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Evaluation of the Efficacy of 3D-guided Piezosurgery in Accelerating Mandibular Orthodontic Teeth Alignment: A Randomized Controlled Trial in Adults.

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Abstract

OBJECTIVE: The aim of this study was to investigate the effects of 3D guided piezocision (a minimally invasive surgical technique) in accelerating orthodontic tooth movements (OTM) since the literature does not provide high quality evidence to confirm that Piezocision results in significant OTM acceleration. Furthermore, no randomized controlled trial (RCT) has utilized 3D piezo-surgical guides to accelerate severe orthodontic de-crowding.

STUDY DESIGN: A Parallel-group randomized controlled trial was conducted on patients with severe mandibular teeth irregularity. Sample size was 34 patients (19 females and 15 males), then subjects were divided into two parallel groups using Minitab® Version 17 software. First group received conventional orthodontic treatment, whereas the second group received 3D-guided piezo-assisted orthodontic one. Little irregularity index (LII) changes were studied using dental cast in four time points before inserting the first archwire (T0), after 1 month of treatment onset (T1), after 2 months (T2), and at the end of the alignment stage (T3) and the overall alignment time (OAT) required to complete anterior alignment of the mandibular arch was also measured.

RESULTS: Ninety-five severe dental crowding patients were evaluated for eligibility, 46 of them fulfilled the inclusion criteria. Thirty-four participants were allocated to the treatment groups randomly. There were no withdrawals during the trial phases. Accordingly, the results of 34 patients were statistically analyzed. OAT was reduced by 48% in the experimental group compared to the control group, with a statistically significant difference between the two groups. Likewise, the time difference between all arch changes was significantly lower when 3D guided piezocision was performed, except for the first arch (T0) and the last arches (T3).

CONCLUSION: Minimally invasive 3D guided piezocision seems to be a very effective and easy technique in accelerating orthodontic tooth movement

KEYWORDS: 3D surgical guide; Piezosurgery; accelerated tooth movement; minimally invasive surgery

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Introduction

Reduction in the duration of orthodontic treatment is considered one of the major challenges facing orthodontists today. Moreover, prolonged orthodontic treatment times have complications such as periodontal disease, caries and root resorptions [1]. Extraction-based orthodontic cases that could last up to 35 months are particularly vulnerable [2]. Therefore, accelerating tooth movement and shortening the treatment time have

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become the common goals of both orthodontists and patients [3, 4].

Recent studies have shown that corticotomy-accelerated orthodontic treatment is associated with regional acceleration phenomenon (RAP) [5, 6, 7]. Although these corticotomies have proven their effectiveness, they are considered to be aggressive therapies [8].

Therefore, minimally invasive flapless techniques, as an alternative to traditional corticotomy, have been introduced into the orthopedic field [9-11]. Piezocision appears to be an effective, safe and minimally invasive procedure in terms of accelerating orthodontic tooth movement [12].

However, no randomized controlled trial (RCT) has employed 3D surgical guided techniques in piezocision planning. This technique could permit the engineering of an easy, accurate, predictable and safe localized alveolar decortication through a minor incision. Thus, without raising a flap, no harm would occur to any nearby anatomical structures.

So, the aim of this randomized controlled clinical trial was to investigate the effect of piezocision with a pre-customized 3D surgical guide in orthodontic treatment.

Material and Methods

Study design

The study was designed as a twoarmed, parallel group RCT to evaluate the influence of 3D-guided piezocision-assisted orthodontic treatment (test group) compared to the traditional orthodontic treatment alone (control group). Participants were recruited from the Departments of Orthodontics at Damascus University Dental School between August 2019 and May 2021. The Local **Research Ethics Committee Approval** was obtained (UDDS-3656-16,032,033/SRC-5671). This trial was funded by the University of Damascus Dental School Postgraduate Research Budget (Ref no: 83054205788DEN).

Sample size estimation

Sample size was calculated using the G*power 3.1.7 software presuming that a reduction of 30 per cent in total treatment duration could be evidenced with a power of 80 per cent at the 5 per cent significance level. The smallest clinically significant difference in the time needed for leveling and alignment of severely crowded incisors was assumed to be 52.8 days depending on a previous report showing that crowding relief of anterior teeth took a mean of 132 days with a standard deviation 39 days [3].

Therefore, a sample of 32 patients was required for both groups. To account for possible withdrawal, the final sample size for the study was set at 17 patients per group, yielding a total of 34 patients.

Patient selection, recruitment, and follow-up

Patients were selected from the Department of Orthodontics at University of Damascus Dental School. The treatment plan of 95 severe dental crowding patients was reviewed, but the number of patients who met the inclusion criteria and agreed to participate in this study after the acquaintance with the information sheet was 46. Thirty-four subjects were equally and randomly assigned to the two groups; figure 1 represents the CONSORT flow diagram. Information sheets were distributed to all patients and informed consents were obtained.

Inclusion criteria

- ✓ Adult healthy patients from both sexes within an age range 17−24 years.
- ✓ Absence of previous orthodontic treatment.
- Class II division I patients requiring first upper premolars extraction.
- ✓ Severe crowding (tooth-size arch-length discrepancy >5 mm) in the anterior mandible with Little's irregularity index (LII).
- Completion permanent dentition (except of third molars).
- Absence of medications intake that interfere with pain perception for at least

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one week before the beginning of the treatment.

Exclusion criteria

- Medical conditions that would affect tooth movement (corticosteroid treatments, NSAIDs consumption, bisphosphonates, hyperparathyroidism, osteoporosis, uncontrolled diabetes).
- ✓ Contraindication to oral surgery (medical–social– psychological).
- ✓ Presence of primary teeth in the mandibular arch.
- Missing permanent mandibular teeth (except for third molars).
- Previous orthodontic treatments.
- History of periodontitis with a loss of alveolar support more than 10 percent.

Randomization and allocation concealment

Patients were assigned to the experimental group or the control group with an allocation ratio of 1:1 using a software-generated list of random numbers. Allocation sequence was concealed using sequentially numbered, opaque, sealed envelopes which were opened only after the completion of premolars extraction. First group received 3D-guided piezocisionassisted orthodontic treatment, whereas the second group received conventional orthodontic treatment (Figure 1). The generation of random allocation sequence, participants' enrollment and assignment to the two groups were performed by one of the academic staff not involved in this research. conventionally ligated. Then, a 0.014inch NiTi archwire (American Orthodontics, Sheboygan, Wisconsin, USA) was inserted and tied to each bracket using 0.010-inch stainless steel ligature wires. For both groups, the following sequence of archwires

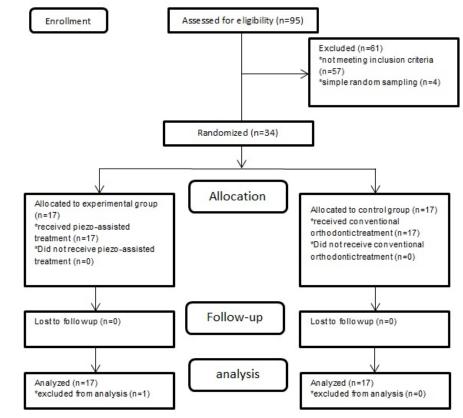


Figure 1. CONSORT flow diagram of patients' recruitment and follow-up.

Orthodontic procedures

All subjects underwent conventional orthodontic treatment with fixed appliances. Fixed orthodontic appliances with an MBT prescription and 0.022-in. slot height (Master Series[®], American Orthodontics[™], Sheboygan, WI USA) were bonded four days following first-premolar extraction. These brackets were was adopted: 0.014-in. NiTi followed by 0.016-in., 0.016 X0.022-in. and 0.017 X 0.025-in. NiTi, and finally 0.019 X 0.025-in. stainless steel [11].

Patients were asked to return every 2 weeks, so that change in archwires was performed when it was felt that an improvement had occurred in teeth positions and there was a possibility of inserting the next archwire without exerting excessive

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force on the engaged teeth. Treatment was considered finished when LII was less than 1 mm, indicating complete alignment of the teeth and the feasibility of inserting the final archwire passively into all brackets [13].

3D piezocision surgical procedure

In the test group, piezocision surgery was performed on the same premolars extraction day to minimize the number of anesthesia depending sessions in terms of patients` comfort and satisfaction. After local Infiltration was injected (lidocaine hydrochloride 2% with epinephrine 1:80,000), a pre-customized 3D surgical guide was placed to perform vertical interproximal micro-incisions (varying between 5 and 8 mm) below each interdental papilla (Figure 2).



Figure 2. 3D piezo-surgical guide.

The incisions began 4 mm below the papilla to prevent any further gingival recessions, then corticotomies (5 mm long and 3 mm deep) guided by the same 3D guide were made using a piezoelectric device(Implant Center™ 2, Satelec, France) with a BS1 cutting tip and irrigation solution pump 80 ml/m (Figure 3).



Figure 3. The guide is in place to perform the incisions and piezocisions.

All of the above-mentioned aspects were pre-planned and applied by CBCT imaging and transferred to the casts in order to produce a reliable and precise surgical 3D guide (Figure 4).

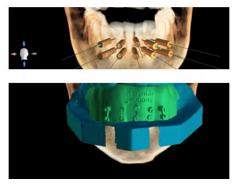


Figure 4. CBCT pre-planning.

No subsequent sutures were performed, and the surgical side was covered by a piece of lodoform gauze. Careful tooth brushing and the use of a mouthwash (Chlorhexidine Gluconate 0.12%) were prescribed for 7 days; ice packs for the first 12 h following surgery; and patients were instructed to take one or two tables of Panadol[®] (acetaminophen; 500 mg) when they suffer from moderate/severe pain. Experimental patients check-ups were scheduled a day after the procedure ensuring absence of postoperative complications, four days post procedure to continue their orthodontic treatment and were followed up every two weeks for orthodontic treatment sequence.

Outcome Measures

The primary outcome measure was the overall alignment time (OAT) required to complete anterior alignment of the dental arch. Followup of this trial was considered finished when the LII was less than 1 mm [13]. The secondary outcome measure was Little's Irregularity Index (LII) measured on study models taken at the following assessment times: before inserting the first archwire (T0), after 1 month of treatment onset (T1), after 2 months (T2), and at the end of the alignment stage which was accomplished when LII was less than 1 mm (T3). Measurements were made according to methodology mentioned by Little (13). LII was measured using a fine tip digital caliper with an accuracy of 0.1 mm (Mitutoyo, Zhejiang, China).

Statistical analysis

Parametric tests were used since Anderson-Darling Normality tests showed normal distributions of the collected data. Two-sample t-tests were used to detect significant differences between the two groups at each assessment time. Single blinding was employed in this trial

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regarding outcome measure assessment and data analysis. Minitab® program version 17.0 (Minitab Inc., Pennsylvania, USA) was used to perform descriptive and inferential statistics. Patients were given serial numbers and patients' allocation was concealed from the principal investigator through the different stages of the trial and at the statistical analysis phase to ensure blindness of the assessor and to avoid detection bias.

Results

34 patients were enrolled in this study as presented in the basic sample characteristics Table (Table No. 1), while descriptive statistics of the evaluated variables are given in Table No. 2. No withdrawals were registered through the whole trial stages.

Table 1: Basic sample characteristics.

A statistical significance was found between the two groups regarding the OAT. The experimental group required less mean treatment time (i.e. 61.9 ± 12.5 days) in the leveling and alignment stage compared to the control group (i.e. 129.1 ± 35.5 days; P <0.0001) with a 48% decrease in the OAT.

The results regarding changes of the LII according to assessed time points are given in (Table No. 3). No statistically significant difference between the two groups was found at T0 and T3 (P = 0.511, P=0.832, respectively), whereas statistically significant differences were observed at T1 and T2 (P <0.001, P=0.003, respectively).

Discussion

This is the first published RCT having the objective of employing 3D guiding

techniques in accelerating severe orthodontic teeth de-crowding utilizing piezocision. It was found that 3D guided piezocision accelerated leveling and alignment and reduced the overall time by about 48%. This could be explained by the regional acceleratory phenomenon (RAP) following the intentional bone injury [7, 14]. This result was in accordance with some other recent clinical trials studying the effectiveness of the flapless piezocision technique in accelerating teeth leveling and alignment. In comparable recent studies [3, 5, 15, 16], similar acceleration rates in the piezocision groups were found. None of them used 3D guiding techniques to achieve safe and accurate piezoelectric cortectomies. However, the trial that had performed guided piezocorticision utilized mild non extraction crowding cases.

Group	Gender n (%)	P-value*	Mean Age (SD)	Min. Age	Max. Age	P-value†
Control	Male 7 (43.75%)		21.27 (1.87)	18	24	
	Female 9 (56.25%)					0.092
	Male 8 (44.4%)	0.531	20.86 (1.98)	17	23	
Experimental	Female 10 (55.6%)					
All sample	34 (100%)		21.03 (1.96)	17	24	

*: employing chi-square test, †: employing two-sample t test, Min: minimum, Max: maximum



Variable	Group	Mean	SD	SE	Min	Q1	Median	Q3	Max
LIITO	Control	11.66	1.17	0.24	10.00	10.88	11.00	12.00	13.00
	Ехр	11.59	0.69	0.32	10.00	10.84	11.50	12.25	14.00
LIIT1 -	Control	8.90	1.14	0.25	6.50	7.25	8.50	9.00	10.00
	Ехр	4.35	1.67	0.42	4.00	4.75	5.00	5.25	6.00
LIIT2 -	Control	5.75	1.12	0.28	4.50	5.00	5.50	6.25	7.80
	Ехр	2.91	0.34	0.21	2.00	2.57	2.75	2.89	3.50
LIIT3 -	Control	0.32	0.12	0.02	0.10	0.25	0.30	0.40	0.50
	Exp	0.24	0.10	0.02	0.10	0.20	0.20	0.30	0.40
OTT -	Control	129.11	35.53	7.55	98.00	101.50	121.00	130.50	179.00
	Exp	61.90	12.52	4.33	49.00	51.00	58.00	62.50	81.00

Table 2: Descriptive statistics of the Little's index of irregularity (mm) and the overall alignment time (days) in the two groups (n = 17 for each group).

LIITO: Little's irregularity index before inserting the first archwire; LIIT1: after 1 month of orthodontic treatment onset; LIIT2: after 2 months; LIIT3: at the end of the alignment stage; Exp.: experimental group; SD: Standard Deviation; SE: Standard Error; Min: minimum; Q1: first quartile; Q3: third quartile, Max: maximum.

Little's Index of	Group	Mean	SD	Mean Difference (%)	95% CI of the difference		P-value	Significance of differences	
Irregularity	Group				Lower Bound	Upper Bound	r-value	umerences	
Before	Control	11.66	1.17	-0.226	-1.004	0.510	0.671	NS	
	Experimental	11.59	0.69	-0.220					
At one month	Control	8.90	1.14	3.2899	3.192	5.488	<0.0001	**	
	Experimental	5.25	1.67	3.2899					
At two months	Control	5.66	1.12	1.8099	1.074	4.544	0.002	*	
	Experimental	2.95	0.34	1.0099					
At three months	Control	0.32	0.12	0.0824	0.0050	0.1597	.0545	NS	
	Experimental	0.24	0.10						

[†]: Two sample t test, ^{*}: significant at P<0.05, ^{**}: significant at P<0.001, NS: Not significant.

In contrast, Uribe et al reported no significant difference in the alignment time between the conventional and the piezocision groups [17]. The difference between our findings and theirs is probably related to the fact that they applied just three cortical incisions in the labial cortical plate (4mm length and 1-mm depth of cortical bone) between the mandibular central incisors, and lateral incisors and canines, while in the current study, five cortical incisions in the labial cortical plate (5to 8-mm length and 3-mm depth of cortical bone) between the six anterior teeth. Additionally, patients in the current study underwent extraction of first premolars which

may have enhanced the effect of the RAP [8, 18].

Other RCTs carried out in the past few years regarding the efficacy of piezocision in accelerating other orthodontic treatments such as canine retraction [19-21] and en masse retraction [22]. Alfawal et al. in a RCT [19] evaluated the effectiveness of piezocision in the

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acceleration of upper canine retraction after first premolar extraction. This showed that the rate of upper canine retraction was significantly higher in the experimental side compared to the control side, by two-fold the first month and 1.5-fold in the second month. These findings are comparable with the studies of Abbas et al [21] and Aksakalli et al [20] that reported an acceleration of the rate of canine retraction by 1.5–2 times during the first 3 months of tooth movement when piezocision was used. To the contrary, Tunçer et al [22] concluded that piezo surgery was ineffective in accelerating en masse retraction for upper anterior teeth following premolar extraction in Class II division 1 patients. The lack of significant results may be explained by underpowered sample size calculation of that study, intending to detect at least 50 per cent difference in the rate of tooth movement instead of 30 per cent as in our study. Nevertheless, the direct comparison between our findings and those studies is not straightforward since these RCTs have been based on canine or en-masse retraction and not crowding relief corrections. No significant difference at T0 in LII was found, which assured that the groups were almost similar in the initial crowding. Furthermore, after a month LII had a mean of 4.25 mm (± 1.67) in the experimental group and a mean of 8.9 mm (± 1.14) for the control group. These results indicated

a 51% higher leveling rate for the experimental group than the control one. This percentage slightly decreased to 49% after 2 months; but further decreased to 25% at the end of the alignment stage (T3). This decrease could be explained by the gradual decrease of the RAP over time which was documented by Wilcko et al., however they report an onset after 1–2 months following bone injury and found that the effects lasted from 2 to 4 months [23].

Conclusion

Minimally invasive 3D guided Piezocision seems to be a very effective and easy technique in accelerating orthodontic tooth movement.

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