Comparison of Direct and Indirect Mini-implant Anchorage in Adults with Maxillary Protrusion: A Randomized Controlled Trial

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The purpose of this randomized controlled trial was to investigate the effects of direct and indirect mini-implant anchorage on tooth movement, skeletal and soft-tissue changes following sliding en masse retraction in adult patients with maxillary protrusion. A total of 30 patients (6 male, 24 female, mean age 23.5±6.29 years) were randomly assigned to group A with direct mini-implant anchorage or group B with indirect mini-implant anchorage. Lateral cephalograms taken before and after retraction were used to evaluate the changes during space closure. Independent sample t tests were performed to compare the baseline cephalometric data and treatment changes between the two groups. Paired sample t tests were performed to examine the changes within each group. The Results showed that no significant difference in anteroposterior skeletal changes was found between the two groups. The occlusal plane rotated clockwise 4.11° (p<0.001) in group A and remained stable in group B. Regarding dental changes, the maxillary molars mesialized by 0.83 mm in group B and showed non-significantly anteroposterior movement in group A. In group A the molars showed significant distal inclination (6.97°, p<0.001) and intrusion (2.74 mm, p<0.001) compared with group B (p<0.001). There was no significant difference in the anteroposterior or vertical movement of the incisors between the two groups. The soft-tissue parameters were significantly improved in both groups (p<0.001) while no differences were found between the groups. In conclusions, both directly and indirectly loaded mini-implants can provide successful anchorage. Indirect mini-implant anchorage enabled better sliding mechanics compared to direct anchorage.

Key words: Mini-implant anchorage, direct anchorage, indirect anchorage, randomized clinical trial, maxillary protrusion

Anchorage control is essential for successful treatment of severe maxillary dentoalveolar protrusion patients. Treatment of this malocclusion usually involves premolars extraction and maximum anchorage to improve the facial profile[1]. It is well known that mini-implant anchorage is capable of providing maximum anchorage for anterior teeth retraction with sliding mechanics[2-7]. The benefits of mini-implant anchorage include independence from patients' compliance, minimally invasive, less discomfort, shortened treatment time by *en masse* retraction of six anterior teeth, low cost, few anatomical limitations because of small dimensions[8]. Therefore, mini-implant anchorage has gained enormous popularity in the orthodontic community[9-13]. To retract anterior teeth, after the extraction of premolars, mini-implants can provide direct and indirect anchorage[14-20]. The force vectors and retraction forces are different for these two methods. The objectives of orthodontic treatment are not only optimal aesthetic appearances in harmony with maxillofacial hard and soft tissues but also functional and stable occlusions by properly positioning all teeth[21,22]. Therefore, high-quality treatment for maxillary protrusion should be guaranteed by not only to obtain soft-tissue profile changes but also to select the appropriate directions of force to move the teeth into the desired pattern.

Previous studies have been conducted on direct mini-implant anchorage in comparison with conventional anchorage, and found that direct anchorage provided maximum anchorage for anterior teeth retraction and led to intrusion of the maxillary incisors and molars[4,5,14]. The literature focused on indirect mini-implant anchorage is still rare. A recent study indicated

that the anchorage loss with indirect anchorage is nearly equivalent to that with direct anchorage[19]. However, the differences of treatment changes between direct and indirect mini-implant anchorage were not described in the previous researches and require further exploration. The purpose of this randomized controlled trial (RCT) was to compare the skeletal, dental, and soft tissue changes following sliding *en masse* retraction of upper anterior teeth between direct and indirect mini-implant anchorage in maxillary protrusion patients.

MATERIALS AND METHODS

Subjects:

This research was approved by the local ethics committee. The sample size was estimated by Power Analysis and Sample Size for Windows software (PASS 2000, NCSS, Kaysville, Utah), calculated on the base of simple comparison. Based on our preliminary study, group sizes of 13 achieved 80 % power to detect a difference of 1 mm in vertical displacement of upper first molar (standard deviation 0.9 mm) with a significance level (alpha) of 0.05. Allowing for 10 % drop out rate, the study was estimated to require 30 patients in total. This RCT was approved by the ethics committee of China-Japan Friendship Hospital, Beijing, China (approval number, 2013-40).

The inclusion criteria were as follows: (1) minimum age of 16 y for female patients and 18 y for male patients; (2) maxillary protrusion with angle class I or class II division I relationship, well aligned maxillary teeth with minimal crowding (less than 3 mm); (3) the treatment plan involved extraction of the bilateral maxillary first premolars (with first or second premolars extracted in the mandibular arch) and maximum anchorage was required in the upper arch; (4) agreed to use mini-implant anchorage during retraction of the upper anterior teeth to obtain good esthetics and correct the molar relationship; (5) full permanent dentition with no congenitally missing teeth (except for the third molars) or a malformed tooth; (6) no serious temporomandibular joint disorder or periodontal disease. The patients who met the inclusion criteria were randomly assigned to two equal groups: group A (direct anchorage) and group B (indirect anchorage). A random allocation sequence was generated using Microsoft Excel 2013 (Microsoft Corporation, Redmond, Washington, USA), and allocations were concealed in sequentially numbered, sealed opaque envelopes opened after written consent was obtained. The principal investigator was blinded to the allocation sequence during experiments and outcome assessment. A flow diagram of patients' recruitment, assignment and follow-up is provided in fig. 1. Thirty patients were included in the final analyses and the patient details are shown in Table 1.

Appliances:

All patients were treated with MBT pre-adjusted appliances with slot size of 0.022×0.028-inch (3M Unitek, Monrovia, CA, USA). All first molars were bonded with molar tubes, and the second molars were
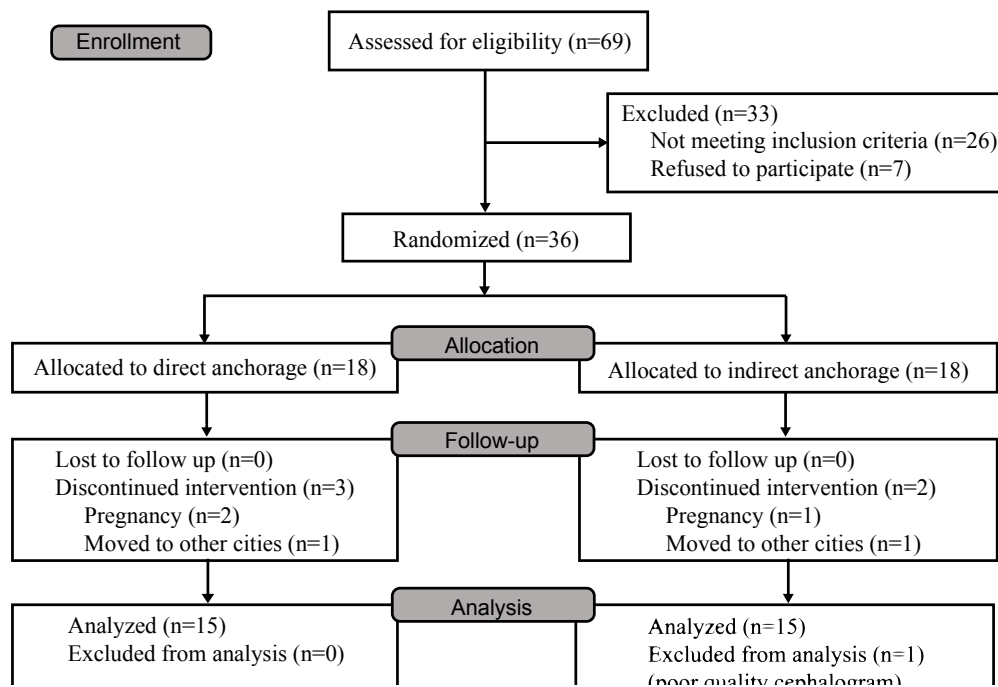

Fig. 1: Consort flow diagram

not bonded to reduce sliding friction in the posterior segment. After initial leveling and alignment, hand-operated self-drilling mini-implants (Ortho Easy, diameter 1.7 mm, length 8.0 mm, Forestadent, Pforzheim, Germany) were placed by the same operator in the buccal alveolar bone between the roots of the upper second premolars and first molars on both sides approximately 8 mm above the archwire. Three weeks after insertion of the mini-implants, *en masse* retraction of the anterior teeth by sliding mechanics was applied using 0.019×0.025-inch stainless steel archwires with crimpable hooks attached distal to the lateral incisors. In group A, the power chains (Ormco, Glendora, CA, USA) were stretched from each mini-implant head to a crimpable hook as direct anchorage (fig. 2A). In group B, the power chains were stretched from the first molar buccal tube to the crimpable hook, and then, the mini-implant was tightened to the second premolar bracket by a ligature wire of 0.25 mm in diameter as indirect anchorage (fig. 2B). The retraction force was approximately 150 g on each side, and the power chains were renewed every 4 w. During the

A.

B.

Fig. 2: (A) direct anchorage (group A), (B) indirect anchorage (group B)

space closure procedure, the archwires had no torque or curve of Spee, and intermaxillary elastics were avoided to eliminate possible side effects.

Cephalometric analysis:

Standardized digital lateral cephalometric films (Promax, Planmeca, Helsinki, Finland) were taken before (T0) and after space closure (T1). To avoid assessment bias, archwires were removed before taking the cephalograms. Dolphin Imaging Software (version 11.7, Dolphin Imaging & Management Solutions, Chatsworth, CA, USA) was used to obtain the cephalometric measurements, and the data were exported to Microsoft Excel 2013 for further analysis. Digitization, tracing, and measurements of the cephalograms were performed by the same examiner who was blinded to the patient allocation of the study. The coordinate system, angular and linear measurements are shown in figs. 3A and B.

Statistical analysis:

All statistical analyses were performed using SAS software (version 9.4; SAS Institute, Cary, NC, USA). Independent sample t tests were performed to compare the baseline cephalometric data and treatment changes between the two groups. Paired sample t tests were performed to examine the treatment changes between T0 and T1 in each group. The statistical significance was determined at the 5 % level of significance.

Measurement reliability:

To identify the measurement reliability, 10 randomly selected cases from each group were digitized and analysed 4 w apart by the same examiner. Intraexaminer reliability was evaluated using the intraclass correlation coefficient, with the highest r value of 0.998 for the SN-MP angle and lowest r value of 0.81 for the SN-PP angle.

RESULTS AND DISCUSSION

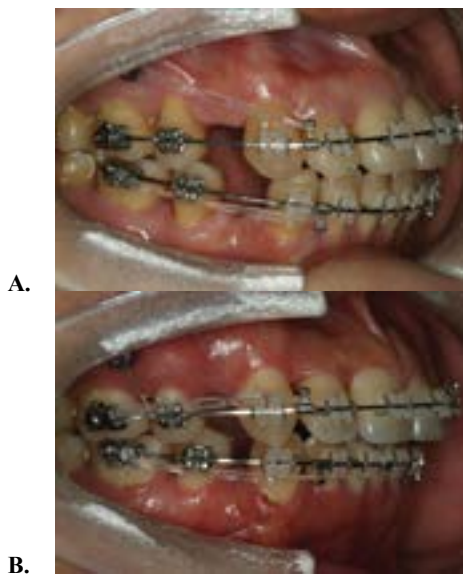Before treatment, no statistically significant differences

TABLE 1: DETAILED INFORMATION OF 30 SUBJECTS AND A COMPARISON OF THE RETRACTION DURATION BETWEEN GROUPS

	Group A (n=15)		Group B (n=15)		P#
	Mean	SD	Mean	SD	
Age at T0 (y)	25.20	7.65	21.80	4.16	0.337
Duration of retraction (mos)	9.67	2.18	8.50	2.03	<0.001*
Distance of space (mm)	6.39	0.64	6.43	0.70	0.988
Sex (male/female)	3/12		3/12		0.217
Angle classification (I/II)	11/4		11/4		0.779

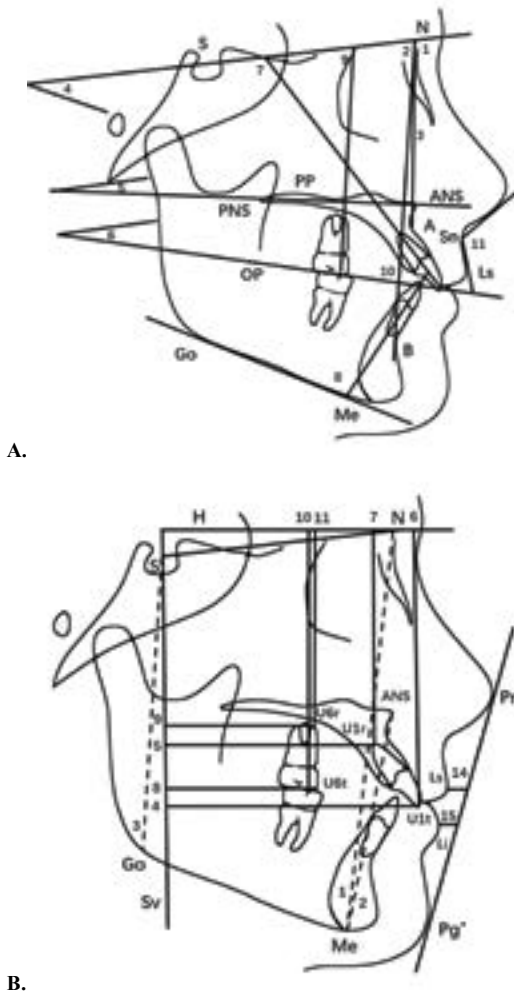#Independent t test, *statistically significant difference

A.

B.

Fig. 3: (A) angular measurements, (B) linear measurements
(A) 1: SNA; 2: SNB; 3: ANB; 4: SN-MP (SN-GO-ME); 5: SN-PP; 6: SN-OP; 7: U1-SN; 8: L1-MP; 9: U6-SN; 10: U1-L1; 11: NASOLABIAL ANGLE. (B) A horizontal plane (h) was constructed by clockwise rotating of sella-nasion (sn) line by 7° at nasion and the vertical plane was perpendicular to it through sella (SV). 1: AFH (N-ME); 2: LAFH (ANS-ME); 3: PFH (S-GO); 4: U1T-SV; 5: U1R-SV; 6: U1T-H; 7: U1R-H; 8: U6T-SV; 9: U6R-SV; 10: U6T-H; 11: U6R-H; 12: OVERBITE; 13: OVERJET; 14: LS-E LINE; 15: LI-E LINE

were observed in patients' age, sex distribution and angle's classification between the two groups (p>0.05, Table 1).

During the retraction period, 3 mini-implants became loosened in group A, but the 30 mini-implants in group B showed stability. Any loosened mini-implants were replaced by a new mini-implant in the same interradicular area neighboring the bone at the original site after bone healing for approximately 4 w. None of the replaced mini-implant subsequently failed. The descriptive statistics containing the means and standard deviations for the respective groups and treatment changes are given in Tables 2-4. There was no significant difference between the two groups in the

pre-treatment cephalometric measurements except for LAFH/AFH % (p=0.008).

As shown in Table 2, there was no significant difference in the anteroposterior changes between the two groups. Vertically, the changes in the SN-MP and SN-PP angles also were not significantly different between the groups. However, the SN-OP angle showed a significant increase (4.11°, p<0.001) in group A compared with that in group B (p<0.001).

As shown in Table 3, the incisor crown showed statistically significant distal movement in group A (−5.99 mm, p<0.001) and group B (−5.64 mm, p<0.001), and the amount of the root apex distal movement was 1.51 mm (p<0.001) in group A and 2.10 mm (p<0.001) in group B. Meanwhile, the maxillary incisor angle (U1-SN) was significantly decreased in both groups (−9.58°, −9.77°, p<0.001, respectively). The incisors (U1t-H) were significantly extruded 0.68 mm in group A and 0.77 mm in group B. There was no significant difference in the anteroposterior or vertical movement of the incisors between the two groups.

The anteroposterior movement of the molars crown in group A was non-significant (−0.36 mm). However, the maxillary molars crown showed mesial movement (0.83 mm) in group B. Meanwhile, the molars root showed mesial movement (1.33 mm) in group A and distal movement (−0.89 mm) in group B. The molars inclined distal (U6-SN) significantly (−6.97°, p<0.001) in group A and showed no significant changes in group B. The molars (U6t-H) were significantly intruded (−2.74 mm, p<0.001) in group A, but there was no significant vertical movement in group B.

As shown in Table 4, the soft-tissue parameter changes, including nasolabial angle increases, Ls-E line and Li-E line decreases, were statistically significant in both groups (p<0.001) but there was no significant difference between the two groups.

All subjects in this prospective RCT were adults to eliminate growth effect and that the molar's physiologic mesial movement could be ignored[23]. Patients were randomly assigned and cephalometric analysis was performed blindly to eliminate examiner bias. Therefore, this RCT was reliable for detecting the true differences in the cephalometric changes during space closure between direct and indirect mini-implant anchorage. We found remarkable anterior teeth retraction, lingual crown tipping, and significantly relatively extrusion in both groups. The crown tipping may have occurred

TABLE 2: SKELETAL MEASUREMENTS BEFORE RETRACTION (T0) AND THE CHANGES DURING RETRACTION (T1-T0) IN GROUPS A AND B

Variable	Group A Mean	SD	Group B Mean	SD	P#	Group A Mean	SD	P##	Group B Mean	SD	P##	P#
SNA (°)	81.26	4.10	82.30	3.07	0.439	-0.92	1.35	0.020*	-0.40	1.04	0.157	0.248
SNB (°)	76.97	3.42	78.91	2.73	0.099	-0.16	1.58	0.701	-0.21	0.81	0.326	0.909
ANB (°)	4.29	2.84	3.40	1.44	0.289	-0.40	1.07	0.014*	-0.26	0.96	0.311	0.173
SN-MP (°)	37.64	5.93	36.39	6.21	0.578	-0.21	2.63	0.758	-0.32	2.03	0.551	0.901
SN-PP (°)	4.04	4.30	3.71	2.88	0.809	0.19	1.35	0.600	-0.09	1.44	0.806	0.587
SN-OP (°)	17.97	3.66	19.05	3.62	0.424	4.11	2.27	<0.001*	0.25	1.45	0.521	<0.001*
AFH (N-ANS) (mm)	127.67	7.27	128.19	7.32	0.849	-1.02	2.78	0.177	-0.67	2.28	0.272	0.712
LAFH (ANS-Me) (mm)	67.41	5.37	66.21	4.53	0.514	-0.79	3.05	0.331	-0.09	1.30	0.785	0.424
LAFH/AFH (%)	56.80	2.17	54.46	2.29	0.008*	-0.29	1.35	0.425	0.22	1.17	0.480	0.282
PFH (S-Go) (mm)	81.15	4.06	81.09	5.73	0.977	0.39	2.96	0.621	1.32	1.82	0.014*	0.309

#Independent t test, ##paired t test, *statistically significant difference

TABLE 3: DENTAL MEASUREMENTS BEFORE RETRACTION (T0) AND THE CHANGES DURING RETRACTION (T1-T0) IN GROUPS A AND B

Variable	T0 Group A Mean	SD	Group B Mean	SD	P#	T1-T0 Group A Mean	SD	P##	Group B Mean	SD	P##	P#
U1t-Sv (mm)	63.39	4.15	60.74	6.57	0.200	-5.99	1.06	<0.001*	-5.64	1.06	<0.001*	0.378
U1r-Sv (mm)	51.45	4.21	49.74	4.69	0.304	-1.51	0.71	<0.001*	-2.10	1.49	<0.001*	0.179
U1t-H (mm)	69.90	3.19	69.49	5.04	0.791	0.68	1.22	0.049*	0.77	1.67	0.094	0.862
U1r-H (mm)	52.59	3.20	52.91	5.43	0.846	1.05	1.30	0.008*	0.27	1.56	0.518	0.148
U6t-Sv (mm)	38.21	4.04	35.32	5.37	0.108	-0.36	0.79	0.101	0.83	0.94	0.004*	0.001*
U6r-Sv (mm)	37.08	3.52	35.45	4.05	0.249	1.33	0.64	0.006*	-0.89	1.50	0.038*	0.010*
U6t-H (mm)	65.83	3.53	63.49	5.03	0.151	-2.74	0.50	<0.001*	0.70	1.47	0.086	<0.001*
U6r-H (mm)	51.95	3.28	50.77	5.35	0.474	-1.98	0.67	<0.001*	0.69	1.60	0.116	<0.001*
U1-SN (°)	110.55	2.92	113.89	4.52	0.024	-9.58	3.50	<0.001*	-9.77	2.68	<0.001*	0.871
U6-SN (°)	69.05	4.18	67.15	5.43	0.292	-6.97	2.45	<0.001*	1.13	5.17	0.410	<0.001*
Overbite (mm)	1.35	1.95	1.47	2.11	0.866	0.80	1.30	0.032*	-0.07	2.05	0.892	0.177
Overjet (mm)	4.29	1.01	4.65	1.20	0.381	-1.45	0.94	<0.001*	-1.34	1.04	<0.001*	0.771
U1-L1 (°)	112.67	6.07	113.08	7.21	0.869	17.75	5.78	<0.001*	15.69	5.89	<0.001*	0.341
IMPA (°)	99.91	4.99	102.52	6.85	0.245	-8.83	3.40	<.001*	-9.56	6.83	<0.001*	0.716

#Independent t test, ##paired t test, *statistically significant difference

TABLE 4: SOFT-TISSUE MEASUREMENTS BEFORE RETRACTION (T0) AND THE CHANGES DURING RETRACTION (T1-T0) IN GROUPS A AND B

Variable	T0 Group A Mean	SD	Group B Mean	SD	P#	T1-T0 Group A Mean	SD	P##	Group B Mean	SD	P##	P#
Nasolabial angle (°)	94.96	7.99	95.39	7.86	0.882	7.30	3.55	<0.001*	6.63	3.83	<0.001*	0.625
Ls-E line (mm)	2.80	1.69	2.17	0.79	0.210	-2.84	1.05	<0.001*	-2.36	0.96	<0.001*	0.200
Li-E line (mm)	4.51	1.95	3.26	1.38	0.053	-2.77	0.71	<0.001*	-2.40	0.69	<0.001*	0.157

#Independent t test, ##paired t test, *statistically significant difference

because the retraction point was located lower than the center of the resistance of the upper anterior teeth when using direct or indirect anchorage, indicating that lingual root torque or increased the length of crimpable hooks are needed to ensure bodily movement of incisors when necessary[24-28]. However, the vertical change of upper incisors during retraction using direct anchorage, still remain controversial. Upadhyay et al.[4,5] stated that direct mini-implant anchorage led to intrusion of the maxillary incisors. Lee et al.[14] reported that the vertical

position of the incisal edge did not change significantly during the retraction period, however results in present study showing the relative extrusion of maxillary incisors. Therefore, during sliding, to avoid extruding when distalize anterior teeth, it is better to incorporate a curve of Spee into the archwire[29].

In the current study, the anchorage loss with indirect mini-implant anchorage was 0.83 mm, which was similar to Monga's findings[19] and are nearly equivalent to those of direct anchorage. The molars were distally tipped significantly in the direct anchorage group. This result may be caused by the frictional force between archwire and appliance on the posterior teeth. But the frictional force was offset by the mesial elastic force loaded on molars in the indirect group. Forward movement and intrusion of the posterior teeth after premolar extraction leads to a reduction in the vertical dimension, which is known as the "wedge effect"[30]. Since the molars can be almost stable anteroposteriorly when using mini-implant anchorage, the vertical movement of posterior teeth is the main influencing factor in the vertical dimension. In group A, the first molar was intruded by 2.74 mm, this result may attribute to the vertical components of the retract force. However, the SN-MP angle showed no significant decrease after space closure. A reason for this outcome might be that only the first molars were intruded, while the second molars did not bond to the appliance and still had occlusion. This undesired localized open bite of the first molars needed to be corrected in subsequent phases via bonding the second molars or intermaxillary elastics in posterior segments and, in turn, may increase the duration of treatment or induce other unfavorable tooth displacement. Fig. 4A shows that after maxillary space closure using direct mini-implant anchorage, the first maxillary molar was intruded. Moreover, the extrusion of the anterior teeth limited the counter-clockwise rotation of the mandible. Therefore, intrusions of both posterior and anterior teeth are needed to improve the vertical dimension in hyperdivergent patients, and mini-implants placed in the maxillary anterior region are also necessary[12,14,28].

The occlusal plane was found to show a clockwise rotation in group A, which was attributed to the intrusion of molars and relative extrusion of anterior teeth and is in line with the results of Finite element method (FEM) studies[15-24]. Nevertheless, the occlusal plane was stable in group B, which resulted from few vertical changes in anterior and posterior teeth. Fig. 4B shows that after maxillary space closure using indirect

mini-implant anchorage, the upper arch was stable. Therefore, standard sliding mechanics can be obtained with indirect anchorage to enable good biomechanical control of the teeth[19].

In this study, the mean duration of space closure in the upper arches due to direct mini-implant anchorage was longer than indirect anchorage, despite the distances of spaces being similar (Table 1). A possible explanation might be that the retraction force generated by direct mini-implant anchorage was upward and backward, thus producing both horizontal and vertical components of force, which may lead to deflection of the archwire[24,25], resulting in increased friction on the posterior segments. Another possible reason was that more mini-implants failures in the direct anchorage group, which may lead to an increase in treatment time.

During retraction, no mini-implants failure was observed in group B. Consistent with our results, Holberg[18] analysed the biomechanical differences between direct and indirect anchorage and their effects on the primary stability of the mini-implants and found that indirect mini-implant anchorage was reliable for reducing peri-implant loading of the bone and the risk of losing the mini-implants. Furthermore, better oral hygiene related to the power chain not directly attaching to mini-implant's head might be another reason for the reduced plaque around the mini-implants, which in turn, lowered the risk of inflammation around the implant sites. However, a larger sample size and statistical analysis are needed to further investigate the stability of different loaded mini-implant anchorage.

Depending on the position of tooth which force apply to, buccolingual change of posterior segment will be
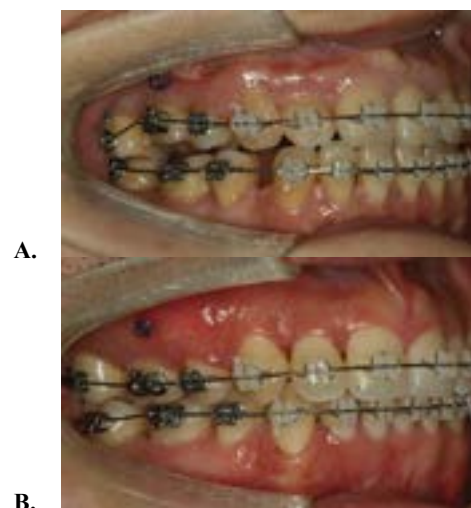

A.

B.

Fig. 4: Maxillary space closure
After maxillary space closure using (A) direct and (B) indirect anchorage and bond the second molars

different. The current study was conducted on two-dimensional lateral cephalograms, and thus, transverse changes cannot be explored due to their inherent shortcomings. In future study, it is necessary to further investigate the ultimate clinical effect using cone-beam computed tomography. In conclusions, both direct and indirect mini-implant anchorage can provide successful anchorage and induce favourable profile changes. In this study, indirect mini-implant anchorage which caused less archwire deformation and molars intrusion, enabled better sliding mechanics compared to direct anchorage.

Acknowledgements:

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