

Skeletal and dentoalveolar changes after total maxillary arch distalization using the casted palatal plate vs. buccal miniscrews: A Randomized clinical trial.

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Abstract

Objectives: To evaluate the skeletal, dento-alveolar and soft tissue changes after skeletally anchored total maxillary arch distalization using the casted palatal plate in comparison with buccal miniscrews.

Materials & Methods: 40 adult patients (33 females and 7 males, average age 20 ± 3.1 years) with distal molar and canine relationships were treated with total maxillary arch distalization. Patients were divided according to the direct skeletal anchorage method into two equal groups; in the first group; 20 patients the casted palatal plate was used, while in the second group; 20 patients buccal miniscrews were inserted.

A total of 35 variables were measured on pre- and post-distalization lateral cephalograms. Paired t-tests were used to evaluate the differences between pre- and post-distalization in each group, and independent t-tests were used to compare treatment changes between the two groups.

Results: A significant distalization combined with intrusion and distal tipping of the maxillary first molar were observed in the plate group (4.33 mm, 1.85 mm and 3.10° , respectively). While the miniscrews group showed less amount of distalization with non-significant intrusion and distal tipping (1.88 mm, 0.8 mm and 2° , respectively). The plate group showed more decrease of SNA, ANB, B-angles and Wits-distance.

There were no significant differences between the two groups regarding sagittal, vertical and angular changes of the maxillary incisors as well as soft tissue changes.

Conclusions: Both of the casted palatal plate and buccal miniscrews might be viable as anchorage devices for total maxillary arch distalization during the treatment of Class II malocclusion patients. However, the casted plate may be considered more effective in either retraction or vertical control.

Clinical relevance: Skeletally anchored maxillary total arch distalization could be an effective treatment procedure for Class II malocclusion.

Introduction

Non-extraction treatment is one of the most challenging modalities in class II malocclusion adult patients. It was frequently accomplished by distal movement of the maxillary posterior teeth in order to achieve a class I occlusal relationship using extra- or intra-oral appliances [1].

However, the major drawbacks with the extra-oral appliances, such as headgear, are the depending on patient compliance and they are esthetically unacceptable [2–4].

Many intra-oral distalizing appliances were introduced to overcome these problems, but they also have common side effects; such as the loss of anchorage observed by mesial movement of the premolars and anterior flaring during distalization. In addition to the relapse of molar distalization during the retraction of the anterior segment [5–8].

To reduce the impact of these consequences, the use of temporary anchorage devices (TADs) has become a new orthodontic treatment strategy over the past decades [9–12].

TADs have been used indirectly for molar distalization through bone-anchored appliances such as the pendulum and distal jet. However, there were some disadvantages regarding the amount of distal tipping created by the force delivery system [13].

Several studies showed the efficiency of using TADs to directly anchor movement of individual teeth or the entire dental arch in three planes with minimum side effects, which make them a proper choice for use in distalizing the whole maxillary arch in non-extraction treatment [11, 12, 14, 15].

Miniplates have been placed in the infrazygomatic region, but flap surgery is required for placement and removal on each side, which may cause swelling and pain [16, 17].

Alternatively, buccal miniscrews (MS), inserted either in the infrazygomatic crest (IZC) [18, 19] or in the interradicular spaces (IR), can be used effectively for total arch distalization.

Clinical studies found that the maxillary posterior teeth could be distalized by 1.29 to 4.22 mm with approximately 0.6 to 7.2 degrees of distal tipping using buccal interradicular miniscrews [20–24]. However, interradicular spaces may have a limited range of action due to the interference with the path of tooth movement. Moreover, re-implantation of miniscrews might be necessary when a large amount of distalization is required [23, 25, 26].

Therefore, several authors have evaluated the quality and the quantity of the palatal bone and the thickness of the palatal soft tissues [27–29]. They concluded that the paramedian palatal area is a very suitable site for mini-implanting without the need for any surgical procedures, because of its proper keratinized tissue, fully dense bone, and sufficient support to place TADs. Besides, it does not have any dental root or significant vessels or nerves [30–33].

The palatal approach of TADs placement has been recommended by some clinicians [34–36]. Recently, the use of the modified C-palatal plate (MCP) for maxillary arch distalization has been reported for Class II corrections in both adolescents and adults [25, 37]. MCPs showed a significant distalization of the maxillary first molars by about 1.65 to 5.4 mm with 0.28 to 4.36 degrees of distal tipping [22, 38, 47, 39–46].

Lee et al, in a retrospective clinical study, compared the treatment effects between palatal and buccally placed TADs, and showed significantly greater amounts of distalization and intrusion with a smaller amount of distal tipping of the maxillary first molars using the MCP [22].

A meta-analysis was conducted to assess the treatment effects of buccally and palatally placed TADs on the maxillary first molars during distalization; they concluded that the IR MS resulted in less distal tipping but also in less distalization and further RCTs or prospective studies on the effect of various designs of TAD-supported distalization are warranted [48].

In addition, a recently published meta-analysis concluded that using of TADs for maxillary total arch distalization could be an effective and stable treatment procedure. However, RCTs or prospective cohort studies are highly recommended to establish a clinical evidence regarding their efficiency [49].

Moreover, there are some disadvantages with MCPP's application regarding its design; it should be adjusted manually on a dental cast to fit the patient's palate because of its prefabricated design, which needs special considerations as inflammation of the palatal tissues may be resulted due to incomplete adaption [37].

In addition, the stability of MCPP depends on the insertion of three mini-screws at the paramedian area, so tight adaptation should be achieved to reduce the potential for plate tipping. However, soft tissue impingement can result when force is applied [50]. As well as the high expected cost of the plate and the three mini-screws.

Depending on the above-mentioned reasons, we introduced the casted palatal plate as a new customized skeletally anchored plate for total maxillary arch distalization during the treatment of class II malocclusion.

The purpose of this study was to evaluate the skeletal, dento-alveolar and soft tissue changes resulting from total maxillary arch distalization using the newly developed casted palatal plate in comparison with buccal miniscrews during the non-extraction treatment of class II malocclusion.

Materials and methods

Study design, ethics and consent to participate:

This two-arms, randomized, single-blind clinical trial was conducted in accordance with the guidelines of the Consolidated Standards of Reporting Trials (CONSORT) [51].

The study protocol was approved by **the Scientific Research Committee of the University of Damascus (No. 2019 - 821)**. **All patients provided written** informed consent prior to enrollment in the study according to the Declaration of Helsinki.

Participants and eligibility criteria:

The sample for this trial consisted of 40 subjects (33 females and 7 males, average age 20 ± 3.1 years) selected from patients evaluated at the Department of Orthodontics-**Faculty of Dentistry-Damascus University** between 15/12/2020 and 06/07/2021 according to the following inclusion criteria: (1) **patients older than 16 years at stages V or VI of cervical vertebral maturation (CVM) according to Baccetti et al [52], (2) skeletal class I or mild skeletal class II, (3) bilateral distal molar and canine relationships, (4) normal or horizontal facial growth type and (5) moderate maxillary arch crowding (< 5 mm).**

Exclusion criteria for the study were: (1) **class II with retro-position of mandible**, (2) **posterior cross bite** (3) **poor oral hygiene**, (4) **previous orthodontic treatment**, (5) **systemic diseases or syndromes**.

A total of 285 subjects were examined, 52 patients were initially accepted according to the eligibility criteria. After the diagnostic records were taken for the selected subjects, 12 patients were excluded and 40 patients were finally enrolled in the trial (figure 1).

Fixed appliances with preadjusted MBT 0.022-inch slot brackets and bands (Ortho Classic, OC-Orthodontics, United States) were delivered on the maxillary arch, including the second molars.

Following initial leveling and alignment, a 0.016 * 0.022-inch stainless steel arch wire was tied into the bracket-slots with wire ligatures.

Then patients were randomly divided according to the anchorage method into two equal groups (table 1): 20 were treated with the casted palatal plate (average age 18.8 ± 2.8 years), and 20 were treated with miniscrews placed buccally in the interradicular space (average age 21.1 ± 3 years).

Sample size calculation:

The sample size calculation was performed via G*power ver. 3.1.9.2. It showed that at least 20 patients were required in each group when paired t-test with an alpha error of 0.05 and power of 95% were employed to identify an effect size of 0.77 depending on the mean and standard deviation of maxillary incisor retraction (3.62 ± 4.7 mm) from a previous study [43].

Randomization, allocation concealment and blinding:

To prevent bias, the allocation was determined randomly by asking one of the academic staff (not involved in this research) to use computer-generated random numbers with an allocation ratio of 1:1.

Allocation sequence was concealed using sequentially numbered, opaque, sealed envelopes, which were opened only after the leveling and alignment stage. Blinding of personnel and participants were not applicable. Therefore, blinding was applied only for outcomes' assessor.

Total arch distalization:

The casted palatal plate consisted from a custom-made Vitalium bar provided with two holes (2 mm of diameter) for mini-screws' insertion localized posteriorly at its medial portion at the paramedian area, and two hooks localized at its posterior lateral sides (about 10 mm of distance to the arch level) (figure 2).

The casted palatal plate was placed on the posterior palatal region between the maxillary 2nd premolars and the first molars using two self-drilling 8 mm length, 1.6 mm diameter mini-screws (AZDENT, Henan, China) inserted in their holes at the paramedian area.

An anterior stainless-steel palatal bar with two hooks extending along the gingival margins of the teeth was inserted in the maxillary first molars' palatal tubes.

Immediately after placement, distalization was initiated by engaging elastics (Ortho Classic, OC-Orthodontics, United States) between the posterior hooks of the casted plate and the hooks of the palatal bar, applying approximately 200 g of force per side (Figure 3A).

The buccally placed miniscrews (8-mm length and 1.6-mm diameter; AZDENT, Henan, China) were installed by the same operator between the maxillary first and second molars approximately 5-mm apical to the cemento-enamel junction. An elastic chain was connected between the mini-screw and a 7-mm hook welded distal to the canine bracket (Figure 3B) applying about 200 g of force per side. In cases of large distalization, repositioning of the inter-radicular miniscrews was necessary toward the end of treatment.

The patients' appointments interval was maintained at 3 to 4 weeks in both groups.

Cephalometric measurements:

Lateral cephalograms of subjects were taken on the same x-ray unit, at a film focus distance of 1.50 mm (a cathode voltage of 70 kV). All images were in natural head position, centric relation, and reposed lips. The magnification errors were corrected via digitizing a scale incorporated with each image to achieve the 1:1 ratio.

All radiographs were traced and measured manually by the same investigator (TR) under standardized conditions.

As a basis of measurements, an X–Y cranial base coordinate system was constructed on the radiographs. An X-axis was drawn 7° to the sella–nasion line (SN) and the Y-axis was illustrated along the Sella perpendicular to the X-axis [53].

Tips of the distobuccal cusps and apex of distobuccal roots for U6 and U7 as well as incisal edge and root apex for U1 were used as dental landmarks, and their perpendicular distances to the Y and X lines were measured for horizontal and vertical changes, respectively.

In cases of double contours, the middle between the two landmarks was used for measurement.

A total of 35 skeletal, dental and soft tissue measurements were made by one examiner as shown in Figure 4. The differences between pre- (T1) and post-distalization (T2) were calculated (T1-T2) and compared between the two groups.

To identify measurement reliability, 10 randomly selected cases were retraced and measured four-weeks apart by the same examiner.

Statistical analysis:

Statistical analyses were performed by SPSS; IBM V 23.0.0 software and statistical significance level was established at $P < 0.05$.

The method error was calculated using Dahlberg's formula: Error of method = $\sqrt{\sum d^2/2n}$ where d is the difference between two measurements and n is the number of double determinations [54]. The intra-class correlation coefficient (ICC) was used to assess intra-examiner reliability.

After confirmation of normal distribution of the data by Shapiro-Wilk test, paired t-tests were used to evaluate the differences between pre- and post-distalization measurements within each group, and two samples independent t-tests were used to compare the pre-distalization measurements and the amount of (T1-T2) changes between the two groups.

Results

The error of the method according to Dahlberg's formula ranged from 0.004 to 0.67, and the ICCs ranged from 0.993 to 1.000, which meant high reproducibility for the measurements.

A comparison of gender distribution, overjet and severity of class II before distalization (T1) showed no significant differences between the two groups. However, the initial age was significantly different (table 1).

The Mean duration of distalization was 11.2 ± 3.7 months for the plate group, while it was 13.03 ± 3.11 months for the miniscrews group, and the difference between the groups in distalization duration was not significant (table 1).

Before distalization (T1), most of the measurements showed non-significant differences between the two groups (table 2), except of, U6C-Y, U7C-Y, and U7R-Y, which were larger in the plate group ($P < 0.05$). SNA and ANB angles were also larger showing a more skeletal class II in the plate group ($P < 0.05$).

The plate group showed 4.33 mm of distalization, 1.85 mm of intrusion and 3.10° of distal tipping of the maxillary first molar. The means of SNA, ANB, B angles and Wits distance decreased significantly ($P < 0.05$) (table 3).

In the miniscrews group, the maxillary first molar showed 1.88 mm of distalization, 0.8 mm of intrusion and 2.0° of distal tipping. However, there were no significant skeletal changes, except of decrease of Wits-distance and increase of Ar-Go-Me angle (table 4).

Comparing the treatment effects between the two groups (table 5), the plate showed greater distalization, distal tipping and intrusion of the maxillary first molar compared to the buccal miniscrews. However, there were no significant differences between the two groups regarding changes of the maxillary incisors.

Regarding soft tissue changes, the upper and lower lips were significantly retracted in the two groups ($P < 0.001$), and all soft tissue variables demonstrated no significant differences between the groups.

Discussion

Recently, temporary anchorage devices (TADs) have been increasingly used in orthodontics to reduce the need for extraction and surgical treatments [55]. That was due to the provision of absolute and skeletal anchorage for dental movements [56, 57], which makes them a proper choice for use in the distalization of the whole upper arch during non-extraction treatment [58].

TADs are able to retract the whole maxillary arch en-masse without dividing the procedure to two stages and eliminate mesial tipping of the premolars and protrusion of the anterior segment [40].

In the last few years, en-masse distalization of the entire maxillary arch has been one of the most successful therapeutic methods to correct class II relationship.

Several studies have showed the efficiency of using TADs in total maxillary arch distalization. However, there are few prospective studies with adequate number of subjects evaluating the treatment effects of these mechanics.

This trial was conducted to evaluate the efficiency of using the customized palatal plate vs. buccally placed miniscrews for total maxillary arch distalization during the non-extraction treatment of class II malocclusion.

Both casted plate and inter-radicular mini-screws were resulted in a significant distal movement of the maxillary first molars. However, there were some significant differences in the treatment effects between the two groups.

The plate group showed 4.33 mm of distalization of the maxillary first molar, combined with 1.85 mm of intrusion and 3.10° of distal tipping. Previous studies also reported similar distalization, intrusion and distal tipping of U6 resulted by the application of MCP in adults [22, 38, 40, 46–48, 59].

The miniscrews group showed 1.88 mm of distalization of the maxillary first molar with non-significant intrusion and distal tipping (0.80 mm and 2.0°, respectively). Previous studies also reported small amounts of U6 intrusion associated with buccal miniscrews [21–23, 60]. Bechtold et al., reported 1.4 mm of significant intrusion when using two miniscrews on each side [20]. However, Yu et al., 2014 reported that distalization with mini-implants on the buccal side would cause the first molar to be distally tipped and extruded [61].

This difference in vertical displacement with mini-screws can be partially due to the vertical position of the mini-screws, and/or the level of the hooks attached to the arch wire [21]. Applying force from a retraction hook at a higher level resulted in initial lingual root movement of the anterior segment, and extrusive distal translation of the posterior segment [62].

Comparing the two groups, the maxillary molars showed significantly greater amount of distalization in the plate group. More intrusion and distal tipping were also resulted in the plate group, but they were not

significantly different from them in the miniscrews group.

This was in agreement with previously published finite element and clinical studies that reported greater distalization associated with MCPD when compared to buccal miniscrews [22, 37, 61]. In addition, a recently published meta-analysis reported that 2.75 mm of U6 distalization was produced by buccal interradicular TADs, but it was 4.07 mm with palatal TADs [48]; this might be due to the larger range of action provided by the palatal area without interference with proximal roots.

Although not similar to previous studies which reported that distalization with palatal plate would result in less tipping than buccal mini-screws [22, 61], this was in agreement with Bayome et al., 2021 who resulted that the buccal inter-radicular TADs were associated with a small amount of first molar distal tipping (1.70°) [48].

On the other hand, the casted plate produced less tipping than other palatally skeletal anchored distalizing appliances, which produced about 8.4° of distal tipping [13]. This reduction in tipping could be attributed to the force vector provided by the appliance that produces more bodily movement [37].

Both casted plate and miniscrews showed significant retraction and palatal inclination with non-significant intrusion of upper incisors. However, the differences between the two groups were not significant. The posterior intrusion as well as non-significant anterior intrusion resulted in a non-significant change of the occlusal plane angle.

Conversantly, studies about MCPD reported significant anterior extrusion, which resulted in a clockwise rotation of the occlusal plane [22, 38, 40, 46, 47, 59]. This may be attributed to the difference in force vector delivered by using hooks of the casted plate at about 10 mm from the wire level, which produced more bodily movement [25].

Song et al., also reported insignificant anterior intrusion using buccal miniscrews [60], meanwhile other studies demonstrated anterior extrusion [20–23]. This may be due to the differences in the position of retraction hooks and/or miniscrews [62].

Regarding skeletal changes, the plate group showed significantly more decrease in ANB, B and Ar-Go-Me angles. This might be because of the larger posterior intrusion in the plate group, which resulted in a limited anterior rotation of the mandibular plane as the S-N:Go-Me angle slightly decreased.

For the soft tissue changes, upper lip was retracted significantly in both groups (4.55 mm in the plate group and 3.2 mm in the miniscrews group), but no significant differences were found between the two groups in amount of retraction as well as other soft tissue changes. This was similar to the findings of Lee et al., study [22].

Limitations:

The current study was conducted on two-dimensional lateral cephalograms. So, it was affected by difficulty in identifying landmarks because of the superimposition of anatomical structures. In addition, the long-term stability after total arch distalization was not evaluated.

Conclusions

Depending on the results of this research, it can be concluded that both of casted palatal plate and buccal miniscrews were effective as direct skeletal anchorage devices during maxillary total arch distalization.

The casted palatal plate can produce greater distalization combined with significant intrusion of the maxillary first molars, while the distalization with buccal miniscrews can be associated with less amount of distal tipping.

The casted plate can achieve more decrease of ANB angle and B angle in the comparison with miniscrews. In addition to a limited anterior rotation of the mandibular plane.

Both of casted palatal plate and buccal miniscrews can lead to similar results regarding the retraction, intrusion and palatal inclination of the maxillary incisors as so as the soft tissue changes.

These results suggest that, both of casted palatal plate and buccal miniscrews might be an effective treatment options for total arch distalization in adult patients with Class II malocclusion, while the casted plate might be more indicated in cases of larger distal movement or vertical control are required.

Declarations

Ethics approval and consent to participate:

The present study was approved by the Scientific Research Committee of the University of Damascus (No. 2019 - 821). **All patients provided written** informed consent prior to enrollment in the study according to the Declaration of Helsinki.

Acknowledgements:

Not applicable.

Author contributions:

TR has been involved in the study design, treatment of the including patients, and manuscript revision. TA performed measurements of outcome variables and drafted the manuscript. GM collected the data and evaluated the statistical results. MY revised the manuscript and supervised the whole trial. All authors read and approved the final manuscript.

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The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Consent for publication:

Not applicable.

Competing interests:

The authors declare that they have no competing interests.

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Tables

Table 1: Demographic data.

	Plate group	Miniscrews group	<i>P</i> value
Age (years)	18.8 ± 2.8	21.1 ± 3	0.02 ^{a*}
Male	5	2	0.407 ^b
Female	15	18	
Overjet (mm)	5.73 ± 2.10	5.65 ± 1.43	0.896 ^a
Class II molar relationship (mm)	4.18 ± 0.61	4.11 ± 1.18	0.83 ^a
Distal canine relationship (mm)	5.30 ± 1.13	5.28 ± 1.33	0.949 ^a
Distalization duration (months)	11.2 ± 3.7	13.03 ± 3.11	0.078 ^a

^aIndependent t-test, ^bChi-square test, **P* < 0.05.

Table 2: Comparison of pre-distalization (T1) variables between the two groups.

	Plate group (n= 20)		Miniscrews group (n=20)		P value
	mean	SD	mean	SD	
Skeletal					
SNA (°)	82.30	2.87	79.35	4.23	0.014*
SNB (°)	75.95	3.02	74.70	4.04	0.275
ANB (°)	6.35	2.30	4.65	1.46	0.008*
SNPog (°)	77.2	3.27	76.25	3.88	0.408
SN-SPP(°)	8.45	2.35	9.50	3.19	0.243
SN-Go Me (°)	31.15	5.39	33.75	5.79	0.150
SN –Ocp (°)	17.15	4.42	19.4	4.90	0.136
B angle (°)	24.20	5.48	24.50	5.54	0.864
N S Ar (°)	125.85	5.24	125.7	7.29	0.941
S Ar Go (°)	145.60	6.73	149.95	7.94	0.069
Ar Go Me (°)	119.8	5.24	118.05	5.74	0.320
Bjork Sum (°)	391.35	4.68	393.7	6.59	0.201
N S Gn (°)	68.65	3.95	69.95	4.97	0.365
Jarabak ratio (S-Go/N-Me)	0.67	0.04	0.66	0.04	0.505
Wits (mm)	2.95	1.99	1.93	2.25	0.135
Dental					
U1C-Y (mm)	69.15	7.73	66.55	6.13	0.25
U1R-Y (mm)	61.18	5.28	59.4	5.12	0.29
U1C-X (mm)	65.90	4.78	69.60	7.18	0.063
U1R-X (mm)	45.95	3.75	49.15	5.55	0.039
U1 angulation (°)	112.4	6.97	108.63	8.40	0.130
U6C-Y (mm)	35.55	3.63	32.18	3.35	0.004*
U6R-Y (mm)	37.9	3.19	36.75	3.43	0.280
U6C-X (mm)	59.7	4.60	61.1	5.97	0.411
U6R-X (mm)	43.15	3.07	44.75	4.54	0.199
U6 angulation (°)	79.25	5.96	76.4	5.20	0.115

U7C-Y (mm)	26.47	3.31	22.83	2.82	0.001*
U7R-Y (mm)	30.84	3.11	28.4	2.84	0.015*
U7C-X (mm)	57.84	4.40	58.15	5.28	0.845
U7R-X (mm)	41.55	3.63	42.75	4.36	0.359
U7 angulation (°)	74.24	5.80	70.80	6.53	0.091
Soft tissue					
UL-Y (mm)	80.50	6.36	77.95	7.74	0.262
LL-Y (mm)	76.50	6.45	73.85	8.15	0.261
UL-E (mm)	-1.30	2.51	-1.33	2.48	0.975
LL-E (mm)	0.03	2.97	-0.53	1.67	0.475
Nasolabial angle (°)	105.1	7.41	101.25	10.25	0.182
Labiomental angle (°)	102.7	23.07	100.20	18.32	0.706

Independent t-test, * $P < 0.05$.

Table 3: Comparison of pre- and post-distalization variables in the plate group.

	Before distalization (T1)		After distalization (T2)		Pvalue ^a
	mean	SD	mean	SD	
Skeletal					
SNA (°)	82.30	2.87	81.35	2.68	0.031*
SNB (°)	75.95	3.02	76.58	2.93	0.103
ANB (°)	6.35	2.30	4.78	2.35	0.000**
SNPog (°)	77.20	3.27	77.6	3.08	0.303
SN-SPP(°)	8.45	2.35	8.43	2.39	0.944
SN-Go Me (°)	31.15	5.39	30.23	5.98	0.105
SN –Ocp (°)	17.15	4.42	18.5	3.85	0.121
B angle (°)	24.20	5.48	23.1	5.05	0.030*
N S Ar (°)	125.85	5.24	125.3	5.38	0.467
S Ar Go (°)	145.6	6.73	145.9	6.98	0.749
Ar Go Me (°)	119.8	5.24	119.2	5.78	0.254
Bjork Sum (°)	391.35	4.68	385.4	24.12	0.261
N S Gn (°)	68.65	3.95	68.35	4.09	0.445
Jarabak ratio (S-Go/N-Me)	0.67	0.04	0.68	0.04	0.119
Wits (mm)	2.95	1.99	1.40	1.71	0.000**
Dental					
U1C-Y (mm)	69.15	7.73	64.20	6.38	0.000**
U1R-Y (mm)	61.18	5.28	59.08	4.54	0.008*
U1C-X (mm)	65.90	4.78	65.00	4.45	0.165
U1R-X (mm)	45.95	3.75	45.95	4.41	1.000
U1 angulation (°)	112.4	6.97	101.15	8.01	0.000**
U6C-Y (mm)	35.55	3.63	31.23	3.27	0.000**
U6R-Y (mm)	37.90	3.19	34.95	3.82	0.001**
U6C-X (mm)	59.70	4.60	57.85	4.06	0.000**
U6R-X (mm)	43.15	3.07	41.70	3.42	0.003*
U6 angulation (°)	79.25	5.96	76.15	5.61	0.007*

U7C-Y (mm)	26.47	3.31	22.95	3.22	0.000**
U7R-Y (mm)	30.84	3.11	28.42	2.99	0.000**
U7C-X (mm)	57.84	4.40	55.68	4.18	0.000**
U7R-X (mm)	41.55	3.63201	40.32	3.37	0.022*
U7 angulation (°)	74.24	5.80	71.42	4.54	0.003*
Soft tissue					
UL-Y (mm)	80.5	6.36	75.95	6.39	0.000**
LL-Y (mm)	76.5	6.45	72.7	6.45	0.000**
UL-E (mm)	1.30	2.51	2.8	2.07	0.000**
LL-E (mm)	-0.03	2.97	1.28	2.60	0.000**
Nasolabial angle (°)	105.1	7.41	112.85	8.92	0.000**
Labiomental angle (°)	102.7	23.07	111.9	18.61	0.023*

^aPaired t-test, * $P < 0.05$, ** $P < 0.01$.

Table 4: comparison of pre- and post-distalization variables in the miniscrews group.

	Before distalization (T1)		After distalization (T2)		P value ^a
	mean	SD	mean	SD	
Skeletal					
SNA (°)	79.35	4.23	79.05	3.59	0.428
SNB (°)	74.7	4.04	75.05	4.03	0.260
ANB (°)	4.65	1.46	4.00	1.34	0.067
SNPog (°)	76.25	3.88	76.4	3.88	0.649
SN-SPP(°)	9.5	3.19	9.85	2.56	0.427
SN-Go Me (°)	33.75	5.79	34.35	4.91	0.347
SN –Ocp (°)	19.4	4.9	20.78	3.76	0.078
B angle (°)	24.5	5.54	25	4.92	0.248
N S Ar (°)	125.7	7.29	126.75	5.81	0.132
S Ar Go (°)	149.95	7.94	148.55	6.40	0.180
Ar Go Me (°)	118.05	5.74	119.65	5.58	0.012*
Bjork Sum (°)	393.7	6.59	394.95	4.67	0.082
N S Gn (°)	69.95	4.97	70.1	4.01	0.805
Jarabak ratio (S-Go/N-Me)	0.66	0.04	0.65	0.04	0.176
Wits (mm)	1.93	2.25	0.13	1.66	0.001*
Dental					
U1C-Y (mm)	66.55	6.13	62.65	6.52	0.000**
U1R-Y (mm)	59.4	5.12	57.28	6.62	0.004*
U1C-X (mm)	69.6	7.18	68.5	5.76	0.234
U1R-X (mm)	49.15	5.55	48.9	4.95	0.752
U1 angulation (°)	108.63	8.40	101.25	5.81	0.000**
U6C-Y (mm)	32.18	3.35	30.3	3.31	0.000**
U6R-Y (mm)	36.75	3.43	35.18	4.07	0.000**
U6C-X (mm)	61.1	5.97	60.3	5.15	0.245
U6R-X (mm)	44.75	4.54	43.85	4.32	0.176
U6 angulation (°)	76.4	5.20	74.4	5.46	0.074

U7C-Y (mm)	22.83	2.82	21.0	3.34	0.000**
U7R-Y (mm)	28.4	2.84	26.73	3.51	0.010*
U7C-X (mm)	58.15	5.28	57.3	5.23	0.166
U7R-X (mm)	42.75	4.36	42.3	4.44	0.370
U7 angulation (°)	70.8	6.53	69.55	6.56	0.281
Soft tissue					
UL-Y (mm)	77.95	7.74	74.75	8.19	0.000**
LL-Y (mm)	73.85	8.15	71.25	8.74	0.000**
UL-E (mm)	1.33	2.48	3.1	1.71	0.000**
LL-E (mm)	0.53	1.67	1.88	1.43	0.000**
Nasolabial angle (°)	101.25	10.25	110.1	9.96	0.000**
Labiomental angle (°)	100.2	18.32	109.5	15.53	0.001**

^aPaired t-test, * $P < 0.05$, ** $P < 0.01$.

Table 5: Comparison of treatment changes between the two groups.

	Plate group (n=20)		Miniscrews group (n=20)		P value between groups ^b
	mean	SD	mean	SD	
Skeletal					
SNA (°)	-0.95	1.82	-0.30	1.66	0.245
SNB (°)	0.63	1.63	0.35	1.35	0.558
ANB (°)	-1.58	1.41	-0.65	1.50	0.050
SNPog (°)	0.40	1.69	0.15	1.45	0.619
SN-SPP(°)	-0.03	1.56	0.35	1.93	0.498
SN-Go Me (°)	-0.93	2.43	0.60	2.78	0.072
SN –Ocp (°)	1.35	3.72	1.38	3.30	0.979
B angle (°)	-1.10	2.10	0.5	1.88	0.015*
N S Ar (°)	-0.55	3.32	1.05	2.980	0.117
S Ar Go (°)	0.30	4.13	-1.40	4.500	0.221
Ar Go Me (°)	-0.6	2.28	1.6	2.580	0.007*
Bjork Sum (°)	-5.95	22.98	1.25	3.04	0.173
N S Gn (°)	-0.30	1.72	0.15	2.68	0.531
Jarabak ratio (S-Go/N-Me)	0.01	0.03	0.00	0.01	0.165
Wits (mm)	-1.55	1.40	-1.80	2.04	0.654
Dental					
U1C-Y (mm)	-4.95	3.35	-3.9	3.14	0.313
U1R-Y (mm)	-2.10	3.17	-2.13	2.89	0.975
U1C-X (mm)	-0.9	2.79	-1.1	3.99	0.855
U1R-X (mm)	0.0	2.81	-0.25	3.49	0.804
U1 angulation (°)	-11.25	8.91	-7.38	6.96	0.134
U6C-Y (mm)	-4.33	1.52	-1.88	1.60	0.000**
U6R-Y (mm)	-2.95	3.50	-1.58	1.55	0.118
U6C-X (mm)	-1.85	1.73	-0.80	2.98	0.181
U6R-X (mm)	-1.45	1.93	-0.90	2.86	0.48

U6 angulation (°)	-3.10	4.58	-2.0	4.74	0.46
U7C-Y (mm)	-3.53	1.61	-1.83	1.25	0.001**
U7R-Y (mm)	-2.42	1.71	-1.68	2.62	0.306
U7C-X (mm)	-2.16	2.22	-0.85	2.64	0.103
U7R-X (mm)	-1.24	2.15	-0.45	2.19	0.263
U7 angulation (°)	-2.82	3.65	-1.25	5.04	0.275
Soft tissue					
UL-Y (mm)	-4.55	3.14	-3.2	2.33	0.131
LL-Y (mm)	-3.80	3.32	-2.6	2.64	0.214
UL-E (mm)	1.50	0.71	1.78	1.55	0.467
LL-E (mm)	1.30	1.13	1.35	1.14	0.890
Nasolabial angle (°)	7.75	4.56	8.85	7.51	0.58
Labiomental angle (°)	9.20	16.64	9.3	11.13	0.982

^bIndependent t-test, * $P < 0.05$, ** $P < 0.01$.

Figures

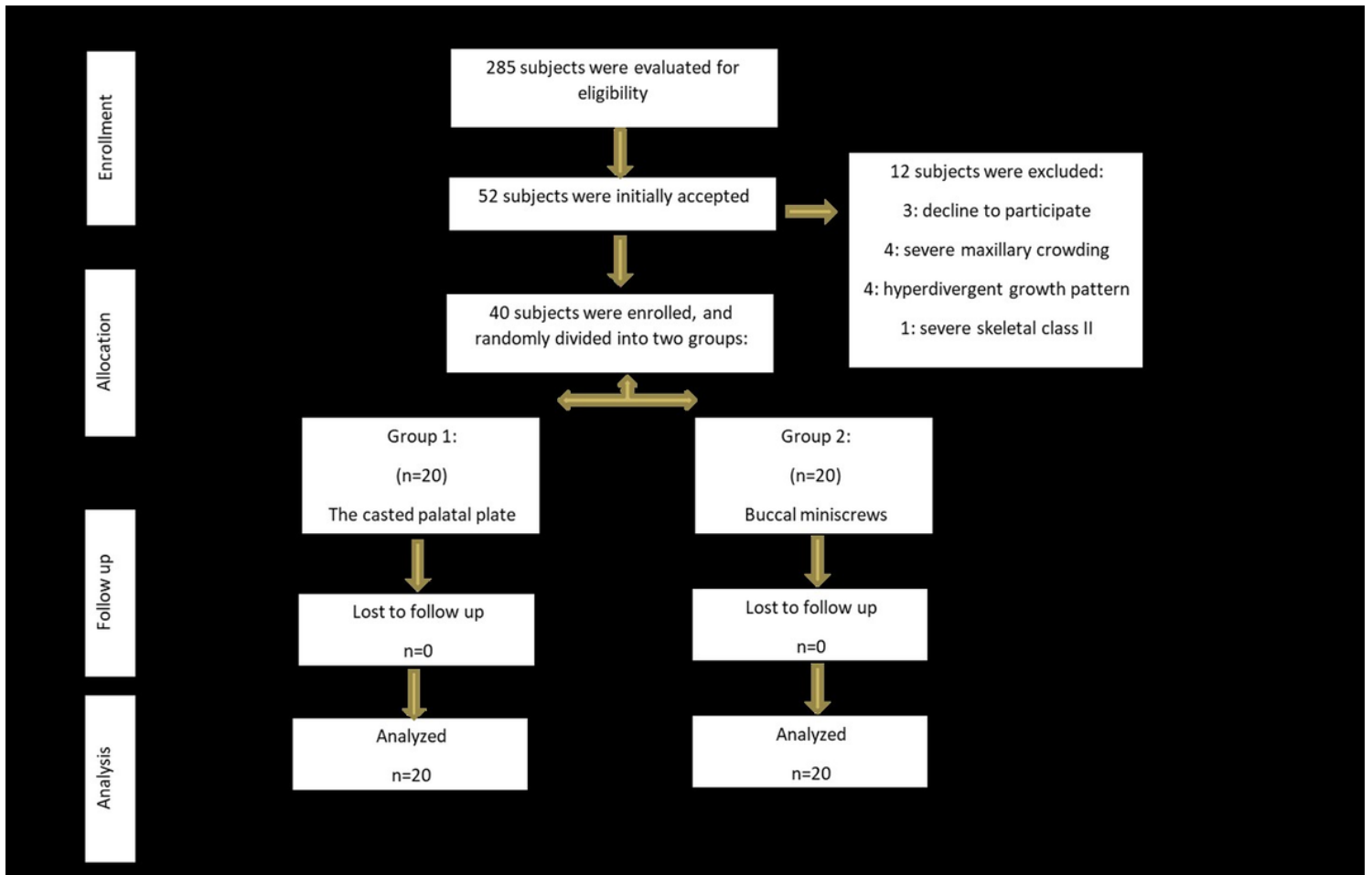


Figure 1

CONSORT flow chart.



Figure 2

The designed casted palatal plate and palatal arch.

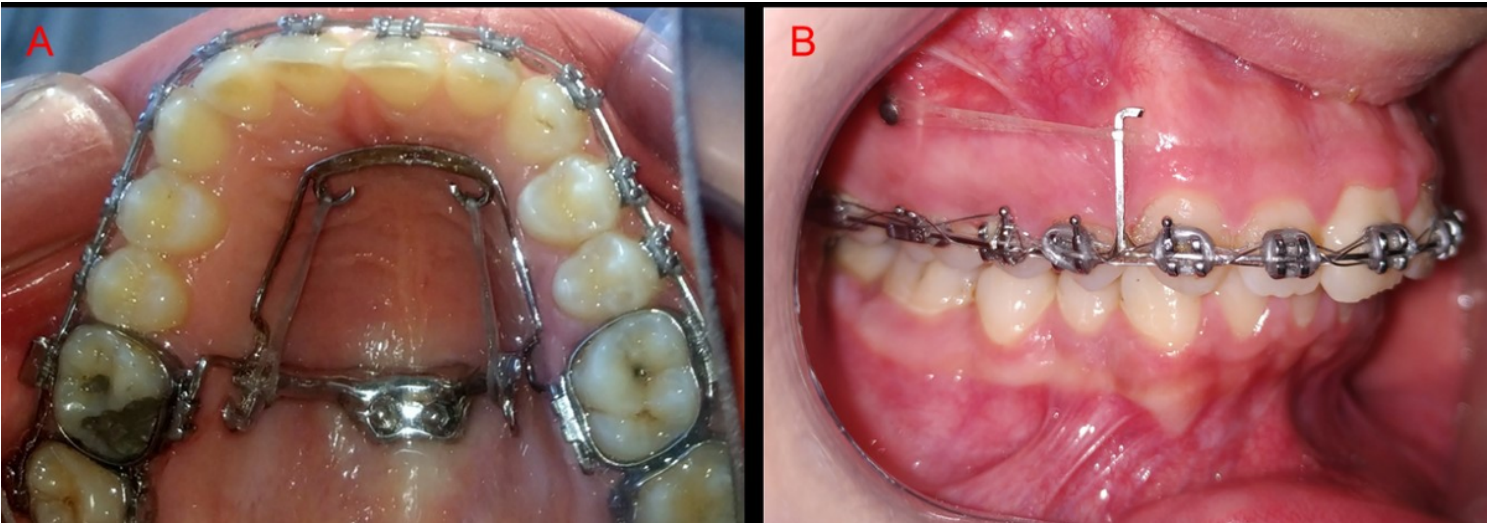


Figure 3

Total arch distalization using: A) The casted palatal plate, B) Buccal miniscrews.

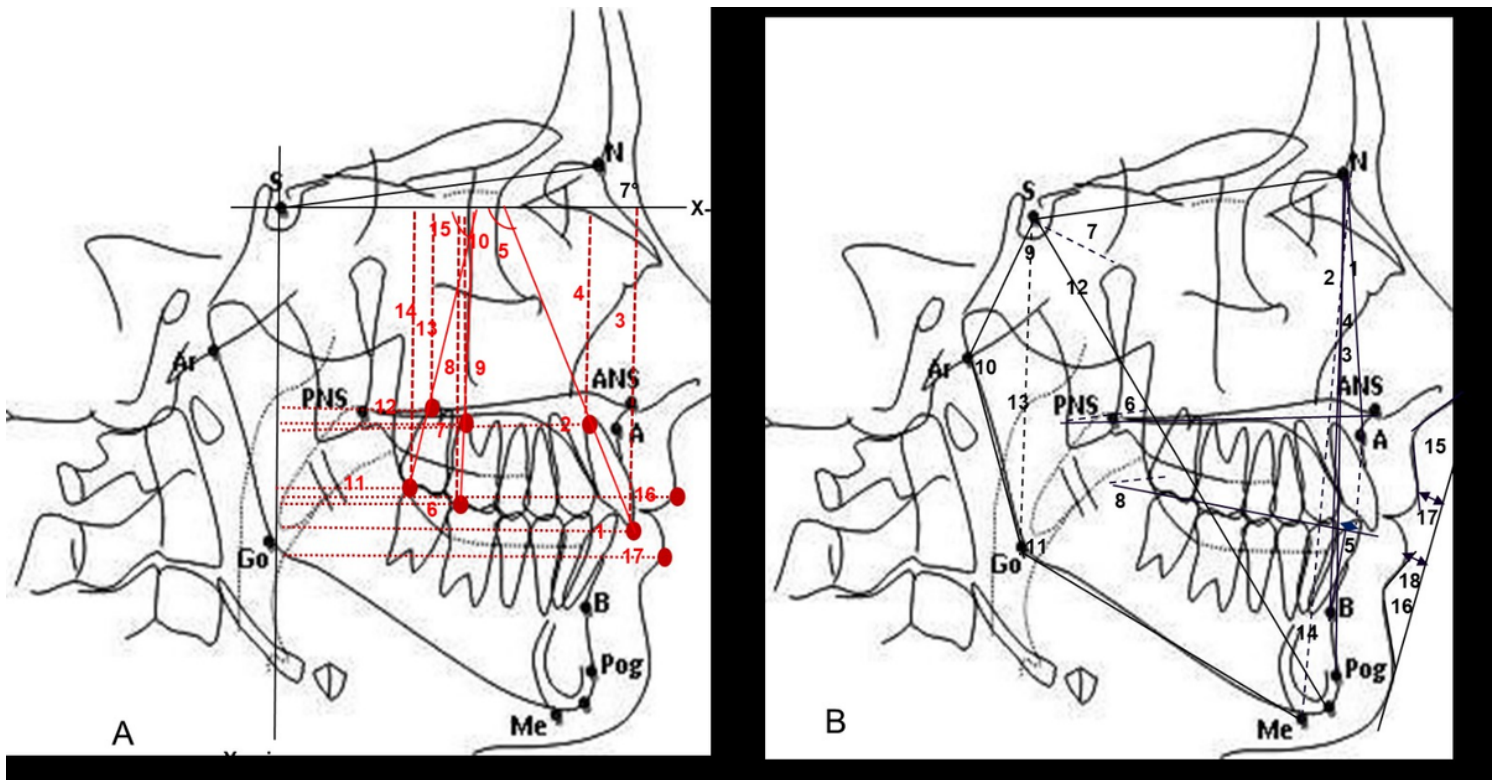


Figure 4

Skeletal, dental and soft tissue measurements; A) horizontal and vertical measurements using the coordinate system: 1) U1C-Y: the horizontal distance from U1 crown to Y line, 2) U1R-Y: the horizontal distance from U1 root apex to Y line, 3) U1C-X: the vertical distance from U1 crown to X line, 4) U1R-X: the vertical distance from U1 root apex to X line, 5) U1 angulation: the angle between U1 axis and X line, 6) U6C-Y: the horizontal distance from U6 crown to Y line, 7) U6R-Y: the horizontal distance from U6 root to Y line, 8) U6C-X: the vertical distance from U6 crown to X line, 9) U6R-X: the vertical distance from U6 root to X line, 10) U6 angulation: the angle between U6 axis and X line, 11) U7C-Y: the horizontal distance from U7 crown to Y line, 12) U7R-Y: the horizontal distance from U7 root to Y line, 13) U7C-X: the vertical distance from U7 crown to X line, 14) U7R-X: the vertical distance from U7 root to X line, 15) U7 angulation: the angle between U7 axis and X line, 16) UL-Y: the horizontal distance from upper lip to Y line, 17) LL-Y: the horizontal distance from lower lip to Y line.

B) Other measurements: 1) SNA, 2) SNB, 3) SNPog, 4) ANB, 5) Wits distance, 6) SN-SPP, 7) SN-Go Me, 8) SN-Ocp, 9) N S Ar, 10) S Ar GO, 11) Ar Go Me, 12) N S Gn, 13) posterior facial height (S-Go), 14) anterior facial height (N-Me), 15) Nasolabial angle, 16) Labiomental angle, 17) UL-E: distance from upper lip to E line, 18) LL-E: distance from lower lip to E line.