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Assessment of Pre-surgical Molding Appliances in Bilateral 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 Retracting spring appliance developed in this study in comparison with previous appliance known as orthopedic plate with anterior acrylic ring.

Materials and Methods: The study was carried out on 16 participants, 8 per group, Non-syndromic complete bilateral 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. Five measurements assessed involved cleft widths, Premaxillary segment, incisal point deviation, alveolar widths and Total arch depth. Statistical Comparison was determined using SPSS program at $p \leq 0.05$.

Results: Descriptive analyses and comparisons of treated samples with anterior acrylic ring versus retracting spring revealed significant differences of most measurements except for widths of (arch &pre-maxilla), incisal point deviation and inter-tuberosity distance at $p \leq 0.05$.

Conclusions: Modifying the molding plate with using anterior acrylic ring appliance may reduce the pre-surgical treatment visits and improve molding effects.

Keywords: cleft lip, cleft palate, Premaxilla, molding appliances.

INTRODUCTION

Incidence of cleft lip and palate has increased from 1per thousand live births in first third of the century to1.5 to 2 per thousand. The incidence varies widely and is the least in the Negroids while The Mongoloids show the highest incidence. [1, 2.]

The geographical variation seems to be less important than the ethnic differences.[3]. Bilateral cleft lips are associated with cleft palate 85% of the time.[4]Potential risk factors include race, ethnicity, and nationality.[5]Maternal cigarette smoking, alcohol consumption and multivitamin use are the three factors most considered with regard to the risks of isolated cleft lip and palate.[6.]

Surgeons have long recognized the challenge of the bilateral cleft deformity. The main obstacles to the repair are the protruding premaxilla and the deficient columella, previously the surgical treatment involved excision of the premaxilla followed by later prosthetic replacement of the anterior dentition but this will removed the upper incisors and deprived the lip of bony support, causing mid-face deficiency, maxillary constriction, malocclusions, and an apparent mandibular prognathism. The focus became preservation and retraction of the premaxilla via pre-surgical orthopedics.[7.]

It was demonstrated that infants with unrepaired CL/P show differences in facial soft tissue movements when compared with non-cleft infants.[8.]

In 1686, Hoffman described the use of a head cap with arms extended to the face to retract the pre-maxilla and narrow the cleft. [9.] Many variations in pre-surgical orthopedic techniques have evolved during the last 40 years.[7.]

The most important aim of pre-surgical jaw orthopedic treatment in bilateral CLP patients might be the management of the protruding and/or asymmetrical premaxilla in order to facilitate lip repair. [10]or guidance of the maxillary segments has been reported.[11].

Hence the aim of this study is to assess the efficiency of molding effect of Orthopedic plate with retracting spring appliance developed in this study in comparison with previous appliance known as Orthopedic plate with anterior acrylic ring.

MATERIALS AND METHODS

The patient inclusion criteria were: only the non-syndromic babies of complete BCLP infants and the patient's family agreed that the patient would undergo molding therapy. Newborn to 1month infants without any surgical intervention; while the patient exclusion criteria were: Other congenital malformations (except for syndactily) or systemic diseases; patients with the life threatening syndromes and respiratory difficulty are not considered for the molding therapy.

Once infants were identified as eligible for inclusion, patients were randomly allocated into two treatment groups (AA & RS), each group will receive different modality of treatment appliance, and therefore group AA will receive Orthopedic plate with anterior acrylic ring appliance while group RS will receive Orthopedic plate with retracting spring 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 continued till the required size of sample was achieved. The number of participants was calculated at 8 per group; therefore the total number of participants was 16. 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).[12,] The endpoint for the treatment of patients with orthopedic appliance was when the anterior alveolar width was less than 3 mm, which was around 4 months of age.[13]

There are several steps involved in the fabrication of the molding appliances which include Impression Making and Appliance fabrication. Different impression procedures have been reported in literature for CLP infants involving patient positioning, tray, and impression material selection are the important factors to consider in any impression procedure.[14,15,] Proper patient and dentist position are mandatory to achieve an accurate impression; hence an upside down infant's position in the mother's lap is important where the infant's neck can be extended for the maximum exposure for the operator.[9,] After size and shape have been roughly estimated, perforated custom acrylic trays can be fabricated or Impression trays are chosen from a collection of variously sized trays made from previously obtained maxillary dental casts. The impression material used for the intraoral cleft defect was heavy bodied silicone elastomeric impression[16] (Protesil, Italy), as in figure.1

Two casts are poured from the impression with dental stone materials. 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.[15,]

Group AA will receive (AA) appliance where Orthopaedic plate with anterior acrylic ring was fabricated according to Ijaz (2003)[17] for complete Bilateral cleft lip and palate individual cases. This appliance was used for retraction and alignment of protruded and rotated premaxillary segment and to increase in columellar length. The technique of fabrication was involved the followings: The defect part in the working cast was boxed in wax, and then the palatal part of orthopedic plate was made from self-cure acrylic. Acrylic ring around the pre maxillary alveolar segment was later fabricated and the plate was finished and polished for the next chair side procedure. The appliance was tried in the baby's mouth for adaptation and the cleft part was then filled with soft acrylic for retention purpose. The appliance wear full time in baby's mouth and instructions were given for thorough cleansing of the plate after every feed. A regular weekly follow up for adjustment of the anterior acrylic ring was scheduled. Adjustment was done by adding 1mm of self-cure acrylic along the ventral surface of the anterior acrylic ring contacting the labial surface of the pre-maxillary segment and removing a little more along the anterior margin of the plate to accommodate distalizing pre-maxilla.

It forces the protruded pre-maxillary segment into alignment with the dental alveolar segments, improving the shape of the maxillary arch taking advantage of the plasticity of the neonatal cartilage which in turn was due to maternal estrogen levels. [18,19].

The guiding principle in the idea of fabrication of the orthopedic plate with Retracting Spring appliance which developed in this study was the application of constant low-grade pressure to reshape and reposition anatomic structures. [20,] The modification of this appliance was depended specifically on using closed coil spring for retraction of premaxilla owing to its valuable features.[1]

Therefore the Orthopedic plate may be modified in such a way two separated parts of orthopedic plates (posterior palatal part and anterior semilunar part) connected by orthodontic closed coil spring of nickel titanium material (the force producing component) that attach to palatal part at its posterior end and to semilunar part at its anterior end.

The technique of fabrication of (RS)for group RS was involved the followings: Firstly fabrication of palatal part where the defect part in the working cast was boxed in wax then stainless steel orthodontic wire gauge 0.7 mm was bended in

the shape of (W letter) that placed in mid-palatal part region with approximately parallel to occlusal plane of the cast and boxed with wax at its bilateral zigzag ends to be free from acrylic coverage while the remaining of wire will insert inside acrylic of palatal part of orthopedic plate. The aim of these bilateral zigzag ends to act as posterior points of attachment for bilateral closed coil spring. The palatal part of orthopedic plate was made from self-cure acrylic. Secondly fabrication of Acrylic semilunar part: A stainless steel orthodontic wire gauge 0.7 mm was bended in the shape of (semilunar) with bilateral right and left hook ends, this wire adapted on the facial surface of the pre-maxillary segment taking approximately its facial configuration and also boxed with wax at its bilateral hook ends to be free from acrylic coverage while the remaining of wire will insert inside acrylic of semilunar part of orthopedic plate. These bilateral hooks' ends were aimed to act as anterior points of attachment for bilateral closed coil spring. The semilunar part of orthopedic plate was also made from self-cure acrylic. Then the two separated acrylic plates were finished and polished, as in figure.2.

The length of closed coil springs were selected appropriately to apply light force while retracting the pre-maxillary segment, and attached to both acrylic parts at their zigzag and hook ends, the latter part should be closed to prevent dislodgement of the spring during appliance wearing. The appliance was tried in the baby's mouth for adaptation and adjustment of force magnitude of closed coil spring that was assessed clinically, where the semilunar part should be placed passively over pre-maxillary segment about 2 mm posterior to its fabricated position, Then the semilunar part place actively in its fabricated position on the facial surface of pre-maxillary segment with aiding of adhesive denture paste. (BONYPLUS 12 Hour Special Fixative Denture Adhesive cream (Switzerland).

After the patient's parent well tried on appliance insertion and removal, an adhesive paste is applied for retention of both acrylic parts. In case of palatal part it's applied only on the tissue sites of alveolar segment. The parents were demonstrated to use the appliance as full time wear in baby's mouth and instructions were given for thorough cleansing and one time changing of adhesive paste per day. A regular fortnightly follow up for adjustment of the force of the closed coil spring, by anterior sliding of its posterior end over zigzag end at a mean of half helix per each visit depending on response of treatment, then a drop of soft acrylic is placed over zigzag to prevent unwanted sliding of spring. In case of rotated pre-maxilla, the spring that attached to rotated side of premaxilla was activated only. The two achieved study maxillary 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 via EXOCAD software of connected computer to achieve a three dimensional digital object saved in STL format in this computer and then analyzed three-dimensionally using software program known as Autodesk Inventor Fusion 2013.

Measurements of dimensions of the upper jaws were performed utilizing previously described reference points[18, 19, 22-26] as the followings: I: incisal point, point on the top of the alveolar crest at which the incisive papilla and the labial frenulum meet; P and P' points, the pre-maxillary cleft edge points: the most lateral points of the pre-maxilla contour on a continuation of the line marking the crest of the ridge; L, L′ points, lateral segment margin of cleft, on the continuation of the line marking the crest of the right and left ridges respectively; C and C' points, cuspid points at which the lateral sulcus crosses the crest of the right and left alveolar ridge respectively; T, T' tuberosity points, at the junction of crest of the right and left ridges with the outline of their tuberosity respectively; A, A' points, anterior cleft margin points of the right and left segments respectively; F, F'=Mid-cleft margin, Intersection of a line connecting canine points to the gingival groove points and the midcleft margin on the right and left segments respectively; G, G' Posterior cleft margin point, Intersection of a line joining the tuberosity points and posterior cleft margin on the right and left segments respectively; LIL' point, Constructed reference points: projection of point I on the L-L' line; M point, Constructed reference points: halfway along the distance T – T'; Pv, P'v points, intersection point between the perpendicular of the pre-maxillary cleft edge points and the vertical plane and finally Pr2 Point, Constructed reference points, it is a projection of point I on the T–T' line, as in figure.3

Three Dimensional Assessment of Maxillary Cast of Bilateral Cleft Lip and Palate involve the following measurements:

1. **Cleft dimensions (widths)**:
   A.Right cleft width: P-L distance. [18] **B.** Left cleft width: P'-L' distance.[18]**C.**Anterior cleft width: A-A' distance. [22.]D. Mid-cleft width (distance F-F') [22, 27.]E. Posterior cleft width (distance G-G') [22.]
2. **Assessment of Premaxillary segment**
   A.Premaxillary width: (P-P') distance; [18]**B.**Premaxillary protrusion: (I-LIL') distance. [23]**C.**Mesial cleft edge height right of premaxila, P–Pv.[24,26.]**D.**Mesial cleft edge height left of premaxila P'–P'v.[24,26.]
3. **Assessment of Incisal pointdeviation:** I– Ms Perpendicular distance: Deviation of incisal point in relation to mid-sagittal plane.[26.]
4. **Assessment of maxillary alveolar width:**
   A. L-L': anterior arch width;[18, 23.]**B.**C-C': intercanine width;[18.]**C.** T-T': intertuberositywidth.[18.]
5. **Total Arch Depth**I–Pr2 distance: Total arch depth.[28]

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 analyses of cleft widths, Pre-maxillary width, Pre-maxillary protrusion, Mesial cleft edge height right and left of pre-maxilla, incisal point deviation, anterior arch width, inter-canine width, inter-tuberosity width and Total arch depth for Anterior Acrylic Ring technique (before and after molding) are listed in table 1.In addition to results of t-test analyses of before versus after molding measurements which revealed significant differences of molding effects for most measurements except for (G-G, P-P', P'–P'v, C-C, T-T and IPr2).

Table 2 listed the descriptive analysesof these measurements for retracting closed coil spring 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 (P-P', C-C and T-T).

Table 3 revealed comparisons of treated samples with Anterior Acrylic Ring versus Retracting closed coil spring techniques; where significant differences for molding effects were shown for most measurements except for all arch widths(A-A, F-F, G-G), pre-maxillary widths (P-P') , Mesial cleft edge height left of pre-maxila (P–Pv'), incisal point deviation (I-Ms), inter-canine width (C-C') and finally inter-tuberosity width(T-T), such results revealed significant improvements of treated cases with Anterior Acrylic Ring versus Retracting closed coil spring techniques.

DISCUSSIONS

The findings of treated samples with Anterior Acrylic Ring technique of this study agreed with study of Raffat and Ijaz 2009 [19] who mentioned that this appliance even maintained arch form during buccinator's activity, and prevented further collapse of lateral alveolar arches. The change in the device is an acrylic ring, extending anteriorly from the plate around pre maxillary segment and makes it to be a true functional device as the child suckles; muscle forces from the tongue are transformed on to the appliance in the form of retraction force to pre maxilla. The cleft area of plate was given a bridge of soft acrylic that not only provided retention but also partially served the purpose of nasal stents (extending up in the nostrils). Various recent studies have given similar results.[18,23].

In addition to inhibiting effect of irregular movements of the tongue, the orthopedic plate might assist in preventing "palatalized articulation."[29.]

Retracting closed coil spring 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 is not to proliferate tissue or initiate growth but to guide the maxillary segments into proper spatial position with each other and with the mandibular arch.

The findings of comparisons among measurements of molding effects of Anterior Acrylic Ring versus Retracting closed coil spring techniques showed significant improvements in most measurements appeared obviously by the Retracting closed coil spring techniques which may advocate the use of this new appliance for molding effect in the future. In addition, the Retracting closed coil spring technique has benefits of both Low force which is important in applying a non-harmful force to oral structure and constant force which important in reducing number of treatment visits where Da Silveira et al 2003[20]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 the Retracting closed coil spring technique that developed in this study may improve the molding effects during pre-surgical period and may reduce the numbers of treatment visits, therefore this new appliance may approved to be used in the treatment of Bilateral complete cleft lip and palate patients.

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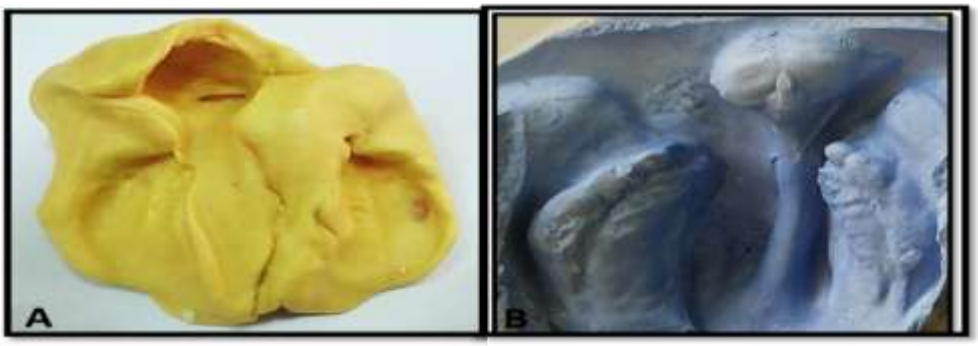

Fig. 1: Steps of fabrication; A: Impression; B: Cast

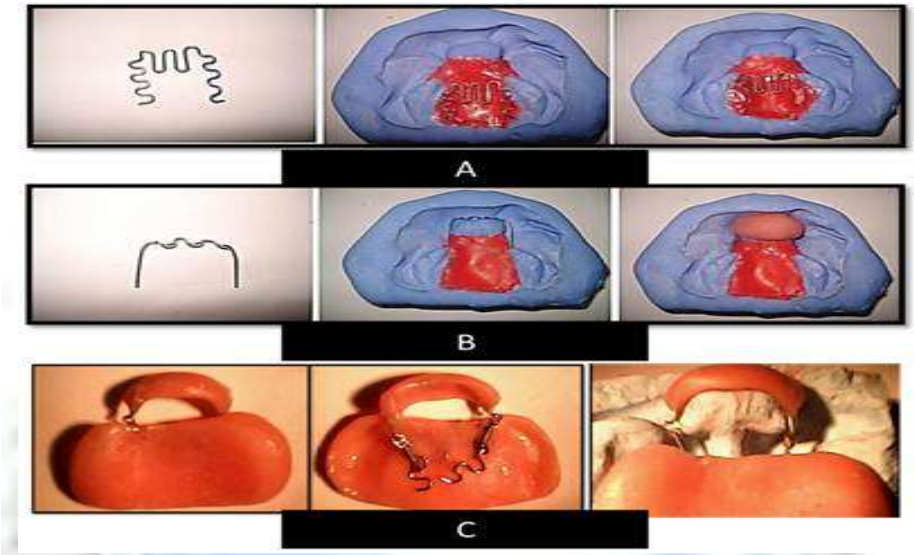

Fig. 2: steps of retracting closed coil spring fabrication; A: palatal plate construction; B: semilunar part construction; C: two parts connected by spring and triad on cast.

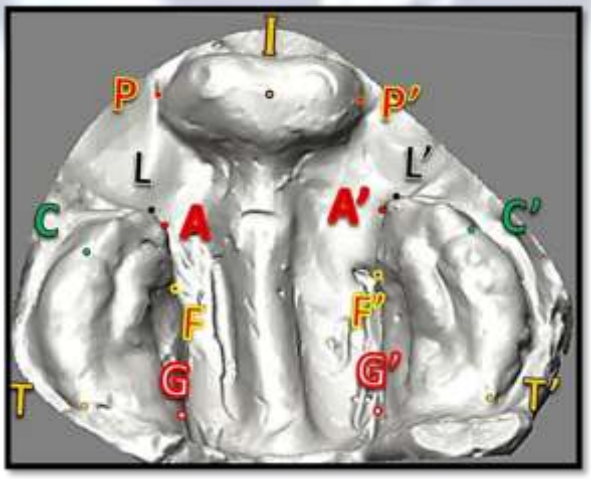

Fig. 3: Reference points on cast

Table (1): Means and Standard deviations for samples of Anterior Acrylic Ring technique.

	Variables*	No.	Min.	Max.	SE	Mean ± SD	t-value	p-value
Cleft Widths	PLb	8	13.92	14.87	0.15	14.43±0.42	3.77	.007 S
	PLt	8	1.88	14.10	1.56	8.33±4.43		
	P'L'b	8	15.77	20.72	.72	17.73±2.05	5.98	.001 S
	P'L't	8	4.31	16.47	1.83	9.1±5.17		
	A-A'b	8	10.91	21.48	1.60	14.42±4.52	2.55	.03 S
	A-A't	8	5.98	14.56	1.24	9.71±3.51		
	F-F'b	8	13.78	21.42	1.20	16.09±.3.42	3.30	.01 S
	F-F't	8	9.22	18.09	1.06	12.19±3.01		
	G-G'b	8	10.32	16.83	.76	13.97±2.16	1.56	.16 NS
	G-G't	8	10.31	15.81	.58	12.19±1.66		
Premaxillary Measurements	P-P'b	8	12.80	17.83	0.69	14.94±.1.94	1.22	.26 NS
	P-P't	8	11.17	18.85	1.04	14.49±2.94		
	P–Pvb	8	4.22	10.04	0.61	6.35±1.73	3.31	.01 S
	P–Pvt	8	1.52	5.76	.52	3.76±1.48		
	P'–P'vb	8	3.46	8.29	.56	4.53±1.60	.05	.96 NS
	P'–P'vt	8	1.33	8.95	1.02	4.47±2.91		
	I-LIL'b	8	12.17	16.59	.61	14.72±1.74	3.96	.005 S
	I-LIL't	8	4.58	15.84	1.67	8.84±4.74		
Incisal Point Deviation	I-Ms b	8	5.59	12.92	1.17	7.57±.3.31	6.45	<.001 S
	I-Ms t	8	.10	3.47	.51	1.75±1.44		
Arch Widths	L-L'b	8	11.81	21.99	1.70	16.35±4.82	-2.301	.05 S
	L-L't	8	4.58	15.84	1.67	8.84±4.74		
	C-C'b	8	22.24	36.57	2.35	29.73±6.66	-1.56	.16 NS
	C-C't	8	28.57	42.47	1.93	32.31±5.47		
	T-T'b	8	28.49	45.02	.32	42.82±1.11	-.65	.54 NS
	T-T't	8	27.81	35.65	1.11	31.03±3.16		
Arch Total Depth	IPr2b	8	30.87	43.33	2.04	37.10±5.78	1.72	.13 NS
	IPr2t	8	27.74	40.07	1.62	33.69±4.58		

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

Table (2): Means and Standard deviations for samples of retracting closed coil spring technique.

	Variables**	No.	Min.	Max.	SE	Mean ± SD	t-value	p-value
Cleft Widths	PLb	8	5.52	12.42	.83	10.64±2.37	9.68	<0.001^{S}
	PLt	8	1.73	3.50	.28	2.47±.81		
	P'L'b	8	9.16	14.43	.65	12.17±1.84	21.77	<0.001^{S}
	P'L't	8	2.53	5.58	.41	3.89±1.18		
	A-A'b	8	12.00	19.67	.81	15.77±2.29	4.50	.003^{S}
	A-A't	8	11.67	12.89	.22	12.25±.62		
	F-F'b	8	15.49	18.98	.40	17.22±.1.15	5.79	.001^{S}
	F-F't	8	10.50	16.46	.73	13.3613±2.06		
	G-G'b	8	12.75	18.69	.70	16.13±1.99	7.68	<0.001^{S}
	G-G't	8	8.33	15.67	.81	12.21±2.30		
Premaxillary measurements	P-P'b	8	12.91	18.97	.73	16.83±.2.07	1.13	.29^{NS}
	P-P't	8	14.84	17.76	.41	15.86±1.16		
	P–Pvb	8	1.84	8.52	.80	6.06±2.07	3.49	.01^{S}
	P–Pvt	8	2.10	3.71	.27	2.72±.77		
	P'–P'vb	8	3.84	6.62	.36	5.63±1.02	5.190	.001^{S}
	P'–P'vt	8	.83	4.91	.49	2.02±1.40		
	I-LIL'b	8	6.89	13.13	.73	10.85±2.07	7.67	<0.001^{S}
	I-LIL't	8	2.02	5.02	.53	3.83±1.50		
Incisal point deviation	I-Ms b	8	.20	7.61	.87	2.97±.2.48	2.30	.05^{S}
	I-Ms t	8	.00	1.72	.27	.74±.78		
Arch Widths	L-L'b	8	15.89	23.04	1.05	20.23±2.97	3.46	.01^{S}
	L-L't	8	13.97	18.44	.84	16.20±2.39		
	C-C'b	8	31.79	38.15	.90	34.39±2.55	-.48	.65^{NS}
	C-C't	8	31.85	38.53	1.02	35.08±2.87		
	T-T'b	8	26.04	36.86	1.46	32.34±4.13	.70	.51^{NS}
	T-T't	8	30.04	33.28	.42	31.32±1.19		
Arch Total Depth	IPr2b	8	28.83	35.18	.75	32.76±2.12	4.26	.004^{S}
	IPr2t	8	26.26	31.18	.66	28.82±1.89		

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

Table (3): Comparisons of treated samples with Anterior Acrylic Ring versus Retracting closed coil spring techniques.

	Variables**	No.	Mean ± SD	t-value	p-value
Cleft Widths	PLa	8	8.33±4.43	3.74	.007 S
	PLr	8	2.47±.81		
	P'L'a	8	9.1±5.17	2.62	.03 S
	P'L'r	8	3.89±1.18		
	A-A'a	8	9.71±3.51	-2.19	.06 NS
	A-A'r	8	12.25±.62		
	F-F'a	8	12.19±3.01	-1.43	.19 NS
	F-F'r	8	13.3613±2.06		
	G-G'a	8	12.19±1.66	-.05	.96 NS
	G-G'r	8	12.21±2.30		
Premaxillary measurements	P-P'a	8	14.49±2.94	-1.77	.12 NS
	P-P'r	8	15.86±1.16		
	P–Pva	8	3.76±1.48	1.80	.11 NS
	P–Pvr	8	2.72±.77		
	P'–P'va	8	4.47±2.91	2.64	.03 S
	P'–P'vr	8	2.02±1.40		
	I-LIL'a	8	8.84±4.74	2.58	.03 S
	I-LIL'r	8	3.83±1.50		
Incisal point deviation	I-Ms a	8	1.75±1.44	1.59	.16 NS
	I-Ms r	8	.74±.78		
Arch Widths	L-L'a	8	8.84±4.74	-4.13	.004 S
	L-L'r	8	16.20±2.39		
	C-C'a	8	32.31±5.47	-1.40	.20 NS
	C-C'r	8	35.08±2.87		
	T-T'a	8	31.03±3.16	-.32	.75 NS
	T-T'r	8	31.32±1.19		
Arch Total Depth	IPr2a	8	33.69±4.58	2.90	.02 S
	IPr2r	8	28.82±1.89		

*measurements in millimeter unit; S : Significant; NS: Not significant. a: AA appliance. r: RR Appliance.