainless steel wire featuring a central helix and loops, which allow for controlled and targeted expansion. Activation of the expander helps in both anterior and posterior expansion. The appliance delivers light, continuous forces over an extended period, minimising tissue trauma and allowing for bodily tooth movement with minimal tipping. This controlled force system characterises it as a slow maxillary expander, making it especially suitable for CLP patients with scarred or delicate palatal tissues.

The present study compared the SFE with the QH appliance to determine whether it serves as a better alternative for maxillary expansion in patients with CLP. The SFE is a newly developed, custom-fabricated appliance, hence,

Null Hypothesis: There is no significant difference in the dentoalveolar effects between the SFE and the QH in CLP patients.

Alternate Hypothesis: There is a significant difference in the dentoalveolar effects between the SFE and the QH in CLP patients.

MATERIALS AND METHODS

A prospective randomised clinical trial was conducted in the Department of Orthodontics and Dentofacial Orthopaedics, Sharad Pawar Dental College, Sawangi (M), Wardha, in collaboration with the Department of Oral Medicine, Diagnosis and Radiology, Sharad Pawar Dental College, Sawangi (M), Wardha, Maharashtra, India, from December 2023 to June 2024. The study was conducted following approval from the Institutional Research Ethics Committee of Datta Meghe Institute of Higher Education and Research (Deemed to be University). Ethical clearance was granted on 06/02/2023, with reference number {DMIHER(DU)/IEC/2023/574}. This prospective clinical trial was registered with the Clinical Trials Registry of India (CTRI) prior to initiation (Registration number: CTRI/2023/11/060255).

Inclusion criteria:

- Patients aged 7 to 12 years.
- Patients with unilateral complete CLP.
- Patients with constricted maxilla with posterior crossbite.
- Patients with Class I or mild Class III malocclusion are suitable for transverse maxillary expansion.

Exclusion criteria:

- Patients with bilateral complete CLP.
- Patients with any other associated syndrome.
- Patients with a history of previous orthodontics.
- Patients with the absence of maxillary first permanent molars and/or primary or permanent canines, which are required to anchor and support the expansion appliance.

Sample size calculation: Sample size formula for the difference between two means:

$$n=\frac{(Z_{\alpha}+Z_{\beta})^2\,(\delta_1^2+\delta_2^2/k)}{\Delta^2}$$

where;

$Z\alpha$ is the level of significance at 5% i.e., 95% confidence interval=1.96

$Z\beta$ is the power of test=80%=0.84

$\delta1$=SD of inter-canine width change (ICWC) in Slow Palatal expansion group=3.65

$\delta2$=SD of inter-canine width change (ICWC) in Rapid Palatal expansion group=2.45

k=1

Δ=Difference between two means of inter-canine width change (ICWC).

=8.5 - 5.25; Based on data from a previous study by Vasant MR et al., [10], the mean inter-canine width change was assumed to be 8.5 mm for the SFE group and 5.25 mm for the QH group.

=3.25

$$n=\frac{(1.46+0.84)^2\,(3.65^2+2.45^2/1)}{(3.25)^2}$$

=14.35

n=15 patients needed in each group.

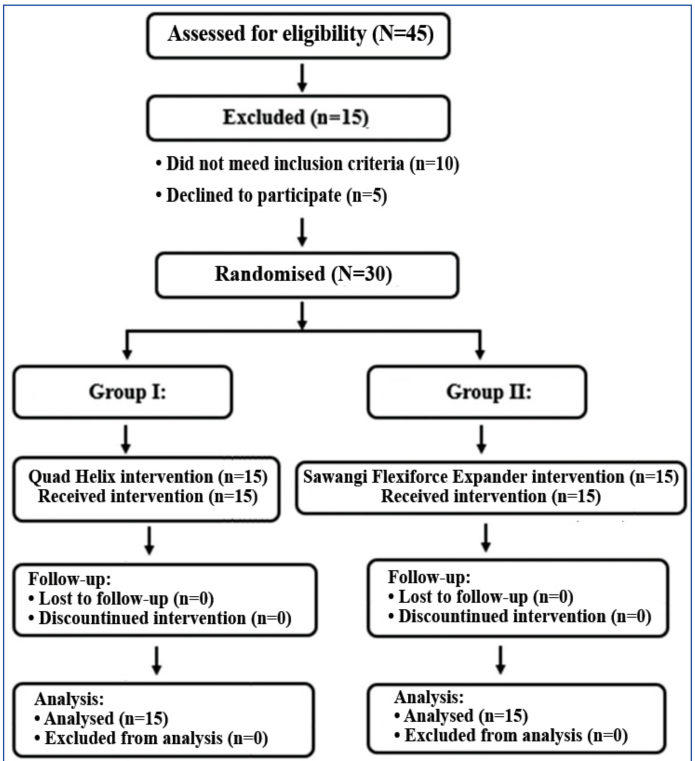
Hence, the total sample size came to be 30. The samples were randomly allocated into two groups and randomisation was done by the chits' system. In the first group, the QH was used for the expansion of the arch, while in the other group, the SFE was used:

Group I (n=15): Expansion done by Quad Helix appliance.

Group II (n=15): Expansion done by SFE.

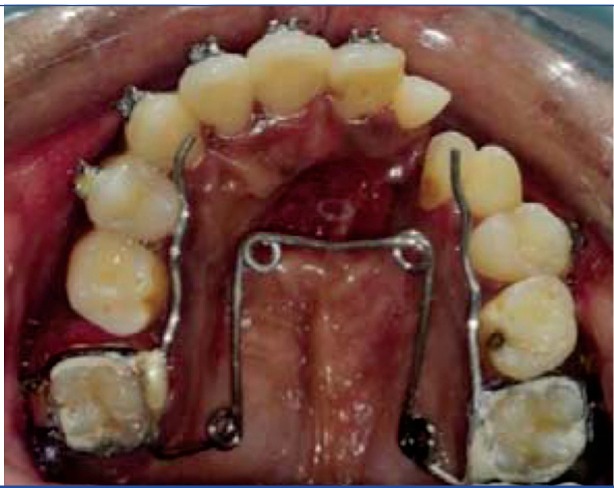
Study Procedure

A total of 30 patients in the age group 7 to 12 years, representing the mixed dentition phase, were selected from the patients coming to the Outpatient Department (OPD) of Orthodontics and Dentofacial Orthopaedics. This developmental stage is optimal for maxillary expansion as the midpalatal suture is still responsive to orthopaedic forces. Early intervention during this period allows for effective correction of transverse discrepancies, reduces the risk of long-term skeletal imbalance, and improves functional outcomes in CLP patients. All pre-treatment records were taken. Each selected patient was included in the sample group only after informed consent was obtained from the parents of each participant [Table/Fig-1].



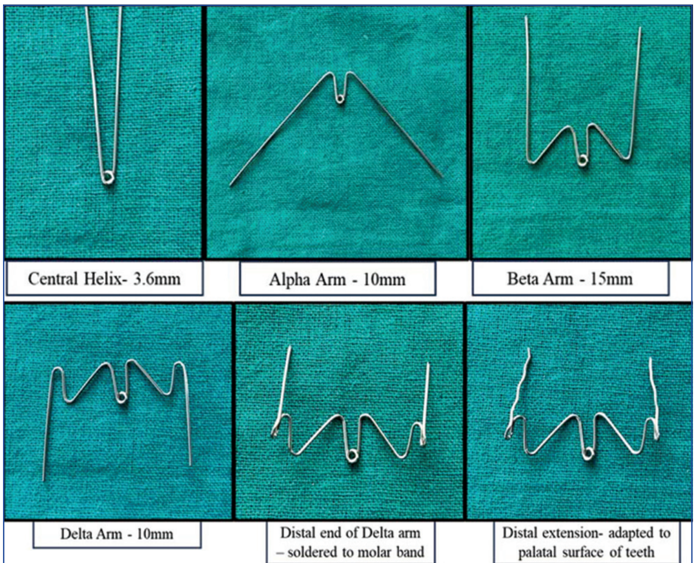
[Table/Fig-1]: The Consolidated Standards of Reporting Trials (CONSORT) statement guidelines.

Quad Helix: The appliance was fabricated using 19-gauge stainless steel wire (0.9 mm in diameter). Band pinching was done on the maxillary first molars, and the appliance was then soldered to the bands [Table/Fig-1]. The QH was expanded according to the standard protocol. Subsequent reactivations of the QH were performed at intervals of four to six weeks, always carried out extraorally prior to recementation. The expansion was considered adequate once the occlusal aspect of the maxillary lingual cusp of the permanent first molar contacts the occlusal aspect of the mandibular buccal cusp of the permanent first molar. The intraoral maxillary occlusal view is shown with the QH appliance [Table/Fig-2].



[Table/Fig-2]: Intraoral maxillary occlusal view showing the QH Appliance.

Sawangi Flexiforce Expander: The SFE is a novel slow palatal expander introduced by the Department of Orthodontics and Dentofacial Orthopaedics, Sharad Pawar Dental College [Table/Fig-3]. The SFE has been filed for patent protection (Application No. 20231076157) and is currently under examination. It is a custom-made appliance designed for both anterior and posterior parallel expansion, overcoming the drawbacks of conventional appliances. It is fabricated from 21-gauge stainless steel wire (0.8 mm diameter) featuring a central helix, two loops and three arm extensions. The distal arm of the appliance is soldered to the molar bands and carefully adapted along the palatal surfaces of the maxillary teeth [Table/Fig-4]. The activation of the central helix allows for anterior expansion, while the activation of the loop encourages posterior expansion. In the present study, the appliance was activated at a rate of 3 mm per month, corresponding to 1.5 mm expansion per quadrant, following a slow and controlled activation protocol suitable for cleft patients. This protocol was derived from a Finite Element Analysis (FEM) conducted by the research team (unpublished data), which demonstrated that 1 mm activation produced insufficient stress levels for expansion, while 3 mm activation achieved optimal force distribution for effective dentoalveolar and skeletal changes. Unlike other expanders, the SFE offers the benefit of being able to expand both the anterior and posterior simultaneously or separately, depending on what is needed.



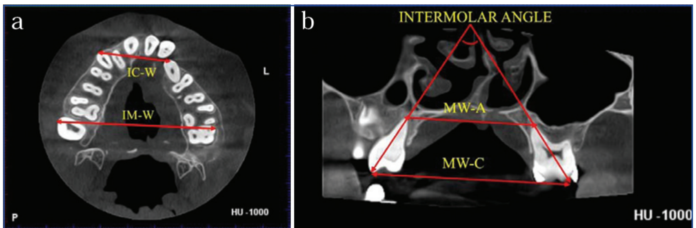
[Table/Fig-3]: Intraoral maxillary occlusal view showing the SFE.

[Table/Fig-4]: Steps of SFE fabrication.

Two CBCT scans for each patient were taken. First, just before the commencement of expansion (T0), and second (T1) was taken after completion of the expansion phase, at approximately 6 months. Expansion was considered complete when correction of the posterior crossbite was achieved. All CBCT measurements were independently assessed by two calibrated observers. Inter-observer reliability was tested using the Intraclass Correlation Coefficient (ICC), which showed excellent agreement (ICC=0.93). No adverse events or complications related to appliance use or CBCT scanning were reported during the study period. Comparison of effects of SFE as against QH was done based on the following parameters, which were analysed through CBCT:

a) Inter-canine width (IC-W): the distance between the cusp tips of canines.
b) Inter-molar width (IM-W): the distance between the mesiopalatal cusp tips of maxillary first molars.
c) Molar tipping: the difference between molar width at apex (MW-A) and molar width at cusp (MW-C).
d) Inter-molar angle: Angle between the apex of the palatal root and the tip of the buccal cusp of the maxillary first molar line of the right and left side.

The landmarks measured in study are shown in the [Table/Fig-5].



[Table/Fig-5]: a) Axial view of CBCT showing IC-W & IM-W; b) Coronal View showing molar tipping and inter-molar angle.

STATISTICAL ANALYSIS

All statistical analyses were performed using SPSS version 27.0. Descriptive statistics (mean and standard deviation) were calculated for each variable. An Independent Sample t-test was used to compare the changes in inter-canine width, inter-molar width, molar tipping, and inter-molar angle between the two groups. A p-value <0.05 was considered statistically significant. Intra-observer and inter-observer reliability were assessed using the ICC, which showed excellent agreement (ICC=0.93).

RESULTS

The study sample consisted of 30 patients aged between 7 and 12 years with unilateral CLP and constricted maxillary arches. Demographic details of the study sample are mentioned in [Table/Fig-6].

The CBCT scans were taken at two time points; pre-expansion (T0) and post-expansion (T1), to evaluate the dentoalveolar changes. The baseline parameters recorded at T0 are presented in [Table/Fig-7], values of parameters at post-expansion T1 are mentioned in [Table/Fig-8].

The changes observed between T0 and T1 were computed and statistically compared using the Independent Sample t-test. [Table/Fig-9].

Demographic Parameters	Group I (QH) (n=15) (Mean±SD)	Group II (SFE) (n=15) (Mean±SD)	Total (N=30) (Mean±SD)
Mean age (in years)	9.4±1.3	9.6±1.2	9.5±1.3
Gender (M/F)	9/6	8/7	17/13

[Table/Fig-6]: Demographic details of the study population.
M: Male; F: Female; No statistical test was applied; this table describes baseline demographic characteristics.

Parameters	Group I (QH) (Mean±SD)	Group II (SFE) (Mean±SD)
Inter-canine width (mm)	22.72±0.30	22.92±0.21
Inter-molar width (mm)	38.01±0.29	38.26±0.25
Molar tipping (°)	12.23±0.42	6.69±0.19
Inter-molar angle (°)	81.69±1.23	93.35±0.92

[Table/Fig-7]: Baseline parameters (T0) for all variables.
IC-W :Inter-canine width, IM-W: Inter-molar Width; No statistical test was applied; this table presents pre-treatment baseline values.

Parameters	Group I (QH) (Mean±SD)	Group II (SFE) (Mean±SD)
Inter-canine width (mm)	26.00±0.18	27.49±0.13
Inter-molar width (mm)	41.48±0.22	43.36±0.18
Molar tipping (°)	12.74±0.42	7.00±0.20
Inter-molar angle (°)	83.31±1.24	96.05±0.96

[Table/Fig-8]: Post-treatment (T1) mean values for all variables.
IC-W: Inter-canine width; IM-W: Inter-molar width; T1; Post-treatment

Parameters	Group I (QH) Mean±SD	Group II (SFE) Mean±SD	t-value	p-value
IC-W (mm)	3.28±0.11	4.57±0.10	33.61	<0.0001
IM-W (mm)	3.47±0.14	5.10±0.12	34.24	<0.001
Molar tipping (°)	0.51±0.05	0.31±0.05	10.95	<0.001
Inter-molar angle (°)	1.62±0.17	2.70±0.29	12.44	<0.001

[Table/Fig-9]: Comparison of dentoalveolar changes in cleft lip and palate patients treated with Quad Helix (QH) and Sawangi Flexiforce Expander (SFE) using the Independent Sample t-test.
p-value derived from an Independent's Sample t-test; Significance level set at p<0.05; IC-W: Inter-canine width; IM-W: Inter-molar width

Statistical analysis revealed the following:

- The mean increase in inter-canine width was significantly greater in the SFE group (4.57±0.10 mm) compared to the QH group (3.28±0.11 mm), indicating more effective anterior expansion (p-value <0.0001).
- Inter-molar width increased by 5.10±0.12 mm in the SFE group and 3.47±0.14 mm in the QH group, a statistically significant difference (p-value <0.001) favoring SFE for posterior arch development.
- The molar tipping change was significantly higher in the QH group (0.51±0.05°) than in the SFE group (0.31±0.05°), indicating better control over tooth inclination with SFE (p-value <0.001).
- The change in inter-molar angle (molar rotation) was also significantly greater in the SFE group (2.70±0.29°) versus the QH group (1.62±0.17°), suggesting that SFE achieved more parallel and bodily expansion (p-value <0.00001).

While molar tipping was greater in the QH group, the inter-molar angle change (molar rotation) was higher in the SFE group. This apparent inverse relationship is due to the different mechanics of the appliances. The QH group exhibited uncontrolled buccal tipping of the molars, resulting in angular displacement but less coordinated posterior expansion.

In contrast, the SFE appliance generated bodily movement of the posterior teeth with better anchorage and force direction control. As a result, both molars moved outward more symmetrically, leading to a greater increase in the inter-molar angle, representing more parallel and bodily expansion, rather than just tipping.

DISCUSSION

Cleft lip and palate patients frequently present with maxillary constriction and posterior crossbites due to disrupted craniofacial development and postsurgical scar formation [11]. If left uncorrected, transverse maxillary deficiency can adversely affect occlusion, speech, aesthetics, and midfacial growth. Orthodontic maxillary expansion during mixed dentition plays a vital role in managing these deficiencies by creating space, improving arch coordination, and facilitating future rehabilitative procedures [8].

Several appliances have been used for slow maxillary expansion, among which the QH is widely accepted due to its simplicity and effectiveness. However, it has limitations in terms of control and the risk of excessive molar tipping [12]. In this context, the SFE, a novel appliance designed to deliver light, continuous, and controlled forces for transverse expansion, was evaluated in the present study.

This study aimed to evaluate and compare the dentoalveolar effects of a novel appliance — the SFE - with the conventional QH appliance in CLP patients aged 7 to 12 years. The results demonstrated that the SFE produced superior outcomes in all measured parameters.

The ease with which palatal expansion was achieved in the current study corroborates the observations of Lilja J et al., [13]. In CLP patients, the palatal suture system is often disrupted, irregular, or absent, which facilitates an orthopaedic response to expansion using the SFE. Other authors have also noted that skeletal resistance in the transverse direction is diminished in cleft palate patients due to the unique anatomical situation in the jaw and palate region [14,15].

The results of the present study were consistent with those reported by da Silva Filho OG et al., who emphasised the importance of appliance design and force characteristics in achieving optimal expansion in CLP cases [16]. The SFE's unique structure, featuring a central helix and posterior loops, may allow for targeted and symmetric expansion, aligning with observations by Jafari A et al., who advocated for differential force systems in complex craniofacial anomalies [17].

The SFE demonstrated significantly greater increases in both inter-canine and inter-molar widths compared to the QH appliance. These findings correlate with the study conducted by Vasant MR et al., suggest that the continuous light forces delivered over extended durations result in more effective and physiologic expansion by producing bodily tooth movement, especially in the presence of scarred palatal tissues often seen in CLP cases [10]. The pattern of expansion observed in the present study was uniform anteroposteriorly. These findings were consistent with the study conducted by Bell RA and LeCompte EJ [18]. This can be attributed to the reduced resistance observed in the treatment group. Additionally, the absence of the mid-palatal suture allows pre-grafting expansion to achieve skeletal segmental movement, although it may lead to an increase in cleft width.

Although some differences were noted in baseline molar tipping and inter-molar angle values between the groups, these may reflect the natural variability seen in CLP patients. As treatment effect was analysed using change from baseline values, the influence of this baseline variation was minimised.

Molar tipping is a known side effect of expansion mechanics, particularly in appliances like the QH, which deliver force primarily through buccal root movement without adequate bodily control [19]. In the present study, the QH group exhibited significantly more molar tipping compared to the SFE group, indicating more controlled and bodily movement in the latter. This result corroborates findings by Figueiredo DSF et al., [20], who emphasised the importance of root control in achieving stable and predictable transverse changes in cleft patients.

Although the QH group demonstrated greater molar tipping, the increase in inter-molar angle was significantly higher in the SFE group. This suggests that the SFE produced more bodily and symmetrical expansion of the maxillary posterior segments, whereas the QH primarily caused uncontrolled buccal tipping with less coordinated molar rotation.

Moreover, the inter-molar angle, which reflects the parallelism and bodily expansion of the maxillary posterior segments, was notably more favourable in the SFE group. This suggests that the SFE appliance minimises buccal flaring and ensures symmetrical arch expansion, a critical factor in cleft management.

The SFE is a custom-fabricated, versatile, and a cost-effective appliance designed specifically for cleft patients. Its simplified stainless-steel framework, which includes anterior and posterior adjustment capabilities, allows individualised treatment planning and biomechanical control. Unlike the QH, which may require frequent reactivation and offers limited force direction control, the SFE delivers light, continuous forces more efficiently. Importantly, it can be fabricated in-house using readily available orthodontic materials, making it particularly suitable for resource-constrained regions like Central India, where access to prefabricated or imported appliances may be limited. This practical and accessible design enhances its clinical utility in cleft care within low-resource environments.

Based on the statistically significant differences observed in inter-canine width, inter-molar width, molar tipping, and inter-molar angle between the two groups, the null hypothesis was rejected, indicating that the SFE and QH appliance produced significantly different dentoalveolar effects in CLP patients.

Limitation(s)

This study has certain limitations that should be acknowledged. Although the sample size was statistically calculated and adequate for comparing the groups, the relatively small number of participants may limit the generalisability of the findings to broader populations. Additionally, the study assessed only short-term dentoalveolar changes; long-term skeletal effects and post-treatment stability were not evaluated. Confounding variables such as cleft severity, oral hygiene, and patient compliance were not controlled, which could have influenced treatment outcomes. Future longitudinal studies with larger and more diverse samples are recommended to evaluate the skeletal responses and broader clinical applicability of the SFE in various cleft subtypes.

CONCLUSION(S)

The present study demonstrated that the SFE is a more effective appliance than the traditional QH in achieving maxillary transverse expansion in patients with unilateral CLP aged 7 to 12 years. The SFE showed significantly greater increases in both inter-canine and inter-molar widths, with notably less molar tipping and more favourable inter-molar angles, indicating better control and more parallel, bodily expansion. Given its light, continuous force delivery, design adaptability, and superior dentoalveolar outcomes, the SFE emerges as a promising and practical alternative for managing maxillary constriction in CLP patients, particularly in resource-constrained settings. These findings support the incorporation of the SFE as a standard slow expansion modality in cleft orthodontic protocols.

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