ORIGINAL RESEARCH

Skeletal Anchorage Augmentation in Extraction/Nonextraction Orthodontic Treatment: A Randomized Clinical Study

Niti Dharmendra Shah[1], Santosh Kumar Goje[2]

Abstract

Aim: To evaluate and compare skeletal, dental, and soft tissue parameters by therapeutic extraction of first premolar and nonextraction distalization of maxillary and mandibular arches in bimaxillary proclination using the skeletal anchorage system.

Materials and methods: About 40 orthodontic patients undergoing extraction or nonextraction treatment are enrolled in a randomized clinical trial. Participants are randomly assigned to either the extraction or nonextraction group and receive treatment augmented with skeletal anchorage. Mini implants were placed in the extraction group for retraction and infra-zygomatic crest (IZC) and buccal shelf screws were placed in the nonextraction group for distalization.

Observations and results: Comparison between the ages of the patients among both Groups showed no significant difference. A significant difference is observed in dental and soft tissue parameters before and after the treatment in group A, whereas skeletal parameters also showed significant changes along with dental and soft tissue parameters in group B.

Conclusion: There is a significant change in the position of incisors by retraction and facial profile improves gradually in group A while for group B, a marked change in lower facial height was even seen. On comparing both the groups, a highly significant difference can be seen with respect to the amount of incisor retraction and change in molar inclination. The time taken for retraction of incisors is less in comparison to distalization.

Clinical significance: With this, we can easily avoid premolar extraction, and in cases of impacted third molars distalization as when indicated can be helpful as a part of the nonextraction treatment plan.

Keywords: Bimaxillary protrusion, Buccal shelf screws, Distalization, Infra-zygomatic crest screws, Mini implants, Premolar extraction, Retraction.

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Introduction

A deviation from ideal occlusion is referred to as malocclusion. Malocclusion can be skeletal, dental, or a combination. The different types of malocclusions are: crossbite, deep bite, open bite, protruded Jaw, retruded jaw, and combinations. Out of many combinations, one of them is a bimaxillary protrusion.[1] A condition marked by protrusive jaws and/or proclined upper and lower incisors and an increased procumbence of the lips is known as bimaxillary protrusion. In Afro-Caribbean (Farrow, 1993), African American, and Asian cultures (Hussein, 2007), it is most frequently predominant, but it can be seen in almost every ethnic group.[2,3] The etiology of bimaxillary proclination is multifactorial and comprises skeletal, dental, soft tissue, habitual, pathological, and environmental variables like mouth breathing, tongue and lip habits, and swollen adenoids or tongue volume.[2] The main treatment plan is dependent on the severity of the dentoalveolar protrusion. Therefore, the goals of orthodontic therapy for bimaxillary protrusion include maxillary and mandibular anterior retraction and retroclination with a consequent decrease in procumbence and convexity of soft tissues. The extraction of four first premolars accompanied by retraction of anterior teeth using optimum anchorage mechanics is the most common way to do this.[4]

Symmetrical extraction of premolars enables retraction and up righting of the upper and lower anterior segments, and this results in the development of a more standard interincisal angle which in turn improves the patient's labial profile as well as overall facial appearance. But for orthodontic purposes, there are many controversies around the extraction of teeth.[4] Charles Tweed, who removed the first four premolars in his case and did alignment and retraction observed that the occlusion was much more stable. As a result of the scientific facts that led to the extraction therapy modality, the Tweed philosophy was born. Appliances transitioned from being totally banded to being largely bonded, and expanding arches became easier, which made it possible to treat borderline situations more successfully without extraction.[3,4] The main controversial reasons for treating with or without extraction of premolars are facial profile, Temporomandibular joint disorders, buccal corridors, stability and impaction risk, bonding, air rotor stripping, and expansion.[4]

It is a very helpful clinical technique that allows to distalize the maxillary first molar to create space for adjusting the discrepancy.[5] As a result, the maxillary anterior protrusion and Class II malocclusion cases have often been corrected by a nonextraction

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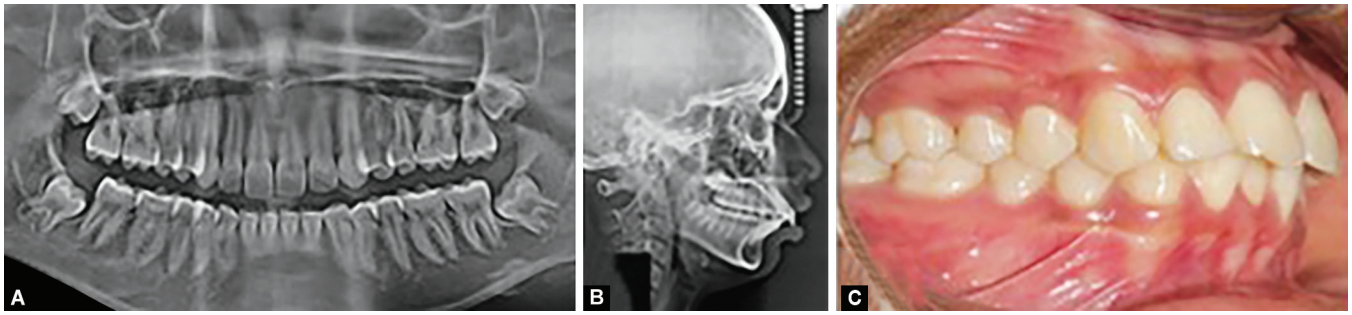


Figs 1A to C: (A) OPG; (B) Lateral cephalogram; (C) Right side view. Pretreatment (Group A)

method using maxillary dentition distalization.[6] Intraoral maxillary molar distalization appliances such as magnets, push coils, super elastic nickel-titanium wires, Jones Jig, pendulum appliance, distal jet, K loop, and Keles slider do not require extensive cooperation from patients.[6] So, the main purpose of a valuable therapeutic procedure is to efficiently distalize the maxillary first molar to obtain room for correcting the difference.

In order to address the disadvantages such as premolar mesialization, incisor protrusion, and overjet increase due to anchorage loss in maxillary molar distalization, temporary anchorage devices (TADs) have been suggested.[6] Lin has developed a new approach for distalization of maxillary dentition with mini screw implantation in the infra-zygomatic crest (IZC) region using a sliding mechanism that decreased the cost of treatment and was easier to master.[7] The invention of infra-zygomatic crest (IZC)/buccal shelf (BS) screws in the field of orthodontics is a magical breakthrough. They have truly changed the viewpoint of anchorage sustainability and have changed orthodontic biomechanics by changing surgical borderline cases to nonsurgical cases and extraction cases to nonextraction cases. However, not many studies have been carried out on bimaxillary protrusion to validate the treatment efficacy of extraction vs nonextraction modalities.

With the increasing use and scope of temporary anchorage devices, equivalent changes in dental and soft tissue seen in that of the extraction method can be obtained by the nonextraction method. Along with this in cases of impacted molars, distalization can be carried out easily. And hence to evaluate the difference in changes of skeletal, dental, and soft tissue effects, between the therapeutic extraction of first premolars and nonextraction skeletal anchorage system in terms of maxillary and mandibular arch retraction and distalization respectively, and related tooth movements in bimaxillary protrusion, this prospective randomized clinical study was taken up.

Materials and Methods

This randomized clinical study was approved by the ethics committee of Sumandeep Vidyapeeth Deemed to be University (approval no. SVIEC/ON/DENT/BNPG20/D21030) to evaluate and compare skeletal, dental, and soft tissue parameters by therapeutic extraction of first premolar and nonextraction distalization of maxillary and mandibular arches in bimaxillary proclination using skeletal anchorage system. Sample size estimation was done using G Power Software and the estimated sample size was found to be 34. The effect size and power of the study were set at 0.80 with an alpha error of 0.05. The level of significance was also set at 5% and a *p*-value of ≤ 0.05 was significant. Considering 20% dropout during follow-up suggested an increase of 6 participants. Hence, a total of 40 participants were included in the study. Participants with permanent dentition, of either gender between 14 and 25 years having bimaxillary proclination, skeletal and dental class I malocclusion, leveled and aligned arches, and ready for retraction of maxillary and mandibular anterior teeth and with average mandibular plane angle were included. Patients with poor oral hygiene, bone loss or weak periodontium, history of drug intake, systemic disease, or previous orthodontic treatment were excluded. A total of 40 participants who met the inclusion criteria were randomly divided into two groups: Group A and group B using the randomization software "research randomizer" (www.randomizer.org). Written informed consent was obtained from all the patients, after a full explanation of the study.

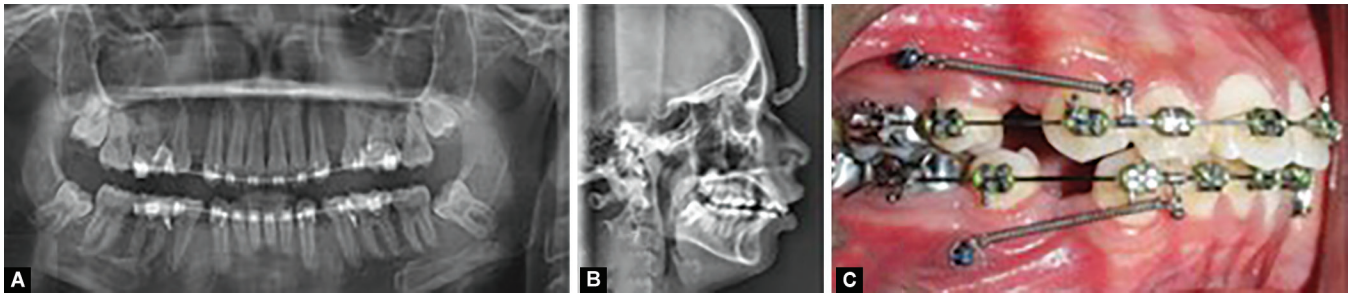
Collection of Radiographic Records

Before taking an orthopantomogram and lateral cephalogram, the patient was instructed to remove any metallic object he/she was wearing then. Lateral cephalogram was taken from a distance of 1.5 m with the head at a right angle to the X-ray beam at a distance of 30 cm (although this has been found to vary slightly). A degree of magnification (around 8%) is expected and a scale was incorporated to help calculate this. The Cephalostat machine incorporates two posts which are placed in the external auditory meatus, the patient's sagittal plane should be parallel to the X-ray film, the teeth in centric occlusion, and the Frankfort plane is aligned horizontally. While orthopantomogram was taken by positioning the patient's tongue pressed against the palate, teeth in the groove of the bite-block, and the indicator light for the midsagittal plane centered and perpendicular to the floor (Carestream; CS 8100 Evo Edition). Before starting the procedure lateral cephalogram and orthopantomogram were obtained.[8]

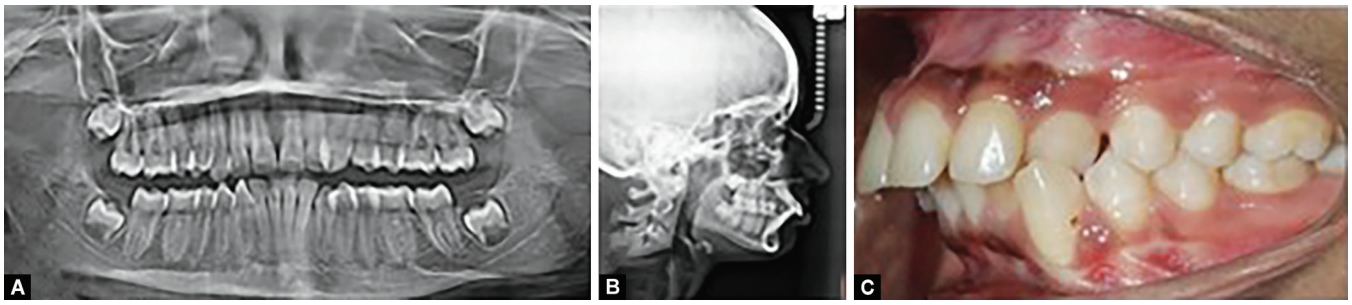
Photographic Records

The head of the patient was oriented such that the occlusal plane lies parallel to the floor. A single cheek retractor on the opposite side was used and a shutter speed of 1/80, ISO 200, and f/29–f/32 and flash setting at TTL was done on DSLR (Canon Mark DII). The right-side flash for the right profile and left-side flash for the left profile were used according to the side taken for intraoral photographs as this will eliminate the soft shadow that appears when both the flashes are on. Lateral intraoral photographs were obtained from the patients and a detailed study of the same was done by the primary Investigator on dolphin imaging cephalometric software 11.5.[9]

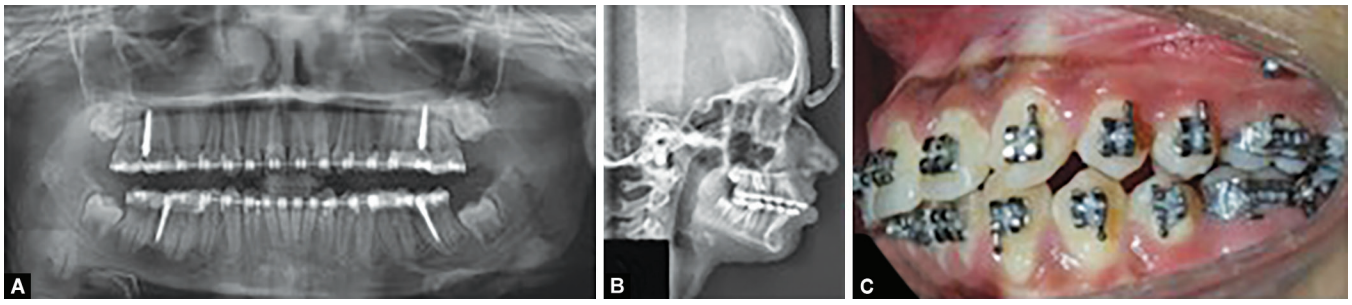
Figures 1 and 2 show radiographic and photographic records for patients of group A and group B. For group A, patients who have already undergone 1st premolar extraction and whose both arches are well leveled and aligned were given inter radicular implants of



Figs 2A to C: (A) OPG; (B) Lateral cephalogram; (C) Right side view. After 6 months of retraction (Group A)



Figs 3A to C: (A) OPG; (B) Lateral cephalogram; (C) Left side view. Pretreatment (Group B)



Figs 4A to C: (A) OPG; (B) Lateral cephalogram; (C) Left side view. After 6 months of distalization (Group B)

1.3 × 8 mm in the maxilla and 1.3 × 9 mm in the mandible between the second premolar and first molar.[10–12] While for patients of group B with well-leveled and aligned arches self-drilling Infrazygomatic screws of 2 × 12 mm were placed in the infra zygomatic crest region above the first molar in the maxilla and BS screws of 2 × 12 mm between the first and second molar in the mandible.[12–14] Stainless steel wire of 19 × 25 SS with a soldered hook between the lateral incisor and canine was placed in a 0.022 × 0.028 inch MBT bracket slot. The retraction was started using a closed-coil nitinol spring applying 300 gm force on each side. Patients were called after every 3 weeks, and spring was activated till complete space closure was obtained in group A. And similarly, spring was activated till complete distalization was obtained in group B. The values were recorded for a period of 6 months after the initiation of space closure and distalization.

After 6 months, lateral cephalogram, orthopantomogram, and side photographs were obtained again (Figs 3 and 4) by performing the same procedure as mentioned above and the acquired data were coded for blinding. Also, it was analyzed by a secondary investigator using the same cephalometric software (Flowchart 1).

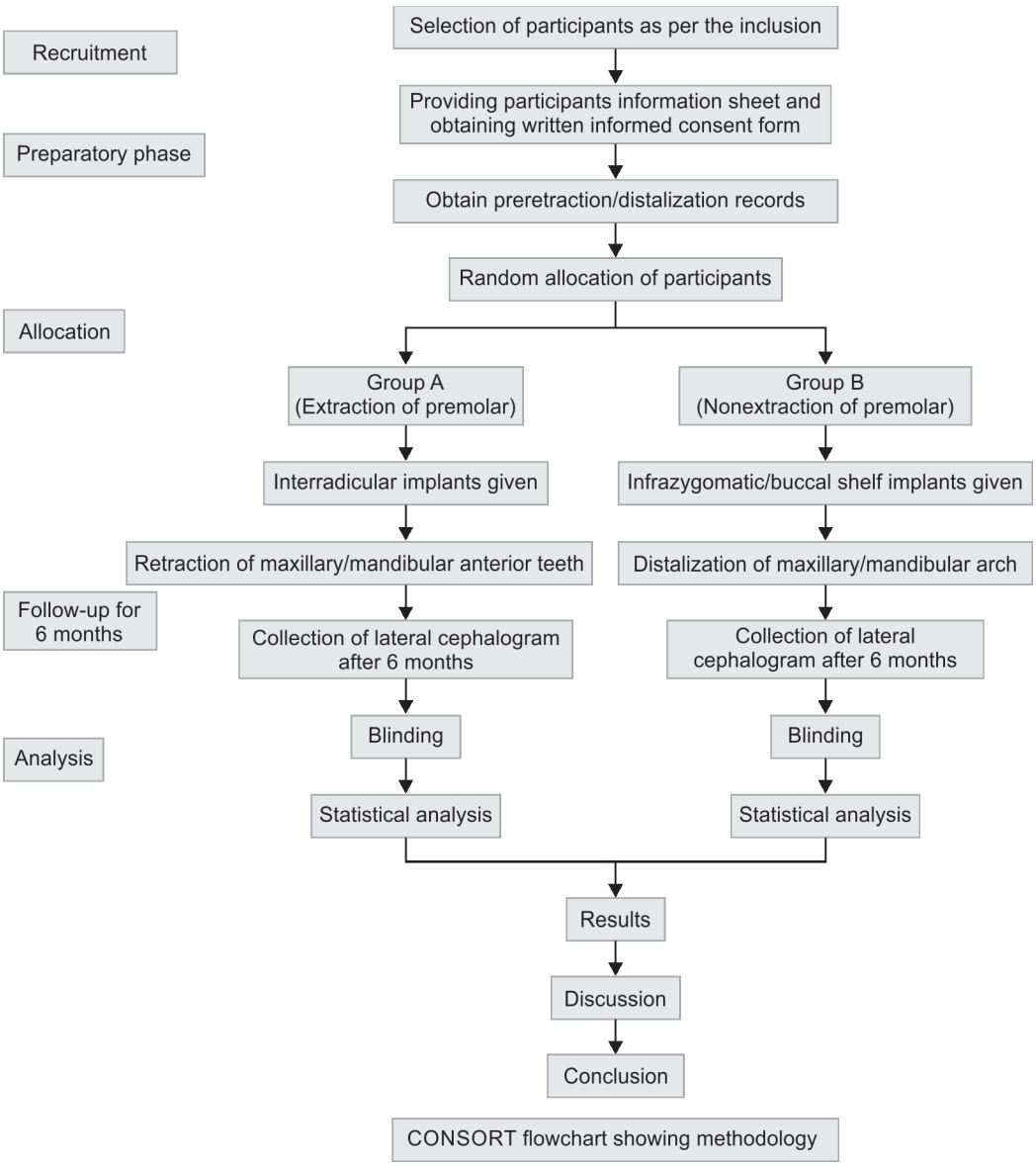
Statistical Analysis

The data collected were entered in Microsoft Excel and subjected to descriptive and inferential statistical analysis using Statistical Package for Social Sciences (SPSS, IBM version 20.0). The level of significance was fixed at 5% and $p \leq 0.05$ was considered statistically significant. Chi-square analysis was used to find the significance of study parameters on a categorical scale. Student *t*-tests (two-tailed, paired, and unpaired) were used to find the significance of study parameters on the continuous scale within and between two groups (Intra and Intergroup analysis).

Observations and Results

The present study was carried out to evaluate and compare skeletal, dental, and soft tissue parameters by therapeutic extraction of first premolar and nonextraction distalization of maxillary and mandibular arches in a bimaxillary proclination using a skeletal anchorage system. The results are based on an analysis of 40 patients subjected to evaluation and comparison of the skeletal, dental, and soft tissue parameters by therapeutic extraction of first premolar and nonextraction distalization of maxillary and

Flowchart 1: Consort flowchart showing methodology



mandibular arches in bimaxillary proclination using skeletal anchorage system in this randomized clinical study. Figure 5 shows the demographic characteristics of the study participants. A major proportion of the study participants were females (55%). The mean age of the male and female participants was found to be 21.55 ± 2.06 and 21.20 ± 1.28 years, respectively.

Table 1 for group A, highly statistically significant changes were seen with respect to U1-VR, L1-VR, U1-HR (°, mm), L1-HR (°, mm), IMPA, interincisal angle, nasolabial angle, overjet, UL-EL between pre- and post-records ($p < 0.001$). Table 2 for group B, highly statistically significant changes were seen with respect to SN-GoMe, N-Me, ANS-Me, U1-VR, L1-VR, U6-VR, L6-VR, U1-HR (°), L1-HR(°), U1-HR (mm), L1-HR (mm), U6-HR (mm), L6-HR (mm), IMPA, interincisal angle, nasolabial angle, overbite, UL-EL, upper and lower pharyngeal space between pre and post-treatment records ($p < 0.001$). When intergroup comparison was done between pretreatment records of group A and group B significant change was observed with respect to overjet and overbite ($p < 0.05$) Table 3.

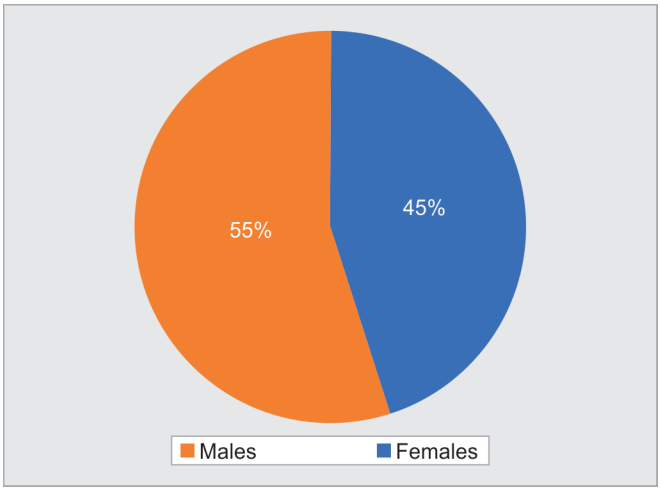


Fig. 5: Demographic data—Male:Female ratio

Table 1: Results (Intragroup) Group A: Comparison of different skeletal, dental and soft tissue parameters in terms of [Mean (SD)] at different time intervals in group A using paired *t*-test

Parameters	*Time interval*	*N*	*Mean*	*Std. deviation*	*Mean difference*	*t-value*	*p-value*
SNA (°)	Pre	20	82.1250	1.34385	–0.35000	1.266	0.221
	Post	20	82.4750	1.28989			
SNB (°)	Pre	20	80.4250	1.15593	–0.33750	1.465	0.159
	Post	20	80.7625	1.13693			
ANB (°)	Pre	20	1.7500	0.34412	0.13750	1.993	0.061
	Post	20	1.6125	0.39299			
A-VR (mm)	Pre	20	67.5125	1.40833	0.07500	1.674	0.110
	Post	20	67.4375	1.33986			
B-VR (mm)	Pre	20	63.7625	1.16550	0.06250	1.751	0.096
	Post	20	63.7000	1.16020			
SN/GoMe (°)	Pre	20	30.7000	0.75481	0.05000	1.710	0.104
	Post	20	30.6500	0.75829			
N-Me (mm)	Pre	20	100.7500	2.00493	–0.06250	2.032	0.056
	Post	20	100.8125	2.01944			
N-ANS (mm)	Pre	20	47.5625	1.42320	0.07500	1.000	0.330
	Post	20	47.4875	1.46556			
ANS-Me (mm)	Pre	20	53.2500	1.69752	–0.08750	1.677	0.110
	Post	20	53.3375	1.69223			
UI-VR (mm)	Pre	20	77.0750	1.16161	5.67500	28.552	<0.001**
	Post	20	71.4000	1.14536			
L1-VR (mm)	Pre	20	74.0875	0.99431	4.98750	33.985	<0.001**
	Post	20	69.1000	0.82078			
U6-VR (mm)	Pre	20	34.2750	1.08488	0.11250	3.327	0.004*
	Post	20	34.1625	1.06461			
L6-VR (mm)	Pre	20	37.4750	1.31013	0.11250	2.651	0.016*
	Post	20	37.3625	1.31158			
U1/HR (°)	Pre	20	128.0375	0.84400	9.90000	99.000	<0.001**
	Post	20	118.1375	0.83302			
L1/HR (°)	Pre	20	51.9125	0.84009	4.97500	38.831	<0.001**
	Post	20	46.9375	0.97964			
U6/HR (°)	Pre	20	96.0500	3.39659	0.16250	1.990	0.061
	Post	20	95.8875	3.33687			
L6/HR (°)	Pre	20	94.0250	2.80613	0.21250	1.973	0.063
	Post	20	93.8125	2.75403			
U1-HR (mm)	Pre	20	60.6925	0.65258	2.25750	33.838	<0.001**
	Post	20	58.4350	0.63889			
L1-HR (mm)	Pre	20	58.5250	0.83862	1.75000	20.119	<0.001**
	Post	20	56.7750	0.78598			
U6-HR (mm)	Pre	20	34.2500	1.13265	0.13750	1.238	0.231
	Post	20	34.1125	1.22064			
L6-HR (mm)	Pre	20	37.1875	1.28215	0.11250	1.143	0.267
	Post	20	37.0750	1.35748			
IMPA (°)	Pre	20	101.9750	1.96164	9.60000	44.671	<0.001**
	Post	20	92.3750	1.56756			

Interincisal group (°)	Pre	20	95.7375	1.32406	–20.22500	74.524	<0.001**
	Post	20	115.9625	1.62480			
Nasolabial angle (°)	Pre	20	85.9625	1.09206	–14.23750	37.361	<0.001**
	Post	20	100.2000	1.32437			
Overjet (mm)	Pre	20	3.5250	0.67327	0.83750	6.646	<0.001**
	Post	20	2.6875	0.47900			
Overbite (mm)	Pre	20	2.6000	0.46876	0.25000	3.162	0.005*
	Post	20	2.3500	0.36635			
UL-El (mm)	Pre	20	2.2000	0.51682	3.20000	14.723	<0.001**
	Post	20	–1.0000	0.62302			
LL-El (mm)	Pre	20	1.0750	0.43755	0.07500	1.831	0.083
	Post	20	1.0000	0.51299			
Upper pharyngeal space (mm)	Pre	20	15.4250	0.76563	0.07500	1.831	0.083
	Post	20	15.3500	0.79637			
Lower pharyngeal space (mm)	Pre	20	11.9750	0.76906	0.07500	1.831	0.083
	Post	20	11.9000	0.78807			

*$p < 0.05$ - Significant; **$p < 0.001$ - Highly significant

Table 2: Results (Intragroup) Group B: Comparison of different skeletal, dental and soft tissue parameters in terms of [Mean (SD)] at different time intervals in group B using paired *t*-test

Parameters	*Time interval*	*N*	*Mean*	*Std. deviation*	*Mean difference*	*t-value*	*p-value*
SNA (°)	Pre	20	82.080	1.2227	0.5930	1.485	0.165
	Post	20	81.4875	1.1337			
SNB (°)	Pre	20	80.375	1.1040	0.675	1.840	0.098
	Post	20	79.7000	1.05319			
ANB (°)	Pre	20	1.9125	0.4536	–0.125	0.364	0.353
	Post	20	1.7875	0.24702			
A-VR (mm)	Pre	20	67.35	1.4518	0.012	21.069	0.7874
	Post	20	67.362	1.4745			
B-VR (mm)	Pre	20	63.7675	1.1598	0.025	20.322	0.0658
	Post	20	63.7125	1.1219			
SN/GoMe (°)	Pre	20	30.725	0.77015	–1.43750	8.503	<0.001**
	Post	20	32.1625	0.964			
N-Me (mm)	Pre	20	101.000	2.008	–1.81250	10.510	<0.001**
	Post	20	102.8125	1.477			
N-ANS (mm)	Pre	20	47.5375	1.3914	–0.0375	1.000	0.3298
	Post	20	47.5000	1.44414			
ANS-Me (mm)	Pre	20	53.4500	1.6455	–1.88750	10.281	<0.001**
	Post	20	55.3375	1.118			
UI-VR (mm)	Pre	20	76.8025	1.3562	1.765	22.801	<0.001**
	Post	20	75.0375	1.33346			
L1-VR (mm)	Pre	20	74.1250	1.29142	1.63750	7.874	<0.001**
	Post	20	72.4875	1.53141			
U6-VR (mm)	Pre	20	34.2500	1.08519	1.52500	13.148	<0.001**
	Post	20	32.7250	1.03205			
L6-VR (mm)	Pre	20	37.5375	1.27804	1.82500	17.490	<0.001**
	Post	20	35.7125	1.28061			
U1/HR (°)	Pre	20	128.2875	1.0738	2.76250	18.016	<0.001**
	Post	20	125.5250	1.406			

(Contd...)

Table 2: *(Contd...)*

Parameters	*Time interval*	*N*	*Mean*	*Std. deviation*	*Mean difference*	*t-value*	*p-value*
L1/HR (°)	Pre	20	51.9625	0.79585	1.8875	22.617	<0.001**
	Post	20	50.0750	1.0037			
U6/HR (°)	Pre	20	96.2	3.3907	–0.10000	1.798	0.088
	Post	20	96.1500	3.32099			
L6/HR (°)	Pre	20	94.225	0.5432	–0.08750	1.926	0.069
	Post	20	94.3125	2.779			
U1-HR (mm)	Pre	20	60.8200	0.65923	–4.84250	20.467	<0.001**
	Post	20	65.6625	0.95033			
L1-HR (mm)	Pre	20	58.5500	0.89810	–6.53750	23.110	<0.001**
	Post	20	65.0875	1.08299			
U6-HR (mm)	Pre	20	34.1875	1.10880	1.21250	10.282	<0.001**
	Post	20	32.9750	1.01922			
L6-HR (mm)	Pre	20	37.1625	1.27030	1.55000	17.592	<0.001**
	Post	20	35.6125	1.24466			
IMPA (°)	Pre	20	101.5875	1.75333	1.96250	37.615	<0.001**
	Post	20	99.6250	1.66721			
Interincisal group (°)	Pre	20	95.8125	1.41857	–1.91250	3.749	<0.001**
	Post	20	97.7250	1.90895			
Nasolabial angle (°)	Pre	20	85.9000	1.20689	–14.37500	39.457	<0.001**
	Post	20	100.2750	1.34482			
Overjet (mm)	Pre	20	3.0000	0.57925	0.46250	3.633	0.002*
	Post	20	2.5375	0.44629			
Overbite (mm)	Pre	20	1.6250	0.37609	–0.32500	4.333	<0.001**
	Post	20	1.9500	0.17396			
UL-El (mm)	Pre	20	2.3125	0.64825	3.27500	14.949	<0.001**
	Post	20	–0.9625	0.59756			
LL-El (mm)	Pre	20	1.2000	0.4701	0.25000	2.476	0.023*
	Post	20	0.8250	0.51363			
Upper pharyngeal space (mm)	Pre	20	15.3500	0.8287	0.85000	12.803	<0.001**
	Post	20	14.5750	0.81958			
Lower pharyngeal space (mm)	Pre	20	11.875	0.7758	0.83750	10.255	<0.001**
	Post	20	11.1375	0.82508			

*$p < 0.05$ - Significant; **$p < 0.001$ - Highly significant

On comparing the post-treatment records Table 4 between Group A and Group B, N-Me, Overbite, and upper and lower pharyngeal spaces show a statistically significant change ($p < 0.05$) while SN-GoMe, ANS-Me, - U1-VR, L1-VR, U6-VR, L6-VR between group A and group B, Similarly UI-HR°, L1-HR°, U1-HR (mm), L1-HR (mm), U6-HR (mm) and L6-HR (mm), change in IMPA and interincisal angle shows highly statistically significant change ($p < 0.001$).

Discussion

The pubertal growth spurt frequently determines the effectiveness and timing of malocclusion treatment. Variations in the direction, timing, and duration of development in the facial area may reduce or enhance the effects of treatment. Treatment of dentofacial abnormalities consequently requires an in-depth understanding of facial morphology and development.[15] Dentoalveolar protrusion, like other dental anomalies, can be upsetting on a social and psychological level.[16] One of the most severe facial malformations is a bimaxillary dentoalveolar protrusion. It starts to stand out in the early stages of mixed dentition and is defined by dentoalveolar flaring of both the maxillary and mandibular incisors, which causes the lips to protrude and the face to be convex. Most patients are mostly worried about the appearance of the dentition, namely the projecting teeth and everted lips.[16] The bimaxillary protrusion, however, is more common in the Asian and African American populations. Many individuals with bimaxillary protrusion seek orthodontic treatment to lessen this procumbency.[17] It has a complicated etiology that includes environmental variables, genetic components, soft-tissue function, volume, and habit.

Table 3: Intergroup (Group A and B): Comparison of different skeletal, dental and soft tissue parameters (Pre) in terms of [Mean (SD)] among both the groups using unpaired *t*-test

Parameters	*Group*	*N*	*Mean*	*Std. deviation*	*Mean difference*	*t-value*	*p-value*
Pre SNA (°)	Group A	20	82.1250	1.34385	0.045	0.621	0.923143
	Group B	20	82.08	1.2227			
Pre SNB (°)	Group A	20	80.3750	1.104	–0.050	0.234	0.888822
	Group B	20	80.4250	1.15593			
Pre ANB (°)	Group A	20	1.7500	0.34412	–0.160	0.621	0.2388
	Group B	20	1.9125	0.4536			
Pre A-VR (mm)	Group A	20	67.35	1.4518	–0.0162	0.320	0.7168
	Group B	20	67.5125	1.40833			
Pre B-VR (mm)	Group A	20	63.7625	1.16550	0.025	0.142	0.93045
	Group B	20	63.7375	1.1598			
Pre SN/GoMe (°)	Group A	20	30.7000	0.75481	–0.025	0.165	0.89677
	Group B	20	30.725	0.77015			
Pre N-Me (mm)	Group A	20	100.7500	2.00493	–0.250	0.156	0.6604
	Group B	20	101.000	2.008			
Pre N-ANS (mm)	Group A	20	47.5625	1.42320	0.0275	0.164	0.896774
	Group B	20	47.5375	1.3914			
Pre ANS-Me (mm)	Group A	20	53.2500	1.69752	–2.085	0.519	0.67272
	Group B	20	55.3375	1.118			
Pre UI-VR (mm)	Group A	20	77.0750	1.16161	0.2700	0.452	0.509
	Group B	20	76.8025	1.3562			
Pre L1-VR (mm)	Group A	20	74.0875	0.99431	–0.03750	0.103	0.919
	Group B	20	74.1250	1.29142			
Pre U6-VR (mm)	Group A	20	34.2750	1.08488	0.02500	0.073	0.942
	Group B	20	34.2500	1.08519			
Pre L6-VR (mm)	Group A	20	37.4750	1.31013	–0.06250	0.153	0.879
	Group B	20	37.5375	1.27804			
Pre U1/HR (°)	Group A	20	128.0375	0.84400	–0.25	0.142	0.225
	Group B	20	128.2875	1.0738			
Pre L1/HR (°)	Group A	20	51.9625	0.79585	0.05	0.320	0.7702
	Group B	20	51.9125	0.84009			
Pre U6/HR (°)	Group A	20	96.2	3.39659	0.15	0.521	0.082
	Group B	20	96.0500	3.39659			
Pre L6/HR (°)	Group A	20	94.225	2.7107	0.2	0.651	0.042
	Group B	20	94.0250	2.80613			
Pre U1-HR (mm)	Group A	20	60.6925	0.65258	–0.12750	0.615	0.542
	Group B	20	60.8200	0.65923			
Pre L1-HR (mm)	Group A	20	58.5250	0.83862	–0.02500	0.091	0.928
	Group B	20	58.5500	0.89810			
Pre U6-HR (mm)	Group A	20	34.2500	1.13265	0.06250	0.176	0.861
	Group B	20	34.1875	1.10880			
Pre L6-HR (mm)	Group A	20	37.1875	1.28215	0.02500	0.062	0.951
	Group B	20	37.1625	1.27030			
Pre IMPA (°)	Group A	20	101.9750	1.96164	0.38750	0.659	0.514
	Group B	20	101.5875	1.75333			

(Contd...)

Table 3: *(Contd...)*

Parameters	*Group*	*N*	*Mean*	*Std. deviation*	*Mean difference*	*t-value*	*p-value*
Pre interincisal group (°)	Group A	20	95.7375	1.32406	–0.07500	0.173	0.864
	Group B	20	95.8125	1.41857			
Pre nasolabial angle (°)	Group A	20	85.9625	1.09206	0.06250	0.172	0.865
	Group B	20	85.9000	1.20689			
Pre overjet (mm)	Group A	20	3.5250	0.67327	0.52500	2.644	0.012*
	Group B	20	3.0000	0.57925			
Pre overbite (mm)	Group A	20	2.6000	0.46876	0.97500	7.255	<0.001**
	Group B	20	1.6250	0.37609			
Pre UL-El (mm)	Group A	20	2.2000	0.51682	–0.11250	0.607	0.548
	Group B	20	2.3125	0.64825			
Pre LL-El (mm)	Group A	20	1.0750	0.43755	–0.1300	0.130	0.09
	Group B	20	1.2000	0.4701			
Pre upper pharyngeal space (mm)	Group A	20	15.4250	0.76563	0.075	0.459	0.186
	Group B	20	15.3500	0.8287			
Pre lower pharyngeal space (mm)	Group A	20	11.9750	0.76906	0.1000	0.621	0.104
	Group B	20	11.875	0.7758			

*$p < 0.05$ Significant; **$p < 0.001$ - Highly significant

Table 4: Comparison of different skeletal, dental and soft tissue parameters (Post) in terms of [Mean (SD)] among both the groups using unpaired *t*-test

Parameters	*Group*	*N*	*Mean*	*Std. deviation*	*Mean difference*	*t-value*	*p-value*
Post SNA (°)	Group A	20	82.4750	1.28989	0.98750	2.574	0.014*
	Group B	20	81.4875	1.13112			
Post SNB (°)	Group A	20	80.7625	1.13693	1.06250	3.066	0.004*
	Group B	20	79.7000	1.05319			
Post ANB (°)	Group A	20	1.6125	0.39299	–0.17500	1.686	0.100
	Group B	20	1.7875	0.24702			
Post A-VR (mm)	Group A	20	67.4375	1.33986	1.60000	3.221	1.0
	Group B	20	65.8375	1.39786			
Post B-VR (mm)	Group A	20	63.7000	1.16020	0.10000	3.178	0.900
	Group B	20	63.7125	1.21028			
Post SN/GoMe (°)	Group A	20	30.6500	0.75829	–1.48750	5.295	<0.001**
	Group B	20	32.1375	1.00156			
Post N-Me (mm)	Group A	20	100.8125	2.01944	–1.80000	3.136	0.003*
	Group B	20	102.6125	1.58420			
Post N-ANS (mm)	Group A	20	47.4875	1.46556	–0.01250	0.027	0.978
	Group B	20	47.5000	1.44414			
Post ANS-Me (mm)	Group A	20	53.3375	1.69223	–1.80000	3.921	<0.001**
	Group B	20	55.1375	1.16267			
Post UI-VR (mm)	Group A	20	71.4000	1.14536	–3.63750	9.254	<0.001**
	Group B	20	75.0375	1.33346			
Post L1-VR (mm)	Group A	20	69.1000	0.82078	–3.38750	8.719	<0.001**
	Group B	20	72.4875	1.53141			
Post U6-VR (mm)	Group A	20	34.1625	1.06461	1.43750	4.336	<0.001**
	Group B	20	32.7250	1.03205			

Post L6-VR (mm)	Group A	20	37.3625	1.31158	1.65000	4.025	<0.001**
	Group B	20	35.7125	1.28061			
Post U1/HR (°)	Group A	20	118.1375	0.83302	–7.13750	22.195	<0.001**
	Group B	20	125.2750	1.17232			
Post L1/HR (°)	Group A	20	46.9375	0.97964	–2.98750	9.656	<0.001**
	Group B	20	49.9250	0.97704			
Post U6/HR (°)	Group A	20	95.8875	3.33687	–0.26250	0.249	0.804
	Group B	20	96.1500	3.32099			
Post L6/HR (°)	Group A	20	93.8125	2.75403	–0.30000	0.338	0.737
	Group B	20	94.1125	2.85905			
Post U1-HR (mm)	Group A	20	58.4350	0.63889	–7.22750	28.226	<0.001**
	Group B	20	65.6625	0.95033			
Post L1-HR (mm)	Group A	20	56.7750	0.78598	–8.31250	27.781	<0.001**
	Group B	20	65.0875	1.08299			
Post U6-HR (mm)	Group A	20	34.1125	1.22064	1.13750	3.199	0.003*
	Group B	20	32.9750	1.01922			
Post L6-HR (mm)	Group A	20	37.0750	1.35748	1.46250	3.551	<0.001**
	Group B	20	35.6125	1.24466			
Post IMPA (°)	Group A	20	92.3750	1.56756	–7.25000	14.168	<0.001**
	Group B	20	99.6250	1.66721			
Post Interincisal group (°)	Group A	20	115.9625	1.62480	18.23750	32.536	<0.001**
	Group B	20	97.7250	1.90895			
Post Nasolabial angle (°)	Group A	20	100.2000	1.32437	–0.07500	0.178	0.860
	Group B	20	100.2750	1.34482			
Post overjet (mm)	Group A	20	2.6875	0.47900	0.15000	1.025	0.312
	Group B	20	2.5375	0.44629			
Post overbite (mm)	Group A	20	2.3500	0.36635	0.40000	4.411	<0.001**
	Group B	20	1.9500	0.17396			
Post UL-El (mm)	Group A	20	–1.0000	0.62302	–0.03750	0.194	0.847
	Group B	20	–0.9625	0.59756			
Post LL-El (mm)	Group A	20	1.0000	0.51299	0.17500	1.078	0.288
	Group B	20	0.8250	0.51363			
Post upper pharyngeal space (mm)	Group A	20	15.3500	0.79637	0.77500	3.033	0.004*
	Group B	20	14.5750	0.81958			
Post lower pharyngeal space (mm)	Group A	20	11.9000	0.78807	0.76250	2.989	0.005*
	Group B	20	11.1375	0.82508			

*$p < 0.05$ Significant; **$p < 0.001$ - Highly significant

Treatment options include orthognathic surgery alone or in conjunction with orthodontic treatment. The four first premolars are typically extracted as part of orthodontic therapy, and the incisors are then retracted and/or up-righted. Le Fort I osteotomy, bilateral sagittal split ramus osteotomy (BSSO), and upper and lower anterior subapical osteotomies are all possible options for orthognathic surgery when necessary.[18] Extraction of premolars being an ideal treatment option for Bimaxillary proclination cases is not always accepted by patients. In the initial years, controversy over extraction vs nonextraction was already going on and it is still in question because of less acceptance of patients for extraction.

Extraction of premolar began with Tweed's edgewise philosophy and Begg's technique but over the years it was observed that facial esthetics are being compromised after extraction of premolar. And this was supported by studies done by Little RM.[19] in 1981 and McReynolds and Little.[20] in 1991 where they concluded that premolar extraction does not guarantee the stability of alignment of teeth, arch width, and length typically decreased after retention whereas crowding increased. The impact on the patient's soft tissue profile is the main consideration when deciding between extraction and nonextraction therapy modalities. Nonextraction treatment plans contend that in some circumstances, extractions damage periodontal health and cause a "dish in" of the face.

Although the introduction of temporary anchorage devices (TADs) has fundamentally changed how orthodontic treatment is planned, it may be overstating the facts to claim that TADs have completely revolutionized the field of contemporary orthodontics. Nevertheless, by altering the discrepancy envelope, TADs have increased the range of orthodontic therapy.[21] It has helped in transitioning surgical treatment plans into non-surgical ones, extraction into non-extracting ones, and many other similar transformations. With or without extraction, TAD's skeletal anchorage is effective for sagittal dental movement, such as distalizing or mesializing the whole dentition.[22] Temporary anchorage devices are a flexible alternative for the practitioner and were utilized for orthodontic anchorage. They are less expensive than endosseous substitutes, and the potential for early loading after installation cuts down on treatment time. They act as an absolute anchorage as they not only retract entire dentitions, but it even reduces unwanted reciprocal movement and can increase treatment effectiveness.[23]

Based on the available data, no comprehensive study was observed on the comparison and evaluation of skeletal, dental, and soft tissue parameters between extraction retraction and nonextraction distalization groups in bimaxillary cases and hence this study was conducted.

To prevent unintentional bias during the planning stage of a study protocol, a randomized controlled trial (RCT) evaluating the effects among study groups is conducted. The randomness of randomization (or random allocation of participants), which implies no pattern or predictability for assigning individuals to treatment and control groups can alleviate these biases and hence randomization was used in this clinical study.[24] Blinding aids in preventing numerous biases from accidentally creeping into the study. Hence, in our study, the co-investigator was blinded to reduce the differential treatment provided to the subjects in the intervention or control groups.[25]

Bimaxillary proclination patients who needed premolar extractions were split into Groups A and B when they entered the research. SNA°, SNB°, ANB°, A-VR, B-VR, N-Me, N-ANS, and ANS-Me had no statistically significant changes between pre- and post-treatment records of skeletal parameters in group A (extraction), as indicated in Table 1 ($p > 0.05$). And it was consistent with the results of premolar extraction, retraction using mini implants, and space closure performed by Deepa Verma et al.[26] and Min Ho Jung.[12]

Changes observed in the incisor position with respect to the vertical reference line in the upper was 5.6 mm and with respect to lower was 4.98 mm, similar changes were observed in the incisor inclination with respect to the horizontal reference plane in the upper was 9.9° and with respect to lower was 4.9° while the changes in linear measurements between incisor and horizontal reference line observed were 2.25 mm and 1.75 mm in the upper and lower arch. Salma Al-Sibaie et al.[27] in her study of assessing the changes following en masse retraction with mini-implants found that the upper incisor edges were significantly retracted and intruded in the mini-implants group (Table 1). Changes observed in molar inclination were due to mesial tipping of molar seen in the extraction group during retraction and the reason can be by not reinforcing the anchorage units, the molars may have moved mesially which was statistically significant but clinically it was non-significant. Nayef H Felemban et al.[28] in their case report have observed similar mesial movement of molar by 2 mm and he concluded it can be because of loss of anchorage. Yao et al.[29] and Kim et al.[30] in their respective studies have found a similar physiological mesial movement of the molar despite the use of mini-implants either due to early extraction of premolar and delay in the retraction process or can be due to anchor loss.

Differences seen in IMPA and Interincisal angle were highly statistically significant by 9.6° and 20.22° between pre and post-records inferring that incisors have retracted. Similarly, the nasolabial angle got increased by 14.2° inferring that the soft tissue profile of the patient has got improved after retraction with this the difference of 3.2 mm between the upper lip to the esthetic line is not only highly statistically significant, but it is even clinically significant by change observed in the facial profile. A highly statistically significant change of 0.8 mm can be seen in overjet which can be clinically appreciated while the change in overbite was 0.25 mm which was statistically significant but clinically not appreciable much (Table 1). According to theories about soft tissue alterations, the degree of anterior dental retraction and the ensuing change in lip position is determined by how anchorage management is done according to Burstone, 1982.[31] Whereas Salma Al-Sibaie et al.[27] in their article found that upper and lower lips were retracted, and the nasolabial angle widened more in the mini-implants group because the upper incisors shifted more distally in that group.

Whereas Lorenz Moser et al.[32] in their article have concluded that neither premolar extraction nor distalization will affect the facial profile. Whereas Madhur Upadhyay et al. and his co-workers[33,34] have found that facial profile improves gradually after retraction along with changes in the inclination of incisors and molar.

In group B (nonextraction): as shown in Table 2, SN-GoMe, N-Me, and ANS-Me show a highly statistically significant change of 1.43°, 1.86 and 1.88 mm respectively and it was clinically appreciable ($p < 0.001$). Similar changes were observed in studies conducted by Gui Chen et al.[35] and Shailesh Vandera et al.[36] where they did complete upper and lower arch distalization by IZC and buccal shelf screws.

U1-VR, L1-VR, U6-VR, L6-VR, U1-HR (°), L1-HR (°), U1-HR (mm), L1-HR (mm), U6-HR (mm), L6-HR (mm), IMPA,

Interincisal angle, nasolabial angle, overbite, UL-EL, and upper and lower pharyngeal space shows highly significant changes between pre- and post-treatment records ($p < 0.001$).

Kavitha Ramsundar et al.[37] and her co-workers in her prospective study concluded that changes in incisor position and interincisal angle were statistically significant whereas that in upper and lower pharyngeal space were not statistically significant which is completely opposite to the results we got in our study.

Change in the incisor position from the vertical reference line between pre and post-records observed was 2.03 and 1.63 mm in the upper and lower arch while the change in molar position observed where 1.5 and 1.8 mm suggesting that distalization of the upper and lower arch has led to distal tipping of the molar and the finding was similar to observations observed by Mitiksha Shahni et al. and her co-workers where she concluded that due to lack of control in tipping movement as bracket are placed labially it leads to distal tipping of molars.[38] Along with incisor retraction, the minor change in overbite of 0.35 mm cannot be clinically appreciable though it is statistically significant. Change in incisor inclination with respect to horizontal reference plane observed was 2.76° and 1.98° which was both, statistically and clinically significant, while the linear change in incisor and molar position with respect to horizontal reference plane observed was 4.8 and 1.2 mm with respect to upper arch suggestive of maxillary incisors extrusion and the intrusion of the molars while a change of 6.5 and 1.5 mm seen with respect to lower arch is suggestive of minor extrusion of molars and intrusion of incisors during distalization and it was clinically significant.[38] Changes seen in IMPA, interincisal angle, and nasolabial angle are 1.96°, 1.91°, and 14.37° which are highly statistically significant and clinically appreciable by a reduction in protrusion and improvement in lip competency is appreciated by a change in UL-EL and LL-EL of 3.2 and 0.25 mm.

Wilson Guilherme Nunes Rosa et al. and his other co-workers in their prospective study found greater incisor retraction and distal tipping of the molars similar to results obtained in our study.[39] A statistically significant change in decrease of upper and lower pharyngeal space of 0.85 mm and 0.83 mm can be seen which cannot be clinically appreciable (Table 2).[13–15]

On comparing the pretreatment records (Table 3) no clinical significance was found and on comparing post-treatment records (Table 4) between group A and group B.

N-Me shows a statistically significant change while SN-GoMe and ANS-Me show a highly statistically significant change between group A and group B, with more change seen in group B, i.e., in the Nonextraction group indicating that there is an increase in lower anterior facial height.

Highly statistically significant change can be observed in U1-VR, L1-VR, U6-VR, and L6-VR between group A and group B, with more change in incisor position can be in group A than in group B while change in the position of molar can be appreciated more in group B because of distalization (distal tipping of molar) than in group A. Similarly UI-HR°, L1-HR°, U1-HR (mm), L1-HR (mm), U6-HR (mm) and L6-HR (mm) high statistically significant change can be observed between the groups with a major change in incisor position seen in group A than in group B and change in molar position more in group B than in group A. Highly statistically significant Change in IMPA and interincisal angle can be seen between group A and group B, with more appreciable changes in group A. Nasolabial angle, overjet, UL-EL, LL-EL has no statistically significant change between group A and group B. Overbite and upper and lower pharyngeal spaces are statistically significant between group A and group B.

Limitations and Future Prospects of the Study

This prospective study was designed as a randomized clinical study. Firstly, the nature of the intervention impeded single-blinding. In this investigation, the examiner was blinded to the group assignments for measuring outcome variables and running statistical analyses, and the patients were chosen at random. Secondly, the sample size was quite small. Our patients tended to be female in the majority. Although there were different sex distributions within the groups. As a result, the findings might not apply to a larger population. Thirdly, during en-masse retraction, the maxillary second molars were excluded. Future research should be planned to study the 3-D movements of the maxillary and mandibular molars during retraction and distalization.

Conclusion

This study evaluated and compared the skeletal, dental, and soft tissue parameters by therapeutic extraction of first premolar and nonextraction distalization of maxillary and mandibular arches in bimaxillary proclination using a skeletal anchorage system. The following conclusions can be drawn: For Group A, there is a significant change in the position of incisors by retraction, and the facial profile improves gradually indicated by increased nasolabial angle and decreased distance between the upper and the lower lip to that of the esthetic line. For Group B, there is a significant change in lower facial height due to distalization along with a gradual decrease in overjet and pharyngeal space. On comparing between Groups A and B, a highly significant difference can be seen with respect to the amount of retraction of incisors and molars. More incisor retraction is evident in group A than in group B, while the change in molar position and pharyngeal space is evident more profoundly seen in Group B. The time duration taken for the retraction of incisors is less in comparison to the time taken for distalization in the nonextraction group.

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