Journal of Chemical Health Risks
www.jchr.org
JCHR (2024) 14(6), 1078-1094 | ISSN:2251-6727

How do Haas and Hyrax expanders affect the periodontal tissues in patients with Unilateral Cleft Lip and Palate? A Randomized Clinical Trial

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(Received: 16 September 2024 Revised: 11 October 2024 Accepted: 04 November 2024)

KEYWORDS

Randomized clinical trial, Expansion, Haas, Hyrax, Cleft patients, Mixed dentition, Rapid palatal expansion

ABSTRACT:

Aim and Background: This randomized clinical trial was to evaluate periodontal effects of Haas and Hyrax maxillary expanders in patients having unilateral cleft lip and palate.

Methods: Twenty-four patients having posterior crossbite were randomly divided into; Haas group (9.5±1.24) years and Hyrax group (9.7±1.26) years. Pre-treatment radiographs were taken, activation regimen was to open the screw two times in the morning and two times in the evening till overcorrection of the crossbite. Retention phase was 6 months then post-retention radiographs were taken. Eligibility criteria included patients having erupted upper first molars, periodontally sound teeth and didn't undergo any previous orthodontic intervention. The outcome was to assess periodontal effects of Haas and Hyrax appliances. Random sequence table was done with 1:1 allocation ratio. Blinding was possible for the statistician and the outcome assessor.

Results: Non-significant thinning of the buccal plate of bone of the anchoring teeth occurred with Haas appliance. Hyrax appliance caused significant decrease in the thickness of mesio-buccal plate of bone of the upper first molar on the non-cleft side by (-0.52± 0.55) (P=0.01), with confidence interval (-0.92, -0.13). There were no significant changes in neither palatal bone plate thickness of the anchoring teeth nor alveolar bone crest level in both appliances. There wasn't any serious harm with either appliances.

Conclusions: Both appliances were considered safe on the periodontal tissues. The periodontal side effects were not clinically significant in the Hyrax appliance.

Journal of Chemical Health Risks
www.jchr.org
JCHR (2024) 14(6), 1078-1094 | ISSN:2251-6727

Clinical significance: The non-significant increase in palatal bone plate thickness in both groups indicated that 6 months-period is not a sufficient retention period that permits compensatory palatal bone deposition after rapid palatal expansion in patients with cleft.

Registration: Trial registration was done at ClinicalTrials.gov with registration number XXXX. Protocol registration was done at the Evidence Based Center at the Faculty of dentistry in the University.

Funding: self-funded

Introduction:

The congenital anomaly that is most common in the orofacial region is cleft lip and palate deformity. For a newborn with a cleft lip and palate, proper management requires interdisciplinary treatment from various specialties, such as maxillofacial surgery, orthodontics, pedodontics, plastic surgery, otolaryngology, genetics, orthodontics, prosthodontics, psychology, and others.[1]

When it comes to treating patients with cleft lip and palate, orthodontists play a crucial role. This role starts with infant orthopedics, facial orthopedics, maxillary expansion, fixed orthodontic treatment, or, in later phases, combined orthodontic surgical treatment. [2]

Maxillary expansion is required to expand the arch, eliminate cross-bites, and align collapsed segments in order to prepare the arch for an alveolar bone graft.. [3]

For gaining an efficient expansion in patients with clefts; palatal expansion should be performed with least periodontal side effects. According to Garib et al (2006)[4]; expanders which are tooth-borne cause forces concentration at the dentoalveolar area, this can cause more periodontal iatrogenic side-effects than expanders that are tooth-tissue-borne which cause forces distribution between the palatal surface and the anchorage teeth.

Surprisingly, the orthodontic literature is not able to find the safest expander with least periodontal side effects due to the lack of high-quality studies about the periodontal effects of these expanders. Very few randomized clinical trials were conducted to study the effect of different palatal expansion appliances in patients with clefts. Most of the found studies [5–8] failed to reach valid results that can be used to build a clinical decision about the periodontal side effects of rapid palatal expansion appliances in patients with cleft lip and palate.

Accordingly, this randomized clinical trial aimed to investigate the periodontal effects of two of the most common rapid maxillary expanders; Haas and Hyrax expanders in patients having unilateral cleft lip and palate at the mixed dentition stage.

Material and Methods:

Trial design and registration:

Randomized clinical trial designed with parallel-groups (allocation ratio is 1:1). The study protocol registration was done on clinicaltrials.gov with given registration number XXXX.

Participants, eligibility criteria, and settings:

Participants recruitment was at the orthodontic clinic of the department of Orthodontics. This study was self-funded. The ethics committee of the institute approved the study. Each included patient signed an informed consent.

Journal of Chemical Health Risks
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JCHR (2024) 14(6), 1078-1094 | ISSN:2251-6727

Inclusion criteria: Patients having unilateral cleft lip and palate, maxillary constriction and posterior crossbite, mixed dentition (8-10 years), permanent upper first molars erupted, teeth are sound periodontally and patient didn't have any previous orthodontic intervention.

Exclusion Criteria: Presence of syndromes, secondary alveolar bone grafting previously done, patients on medications that affect growth and presence of active periodontal disease.

Interventions:

Case history, clinical examination and full diagnostic records were taken for each patient. For both groups, banding(Ortho Organizers bands)was done for upper first permanent molars which were chosen as the anchor teeth.

For the Haas appliance (tooth-tissue borne), adaptation of a stainless-steel metal framework of 1mm wire on palatal surfaces of teeth starting from the upper canines anteriorly to the upper first molars posteriorly. Soldering to bands on the upper first permanent molars was then done. A two-dimensional screw (Leone, regular size) was positioned on the deepest middle part of the palate where acrylic framework was constructed around it using acrylic resin (self-curing Acrostone) extending from the most palatally positioned tooth anteriorly to molars. The acrylic framework was split anteroposteriorly into two halves to allow expansion **(Figures 1,2)**.

For the Hyrax appliance (tooth borne); adaptation of a stainless-steel metal 1mm wire on teeth palatal surfaces starting from the upper canines anteriorly to the upper first molars posteriorly. A Hyrax (Leone ,9 mm) body was located on the middle deepest part of the palate. The stainless-steel wire was soldered to the upper molar bands, the anterior legs and the posterior legs of the hyrax appliance. [9,10] **(Figures 3,4)**

Finishing, polishing of appliances and cementation in patient's mouth with glass ionomer cement (Medicem) was done. The activation regimen followed was to open the screw two times in the morning and two times in the evening. [6–8,11,12]

Patients were followed up weekly till posterior crossbite is corrected. Correction meant contact between the palatal cusp tip of the upper posterior and the buccal cusp tip of the lower posterior teeth. The expander then was left as a retentive appliance in the patient's mouth after stabilization of the screw with composite resin. The follow up visits of the patients were every month during the period of retention. After six months, patients were sent for the second CBCT after removing the expander. Transpalatal arch was constructed for each patient after removing the expander then referral of the patient for secondary alveolar bone grafting was done. The CBCT machine was with certain specifications: KVP=120, mAs=37.10, acquisition time=17.8 seconds, voxel=0.3, FOV=23*17 where the full face total effective dose was 0.068mSv.

A standardized three-dimensional analysis was performed using Anatomage software version 6.3. Localization of landmarks was determined by using the generated 3 multiplanar projections (sagittal, coronal, axial). The used landmarks, reference lines and planes are shown in **(Table 1).**

Outcomes:

Periodontal changes were assessed using CBCT measurements after 6 months **(Table 2), (Figure 5).**

Sample size calculation:

In a study by De Almeida 2017 [13], each group had normally distributed response with standard deviation 0.76. If the true difference between both groups is 1 regarding alveolar crest level, 10 subjects per group will be included for being able to reject the null hypothesis

Journal of Chemical Health Risks
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JCHR (2024) 14(6), 1078-1094 | ISSN:2251-6727

that the population means of both groups are equal with probability (power) 0.8 and 0.05 significance level. To counteract attrition bias, there was an increase in the sample to twelve patients in each group. PS calculator software was used to calculate the sample size.

Interim analyses and stopping guidelines:

Not applied.

Randomization:

Randomization followed the steps of sequence generation, allocation concealment and implementation. A random sequence table was computer generated in allocation ratio 1:1 where dividing patients into two groups was done before the study started. The numbers were written on small pieces of paper and kept in well-sealed envelopes. Upon patient recruitment, each patient picked an envelope donating his/her allocation number in any of the two groups.

Blinding:

Blinding to the operator and patients was not applicable because of the nature of the study. The outcome assessor and the data analyst were blinded.

Statistical analysis:

This was done using SPSS 20®, Graph Pad Prism® and Microsoft Excel 2016. Quantitative variables description is done using the Mean, Standard Deviation (SD), and confidence interval 95% of the mean. To test normality of all quantitative variables; Shapiro-Wilk test and Kolmogorov Normality test were used to decide the suitable parametric and non-parametric tests that will be used. These tests revealed that all data originated from normal distribution. Comparison between pre and post measurements in each group was done by paired sample t test. Comparing the difference between two groups was done by independent samples t test. Dahlberg error (DE), relative Dahlberg error (RDE) and Concordance Correlation Coefficient (CCC) tests were used to test the reliability analysis for intra and inter observer measurements. As CCC value was close to 1.0, this indicated higher reliability of the measurement. Poor agreement was expressed by CCC values below 0.6, fair to good agreement was expressed by values between 0.6 and 0.9, and excellent agreement was expressed by values higher than 0.9. Significance level is determined at $P < 0.05$ (S). All statistical tests were assumed as two tailed tests.

Results:

Patient flow:

Random allocation of twenty-four patients into two groups was done; 12 patients were treated with Haas expander with mean age 9.5±1.24 years, and 12 patients had Hyrax expander with mean age of 9.7±1.26 years **(Figure 6)**. The study's starting date was in March 2020 and it ended in July 2023.

Losses and exclusions after randomization, together with reasons:

Four patients were lost in the follow up visits. In the Haas group, two patients couldn't come in the follow-ups due to long distance from the clinic. In the Hyrax group, two patients faced difficulty in the appliance activation.

Follow-up period:

Time of follow up was 6 months from the day of appliance cementation till removal.

Baseline characteristics:

There was insignificant difference between groups when comparing the age (P=0.72), gender (P=0.32) and side of cleft (P=0.32) **(Table 3).**

Journal of Chemical Health Risks
www.jchr.org
JCHR (2024) 14(6), 1078-1094 | ISSN:2251-6727

Numbers analyzed for each outcome:

Analysis of the results of 10 patients per group was performed. There were no significant differences between the Haas and Hyrax groups at T1 in any of the studied measurements **(Table 4)**. Comparison of the pre and post expansion measurements in each group was performed then comparison between the results of both groups was done. The CCC values indicated excellent agreement for both intra and inter observer readings as values ranged between 0.997 and 1.000.

For the Haas group, there was non-significant change between all pre-treatment and post-treatment measurements including the thickness of buccal plate of bone, thickness of palatal plate of bone and crest level of buccal alveolar bone at upper first permanent molars **(Table 5).**

For the Hyrax group, there was non-significant change between all pre-treatment and post-treatment measurements including the thickness of buccal plate of bone, thickness of palatal plate of bone and crest level of buccal alveolar bone at upper first permanent molars except mesio-buccal bone plate thickness of upper first molar in non-cleft side where there was a significant decrease as P=0.01, by (-0.52± 0.55) mean difference with confidence interval (-0.92,-0.13) (**Table 6)**

When comparing both groups, there was non-significant change between groups in all measurements. (**Table 7)**

Harms:

Palatal inflammation was observed under the acrylic part in most of the patients with the Haas appliance while in some patients, frictional keratosis was observed.

Discussion:

In this randomized clinical trial, comparison between two of the most common rapid maxillary expansion appliances were performed. Previous studies performed to compare different expansion appliances in patients with clefts were either retrospective [10], non-randomized clinical trials [14], randomized clinical trials using digital casts [5–8,15]. Other studies used pre and immediate post expansion CBCTs where the time interval between both exposures was three month or less [9,16,17] which is not accepted according to ALARA principle [18]. Some studies included patients in the permanent dentition while it was proven that mixed dentition is the best age for expansion for maximum orthopedic effects[19].

It's needed to differentiate the periodontal effect of rapid palatal expansion in the mixed dentition from the periodontal effect observed in the permanent dentition and that's why we investigated this point in the current study.

Cone beam computed tomography in the current study was taken with certain specifications according to Wood et al., (2013)[20] who concluded that for accurate assessment of buccal bone thickness, voxel size smaller than or equal to 0.3 mm is needed. Accordingly, accuracy in the periodontal measurements in the present study was expected. The second CBCT was taken without the appliance in place to ensure accurate measurements where CBCT examinations taken at T2 with the maxillary expander in patient's mouth, could result in inaccurate measurements because of the presence of metallic molar bands [21,22].

The current study can be considered the first randomized clinical trial to compare periodontal side effects of two of the most popular rapid palatal expansion appliances; Haas and Hyrax in unilateral cleft lip and palate patients

Journal of Chemical Health Risks
www.jchr.org
JCHR (2024) 14(6), 1078-1094 | ISSN:2251-6727

in the mixed dentition stage using CBCTs pre-expansion and post retention with the activation regimen two turns twice per day.

Periodontal effects of expansion are of great importance. It's important to study the effect of expansion on buccal and palatal bone thickness to determine the safety of the appliance. Previous studies were conducted on non-cleft patients to study the periodontal side effects of different maxillary expanders while studies in patients with cleft lip and palate were scarce. Garib et al., (2006)[4] evaluated the periodontal changes after rapid palatal expansion in non-cleft patients using CBCT before expansion and after a period of retention of 3-months. It was concluded that rapid palatal expansion resulted in reduction of the thickness of buccal plate of bone of anchor teeth by 0.6-0.9 mm and an increase in the thickness of the lingual plate of bone by 0.8-1.3 mm. This indicates that retention time should be greater than 3 months for proper recovery of lingual and buccal bone plate thickness. In 2014, Garib et al.,[23] also evaluated the immediate changes in the bone plates buccally and lingually after rapid palatal expansion in the early mixed dentition, by comparing computed tomography taken before and 30 days after expansion when the period of activation of the screw ended. It was found that after rapid maxillary expansion, no immediate undesirable periodontal effects on bony tissues occurred.

Ballanti et al.,(2009)[24] evaluated the periodontal effects of rapid palatal expansion using computed tomography (CT) in non-cleft patients six months after expansion. It was found that buccal bone reduction occurred but no compensating deposition of bone on the lingual side was observed. However, there wasn't any attachment loss, dehiscence, fenestration, or permanent harm to the periodontal or to the bone of supporting teeth was observed.

In addition, in a retrospective study [25] the periodontal effects of rapid palatal expansion on the long-term were investigated by CBCT in non-cleft patients obtained after finishing complete orthodontic treatment. It was concluded that non-significant reduction of buccal bone occurred. In a systematic review of literature [26], the periodontal effects of rapid palatal expansion were investigated using (CBCT). In all the included studies, there was significant decrease in thickness of buccal bone and level of marginal bone in anchor teeth. It was said that decrease of alveolar buccal bone at first molars level was less than 1 mm in all the studies in this systematic review except one study [22] which was more than 1 mm. The reason is that this study reported a rate of activation similar to slow maxillary expansion. That's why it was suggested that this expansion rate caused more thinning of buccal bone than rapid palatal expansion.

In the current study, the periodontal measurements for the Haas group revealed a non-significant change between all pre-treatment and post-treatment measurements. For the Hyrax group; there was also a non-significant change between all pre and post-treatment measurements except the mesio-buccal bone plate thickness of the upper first molar on the non-cleft side where there was a significant decrease in post-treatment measurements. In accordance with the current results, De Almeida et al., (2017)[13] compared pre and post expansion CBCTs in patients with bilateral cleft lip and palate after rapid palatal expansion with Haas and Hyrax appliances and stated that there was a significant decreases of the thickness of buccal plate of bone, however, the thinning was less than 1 mm and had no clinical significance. This agrees with the current study, where with Hyrax appliance the mean thinning in the thickness of buccal plate of bone was about 0.5mm. No

other studies were conducted in patients with cleft lip and palate to investigate the periodontal side effects of palatal expansion in these patients.

In the current study, the absence of significant formation of palatal compensatory bone six months after expansion indicates the need for more than six-month retention period after palatal expansion in patients with cleft lip and palate to permit palatal bone formation.

The periodontal effect of rapid palatal expanders in patients with cleft lip and palate seems different from their effect in non-cleft patients which can be due to the reason that the median palatine suture is absent in these patients which makes expansion easier with less force and less detrimental effect on the periodontal tissues.

Short follow up period is a limitation in the present study. Limited generalizability of the results can be expected because this research was done by one practitioner in one center. In addition, future long-term studies of the effect of expanders on periodontal tissues in patients with cleft are recommended.

Conclusions:

Within the limitations of the present study, it could be concluded that:

1- Non-significant decrease in the thickness of buccal plate of bone occurred with Haas appliance.

2- The decrease in mesio-buccal bone plate thickness of the upper first molar on the non-cleft side with the Hyrax appliance was 0.5mm which is not clinically significant.

3-Non-significant increase in palatal bone plate thickness occurred with both appliances.

4- Non-significant changes in alveolar bone crest level occurred with both appliances.

Clinical Significance:

1-Haas and Hyrax appliances were considered safe on the periodontal tissues in patients with unilateral cleft lip and palate.

2-The non-significant increase in palatal bone plate thickness with both appliances indicated a retention period of more than 6 months is needed after maxillary expansion in patients with cleft.

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Table 1: Skeletal and dental landmarks and planes used on CBCT

No.	**Landmark/Abb.**	Definition
1	**Nasion/ N**	The most anterior and midpoint of the fronto-nasal suture.
2	**Sella/ S**	The center point of the pituitary fossa in the middle cranial fossa.
3	**Orbitale/ Or R/L**	The most inferior point of each infra-orbital rim.
4	**Porion/ Po R/L.**	The most outer and superior bony points of the external auditory meatus.
5	**Menton/ Me**	The most inferior midpoint of the chin on the outline of the mandibular symphysis.
6	**Gonion/ Go, R/L**	The right and the left midpoint on the angles of the mandible, halfway between the corpus and ramus.
7	**Inter-Gonion/ InGo**	Midway between right and left gonions, estimated by the software.

Journal of Chemical Health Risks
www.jchr.org
JCHR (2024) 14(6), 1078-1094 | ISSN:2251-6727

8	**Mesiobuccal alveolar bone crest /MBAC (R/L)**	Mesiobuccal alveolar bone crest point on right and left sides.
9	**U6 MB root R/L**	The point of MB root of upper right and left first molars opposite to cementoenamel junction.
10	**U6 DB root R/L**	The point of DB root of upper right and left first molars opposite to cementoenamel junction.
11	**U6 P root R/L**	The point of palatal root of upper right and left first molars opposite to cementoenamel junction.
12	**U6 MB tip, R/L**	Cusp tip of the mesio-buccal cusp of the upper right and left first molars.
13	**U6 MB alv bone, R/L**	Most buccal point of buccal alveolar bone infront of the MB root of upper first molar at the level of the cementoenamel junction.
14	**U6 DB alv bone, R/L**	Most buccal point of buccal alveolar bone infront of the DB root of upper first molar at the level of the cementoenamel junction.
15	**U6 P alv bone, R/L**	Most palatal point of palatal alveolar bone infront of the palatal root of upper first molar at the level of the cementoenamel junction.
Plane/Line		Definitions
Frankfort Horizontal plane /FHP		Plane defined by 3 landmarks: right and left orbitale, right porion.
Midsagittal plane/MSP		Plane through sella and nasion and perpendicular to the Frankfort Horizontal Plane.
Mandibular plane/MP		A plane that passes through the menton and both gonions (right and left).
Anterior cranial base line/SN		The line passing through the sella and the nasion points.

Journal of Chemical Health Risks
www.jchr.org
JCHR (2024) 14(6), 1078-1094 | ISSN:2251-6727

Table 2: Measurements on CBCT

Periodontal			
1	Buccal alveolar bone crest level	**ACL**	The vertical distance between the mesiobuccal cusp tip of the first permanent molar and the buccal alveolar bone crest at the mesiobuccal cusp.
2	Mesio-buccal bone plate thickness	**BBPT(MB)**	Buccal bone plate thickness measured from the most buccal point of the buccal alveolar bone plate opposite to the cementoenamel junction to the mesiobuccal roots of the first right and left permanent molars.
3	Disto-buccal bone plate thickness	**BBPT(DB)**	Buccal bone plate thickness measured from the most buccal point of the buccal alveolar bone plate opposite to the cementoenamel junction to the distobuccal roots of the first right and left permanent molars.
4	Lingual bone plate thickness	**LBPT**	Lingual bone plate thickness measured from the most palatal point of the lingual alveolar bone plate opposite to the cementoenamel junction to the palatal root of the first permanent molars.

Table 3: Baseline characteristics for both groups

		Group		**P value**
		Haas group	Hyrax group	
Age		9.5±1.24	9.7±1.26	0.72
Gender	Male	8 (80%)	6 (60%)	0.32
	Female	2 (20%)	4 (40%)	
Side of cleft	Right	4 (40%)	2 (20%)	0.32
	Left	6 (60%)	8 (80%)	

**Significant difference as P<0.05.*

Table 4: Intergroup comparability at T1

	Haas group		**Hyrax group**		**Mean Difference**	**Std. Error Difference**	**95% Confidence Interval of the Difference**		**P value**
	Mean	Standard Deviation	Mean	Standard Deviation			Lower	Upper	

Journal of Chemical Health Risks
www.jchr.org
JCHR (2024) 14(6), 1078-1094 | ISSN:2251-6727

ACL R	7.79	0.85	7.73	1.09	-0.06	0.44	-0.98	0.86	0.894
ACL L	7.49	1.55	7.10	1.33	-0.39	0.65	-1.74	0.97	0.559
BBPT MB R	1.71	0.53	1.82	0.79	0.11	0.301	-0.52	0.74	0.71
BBPT MB L	1.98	0.74	1.51	0.59	-0.47	0.30	-1.10	0.16	0.135
BBPT DB R	1.89	0.77	1.61	0.87	-0.29	0.37	-1.06	0.48	0.441
BBPT DB L	2.08	0.8	2.07	0.96	-0.01	0.39	-0.84	0.82	0.98
LBPT R	1.67	0.65	1.43	0.59	-0.24	0.27	-0.82	0.34	0.39
LBPT L	1.91	0.81	1.65	0.51	-0.26	0.30	-0.90	0.37	0.399

**Significant difference as P<0.05.*

Table 5: Mean and standard deviation of pre and post expansion periodontal measurements of group 1 Haas group, and comparison between them using Paired t test:

	Haas group				Paired Differences					P value
	Pre		Post		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		
	Mean	Standard Deviation	Mean	Standard Deviation				Lower	Upper	
ACL R	7.79	0.85	7.63	1.38	-0.16	0.93	0.29	-0.83	0.50	0.594
ACL L	7.49	1.55	7.85	1.27	0.36	1.43	0.45	-0.66	1.38	0.444
BBPT MB R	1.71	0.53	1.52	0.23	-0.19	0.61	0.19	-0.24	0.63	0.344
BBPT MB L	1.98	0.74	1.51	1.51	-0.47	2.11	0.67	-1.97	1.04	0.502
BBPT DB R	1.89	0.77	1.80	0.75	-0.09	0.96	0.30	-0.78	0.59	0.770
BBPT DB L	2.08	0.80	1.84	0.59	-0.23	1.07	0.34	-0.53	0.99	0.511
LBPT R	1.67	0.65	1.86	0.75	0.20	1.01	0.32	-0.52	0.92	0.553
LBPT L	1.91	0.81	2.02	0.75	0.11	1.32	0.42	-0.83	1.05	0.803

**Significant difference as P<0.05.*

Journal of Chemical Health Risks
www.jchr.org
JCHR (2024) 14(6), 1078-1094 | ISSN:2251-6727

Table 6: Mean and standard deviation of pre and post expansion periodontal measurements of group 2 Hyrax group, and comparison between them using Paired t test:

	Hyrax group				Paired Differences					P value
	Pre		Post		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		
	Mean	Standard Deviation	Mean	Standard Deviation				Lower	Upper	
ACL R	7.73	1.09	7.46	1.18	-0.27	1.11	0.35	-1.06	0.52	0.459
ACL L	7.10	1.33	7.63	1.20	0.53	1.34	0.43	-0.43	1.49	0.243
BBPT MB R	1.82	0.79	1.30	0.47	-0.52	0.55	0.17	-0.92	-0.13	0.015[a]
BBPT MB L	1.51	0.59	2.22	0.96	0.72	1.13	0.36	-0.09	1.52	0.076
BBPT DB R	1.61	0.87	2.09	0.77	0.48	0.82	0.26	-0.11	1.07	0.099
BBPT DB L	2.07	0.96	2.03	0.81	-0.04	1.25	0.39	-0.94	0.85	0.918
LBPT R	1.43	0.59	1.56	0.58	0.13	0.97	0.31	-0.82	0.56	0.679
LBPT L	1.65	0.51	1.89	0.63	0.24	0.75	0.24	-0.29	0.77	0.337

[a] *Significant difference as P<0.05.*

Table 7: Mean and standard deviation of difference between pre and post expansion periodontal measurements of group 1 Haas and group 2 Hyrax appliance group, and comparison between them using Independent t test:

	Haas group		Hyrax group		Difference				
	Mean	Std. Deviation	Mean	Std. Deviation	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference		P value
							Lower	Upper	
ACL R	-0.16	0.93	-0.27	1.11	0.11	0.46	-0.85	1.07	0.814

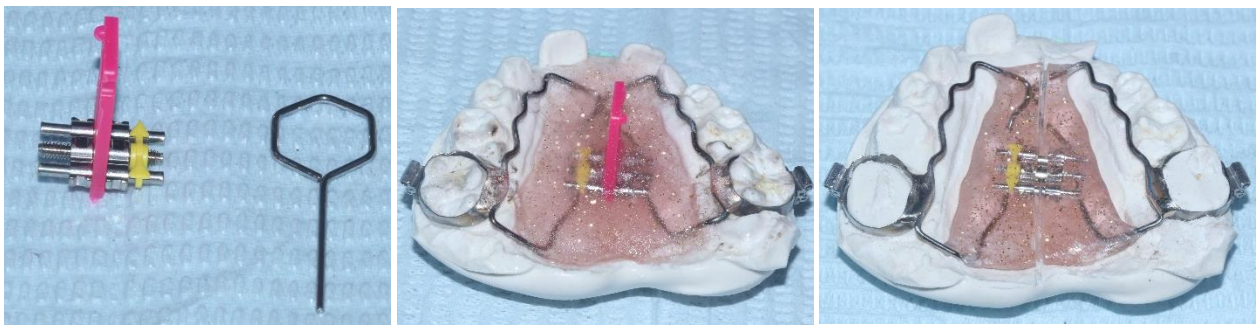
Journal of Chemical Health Risks
www.jchr.org
JCHR (2024) 14(6), 1078-1094 | ISSN:2251-6727

ACL L	0.36	1.43	0.53	1.34	0.17	0.62	-1.47	1.13	0.787
BBPT MB R	-0.19	0.61	-0.52	0.55	0.33	0.25	-0.87	0.21	0.22
BBPT MB L	-0.47	2.11	0.72	1.13	1.18	0.76	-2.77	0.41	0.136
BBPT DB R	-0.09	0.96	0.48	0.82	0.57	0.40	-1.41	0.27	0.170
BBPT DB L	-0.23	1.07	-0.04	1.25	0.19	0.52	-0.91	1.28	0.71
LBPT R	0.20	1.01	0.13	0.97	0.07	0.44	-1.00	0.87	0.87
LBPT L	0.11	1.32	0.24	0.75	-0.13	0.48	-1.14	0.87	0.784

**Significant difference as P<0.05.*

Figures:

A B C



D E F

Fig.1: Steps of Haas expander construction (A -F)

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www.jchr.org
JCHR (2024) 14(6), 1078-1094 | ISSN:2251-6727

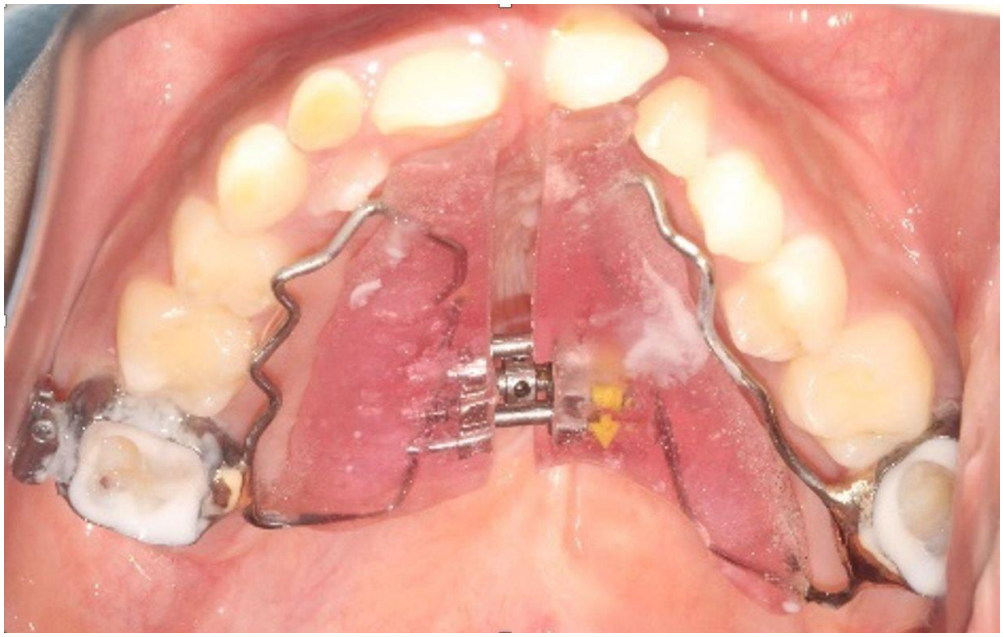
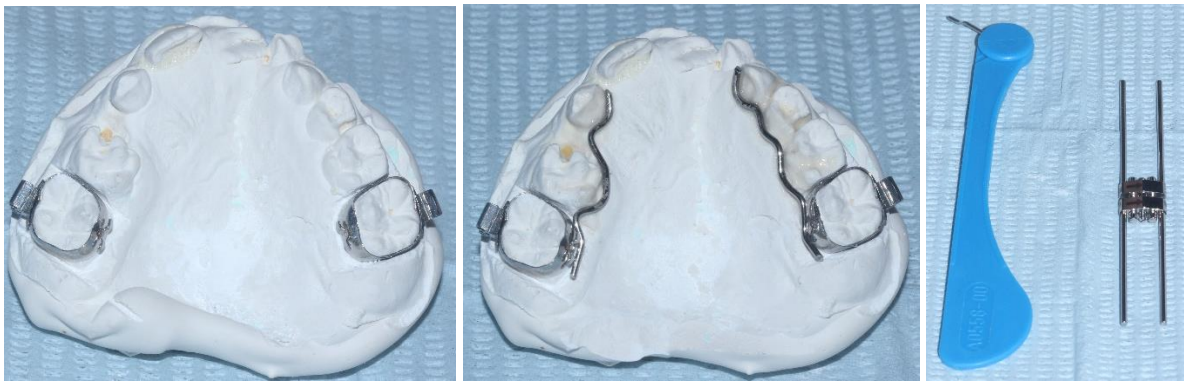
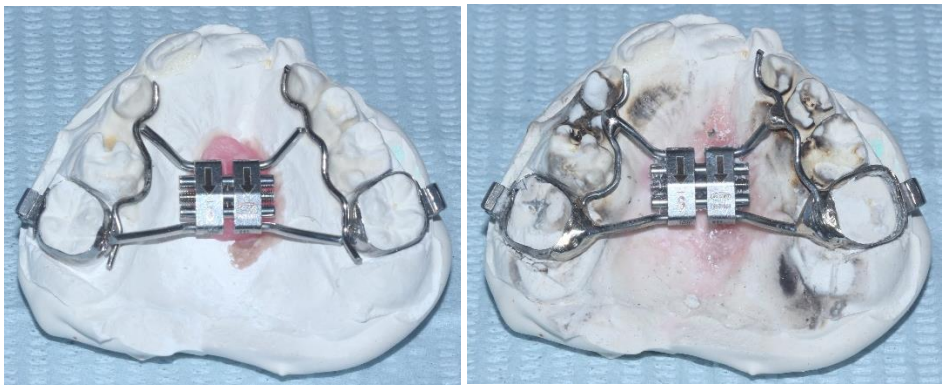


Fig.2: Intraoral view of Haas expander



A B C



D E

Fig.3: Steps of Hyrax expander construction (A -E)

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JCHR (2024) 14(6), 1078-1094 | ISSN:2251-6727

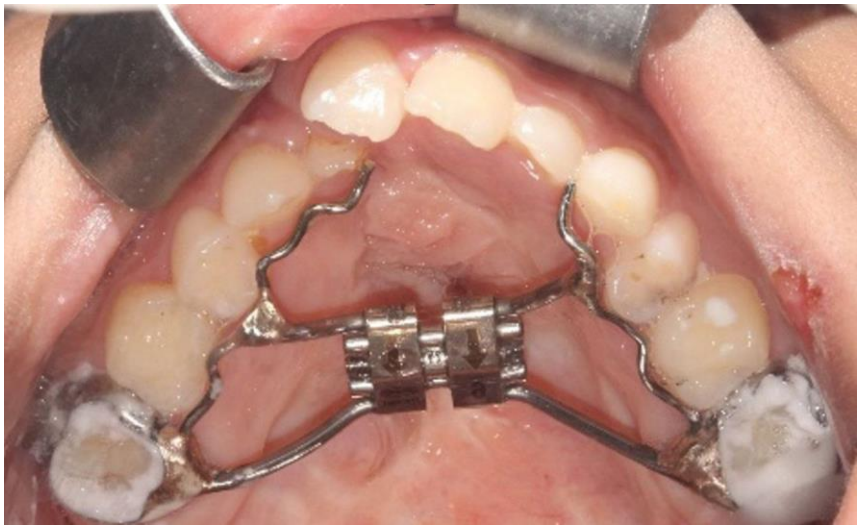

Fig.4: Intraoral view of Hyrax expander

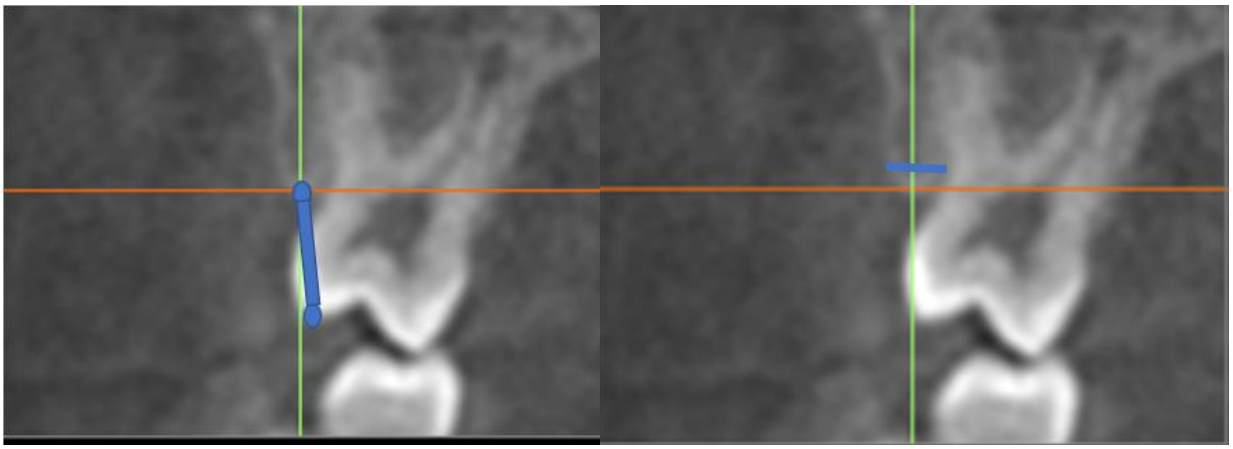

Fig.5: A) Buccal alveolar bone crest level B) Buccal bone plate thickness

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JCHR (2024) 14(6), 1078-1094 | ISSN:2251-6727

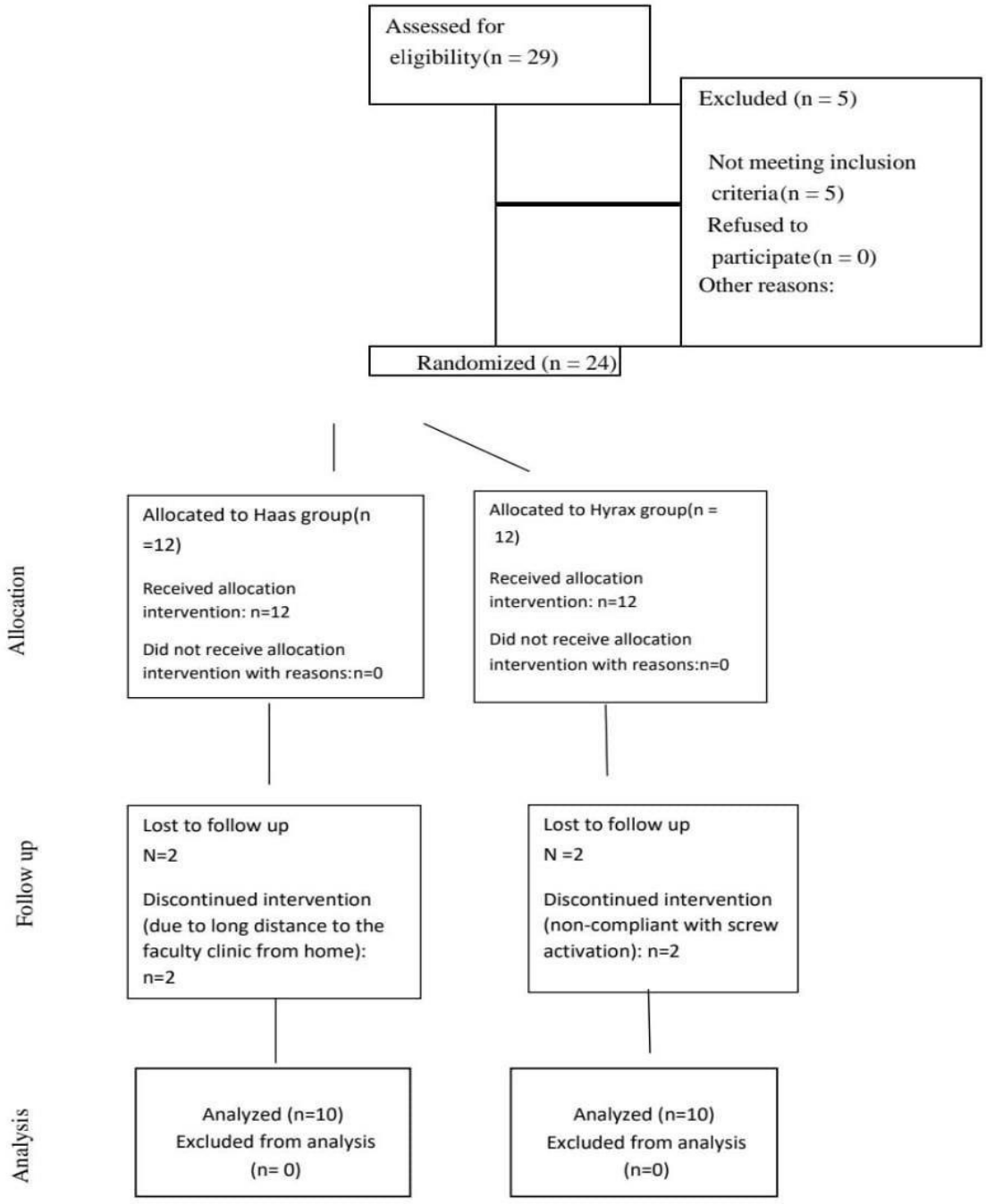

Fig.6: CONSORT 2010 flow diagram