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# Assessment of Pre-surgical Molding Appliances in Unilateral Cleft Lip and Palate Patient (Clinical Study)

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**ABSTRACT**

**Aim:** The aim of this study is to assess the efficiency of molding effects of pre-activated appliance developed in this study in comparison with previous appliance developed by Da Silveira et al 2003.
**Materials and Methods:** The study was carried out on 24 participants, 12 per group, Non-syndromic complete unilateral cleft lip and palate, newborn to1month infants. The working casts of both groups were scanned using CAD/CAM System and the 3D object analyzed using Autodesk Inventor Fusion. Six measurements were assessed involved cleft (widths&size), incisal point deviation, arch width (anterior &posterior) both mid and posterior palatal heights and Total arch depth. Statistical Comparison was determined using SPSS program at $p \leq 0.05$.
**Results:** The descriptive analyses and comparisons of treated samples with Da Silveira et al versus Pre-activated technique revealed significant differences for molding effects of all measurements except for (inter-tuberosity distance) at $p \leq 0.05$.
**Conclusions:** Modifying the molding plate with using Pre-activated appliance may reduce the pre-surgical treatment visits and may improve molding effects.
**Key Words:** cleft lip, cleft palate, molding appliances.

## INTRODUCTION

Cleft lip with cleft palate is the most common presentation in most racial groups.[1,2.]

Cleft lip and palate comprised 65 per cent of all anomalies affecting the head and neck.[3.]Cleft lip and palate presents many features at different levels of severity and need multidisciplinary approach [4].

The causes of Cleft lip and palate are unknown. However, it is widely accepted that the causes of cleft are multifactorial. [5,6.]Unilateral clefts account for nearly 80 percent of all clefts seen, while bilateral clefts account for the remaining 20 percent.[7.]

Unilateral cleft lips are with cleft palate 70% of the time. [8.]Persons with complete unilateral cleft lip and palate UCLP demonstrate the combined effects of the presence of a cleft of the lip and alveolusthat is the pre-maxilla on the non-cleft side being rotated ventrally) and the presence of a cleft palate where the maxilla and mandible are relatively retrusive accompanied by a steep mandibular plane.[9,10.]

For the infant, the main problem is feeding.[11,12.]The concept of pre-surgical orthopedic was introduced at University of Glasgow byKerr McNeil in 1954 as an adjunctive neonatal therapyaiming at nonsurgical reduction of the size of the alveolar cleft. [13.]

Clinical goals ofmolding appliance include alignment and approximation of the alveolar segments.[14,15,16,17,18.]The use of pre-surgicalorthopedics has eliminated theneed for preliminary lip adhesion surgery at most centers.[19.]

Therefore the aim of this study is to assess the efficiency of pre-activated appliance developed in this study in comparison with molding effect of Da Silveira et al.,2003 appliance.[20.]

## MATERIALS AND METHODS

The patient inclusion criteria were: Only the Non-syndromic babies of complete UCLP infants born at term and the patient's family agreed that the patient would undergo moldingtherapy. Newborn to 1 month infants without any

surgical intervention; while the patient exclusion criteria were: Other congenital malformations (except for syndactily) or systemic diseases;[21.] Patients with the life threatening syndromes respiratory difficulty and Simonart's bands are not considered for the pre-surgical treatment. [22.23.]

Once infants were identified as eligible for inclusion, patientswere randomly allocated into two treatment groups (A & B), each group will receive different modality of treatment appliance, and therefore group A will receive Da Silveira et al appliance while group B will receive pre-activated appliance, and this according to the sequence of attendance to the P.O.P department of college of dentistry at Mosul university and it was continuedtill the required size of sample wasachieved. The number of participants was calculated at 12 per group; therefore the total number of participants was 24.The age of initiating molding varied from 10 to 52 days (mean, 31 days). The treatment duration was from 88 to 130 days (mean, 109 days). [24]The endpoint for the treatment of patients when the anterior alveolar width was less than 3 mm, which was around 4 months of age.[17]

Several steps involved in the fabrication of the molding appliances which include ImpressionMaking and Appliance fabrication.For an accurate impression proper patient and dentist position are vital. It was indicated to use an upside downin the mother'slap in such a way that the infant's neck can be extended forthe maximum exposure for the operator. [25, 26, 27.]Perforated impression trays are chosen from a collection of variously sized trays made from previously obtained maxillary dental casts, as in figure.1. The impression material used for the intraoral cleft defect was heavy bodied silicone elastomeric impression (Protesil, Italy), as in figure.1. Two casts are poured from the impression. The first cast used as a study cast for pre-orthopedic 3D assessment, while the second copy of cast used as a working cast for appliance fabrication.[26.]

The appliance fabrication involve wax sheet is inserted to fill in the cleft areas between thealveolar segments to allow for alveolar molding and approximation of segments.The palatal plate is made of self-cure acrylic resin; the modified nasal stent is then added to theplate.The framework of the stent is a .07 mm stainlesssteel orthodontic wire. It is incorporated into theplate at the site of the cleft before curing. It is bent toconform to the alar defect. Before insertion, the appliance was well finished and polished and ready to be inserted inside patient mouth.

At delivery, the appliance is fit to the upperarch; a retentive loop is placed at the distal end of thewire; and a small piece of self-cured resin is added to the tip of the nasal stent in a ball shape. as in figure.1.

Once the appliance is adjusted, the parentsare given detailed instructions for placement, removal, and care of theappliance. The applianceis retained with BONYPLUS 12 Hour Special Fixative Denture Adhesive cream (Switzerland).The patient is followed weekly for adjustments. The nasal and alveolar moldings are initiated at the same time. Corrections are made to improve comfort, and guide alveolar segments' reposition, as treatment progresses, modifications to the nasal stent are necessary andeasily achieved by bending the wire with orthodonticpliers and by adding more self-cured resin to its tip.

Modificationsfor Group A that will receive Da Silveira., et al appliance follow the protocol described by Grayson et al[27], this is achieved through the selective removalof acrylic from the region into which one desires thealveolar bone segments to move. At the same time, soft dentureliner (BONYPLUS SMILE WITH CONFIDENCE™Denture Relining Cushion Stabilizer, Switzerland)is added to the appliance in the region from whichone desires the alveolar bone to be reduced, as in figure.1

Group B will receive Pre-activated molding appliance, the guiding principle in the idea of this modification design was frequent cast modifications were made fortnightly at the same areas on which soft denture liner was planned to be applied clinically as in technique of Da Silveira et al 2003[20] i.e. the activation of appliance was made in lab (indirect activation) instead of direct clinical activation with soft denture liner and so called previously activated appliance that abbreviated as (Pre-activated) which in turn save dental chair side time and may be more comfortable to both patients and their parents.

The palatal plate and the stent were made as done with Da Silveira., et al technique. The applianceis also retained with denture paste adhesive.The patient is followed fortnightly for insertion of new appliance. The fabrication of new appliance involve certain changes made on working cast where any region of the required surface to be moved in the opposite direction, a layer of 1mm thickness of stone cast is removed to allow for acrylic plate to be seated actively on this region and try to mold it the opposite direction, therefore when the greater segment planned to be moved in inward palatal direction, the reduction on cast was made on facial surface of that region using low speed straight hand piece with1mm bur'sdiameter, this bur must work parallel to the surface to be reduced.

The bur firstly made many depth grooves of 1mm in depth on region to be modified then the areas in between were removed keeping the configuration of that area as near the origin as possible. After that a new appliance was made in

the same manner for both palatal plate and acrylic stent.Such cast modifications were frequently made fortnightly and so a series of appliances with new activation were made and ready to be worn at regular scheduled time which mostly fortnightly and depending on patient's response and compliance, as in figure.2. The appliance is worn continuously except for cleaning after feeding until cleft lip surgery is performed, usually at age 3 or 4months,.

The two achieved study casts for each case (pre and post-molding casts) were scanned by Identica scanner of Ceracube® Dental CAD/CAM System (MEDIT, South Korea) and processed into a three dimensional digital object saved in STL format and then analyzed using software program known as Autodesk Inventor Fusion 2013, as in figure.3.

In this study, the measurements of dimensions of the upper arch of unilateral cleft cases were performed utilizing previously described reference points [28-,33]as the followings: I= incisal point, on the crest of the ridge on the line drawn from the labial frenum to the incisive papilla;P = pre-maxillary margin of cleft, on the continuation of the line marking the crest of the ridge. L= lesser segment margin of cleft, on the continuation of the line marking the crest of the ridge; C, C' = canine points, Point at which the lateral sulcus crosses the crest of the ridge; T, T' =(inter-tuberositypoints), at the junction of the crest of the ridge with theoutline of the tuberosity;F, F'=Mid-cleft margin, Intersection of a line connecting canine points to the gingival groove points and the mid-cleft margin on the greater or lesser segment respectively.G, G'=Posterior cleft margin, Intersection of a line joining the tuberosity points and posterior cleft margin on the greater and lesser segment respectively, as in figure.3. Also X point, halfway along the distance C-C' line; FMF' point: midpoint of line joining FF'; GMG' Point, Constructed reference points: midpoint of line joining GG'. Finally M point was constructed halfway along the distanceT–T'.

**The measurements involved the followings:**

**A. Cleft Dimensions which include:**

a) Anterior cleft width (distance P-L). [10]
b) Mid-cleft width (distance F-F') [33.]
c) Posterior cleft width (distance G-G'). [33,34.]
d) **Cleft size**:[35]
   1. A + B = palatal area;
   2. C = cleft area; ;
   3. A + B + C = total palatal area; ;

   C x100/A + B + C = cleft size. ;

**B. The Incisal Point Deviation:** I-YM: horizontal dimension from I point to YM-axis to. [36.]
YM-axis: is a constructed antero-posterior plane were passing perpendicular on T-T' plane at M point.

C. **Assessment of Arch Widths:**
   1. Anterior arch width C-C' [10]
   2. Posterior arch width at tubercles T-T'. [10]

**D. Assessment of Total arch depth:** IPr2 distance.[10]

**E. Assessment of Palatal Heights:**
A triaxial reference system was defined by an x-y plane containing the bilateral tuberosity points and the incisal point, where (x plane: line connected T-T' points) and (y plane: line pass through I point and Pr2 point). [10]

1. Mid-palatal height (distance FMF' - x-y plane)* [33.]
2. Posterior palatal height (distance GMG'- x-y plane) [33.]

The comparisons between two samples within each age group or between groups were determined using SPSS program and by Students (t-test) at $p \leq 0.05$ level of significance.

## RESULTS

The descriptive analysesof cleft widths, cleft size,incisal point deviation, anterior arch width, posterior arch width, both mid and posterior palatal heights and Total arch depth for Da Silveira et al technique (before and after molding) are listed in table1.In addition to results of t-test analyses of before versus after molding measurements which revealed significant differences of molding effects for all measurements except for (C-C and T-T). Table 2 listed the descriptive analysesof these measurements for Pre-activated technique (before and after molding). In addition to results of t-test analyses of before versus after molding measurements which revealed significant differences of molding effects for all measurements except for (C-C,T-Tand IPr2).

Table 3 revealed comparisons of treated samples with Da Silveira et alversus Pre-activated techniques; where significant differences for molding effects were shown for all measurements except for (T-T), such results revealed significant improvements of treated cases withPre-activated techniques in cleft widths, cleft size,incisal point deviation, anterior arch width and both mid and posterior palatal heights.

## DISCUSSION

The findings of treated samples with Da Silveira et al techniques of this study agreed with study of many authors [37,38,39]who mentioned that treatment of an infant with cleft lip, alveolus and palate using a maxillary plate and resulting pre-surgical reduction of cleft width in the alveolus and palate have been approved worldwide for many years and was described several times.The devices allowed continued growth by a passive moldingaction without permitting medial movement of the buccal segments. Such molding effects resulted from gradual alteration of the tissue surface of the acrylic plate; the alveolar segments are gently molded into the desired shape and position by direction of alveolar growth [19].It was confirmed the preventive effect of the palatal appliances on the transverse dimension; the anterior and posterior arch widths before palatoplasty were significantly greater in the group of unilateral CLP patients that received infant orthopedics than in the control sample, although the two groups were very homogeneous at the infant stage regarding these variables. [40]

Pre-activated technique findings show considerable improvement of most measurement, such improvements agreed with the principles of molding that described by Singla and Kaur 2008[41]who said that the primary purpose of the appliance prior to lip closure isnot to proliferate tissue or initiate growth but to guide themaxillary segments into proper spatial position with eachotherand with the mandibular arch. The findings of comparisons among measurements of molding effects of Da Silveira et al versus Pre-activated technique showed significant improvements in the measurements appeared obviously by the Pre-activated technique which may advocate the use of this new appliance for molding effect in the future. In addition, the Pre-activated technique has benefit of reducing number of visits where Da Silveira et al 2003 said that the increased number of visits by the family for adjustments and the added workload of team members involved in the nasal alveolar molding process increase the time burden and cost of early cleft treatment.

## CONCLUSIONS

The modification of molding appliance with Pre-activated technique that developed in this study may improve the molding effects during pre-surgical period and may reduce the numbers of treatment visits, hence this new appliance may approved to be used in the treatment of Unilateral complete cleft lip and palate patients.

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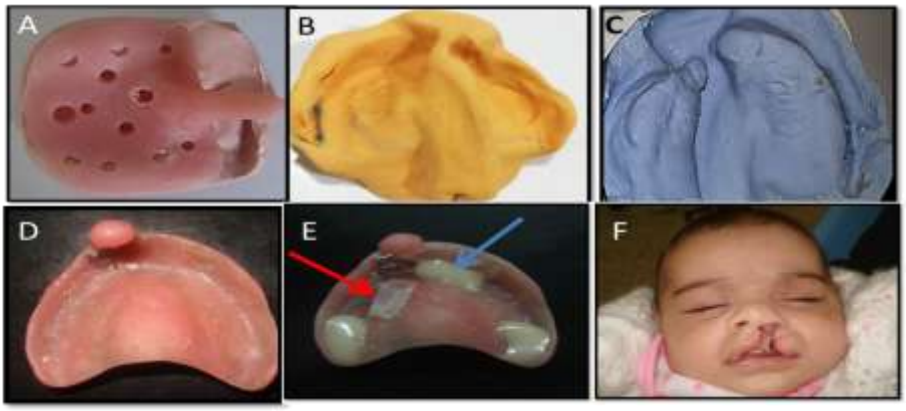


**Fig.1: steps of appliance fabrication; a: special tray made on previous cast; b: impression; c: cast; d: appliance; e: application of soft liner of red arrow and adhesive of blue arrow; f: appliance insertion**

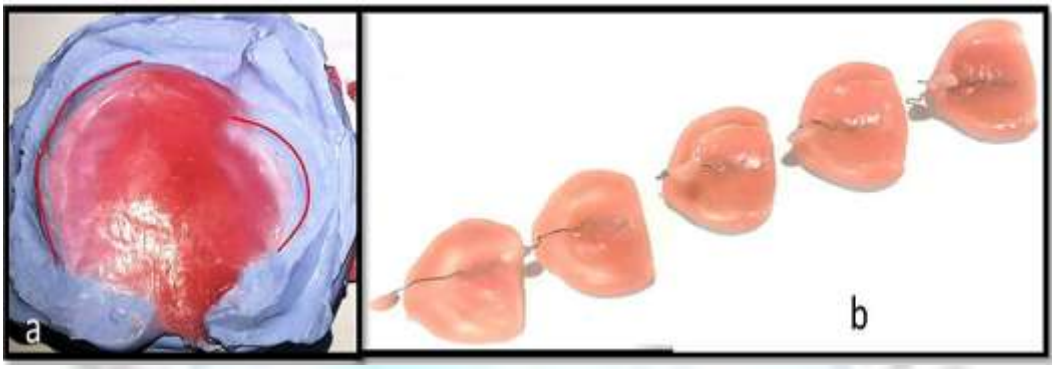


**Fig.2: Steps of pre-activation of working cast; A: cast reduction as shown with red line, B: series of treatment appliances.**


**Fig. 3: Scanning procedure A. study cast inserted in the Identica scanner and ready for scanning . B. scanner with connected computer.**

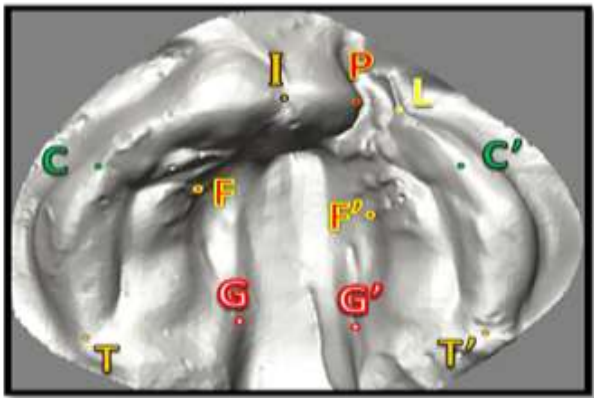


**Fig. 4: Reference Points on Cast.**

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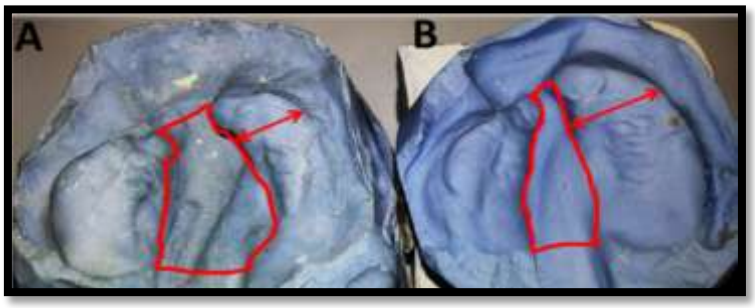


**Fig. 5: cleft widths changes due to molding with Pre-activated appliance; A. Before treatment. B. After treatment.**

**Table (1):Means and Standard deviations for samples of Da Silveira et al technique.**

| | Variables* | No. | Min. | Max. | SE | Mean ± SD | t-value | p-value |
|---|---|---|---|---|---|---|---|---|
| Cleft Widths | PLb | 12 | 10.05 | 17.64 | .75 | 12.78±2.59 | 10.34 | <0.001$^{S}$ |
| | PLt | 12 | 2.19 | 10.80 | .78 | 6.44±2.69 | | |
| | F-F'b | 12 | 14.5 | 17.64 | 0.64 | 14.51±.2.22 | 5.68 | <0.001$^{S}$ |
| | F-F't | 12 | 7.38 | 14.34 | .57 | 10.02±1.99 | | |
| | G-G'b | 12 | 10.03 | 19.19 | .849 | 13.77±2.94 | 4.46 | <0.01$^{S}$ |
| | G-G't | 12 | 5.75 | 10.80 | .46 | 9.21±1.58 | | |
| Cleft Size | b | 12 | 37.16 | 50.05 | .97 | 40.18±3.35 | 12.09 | <0.001$^{S}$ |
| | t | 12 | 23.18 | 32.39 | .76 | 26.68±2.62 | | |
| Incisal Point Deviation | I-Ym b | 12 | 5.05 | 8.56 | .40 | 6.84±.1.37 | 2.43 | 0.03$^{S}$ |
| | I-Ym t | 12 | 2.38 | 8.81 | .61 | 4.77±.2.14 | | |
| Anteriorarch Widths | C-C'b | 12 | 29.67 | 36.80 | .71 | 33.47±2.47 | 0.81 | 0.43$^{NS}$ |
| | C-C't | 12 | 27.88 | 37.91 | .83 | 32.75±.2.89 | | |
| Posterior arch Widths | T-T'b | 12 | 31.79 | 38.63 | .54 | 33.88±.1.89 | .83 | 0.42$^{NS}$ |
| | T-T't | 12 | 25.96 | 36.69 | 1.0 | 32.80±.3.70 | | |
| Total Arch Depth | IPr2b | 12 | 18.50 | 28.70 | 1.08 | 23.67±3.74 | -4.29 | <0.01$^{S}$ |
| | IPr2t | 12 | 27.31 | 32.14 | .46 | 29.42±1.59 | | |
| Mid Palatal Height | (FMF'tox-y)b | 12 | 4.34 | 7.29 | .33 | 5.90±1.1.16 | -4.97 | <0.001$^{S}$ |
| | (FMF'tox-y)t | 12 | 6.48 | 10.77 | .417 | 8.35±.1.45 | | |
| Posterior Palatal Height | GMG' tox-y)b | 12 | 3.02 | 5.76 | .303 | 4.37±.1.05 | -4.1 | <0.001$^{S}$ |
| | GMG' tox-y)t | 12 | 4.14 | 8.54 | .41 | 6.49±1.42 | | |

***Measurements in millimeter unit; $^{S}$: Significant; $^{NS}$: Not significant. b: before treatment, t: after treatment**

**Table (2):Means and Standard deviations for samples of Pre-activated technique.**

| | Variables* | No. | Min. | Max. | SE | Mean ± SD | t-value | p-value |
|---|---|---|---|---|---|---|---|---|
| Cleft Widths | PLb | 12 | 8.40 | 16.68 | .84 | 12.26±2.92 | 12.26 | <0.001[S] |
| | PLt | 12 | .00 | 5.12 | .47 | 2.66±1.61 | | |
| | F-F'b | 12 | 11.62 | 16.58 | .50 | 14.26±.1.75 | 11.36 | <0.001[S] |
| | F-F't | 12 | 4.17 | 7.98 | .47 | 6.62±1.60 | | |
| | G-G'b | 12 | 7.74 | 10.88 | .33 | 9.75±1.14 | 6.35 | <0.001[S] |
| | G-G't | 12 | 6.16 | 8.65 | .29 | 7.37±1.02 | | |
| Cleft Size | b | 12 | 30.63 | 43.08 | 1.15 | 38.01±3.99 | 18.88 | <0.001[S] |
| | t | 12 | 13.78 | 19.24 | .56 | 15.29±1.93 | | |
| Incisal Point Deviation | I-Ym b | 12 | 2.00 | 9.74 | .92 | 7.15±.3.19 | 6.974 | <0.01[S] |
| | I-Ym t | 12 | .10 | 1.15 | .16 | .71±.60 | | |
| Anteriorarch Widths | C-C'b | 12 | 29.21 | 38.07 | .78 | 34.13±2.70 | 4.22 | <0.01[S] |
| | C-C't | 12 | 28.90 | 31.90 | .41 | 30.31±1.41 | | |
| Posterior arch Widths | T-T'b | 12 | 29.69 | 34.11 | .46 | 31.31±.1.58 | -1.783 | 0.1[NS] |
| | T-T't | 12 | 26.86 | 36.08 | .76 | 32.69±2.6 | | |
| Total Arch Depth | IPr2b | 12 | 20.23 | 29.39 | .710 | 24.29±2.46 | -.92 | 0.38[NS] |
| | IPr2t | 12 | 24.56 | 27.39 | .30 | 25.96±1.03 | | |
| Mid Palatal Height | (FMF'tox-y)b | 12 | 5.46 | 9.06 | .29 | 7.62±1.02 | -4.65 | <0.01[S] |
| | (FMF'tox-y)t | 12 | 8.00 | 10.54 | .26 | 9.42±.91 | | |
| Posterior Palatal Height | GMG' tox-y)b | 12 | 5.05 | 8.91 | .44 | 6.53±.1.53 | -4.48 | <0.01[S] |
| | GMG' tox-y)t | 12 | 7.90 | 9.05 | .14 | 8.4±.48 | | |

***Measurements in millimeter unit; [S]: Significant; [NS]: Not significant. b: before treatment, t: after treatment**

**Table (3):Comparisons of treated samples with Da Silveira et al versus Pre-activated techniques.**

| | Variables* | No. | Mean ± SD | t-value | p-value |
|---|---|---|---|---|---|
| Cleft Widths | PLd | 12 | 6.44±2.69 | 3.29 | <0.01 S |
| | PLp | 12 | 2.66±1.61 | | |
| | F-F'd | 12 | 10.02±1.99 | 4.71 | <0.01 S |
| | F-Fp | 12 | 6.62±1.60 | | |
| | G-G'd | 12 | 9.21±1.58 | 4.02 | <0.01 S |
| | G-G'p | 12 | 7.37±1.02 | | |
| Cleft Size | d | 12 | 26.68±2.62 | 14 | <0.001 S |
| | p | 12 | 15.29±1.93 | | |
| Incisal Point Deviation | I-YM d | 12 | 4.77±.2.14 | 6.91 | <0.001 S |
| | I-YM p | 12 | .71±.60 | | |
| Anterior Arch Widths | C-C'd | 12 | 32.75±.2.89 | 3.8 | <0.01 S |
| | C-C'p | 12 | 30.31±1.41 | | |
| Posterior Arch Widths | T-T'd | 12 | 32.80±.3.70 | 0.07 | .94 NS |
| | T-T'p | 12 | 32.69±2.6 | | |
| Total arch depth | IPr2d | 12 | 23.67±3.74 | 7.33 | <0.001 S |
| | IPr2p | 12 | 25.96±1.03 | | |
| Mid palatal height | (FMF'tox-y)p | 12 | 8.35±.1.45 | -2.48 | 0.03 S |
| | (FMF'tox-y)p | 12 | 9.42±.91 | | |
| Posterior palatal height | GMG' tox-y)d | 12 | 6.49±1.42 | -4.62 | <0.01 S |
| | GMG' tox-y)p | 12 | 8.4±.48 | | |

***measurements in millimeter unit; S : Significant; NS: Not significant.**
**d:Da Silveira et al technique. p: Pre-activated technique**