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Efficiency of Piezotome-Corticision Assisted Orthodontics in Alleviating Mandibular Anterior Crowding - A Randomized Controlled Clinical Trial

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in Alleviating Mandibular Anterior Crowding - A
Randomized Controlled Clinical Trial

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Efficiency of Piezotome-Corticision Assisted Orthodontics in Alleviating Mandibular Anterior Crowding - A Randomized Controlled Clinical Trial

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CHAPTER I – INTRODUCTION

BACKGROUND

Factors Affecting Orthodontic Tooth Movement

According to the American Association of Orthodontists (AAO), depending on treatment options and individual characteristics, the length of comprehensive orthodontic treatment ranges between 18–30 months [1]. Orthodontic treatment time ranges between 21-27 months for nonextraction and 25-35 months for extraction therapies [2]. An increased risk of problems due to caries, periodontal disease and root resorption are associated with prolonged treatment time. To increase patient satisfaction in addition to decreasing the mentioned risks, reducing the treatment time has become a primary goal for orthodontists. Since orthodontic tooth movement (OTM) is produced by a gradual remodeling (apposition and resorption cycle) of supporting alveolar bone, factors affecting this cycle could modulate the rate of tooth movement [3].

Attempts to decrease the treatment time can be divided into different categories. One is the local or systemic administration of biologic factors [4, 5] such as parathyroid hormone (PTH) [6], thyroxine [7], Vitamin D3 [1,25 (OH)₂D₃] [8], and prostaglandins [9]. The pharmacological approaches that have been shown to increase tooth movement have also resulted in numerous adverse reactions, such as, local pain [10], severe root resorption [11], and drug-induced side effects. For this reason, the trend has turned towards finding a physical or mechanical approach that can accelerate tooth movement without the side effects. These physical approaches include, but are not limited to: electrical currents [12, 13] magnets [14], laser beams [15], mechanical vibration [16], and ultrasound [17]. The treatment designs which have recently received most attention involve the surgical

manipulation of bone using either dental distraction [18], alveolar surgery to undermine interseptal bone [19], corticotomies [20], osteotomies [21] and the most recent approach, corticision [22, 23]. All these approaches are focused on controlling the microenvironment of alveolar bone in an attempt to reduce tissue resistance.

History of Corticotomy

The use of corticotomy to correct malocclusion was first described in 1892 by L.C. Brian and G. Cunningham in 1893 [24, 25]. Brian proposed making linear corticotomies surrounding the teeth as a means of mobilizing teeth for immediate movement and presented some cases at the American Dental Society of Europe. Cunningham proposed the idea that immediate correction of irregular teeth is possible at the Dental Conference in Chicago. In 1931, Bichlmayr applied corticotomy-osteotomy for patients older than 16 years to correct maxillary protrusion after extraction of first premolars with palatal osteotomies and removal of alveolar bone distal to the canines using removable orthodontic appliances [26]. In 1959, Heinrich Kole introduced a surgical procedure which involved the reflection of full-thickness flaps followed by removal of the interdental alveolar cortical bone, leaving the medullary bone intact with a through-and-through subapical osteotomy [27-29]. He believed this procedure allowed for blocks of bone to move rather than the individual teeth which in return could minimize root resorption and retention time. Later in 1978, Generson treated open-bite malocclusions using selective alveolar decortication in conjunction with orthodontics and eliminated the subapical osteotomy [30]. In 1990, Gantes used a surgical technique that involved circumscribing corticotomies buccally and lingually around the six maxillary anterior teeth including buccal and lingual corticotomies over the first premolar extraction socket [31]. In 1991,

Suya reported treating 395 adult Japanese patients by means of a refinement of the abovementioned methods which substituted the subapical horizontal osteotomy by horizontal corticotomy and termed it Corticotomy-Facilitated Orthodontics (CFO) [32]. Suyu believed that teeth are handles by which the bands of less dense medullary bone are moved block by block and CFO allows for moving blocks of bone rather than only individual teeth. In 2001, Wilcko and Wilcko [33] patented and trademarked their technique as “Periodontally Accelerated Osteogenic Orthodontics” procedure. Upon raising labial and lingual full-thickness flaps, interdental decortication is performed slightly into the medullary bone using a surgical bur. Flaps are sutured following application of demineralized freeze-dried bone (DFDBA) and bovine bone infused with Clindamycin phosphate solution. Orthodontic tooth movement is initiated during the week prior to the surgery and orthodontic appliances are activated every 2 weeks. The authors attributed the enhanced tooth movement to a regional acceleratory phenomenon (RAP). More specifically, a redirection of this normal physiologic bone response to insult is exploited to mobilize and accelerate tooth movement [33]. In 2009, Lee et al. introduced “speedy surgical orthodontics” in order to treat maxillary protrusion in adults using a perisegmental corticotomy, a C-palatal miniplate, and a C-palatal retractor. It differs from the techniques described above in that it involves moving a corticotomized bone block of 6 maxillary anterior teeth instead of blocks of a single tooth [34].

Rapid Acceleratory Phenomenon

It was believed that a corticotomy makes tooth movement faster because the bone block moves with the tooth [32]. However, tooth movement after a corticotomy should be considered a combination of classical orthodontic tooth movement and the movement of

bone blocks containing a tooth, because the force applied to a tooth is transmitted into the osteotomy gap through the periodontal ligament (PDL). The velocity of orthodontic tooth movement is affected by bone turnover [7, 35-37], bone density [36, 37], and hyalinization of the PDL [38]. Bone turnover is accelerated after bone fracture, osteotomy, or bone grafting [39-41]. This could be explained by a regional acceleratory phenomenon (RAP), which was first described by Frost in 1983 [39-41]. RAP occurs in bone following a noxious stimulus and accelerates regional hard and soft tissue processes above normal levels [39-41]. This localized process includes perfusion, growth of bone and cartilage, accelerated bone turnover and modeling. RAP begins within a few days of the insult, peaks at 1 to 2 months with its effect prolonged 6 to more than 24 months [41]. RAP starts in the alveolar bone with an initial burst of osteoclast activity which decreases bone density, followed by enhanced osteoblast activity which increases bone density [42]. It has been shown that osteoclast activity is important in tooth movement. Factors such as bisphosphonates can reduce this activity and decrease the rate of tooth movement [43]. On the other hand, factors that can increase this activity and decrease bone density can be expected to result in faster tooth movement. Baloul et al. analyzed bone mineral content (BMC) and bone mineral density (BMD) associated with alveolar decortication combined with tooth movement [44]. In the tooth movement and selective alveolar decortication groups, BMC demonstrated a decrease starting at 7 days with statistically significant decrease by 14 days, and was restored to levels greater than baseline at 42 days with no statistically significant changes in BMD. On a molecular level, Baloul et al. showed that selective alveolar decortication increases osteoclastogenesis as evidenced by the increased expression of RNA markers of osteoclasts and their key regulators such as RANKL, M-

CSF (macrophage colony stimulating factor), osteoprotegerin, CTR (calcitonin receptor), TRACP-5b (tartrate-resistant acid phosphatase 5b) and cathepsin K. Some of these values reached their maximum level during the first week and declined to the original level after two weeks. In another study by Teixeira et al. [45], the effects of surgically enhanced orthodontic tooth movement on 92 cytokines were evaluated. They found 37 of them were increased significantly during OTM and also showed that adding small perforations in the cortical bone increases most of those cytokines to a higher level. Considering all the cellular processes present, a major benefit of surgically assisted orthodontics is that the main effects of RAP seem to be restricted to the sites of stimuli with areas of not in close proximity being unaffected [46-48].

Effect of Corticotomy on Tooth Movement

Orthodontic forces in conjunction with corticotomy procedures produce faster tooth movement than orthodontic forces alone [2, 49, 50, 51]. According to Hajji, the active orthodontic treatment time in patients with corticotomies was 3 to 4 times faster compared with patients without corticotomies [51]. Also, case reports by Suya and Wilcko [32, 33], have indicated that orthodontic treatment can be completed in 4-9 months with corticotomies as opposed to conventional orthodontics that takes 18-30 months [1]. Wilcko and Wilcko concluded that their technique provides efficient and stable orthodontic tooth movement and teeth can be moved further in one third to one fourth of the time required for traditional orthodontics alone [52].

Several animal studies have evaluated the effect of corticotomies on tooth movement. Lino et al. performed corticotomies around the mandibular left third premolar region on 12 adult male beagles and showed approximately twice as much tooth movement as the

control side. The rate of tooth movement was faster for the first 2 weeks after the corticotomies with no significant difference thereafter. Hyalinization was present on the corticotomy side at week 1 only and throughout week 4, in the experimental and control groups, respectively [53]. Mostafa et al. performed corticotomies on 6 dogs to distalize the first maxillary premolars after extraction of the second premolars. The first premolars were distalized against the mini-screws with nickel-titanium coil springs bilaterally. The corticotomy side had double the amount of tooth movement than the control side (2.3 vs 4.7 mm) [54]. Sanjideh et al. performed a split-mouth study in foxhounds to determine whether alveolar corticotomies and a second corticotomy after 4 weeks increased the rate of tooth movement [55]. There was twice as much total mandibular tooth movement on the experimental (2.4mm) than on the control (1.3mm) side after ten days. At the peak velocity, the rate of tooth movement was 85 per cent faster compared to the control side. It was observed that this acceleratory effect was transient; it peaked between 22 and 25 days, and decreased with no significant difference after 7-8 weeks. This is due to a transition from the catabolic to the anabolic phase of RAP, when density of bone is minimum and the resistance to tooth movement is the least. In addition, performing a second corticotomy helped to maintain higher rates of tooth movement for a longer period. However, the differences in tooth movement between one and two corticotomy procedures were small. The authors concluded that the cost benefit of a second corticotomy procedure was not justified since flap reflection can cause crestal bone resorption and bone dehiscence. Not to mention, patient acceptance can be challenging due to the invasive nature of the procedure [55]. In order to determine the effects of increased surgical trauma on the rates of tooth movement and apical root resorption, Cohen et al. [56] in a canine model,

compared two surgical techniques with distinct level of invasiveness. The specific techniques evaluated, with a split-mouth design were, periodontal ligament distraction (RAP) and dentoalveolar distraction (RAP+). Interseptal bone mesial to the second premolars was undermined by grooving vertically inside the extraction socket along the buccal and lingual sides (RAP side) after maxillary first premolars extractions. On the RAP + side, a horizontal incision was made from canine to the third premolar, and a full thickness flap was raised, the buccal plate between the second premolar and canine was removed, and a vertical osteotomy was made to the lingual surface connecting to the extraction space. It was concluded that the increased surgical trauma increased the rate and amount of tooth movement, however, apical root resorption was not clinically significant.

According to a recent systematic review by Long et al. [49], only two studies on corticotomies were considered of medium to high quality. Fischer [57] studied a sample of 6 patients with bilateral palatally impacted canines in a split-mouth fashion. A series of circular holes were made along the bone mesial and distal to impacted canines following their surgical uncovering. These holes were made with a 1.5mm round bur approximately 2mm apart and extended into the edentulous space of the canines. The treatment time was reduced in the corticotomy-assisted canine impactions by 28% to 33% compared to the non-corticotomy teeth [57]. Aboul-Ela et al. evaluated mini-implant-supported maxillary canine retraction with and without corticotomy-facilitated orthodontics (CFO) in a split-mouth fashion. CFO was performed following the submarginal Luebke-Ochsenbein flap design. The flap was extended 4 mm apical to the free gingival margin from the mesial surface of the maxillary lateral incisor to the mesial surface of the maxillary second premolar. Corticotomy perforations were made extending from the lateral incisor to the

first premolar area with a number 2 round bur. The depth of the holes approximated the width of the buccal cortical bone. However, the exact location and number of the holes were not specified in the study. The rate of canine retraction was two times faster on the corticotomy side than on the control side during the first and second months. This monthly rate declined to 1.6 times higher in the third month and 1.06 times higher by the end of the fourth month [58]. In a recent study, 20 adult patients with moderate crowding (3-5mm) of lower anterior teeth were treated by non-extraction with either orthodontics alone or a modified technique of corticotomy in conjunction with orthodontics. The corticotomy technique involved flap reflection and interradicular alveolar decortication from the distal of the right to the distal of the left mandibular canine using a bur with no bone graft. The specific end point of the study was not specified. Treatment duration for the orthodontics only group was 49 weeks as opposed to 17.5 weeks for the corticotomy-facilitated orthodontics group [59]. There was no statistical difference in the probing depth, bone density, and root resorption from baseline to six months post-treatment between the two groups.

According to another systematic review by Hoogeveen et al. [92], who reviewed 18 randomized clinical trials, controlled clinical trials and case reports of 5 or more subjects, the conclusion was that these surgical procedures cause a temporary phase of accelerated tooth movement which could shorten the duration of orthodontic treatment. They also concluded that these procedures are safe for the oral tissues. However, no prospective studies have compared the overall treatment time and treatment outcome with those of a control group [92].

Minimally-invasive Corticotomies

Although quite effective, due to the invasive nature of conventional corticotomies following the necessity to raise large flaps, they have met with some resistance from patients and the dental community. An alternative approach was introduced by Park et al. [60] and was called “corticision”. It consists of transmucosal cortical incisions, using a combination of blades and a surgical mallet, without the need for flap reflection. The authors demonstrated that performing corticision in a feline model causes extensive direct resorption of bundle bone with faster removal of hyalinized tissue, which is the initial obstacle to orthodontic tooth movement, compared to the control group. They also showed that corticision accelerates the anabolic as well as catabolic remodeling. At the injury site, new bone with new lamellation developed after 21 days. Histological analysis showed neither pathologic changes nor root resorption following this technique.

The initial corticotomies were performed using burs that could potentially damage both the teeth and the bone, due its close proximity to the root apices and excessive heat generation. As a result of this heat generation, marginal osteonecrosis and impaired bony regeneration follow [61]. To minimize these side effects, piezoelectric incisions have been reported to be safe and effective in osseous surgeries, such as preprosthetic surgery, alveolar crest expansion, and sinus grafting [62, 63]. In a histological study by Vercellotti et al. on four adult female hounds, investigated the rates of postoperative bone healing as a means to compare the effectiveness of a piezosurgery knife compared with a standard diamond or carbide bur. Their results indicated that the piezosurgery knife provided a more favorable osseous response than traditional carbide and diamond burs [64].

Moreover, due to its micrometric and selective cut, the piezoelectric knife is said to lead to safe and precise osteotomies without any osteonecrotic damage [63]. Furthermore, it works only on mineralized tissues, sparing soft tissues and their blood supply [64]. Vercellotti and Podesta later used a piezoelectric knife to make corticotomies along with a luxation maneuver on eight patients, which they termed Monocortical Tooth Dislocation Ligament Distraction (MTDLD) [65]. In 2013, Kim et al. [91] performed cortical punctures using a piezotome in ten beagle dogs, divided into control and experimental groups. They concluded after the measurements in weeks 1-6 that the cumulative distance was greater in the piezopuncture group: 3.26 fold greater in the maxilla and 2.45 fold greater in the mandible. They also observed that anabolic activity was increased by 2.55 fold in the maxilla and 2.35 fold in the mandible. They reported that acceleration was the greatest in the first 2 weeks in the maxilla and in the second week in the mandible [91]. In 2009, Dibart et al. [66] described a new minimally invasive procedure called Piezocision, which was limited to buccal piezoelectric microincisions interproximally combined with bone augmentation via tunneling. In both cases presented in this article, the active orthodontic treatment was completed in 8 months. Healing was uneventful; no swelling, bruising, or major discomfort was associated with this procedure [66, 67]. In the most recent article by Kesser and Dibart [68], Invisalign treatment was combined with piezocision. Since there was no need for grafting, the procedure was performed in 20 minutes with no use of sutures and the active orthodontic treatment was completed in 18 weeks [67]. In a recent preliminary study, an endoscopically assisted tunnel approach was used for piezosurgical corticotomies in nine consecutive patients. After a labial full-thickness vertical incision (5 to 10mm) at the upper or lower midline and/or distal to

maxillary canines, the subperiosteum was dissected over the roots of the involved teeth. The interproximal corticotomies were extended through the entire thickness of the cortical layer without penetrating the medullary bone. An augmentation procedure was performed in four patients with thin cortical bone [69]. The authors revealed no loss of tooth vitality, no changes in periodontal probing depth, good preservation of the papillae, and no gingival recession. No evidence of crestal bone height reduction or apical root resorption was detected [69].

Tooth Movement Model

Mandibular crowding has been used as a model to investigate the rate of mandibular anterior alignment in non-extraction treatment with conventional orthodontics [70, 71, 73, 74]. Pandis et al. [70] and Fleming et al. [71] reported duration of alignment but used different end points: irregularity index of less than 1mm for the former and 8 weeks after placement of 0.019 X 0.025-in stainless steel archwire for the latter. The self-ligating group in the Pandis et al. study used Damon 2 0.022-in slot brackets (Ormco, Glendora, CA) and a 0.014-in Cu-NiTi Damon (Ormco) wire followed by a 0.014 X 0.025-in Cu-NiTi Damon (Ormco) wire [70]. Pandis and Fleming used the irregularity index defined by Little [72] to evaluate the amount of crowding of the mandibular anterior and the entire mandibular dentition, respectively [70, 73]. According to Pandis et al., the mean time to align the mandibular anterior teeth in the self-ligating bracket group was 91.03 days and in the severe crowding group with irregularity index of more than 5mm it was 117 days [70]. Pandis et al. and Miles reported reduction of irregularity at various times of alignment. Miles demonstrated that the irregularity index went from 5.7mm to 1.4mm in twenty

weeks using 0.014-in Cu-NiTi Damon (Ormco, Glendora, CA) followed by 0.016 X 0.025-inch Cu-NiTi Damon (Ormco, Glendora, CA) [74].

Questionnaire

As corticotomy-assisted orthodontics is becoming popular, it might be avoided due patient's fear of undergoing surgery. In a study by Tseng that assessed the pain perception following mini-implant assisted orthodontics using a Visual Analogue Scale (VAS), pain perception peaked 24 hours following the procedure [75]. In another study by Chen et al. that assessed changes in the level of pain in patients undergoing microimplants, no significant difference was seen in the pain generated in comparison to other orthodontic procedures [76]. Pain during orthodontic treatment is a major concern; it is common after a simple procedure such as placement of molar separators. The pain perception from the orthodontic procedure peaks 1 day after the start of the treatment and is reduced to normal levels 7 days later [77-78]. The highest intensity of pain was 40 mm or more in mean VAS score the day after placement of an elastic separator, appliance, or archwire, and fell to less than 10 mm 7 days later. However, the experience of pain varies substantially among subjects [76-83]. In a recent study, Cassetta studied the impact of corticotomy-assisted orthodontics on oral health-related quality of life (OHRQoL) in piezoelectric surgery and conventional rotary groups. Functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap were recorded from the questionnaire at baseline, 3 and 7 days after surgery. Although the OHRQoL deteriorated from baseline to 3 days after surgery in both groups, it was completely recovered to baseline after 7 days. These values were not statistically different between the two surgical groups [84].

RATIONALE

Despite the encouraging results obtained from the animal studies, the evidence to support the surgical dentoalveolar procedures has been primarily limited to case reports [32, 33, 36, 37]. The conventional corticotomies involve raising extensive flaps and removing a considerable amount of bone. In order to achieve rapid orthodontic tooth movement without the downside of an extensive and traumatic surgical approach, one can use a less invasive piezocision procedure to decrease orthodontic treatment time [66-68]. This procedure is ideal for adult patients with time limitations. So far, there has been no study other than anecdotal reports [66-68] stating the efficiency of this technique. A systematic clinical evaluation on the merit of this approach to enhance tooth movement is needed. Hence, this randomized controlled clinical trial was designed to assess the efficiency of piezotome-corticision in alleviating mandibular anterior teeth crowding.

As corticotomy has gained orthodontists' attention as a means of accelerating treatment time, it might be faced with patients' avoidance due to anxiety and fear of pain [81]. Most patients report pain and discomfort during orthodontic treatment [75-83]. Therefore, patients might be concerned about pain after the piezotome-corticision procedure. However, there is lack of evidence in patient perception of pain, comfort, and satisfaction after corticotomy procedures. Therefore, the level of pain, ease, and satisfaction with the piezotome-corticision procedure was investigated in this study.

HYPOTHESIS

We hypothesized that the piezotome-corticision procedure will have a transient acceleratory effect on the rate of tooth alignment and a reduction in the rate of lower incisors alignment. In addition, the subjects in the piezotome-corticision orthodontics group will experience a different level of pain, comfort, and satisfaction as opposed to the conventional orthodontics group.

SPECIFIC HYPOTHESIS

1. There will be an increase in the rate of alignment of mandibular anterior teeth in the piezotome-corticision assisted orthodontics compared to the conventional orthodontics group.
2. There will be an increase in pain score, discomfort, and dissatisfaction experienced by the subjects in the piezotome-corticision assisted orthodontics compared to the conventional orthodontics group.

SPECIFIC AIMS

1. To compare the time required to achieve complete alignment of crowded mandibular anterior teeth (canine to canine) between piezotome-corticision assisted and conventional orthodontics.
2. To investigate the rate of alignment of mandibular anterior teeth at different time points until complete alignment is achieved using dental casts taken at every visit.
3. To compare subjects' perception of pain, comfort and satisfaction between the piezotome-corticision assisted and conventional orthodontics using two questionnaires.

MATERIALS AND METHOD

Sample Size Calculation

The primary outcome in this study was the treatment time to complete alignment of mandibular anterior teeth determined from serial dental casts using Little's irregularity index [72]. The primary outcome measured in days was used to calculate the sample size. Alleviation of crowding of the mandibular anterior teeth in severely crowded non-extraction cases takes on average 117 ± 46 (SD) days [70]. We hypothesized that a 40% reduction in treatment time in the piezotome-corticision group would produce a clinically significant difference. According to the power analysis and assuming a large effect size difference between groups with 40% of improvement in treatment (i.e., Cohen's *d* of 0.75), the power analysis yields a total sample size estimate of 30 participants at a conventional alpha-level ($p = 0.05$) and desired power ($1 - \beta$) of 0.80, yielding 15 patients per group. Assuming an overall attrition rate of 28%, initial recruitment should target a total of 42 patients with 21 patients per group. All calculations were performed with the computer application G-Power [85], which is based on the formulas of Cohen [86].

Screening Process

The study design was approved by the Institutional Review Board at the University of Connecticut Health Center, Farmington, CT. The CONSORT 2010 statement [87] was used as a guide for this randomized controlled clinical trial. The subjects, presenting to the Orthodontic clinic at the University of Connecticut Health Center, were assessed for eligibility according to the following inclusion and exclusion criteria. The radiographs

were taken as part of initial orthodontic records appointment and standard of care. Written consent was received from all subjects prior to starting this research study.

Inclusion Criteria:

1. Adult patients 18 or older
2. Single arch or double arch treatment
3. Non-extraction treatment in the mandibular arch
4. Presence of full complement dentition from first molar to first molar
5. No spaces in the mandibular arch
6. Mandibular anterior irregularity index greater than 5
7. Patient with healthy periodontium and no more than 2mm attachment loss
8. The amount of crowding should allow for bracket placement
9. No therapeutic intervention planned involving intermaxillary or other intraoral or extraoral appliances including elastics, lip bumpers, maxillary expansion appliances, or headgear prior to the complete alignment of mandibular anterior teeth.

Exclusion criteria:

1. Failure to provide oral and written consent to participate
2. Medical problems that affect tooth movement (Refer to Appendix I)
3. Presence of primary teeth in the mandibular anterior area
4. Missing permanent mandibular anterior teeth
5. Inability to place brackets in the anterior mandibular teeth

6. Breakage of any of the mandibular anterior brackets that have not been replaced within a week

Randomization

Of the 112 patients screened, 74 did not meet the inclusion criteria or declined to participate, leaving a sample size of 38 patients (Figure 1). Patients who met the inclusion criteria (Figure 1) were randomly assigned to the control and experimental groups using block randomization. Randomization sequences were generated using random block sizes of six and eight and allocation ratio of 1:1 with the “Random Allocation Software” program to ensure balanced numbers in each group at any time during the study. The allocation sequences were sealed around aluminum foil in envelopes with identical appearance, and were stored in a box. Once patients were enrolled in the study, the study coordinator (RM) picked and opened the envelopes sequentially. Delivering the allocation sequences in envelopes protected the assignment schedule and eliminated selection bias.

Treatment Sequence

Mandibular teeth first molar to first molar were bonded with 0.022-inch self-ligating Carriere brackets (Ortho Organizer, Carlsbad, CA). The orthodontic wires were placed during the piezotome-corticision procedure appointment for the experimental group [54] and during the bonding appointment for the control group. Experimental subjects were followed 1 week after the first wire placement to collect the first questionnaire and follow-up for the surgical procedure. Following this, experimental subjects were followed up monthly (every 4-5 weeks) during which they had alginate impressions taken. All control

subjects were followed monthly (every 4-5 weeks) after the first wire placement. At each appointment alginate impression were taken for the control group. The second questionnaire was administered and collected at the first appointment after the first wire placement. The archwire sequence for both groups was a 0.014-in Cu-NiTi wire for the first two visits (8-10 weeks) followed by a 0.014 X 0.025-in Cu-NiTi wire [70]. The time (T_0) the subjects receive their first archwire was recorded. The alignment of the mandibular anterior teeth was clinically checked using a periodontal probe at every appointment and confirmed on dental casts to determine the end point of the study. Also, the positions of the brackets were evaluated during each appointment and if needed they were repositioned to achieve better alignment. When the irregularity index of 0-1.5 mm was achieved between the mandibular anterior teeth and an improvement in alignment did not exceed 0.5mm between two consecutive appointments, the subjects were considered complete. In addition, if it was determined that repositioning of the brackets would no longer help with alignment and a bend in the wire was deemed necessary to complete the alignment, the subject was considered complete. The time taken to reach complete alignment ($T_f - T_0$) for each patient and the rate of tooth alignment were calculated. Subjects refrained from using analgesics containing ibuprofen, as the rate of tooth movement could be affected [88].

Piezotome-corticision Procedure

Subjects underwent the piezotome-corticision procedure at the University of Connecticut Orthodontic Clinic. This procedure was performed by one of the manuscript authors (KA/TS) according to the technique explained by Dibart et al. [66-68]. Panoramic radiographs were utilized to assess the long axes of the teeth and root proximity prior to

the procedure. Local anesthetic was administered using 2% Lidocaine with 1:100,000 Epinephrine. The depth of gingival tissue was determined by bone sounding using a Williams periodontal probe. A #15C Bard-Parker scalpel was used to make three incisions through the gingiva, 4mm below the interdental papilla to preserve the coronal attached gingiva. These three vertical incisions were made interproximally between mandibular canines and lateral incisors, and central incisors on the labial aspect of the mandible through the gingiva and the underlying bone. The incisions were 4mm in length. After the incisions were made, the gingiva was slightly elevated laterally to visualize the bone and roots. A piezosurgery knife (BS1 insert, Satelec Acteon Group), which is an ultrasonic microsaw, was used to create the cortical alveolar incisions to a depth of 1mm within the cortical bone. The depth of the cortical incision was a variation on the technique described by Dibart in an effort to increase safety of the procedure. This was based on a study by Farnsworth et al. who studied the average cortical bone thickness between mandibular lateral incisor and canine in an axial slice using cone beam computed tomography. Their results revealed that the mean cortical thickness was 1.2 mm in adults ranging from 20 to 45 years of age [89]. Therefore, the depth of the cortical incision was limited to 1mm for a safety margin in these severely crowded cases, by ensuring that the BS1 insert penetration does not exceed the measured depth of the gingiva plus 1mm of cortical incision. Postoperatively, subjects were advised to rinse with chlorhexidine mouthwash twice a day for one week and to take acetaminophen as needed. All experimental subjects were contacted the day after the procedure to ensure no complications with surgery and were followed up one week post-surgery to assess for signs of infection.

Questionnaires

All subjects were asked to fill out two questionnaires [76, 82] during the first week and one month after placement of the first wire using a VAS.

The first questionnaire was comprised of the following questions:

How much pain/discomfort did you have at the following time points?

1. Immediately after your first wire placement
2. 1 hour after your first wire placement
3. 12 hours after your first wire placement
4. 7 days after your first wire placement

The second questionnaire was comprised of the following questions:

1. Did you take any type of pain medication after your treatment? If yes, when?

Indicate which one of the following pain killers?

- ☐ Salicylate NSAIDs (Example: Aspirin, Diflunisal, etc.)
- ☐ Propionic NSAIDs (Example: Ibuprofen/Motrin/Advil, Naproxen, etc.)
- ☐ Aniline analgesic (Example: Acetaminophen/Tylenol)
- ☐ Opioids (Example: Codeine, Hydrocodone, Morphine, etc.)
- ☐ Combination drugs (Example: Vicodin/Acetaminophen and Hydrocodone)
- ☐ Other

If other, please write the name of the medication below:

-
2. Are you satisfied with your treatment?
 3. How easy was the procedure to you?
 4. Would you undergo this procedure again?
 5. Would you recommend this procedure to a friend?

Methods of Data Collection

Little's irregularity index [72] was used to measure the amount of crowding on the dental models at every appointment. The proposed scoring method involved measuring the linear displacement of the anatomic contact points (as distinguished from the clinical contact points) of each mandibular incisor from the adjacent tooth anatomic point. The sum of these five displacements represents the irregularity index. Perfect alignment from the mesial aspect of the left canine to the mesial aspect of the right canine would theoretically have a score of 0, with increased crowding represented by greater displacement and, therefore, a higher index score [72]. Patient codes were assigned to the models prior to measurement to ensure blinding of the outcome assessors. Two outcome assessors were calibrated in the assessment of the Little's irregularity index. The irregularity index was measured twice by two blinded outcome assessors using a fine-tip digital caliper (Mitutoyo Corp, Japan). The subjects were instructed to record their level of pain: immediately, 1 hour, 12 hours, and 7 days after the first wire placement [76, 82]. They were also asked to report if they had taken any pain medications, their level of ease and satisfaction with the procedure, if they would undergo this procedure again, and if they would recommend it to a friend. A 100 mm Visual Analog Scale (VAS) was used to evaluate the level of pain, ease, and satisfaction of all the subjects, with anchors at each end of the line that read "no pain (easy, satisfied)" (0 mm) and "most pain (complicated, not satisfied)" (100 mm). One of the authors (LD) measured the VAS data. The reliability of the dental cast measurements was assessed using Cronbach's alpha [90] for 9 dental models made 2 weeks apart. Cronbach's alpha was 0.99 for intra- and inter-examiner measurements.

CHAPTER II – MANUSCRIPT

(for submission to a peer-reviewed journal)

Efficiency of Piezotome-Corticision Assisted Orthodontics in Alleviating Mandibular Anterior Crowding - A Randomized Controlled Clinical Trial

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**Efficiency of Piezotome-Corticision Assisted Orthodontics in Alleviating
Mandibular Anterior Crowding - A Randomized Controlled Clinical Trial**

ABSTRACT

Objective: The aim of this study was to investigate the duration of mandibular-crowding alleviation with piezotome-corticision orthodontics compared with conventional orthodontics and the accompanying effects on patient's pain and satisfaction.

Materials and Methods: Thirty eight subjects were selected based on the following inclusion criteria: adult patients 18 or older, single arch or double arch treatment, non-extraction treatment in the mandibular arch, presence of a full complement of dentition from mandibular first molar to first molar, no spaces in the mandibular arch, mandibular anterior irregularity index greater than 5, patient with healthy periodontium and no more than 2mm attachment loss, the amount of crowding should allow for bracket placement in every tooth mesial to the mandibular second molar, and no therapeutic intervention

planned with any intraoral or extraoral appliance. The patients were randomly assigned to 2 groups: 1 group received piezotome-corticision procedure in conjunction with orthodontics and the other conventional orthodontics. Irregularity index was measured every 4-5 weeks in both groups. The time to alignment was calculated in days. Visual Analogue Scale (VAS) was used to measure the level of pain, ease, and satisfaction with the procedures.

Results: Overall, no difference in the time required to correct mandibular crowding with piezotome-corticision assisted and conventional orthodontics was observed. The experimental group had 1.3 times faster correction in only the first 8-10 weeks when comparing the mean rate of alignment to the control group. However, this difference was not statistically different. There was no significant difference in pain levels immediately, 1 hour, 12 hours, and 7 days after the start of treatment between the two groups. The level of patient satisfaction and ease with the procedures were similar between the two groups.

Conclusion: Piezotome-corticision assisted orthodontics seems not to be more efficient in alleviating mandibular anterior crowding than conventional orthodontics. Slight increase in the rate of tooth movement was observed only during the first 8-10 weeks but it was neither statistically nor clinically significant. The level of pain, ease and satisfaction with both procedures were not significantly different. There are additional aspects of treatment with corticision that need to be considered which include the necessity of the clinician's familiarity with the technique and indications, the dictates of the patient's malocclusion, and finally the cost of a procedure that appears to have limited effect in enhancing the rate of tooth movement.

INTRODUCTION

The length of comprehensive orthodontic treatment ranges between 18–30 months with 21-27 months for nonextraction and 25-35 months for extraction therapies, respectively [1, 2]. An increased risk of problems due to caries, periodontal disease and root resorption have been associated with prolonged treatment time. Reducing orthodontic treatment time is one of the primary goals for orthodontists as it leads to increased patient satisfaction. Since orthodontic tooth movement (OTM) is caused by a gradual remodeling (apposition and resorption cycle) of supporting alveolar bone, factors affecting this cycle could modulate the rate of tooth movement [3].

The attempts to shorten the treatment time can be divided into different categories, including local or systemic administration of biologic and pharmacological factors [4-9]. Due to the adverse reactions witnessed with these approaches [10,11], the trend has turned towards finding a physical or surgical approach that can accelerate tooth movement. Such approaches include electrical currents [12, 13], magnets [14], laser beams [15], mechanical vibration [16], ultrasound [17], dental distraction [18], alveolar surgery to undermine interseptal bone [19], corticotomies [20], osteotomies [21] and corticision [22, 23].

L.C. Brian and G. Cunningham were the first to use corticotomy to correct malocclusion in 1892 and 1893, respectively [24, 25]. In 1931, Bichlmayr applied corticotomy-osteotomy to correct maxillary protrusion [26]. In 1959, Heinrich Kole introduced a surgical procedure involving the reflection of full-thickness flaps followed by removal of the interdental alveolar cortical bone, leaving the medullary bone intact with a through-and-through subapical osteotomy [27-29]. Later, Generson, Gantes, and Suyu modified

Kole's technique [30, 31, 32]. It was believed that corticotomy makes tooth movement faster because the bone blocks move with the tooth [27-29, 32]. In 2001, Wilcko and Wilcko [33] patented and trademarked their technique as "Periodontally Accelerated Osteogenic Orthodontics" procedure. The procedure involves raising labial and lingual full-thickness flaps, performing interdental decortication slightly into the medullary bone using a surgical bur and applying a bone graft. The authors attributed the enhanced tooth movement to a regional acceleratory phenomenon (RAP).

Orthodontic tooth movement is influenced by bone turnover [7, 35-37], bone density [36, 37], and hyalinization of the periodontal ligament (PDL) [38]. Bone turnover is accelerated after bone fracture, osteotomy, or bone grafting [39-41] which could be explained by a regional acceleratory phenomenon (RAP), first described by Frost in 1983 [39-41]. RAP occurs in bone following a noxious stimulus and accelerates regional hard and soft tissue processes above normal levels [39-41]. It begins within a few days of the insult, peaks at 1 to 2 months with its effect prolonged 6 to more than 24 months [41]. RAP starts in alveolar bone with an initial burst of osteoclast activity which decreases bone density followed by enhanced osteoblast activity which increases bone density [42, 43]. Baloul et al. [44] in a recent study demonstrated a decrease in bone mineral content (BMC) starting at 7 days with a statistically significant decrease by 14 days, and restored to levels greater than baseline at 42 days and no significant difference in bone mineral density (BMD) comparing the selective alveolar decortication to control group. The authors also showed an increase in the expression of osteoclast RNA markers and their key regulators, with their levels reaching a maximum level during the first week and declining to the original level after two weeks [44]. In another study, Teixeira et al. [45]

showed adding small perforations in the cortical bone increases most of the 92 cytokines studied to a higher level.

Orthodontic forces in conjunction with corticotomy procedures produce faster tooth movement than orthodontic forces alone [2, 49, 50, 51]. Suya and Wilcko [32, 33] have indicated that orthodontic treatment can be completed in 4-9 months with corticotomies. According to Hajji, the active orthodontic treatment time in patients with corticotomies was 3 to 4 times more rapid compared with patients without corticotomies [51, 52]. In addition, numerous animal studies have evaluated the effect of corticotomies on tooth movement. Lino, Mostafa, and Sanjideh showed approximately twice as much tooth movement in the corticotomy than the control side with a transient acceleratory effect [53-55]. Sanjideh et al., by performing a second corticotomy, showed that higher rates of tooth movement could be maintained for a longer period, however, the difference between one and two corticotomies was small. The authors concluded that the cost benefit of a second corticotomy procedure was not justified [55]. It has been shown that the rate and amount of tooth movement increases with increased severity of surgical trauma [56]. According to a recent systematic review by Long et al. [49], the two following studies were considered of medium and high quality. Fischer [57] showed that the treatment time was reduced in the corticotomy-assisted canine impactions by 28% to 33% compared to the control side. Aboul-Ela concluded that the rate of maxillary canine retraction was two times faster on the corticotomy than the control side during the first and second months and declined to 1.6 times higher in the third month and 1.06 times higher by the fourth month [58]. In a recent study, 20 adult patients with moderate crowding of lower anterior teeth were treated by non-extraction with either orthodontics alone or corticotomy-facilitated orthodontics. It

was observed that treatment duration for corticotomy-facilitated orthodontics and orthodontics alone was 17.5 and 49 weeks, respectively [59]. According to another systematic review by Hoogeveen et al. [92], who reviewed 18 randomized clinical trials, controlled clinical trials and case reports of 5 or more subjects, the conclusion was that these surgical procedures cause a temporary phase of accelerated tooth movement which could shorten the duration of orthodontic treatment. They also concluded that these procedures are safe for the oral tissues. However, no prospective studies have compared the overall treatment time and treatment outcome with those of a control group [92].

In an attempt to make the conventional corticotomies less invasive, Park and Kim et al. [60] introduced “corticism”, which involves transmucosal cortical incisions without the need for flap reflection. The authors showed acceleration in the anabolic as well as catabolic remodeling in the feline model with no pathologic changes or root resorption following this technique. In addition, a piezotome has been utilized in osseous surgeries due to potential damage to teeth and bone with burs as a result of heat generation and marginal osteonecrosis [61]. There is some evidence that piezoelectric incisions provide a more favorable osseous response than traditional carbide and diamond burs [62-64]. It works only on mineralized tissues, sparing soft tissues and their blood supply [64, 65]. In 2009, Dibart [66] described a new minimally invasive procedure using a piezotome called Piezocision, entailing interproximal piezoelectric microincisions buccally combined with bone augmentation via tunneling. The authors reported completing orthodontic treatment in 8 months in two cases [66] and 18 weeks in an Invisalign case [68]. Healing was uneventful; no swelling, bruising, or major discomfort was associated with this procedure [66-68]. In a recent preliminary study, an endoscopically assisted tunnel approach was

used in conjunction with piezosurgical corticotomies in nine consecutive patients with focus on the associated side effects [69]. The authors revealed no adverse effects associated with the procedure. In 2013, Kim et al. [91] performed cortical punctures using a piezotome in ten beagle dogs, divided into two groups of control and experimental. They concluded after the measurements in weeks 1-6 that the cumulative distance was greater in the piezopuncture group: 3.26 fold greater in the maxilla and 2.45 fold greater in the mandible. They also observed that anabolic activity was increased by 2.55 fold in the maxilla and 2.35 fold in the mandible. They reported that acceleration was the greatest in the first 2 weeks in the maxilla and in the second week in the mandible [91].

Mandibular crowding has been used as a model for investigating the rate of mandibular anterior alignment in non-extraction treatment with conventional orthodontics [70-74]. Pandis et al. [70] and Fleming et al. [71] reported duration of alignment but used different end points: irregularity index of less than 1mm versus 8 weeks after placement of 0.019 X 0.025-in stainless steel archwire, respectively. The self-ligating group in the Pandis et al. study used a 0.014-in Cu-NiTi Damon (Ormco) wire followed by a 0.014 X 0.025-in Cu-NiTi Damon (Ormco) wire [70]. Pandis et al. and Fleming et al. used the irregularity index defined by Little [72] to assess the amount of crowding of the mandibular anterior and the entire mandibular dentition, respectively [70, 73]. The mean time to align the mandibular anterior teeth in the self-ligating bracket group was 91.03 days and in the severe crowding group (irregularity index > 5mm) was 117 days [70]. Pandis et al. and Miles reported reduction of irregularity at various times of alignment. Miles showed that the irregularity index went from 5.7mm to 1.4mm in twenty weeks upon using 0.014-in Cu-NiTi Damon

(Ormco, Glendora, CA) followed by 0.016 X 0.025-inch Cu-NiTi Damon (Ormco, Glendora, CA) [74].

As corticotomy-assisted orthodontics is becoming popular, it might be avoided due to the patient's reluctance to undergo the procedure. In a study by Tseng that assessed the pain perception following mini-implant assisted orthodontics using a Visual Analogue Scale (VAS), pain perception peaked 24 hours following the procedure [75]. In another study by Chen et al. that assessed changes in the level of pain in patients undergoing microimplants, no significant difference was seen in the pain generated in comparison to other orthodontic procedures [76]. Pain during orthodontic treatment is a major concern; it is common after a simple procedure such as placement of molar separators. However, the experience of pain varies substantially among subjects [76-83]. In a recent study, Cassetta studied the impact of corticotomy-assisted orthodontics on oral health-related quality of life (OHRQoL) in piezoelectric surgery and conventional rotary groups. Although the OHRQoL deteriorated from baseline to 3 days after surgery in both groups, it was completely recovered to baseline after 7 days with no statistical difference between the two surgical groups [84].

The purpose of this study was to compare the time required to achieve complete alignment of crowded mandibular anterior teeth (canine to canine) between piezotome-corticision assisted and conventional orthodontics. Additionally, the subjects' perception of pain, ease and satisfaction were investigated between the piezotome-corticision assisted and conventional orthodontics using two questionnaires.

MATERIALS AND METHODS

According to Pandis et al. it takes 117 ± 46 (SD) days for complete alignment of the mandibular anterior teeth with severe crowding in non-extraction cases when serial dental casts were analyzed using Little's irregularity index [70]. For a clinically significant 40% faster alignment in the piezotome-corticision group compared to the control group at an alpha-level ($p = 0.05$) and desired power of 80%, a sample size of 30 would be required [85, 86]. Assuming an overall attrition rate of 28%, initial recruitment should target a total of 42 patients with 21 patients per group. Thirty eight patients were included in this preliminary study.

Subjects were selected from a large pool of patients presenting to the orthodontic clinic at the University of Connecticut Health Center based on the following inclusion criteria: (1) adult patients 18 or older, (2) single arch or double arch treatment, (3) non-extraction treatment in the mandibular arch, (4) presence of full complement dentition from mandibular first molar to first molar, (5) no spaces in the mandibular arch, (6) mandibular anterior irregularity index greater than 5, (7) patients with healthy periodontium and no more than 2 mm attachment loss, (8) the amount of crowding should allow for bracket placement in all teeth anterior to the mandibular second molar, (9) no therapeutic intervention planned involving intermaxillary or other intraoral or extraoral appliances including elastics, lip bumpers, maxillary expansion appliances, or headgear prior to the complete alignment of mandibular anterior teeth. The exclusion criteria were: (1) failure to provide oral and written consent to participate, (2) medical problems that affect tooth movement (Appendix I), (3) presence of primary teeth in the mandibular anterior area, (4) missing permanent mandibular anterior teeth, (5) inability to place brackets in any of the

teeth anterior to the second mandibular molar, (6) breakage of any of the mandibular anterior brackets that have not been replaced within a week. The demographics and sample characteristics are listed in Table I. Ethical approval was obtained from the Institutional Review Board at the University of Connecticut Health Center, Farmington, Connecticut, USA. The CONSORT 2010 statement [87] was used as a guide for this clinical trial. Written consent was received from all subjects prior to starting this research study.

Of the 112 patients screened, 74 did not meet the inclusion criteria or declined to participate, leaving a sample size of 38 patients (Figure 1). Patients who met the inclusion criteria (Figure 1) were randomly assigned to the control and experimental groups using block randomization. Randomization sequences were generated using random block sizes of six and eight and allocation ratio of 1:1 with the “Random Allocation Software” program to ensure balanced numbers in each group. The allocation sequences were sealed around with aluminum foil in envelopes with identical appearance, and were stored in a box.

Once patients were enrolled in the study, the study coordinator (RM/LD) picked and opened the envelopes sequentially. Subjects were assigned to a particular group based on the allocation sequence in the envelopes. Mandibular teeth first molar to first molar were bonded with 0.022-inch self-ligating Carriere brackets (Ortho Organizer, Carlsbad, CA). The orthodontic wires were placed during the piezotome-corticision procedure appointment for the experimental group [51] and during the bonding appointment for the control group. Experimental subjects were followed 1 week after the first wire placement to collect the first questionnaire (see table IV). Questionnaire 1 was collected from control

subjects at the first monthly follow up. Subjects were followed monthly (every 4-5 weeks) after the first wire placement during which alginate impressions were taken. The second questionnaire (see table V) was administered and collected at the first 4-5 week appointment after the first wire placement. The archwire sequence for both groups was a 0.014-in Cu-NiTi wire for the first two visits followed by a 0.014 X 0.025-in Cu-NiTi wire [70]. The time (T_0) the subjects receive their first archwire was recorded. The alignment of the mandibular anterior teeth was clinically checked using a periodontal probe at every appointment and confirmed on dental casts to determine the end point of the study. Also, the positions of the brackets were evaluated during each appointment and if needed they were repositioned to achieve better alignment. When the irregularity index of 0-1mm was achieved between the mandibular anterior teeth and an improvement in alignment did not exceed 0.5mm between two consecutive appointments, the subjects were considered complete. In addition, if it was determined that repositioning of the brackets would no longer help with alignment and a bend in the wire was deemed necessary to complete the alignment, the subject was considered complete. The time taken to reach complete alignment ($T_f - T_0$) for each patient and the rate of tooth alignment were calculated. Subjects refrained from using analgesics containing ibuprofen, as the rate of tooth movement can be affected [88]. All subjects were asked to fill out two questionnaires [76, 82] during the first week and one month after placement of the first wire using a VAS (Appendix II).

Experimental subjects underwent the piezotome-corticision procedure at the University of Connecticut Orthodontic Clinic. This procedure was performed by one of the authors (KA/TS) according to the technique explained by Dibart et al. [66-68]. Panoramic

radiographs were utilized to assess the long axes of the teeth and root proximity prior to the procedure. Local anesthetic was administered using 2% Lidocaine with 1:100,000 Epinephrine. The depth of gingival tissue was determined by bone sounding using a Williams periodontal probe. A #15C Bard-Parker scalpel was used to make three incisions through the gingiva, 4mm below the interdental papilla to preserve the coronal attached gingiva. These three vertical incisions were made interproximally between mandibular canines and lateral incisors, and central incisors on the labial aspect of the mandible through the gingiva and the underlying bone. The soft tissue incisions were 4mm in length. After the incisions were made, the gingiva was slightly elevated laterally to visualize the bone and roots. A piezosurgery knife (BS1 insert, Satelec Acteon Group), which is an ultrasonic microsaw, was used to create the cortical alveolar incisions to a depth of 1mm within the cortical bone. According to a study by Farnsworth et al. using cone beam computed tomography, the cortical bone thickness between mandibular lateral incisor and canine 4mm apical to the crest of the alveolar bone was reported to be 1.2 mm in adults ranging 20 to 45 years old [86]. The depth of the cortical incision was limited to 1mm by ensuring that the BS1 insert penetration did not exceed the measured depth of the gingiva plus 1mm of cortical incision. Postoperatively, subjects were advised to rinse with chlorhexidine mouthwash twice a day for one week and take acetaminophen as needed. All experimental subjects were contacted the day after the procedure to ensure no complications with surgery and were followed up one week post-surgery to assess for signs of infection and ensure normal healing.

Little's irregularity index [72] was used to measure the amount of crowding on the dental models at every appointment. Patient codes were assigned to the models prior to

measurement to ensure blinding of the evaluators. Two outcome assessors were calibrated in the assessment of the Little's irregularity index. The irregularity index was measured twice by two blinded outcome assessors using a fine-tip digital caliper (Mitutoyo Corp, Japan). The subjects were instructed to record their level of pain: immediately, 1 hour, 12 hours, and 7 days after the first wire placement [76, 82]. They were also asked to report if they had taken any pain medications, their level of ease and satisfaction with the procedure, if they would undergo this procedure again, and if they would recommend it to a friend. A 100 mm Visual Analog Scale (VAS) was used to evaluate the level of pain, ease, and satisfaction of all the subjects, with anchors at each end of the line that read "no pain (easy, satisfied)" (0 mm) and "most pain (complicated, not satisfied)" (100 mm). The study coordinator (RM/LD) measured the VAS data. The reliability of the dental cast measurements was assessed using Cronbach's alpha [90] on 9 dental models made 2 weeks apart. Cronbach's alpha was 0.99 for intra- and inter-examiner measurements.

Statistical analysis:

The data were tabulated and analyzed by statistical software (Version 20.0; SPSS software). Demographics and clinical characteristics of the sample were investigated with conventional descriptive statistics. The comparisons of treatment duration and alignment rate at every time point between the experimental and control groups were analyzed with the Mann-Whitney U test. The Mann-Whitney U test was used to compare the VAS scores from the first questionnaire and questions 2 and 3 from the second questionnaire. A chi-square test was used to analyze the categorical data from questions 1, 4 and 5 in the second questionnaire.

RESULTS

Of the 112 patients screened, 74 did not meet the inclusion criteria or declined to participate, leaving a sample size of 38 patients (Figure 1). Out of the 38 patients enrolled in the study, 19 were allocated to the control group and 19 to the experimental group. Ten patients were removed after enrollment: 1 control patient did not receive any intervention due to a change of the treatment plan and 1 experimental patient was lost to follow-up. One experimental patient took medication for an unrelated medical procedure requiring exclusion from the study. Another control patient requested to be removed from the study due to an unrelated personal reason. After obtaining records, two patients, one control and the other experimental were excluded due to periodontal disease which was not clinically evident during recruitment. Two control patients were excluded due to inadequate irregularity determined by the outcome assessors. Two patients, one control and one experimental, did not return to start any treatment. Of the remaining subjects, 11 control and 12 experimental have completed the study and 1 experimental subject is in active treatment and two control and two experimental subjects are waiting to start treatment. The data collected from subjects who participated in part of the study were used for selective areas of the data analysis.

Table I shows the demographics of both groups. The treated sample consisted of 11 males (42%) and 15 females (58%). The mean initial age for the whole sample was 29.75 years; mean ages were 29.96 (SD, 11.45) and 29.50 (SD, 9.66) years for the experimental and control groups, respectively. The initial irregularity index means for the control and experimental groups were 7.77 (SD, 1.74) and 7.86 (SD, 1.53) mm, respectively.

Table II shows the mean treatment time to alignment for both groups. There was no significant difference between the experimental and control groups in terms of total time to alignment. This prompted further data analysis, shown in Table III, comparing the alignment rates between the two groups at every time point. The rate of alignment also was not significantly different between the experimental and control group at any time point during the study. However, a trend of higher alignment rate was noticed during the time T0-T1 and T1-T2 time points.

In Table IV, VAS scores from the first questionnaire gathered from 26 patients are shown. There was no significant difference in the level of pain between the two groups immediately, 1 hour, 12 hours, and 7 days after the first wire placement ($p>0.05$). The pain peaked 12 hours after the first wire placement and subsided after 7 days. Table V lists the results of the second questionnaire. Subjects in both groups showed similar levels of ease and satisfaction with their treatment ($p>0.05$). Seventy-one percent of the experimental and 50% of the control groups took medication for pain management. Both groups showed similar levels of interest (83-93%) to undergo treatment again and recommend their treatment to a friend.

DISCUSSION

The subjects selected for this study had a non-extraction treatment in the mandibular arch. We recruited 38 patients; however 10 patients were excluded from the study. One due to change in treatment plan, two due to periodontal disease, two did not return for treatment, two did not have adequate irregularity of mandibular anterior teeth, one relocated, one requested to be removed and one took an excluding medication. A

substantial amount of patient cooperation was necessary; the patients were expected to comply with the instructions and keep their follow-up visits.

Corticotomy has been claimed to reduce the treatment time [33, 36, 37] because the resistance of the dense cortical bone to orthodontic tooth movement is removed. In this study, three cortical incisions were made in the labial cortical plate between the mandibular central incisors, and lateral incisors and canines without the use of a flap and bone graft, a modification of the technique described by Dibart [66]. The more invasive conventional corticotomies require a full-thickness flap, corticotomies into the trabecular bone using burs, followed by bone grafts [33, 36, 37]. We did not find a statistically significant difference in the mean time to correct mandibular crowding between the experimental and control groups, which could be attributed to the less aggressive nature of our surgical technique. There is more RAP effect associated with more extensive surgical techniques [56]. Our results are different to the findings from Shoreibah et al. [59], who used a more aggressive technique than we did, involving flap reflection and interradicular alveolar decortication from the distal of mandibular canine to canine with a bur and no bone graft. The discrepancy between these studies and ours might also be due to the complexity of the malocclusion being treated and lack of specific outcome measures and a final outcome.

In our study, mandibular crowding was selected as a model for investigating the efficiency of piezotome-corticision in mandibular anterior tooth movement [70]. The results of this study suggest that the overall treatment time needed to alleviate crowding in piezotome-corticision assisted and conventional orthodontics groups was not significantly different which is inconsistent with previous anecdotal studies that reported

a drastic decrease in orthodontic treatment time [33, 36, 37, 51]. These studies have failed to compare the speed of tooth movement to a control sample. In a recent study by Shoreibah et al. [59], the comparison was made between corticotomy facilitated and conventional orthodontics in 20 adult subjects with Class I malocclusion and 3-5mm of lower anterior crowding treated by non-extraction. The treatment duration in the corticotomy facilitated and conventional orthodontics was 17 and 49 weeks, respectively. Our inclusion criteria were similar to the above-mentioned study, with the exception that we recruited subjects with mandibular anterior irregularity index of more than 5mm. The total treatment duration for our study with more severely crowded cases was 112.64 and 101.08 days for the control and experimental groups, respectively; similar to the treatment duration of 17 weeks with moderate crowding in the corticotomy group by Shoreibah et al. The mean treatment time to alignment for mandibular anterior teeth in conventional orthodontics with moderate crowding (irregularity index <5mm) takes 89.5 days and 117.1 days for severely crowded cases [70], which is consistent with our results. We further analyzed the rate of tooth movement at every time point. The effects of corticotomies are limited to a maximum of 1-2 months in the canine model, suggesting that these effects in humans may be limited to 2-3 months, during which 4-6 mm of tooth movement might be expected to occur [2]. In a clinical investigation by Aboul-Ela et al., the rate of canine retraction was two times faster on the corticotomy side than on the control side during the first and second months and declined to 1.6 in the third and 1.06 times in the fourth month [58]. The rate of tooth movement and duration of the RAP effect was not detectable our study. In our study, the rate of tooth movement was increased, on average by 1.3 times higher in the experimental vs. the control group, in the

first 8 to 10 weeks after surgery. This rate peaked in the first 4-5 weeks and subsided after 8-10 weeks to a rate similar to the control group. Perhaps, in instances where further orthodontic tooth movement is desired, an additional corticision procedure could be performed to increase and maintain the higher rates of tooth movement for a longer period before the decline of the RAP level. However, this difference in tooth movement was reported to be small between one and two corticotomy procedures in a canine model [55].

Pain during orthodontic treatment is a major concern. In most orthodontic treatments, pain generally increases with time, according to measurements at 4 and 24 hours, and then decreases to normal levels of sensation 7 days after treatment. A pain assessment of 40 to 50 on the 100-point VAS scale was shown 1 day after orthodontic treatment [77]. In a study by Kuroda et al. [83], VAS scores for miniscrew placement with or without flap reflection peaked 1 hour after surgery when the average pain intensity reached 65.7 and 19.5, respectively. After 7 days, none of the screw only group reported pain, whereas approximately 10% of the patients with a screw after flap reported pain. In our study, the pain score in both groups peaked 12 hours after the first wire placement. However, the difference in the VAS score immediately, 1 hour, 12 hours, and 7 days after the first wire placement was not statistically significant between the two groups.

A direct comparison between this study and previous studies was limited by several factors, such as difference in study design, technique, and method used for measuring movement. In addition, there is lack of moderate to high quality clinical trials on the subject [49]. This randomized clinical trial was designed based on a study by Pandis et al., investigating the efficiency of mandibular anterior crowding resolution in

conventional orthodontics [70]. We followed the same wire sequence as used by Pandis et al. to have a reference of comparison to a previous study on the rate of alignment with self-ligating brackets. In addition, close attention was given to minimize bias by diligent inclusion and exclusion criteria. However, in order to examine the true effect of the corticotomy procedure, more prospective clinical studies with increased sample size are required.

According to this study, combining a corticision surgical procedure with routine orthodontics cannot induce an effective RAP phenomenon to achieve a faster desired tooth movement. A trend of higher rate of alignment within the first two months was seen when comparing the means of alignment rates between the two groups. However, this rate was neither clinically nor statistically significant. Although no major adverse effects, discomfort, pain, and dissatisfaction were seen in our study or other studies [66-68, 59], it does not seem justified to increase the likelihood of infection, bleeding, and swelling for a short period of enhanced tooth movement. Furthermore, there are additional aspects of treatment with corticision that need to be considered which include the necessity of the clinician's familiarity with the technique and indications, the dictates of the patient's malocclusion, and finally the cost of a procedure that appears to have limited effect in enhancing the rate of tooth movement.

CONCLUSION

1. There was no difference in the time required to correct mandibular anterior crowding between the piezotome-corticision assisted and conventional orthodontics.
2. The piezotome-corticision technique accelerated the rate of alignment of

mandibular anterior teeth the first 8 to 10 weeks after the procedure. However, this difference was neither statistically nor clinically significant.

3. The difference in the level of pain, ease, and satisfaction with the procedure was not statistically significant between the piezotome-corticision assisted and conventional orthodontics.

CHAPTER III

DISCUSSION

The subjects selected for this study all had non-extraction treatment in the mandibular arch. We recruited 38 patients; however 10 patients were excluded from the study. One was excluded due to relocation, one for change in treatment to extraction, one took an excluding medication due to an unrelated operation and one requested to be removed for a personal reason. Two patients did not return for any treatment. After obtaining records, two patients were excluded due to periodontal disease which could not be determined prior to records. Two patients were excluded due to inadequate irregularity of mandibular anterior teeth after measurement by outcome assessors. A substantial amount of patient cooperation was necessary; the patients were expected to comply with the instructions and keep their follow-up visits.

It has been claimed that Corticotomy reduces the treatment time (33, 36, 37) because the resistance of the dense cortical bone to orthodontic tooth movement is removed. In this study, three cortical incisions were made in the labial cortical plate between the mandibular central incisors, and lateral incisors and canines without the use of a flap and bone graft, a modification of the technique described by Dibart et al. [66]. The more

invasive conventional corticotomies require a full-thickness flap, corticotomies into the trabecular bone using burs, followed by bone grafts [33, 36, 37]. We did not find a statistically significant difference in the mean time to correct mandibular crowding between the experimental and control groups, which could be attributed to the less aggressive nature of our surgical technique. There is a greater RAP effect associated with more extensive surgical techniques [56]. Our results are different to the findings from Shoreibah et al. [59], who used a more aggressive technique than we did, involving flap reflection and interradicular alveolar decortication from the distal of mandibular canine to canine with a bur and no bone graft. The discrepancy between these studies and ours might also be due to the complexity of the malocclusion being treated and lack of specific outcome measures and a final outcome.

In our study, mandibular crowding was selected as a model for investigating the efficiency of piezotome-corticision in resolution of mandibular anterior teeth crowding [70]. The results of this study suggest that the overall treatment time needed to alleviate crowding in piezotome-corticision assisted and conventional orthodontics groups was not significantly different which is inconsistent with previous anecdotal studies that reported a drastic decrease in orthodontic treatment time [33, 36, 37, 51]. These studies have failed to compare the speed of tooth movement to a control sample. In a recent study by Shoreibah et al. [59], the comparison was made between corticotomy facilitated and conventional orthodontics in 20 adult subjects with class I malocclusion and 3-5mm of lower anterior crowding treated by non-extraction. The treatment duration in the corticotomy facilitated and conventional orthodontics was 17 and 49 weeks, respectively. Our inclusion criteria were similar to the above mentioned study with the exception that

we recruited subjects with mandibular anterior irregularity index of more than 5mm. The total treatment duration for our study with more severely crowded cases was 112.64 and 101.08 days for the control and experimental groups respectively; similar to the treatment duration of 17 weeks with moderate crowding in the corticotomy group by Shoreibah et al. The mean treatment time to alignment for mandibular anterior teeth with moderate crowding (irregularity index <5mm) takes 89.5 days and 117.1 days for severely crowded cases in conventional orthodontics [70], which is consistent with our results.

We further analyzed the rate of tooth movement at every time point. We included the data collected from excluded patients who participated in the study but were excluded afterwards. The effect of corticotomies are limited to a maximum of 1-2 months in the canine model, suggesting that these effects in humans may be limited to 2-3 months, during which 4-6 mm of tooth movement might be expected to occur [2]. In a clinical investigation by Aboul-Ela et al., the rate of canine retraction was two times faster on the corticotomy side than on the control side during the first and second months and declined to 1.6 and 1.06 times in the third and fourth month, respectively [58]. In our study, the rate of tooth movement was increased, by 1.3 times higher in the experimental vs. the control group, in the first 8 to 10 weeks after surgery. This rate peaked in the first 4-5 weeks and subsided after 8-10 weeks to a rate similar to the control group. However, this difference was not statistically significant at either time point (first month and second month) and the RAP effect was not as detectable as other reported studies. Perhaps, in instances where further orthodontic tooth movement is desired, an additional corticision procedure could be performed to increase and maintain the higher rates of tooth movement for a longer period before the decline of RAP level. However, this difference

in tooth movement was reported to be small between one and two corticotomy procedures [55].

Pain during orthodontic treatment is a major concern. In most orthodontic treatments, pain generally increases with time, according to measurements at 4 and 24 hours, and then decreases to normal levels of sensation 7 days after treatment. A pain assessment of 40 to 50 on the 100-point VAS scale was shown 1 day after orthodontic treatment [77]. In a study by Kuroda et al. [83], VAS scores for screw placement with or without flap reflection peaked 1 hour after surgery when the average pain intensity reached 65.7 and 19.5, respectively. After 7 days, none of the screw only group reported pain, whereas approximately 10% of the patients with a screw after flap reported pain. In our study, the pain score in both groups peaked 12 hours after the first wire placement. A trend of higher mean pain scores was noted in the piezotome group compared to the control group. However, the difference in the VAS score immediately, 1 hour, 12 hours, and 7 days after the first wire placement was not statistically significant between the two groups.

A direct comparison between this study and previous studies was limited by several factors, such as difference in study design, technique, and method used for measuring movement. In addition, there is a lack of moderate to high quality clinical trials on the subject [49]. This randomized clinical trial was designed based on a study by Pandis et al., investigating the efficiency of mandibular anterior crowding resolution in conventional orthodontics [70]. We followed the same wire sequence as used by Pandis et al. to have a reference of comparison to a pre-existing study. In addition, close attention was given to minimize bias by diligent inclusion and exclusion criteria.

However, in order to examine the true effect of the corticotomy procedure, more prospective clinical studies with increased sample size are required.

According to this study, combining a corticision surgical procedure with routine orthodontics cannot induce effective RAP phenomenon to achieve a faster desired tooth movement. A trend of higher rate of alignment within the first two months was seen when comparing the means of alignment rates between the two groups. However, this rate was neither clinically nor statistically significant. Although no major adverse effects, discomfort, pain, and dissatisfaction were seen in our study or other studies [66-68, 59], it does not seem justified to increase the likelihood of the patient's infection, bleeding, and swelling for a short period of enhanced tooth movement. Furthermore, there are additional aspects of treatment with corticision that need to be considered which include the necessity of the clinician's familiarity with the technique and indications, the dictates of the patient's malocclusion, and finally the cost of a procedure that appears to have limited effect in enhancing the rate of tooth movement.

CHAPTER IV

CONCLUSION

1. There was no difference in the time required to correct mandibular anterior crowding between the piezotome-corticision assisted and conventional orthodontics.
2. The rate of alignment of mandibular anterior teeth was neither statistically nor clinically different at any time point during the study.
3. The difference in the level of pain, ease, and satisfaction with the procedure was not statistically significant between the piezotome-corticision assisted and

conventional orthodontics.

SIGNIFICANCE OF RESULTS

The data from this study will not only help clinicians choose the appropriate modality of treatment for their patient but also provide a platform for future investigations in similar areas.

FUTURE DIRECTIONS

This research has some significant implications in the fields of periodontics and orthodontics, but future experiments are needed to extend the knowledge about the understanding of these procedure.

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FIGURES

Figure 1. Consort flow diagram for patient participation.

CONSORT 2010 Flow Diagram

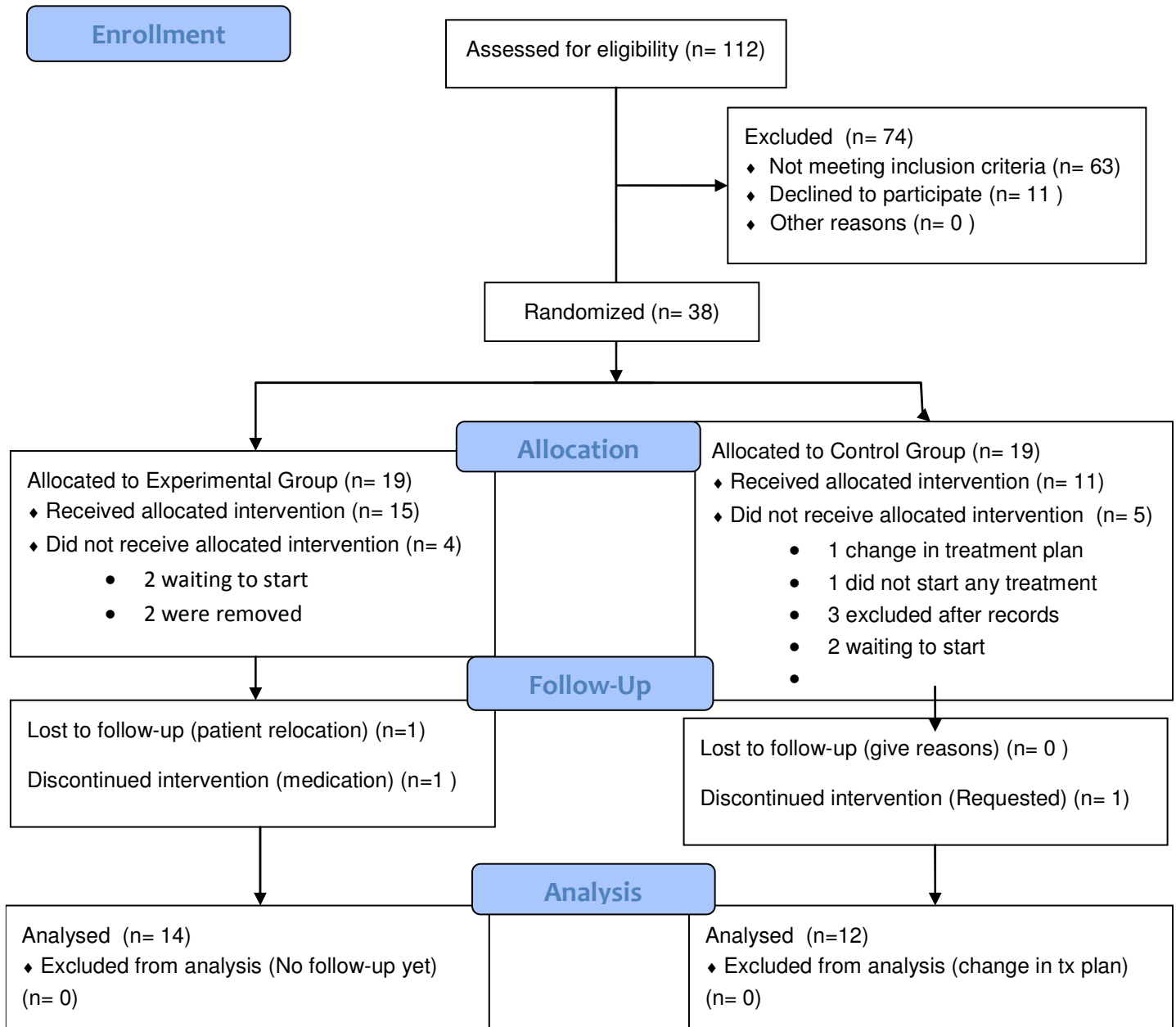


Figure 2. Occlusal views of mandibular arches of representative subjects in the experimental (top) and control (bottom) groups, before (left) and at the conclusion (right) of treatment.

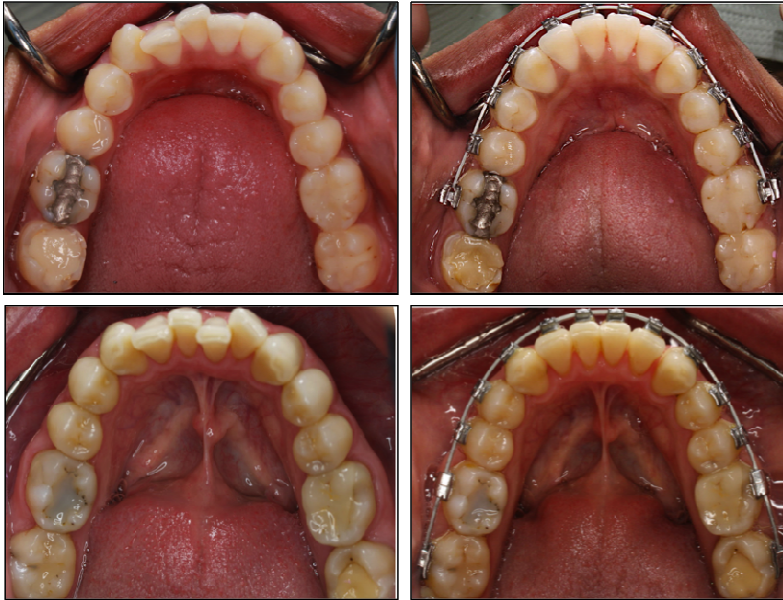


Figure 3. Graph of variation in treatment time and rate of the experimental and control groups

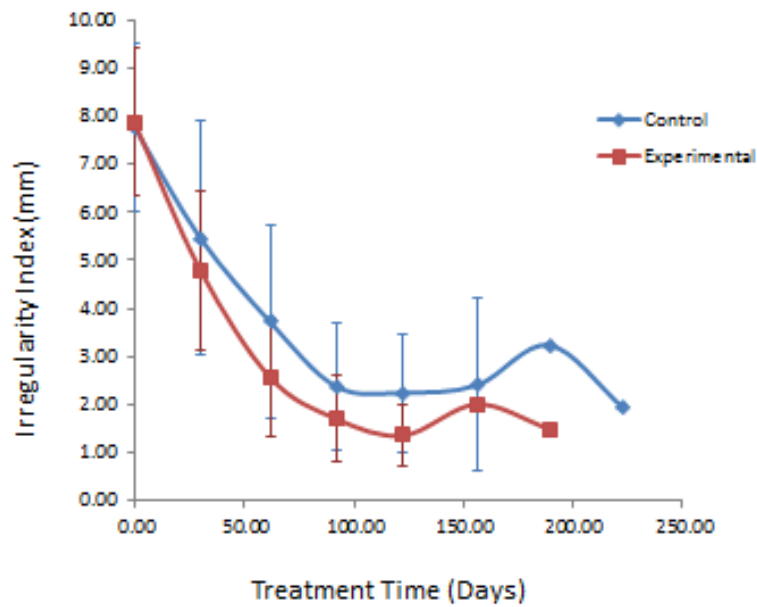
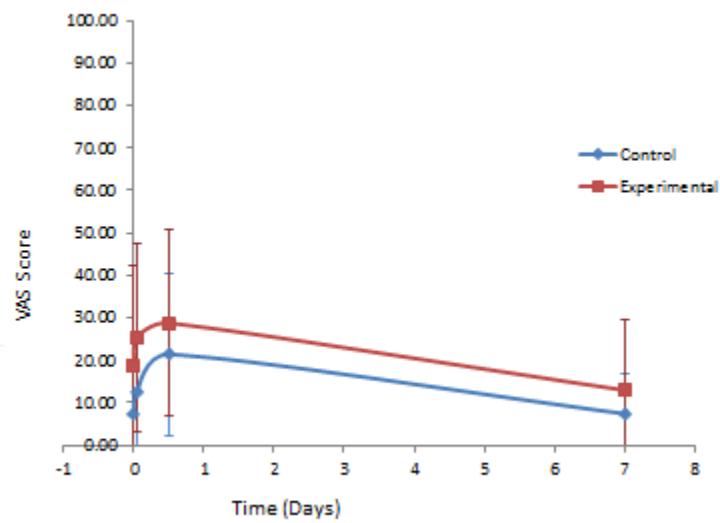


Figure 4. Pain scores in the control and experimental groups.



TABLES

Table I. Demographics and clinical characteristics of sample

Variable	Total (n=26) Mean	Control (n=12) Mean	SD	Experimental (n=14) Mean	SD
Age (mean)	29.75	29.50	9.66	29.96	11.45
Gender					
Male	11	5		6	
Female	15	7		8	
Crowding (irregularity index) (mm)	7.82	7.77	1.74	7.86	1.53

Table II. Mean treatment time to alignment by the experimental and control groups

Groups	Mean Time of Alignment (Days)	Standard Deviation	P Value NS(0.58)
Control (11)	112.64	50.39	
Piezotome-Corticision (12)	101.08	34.51	
NS Not significant			

Table III. Alignment rate in the experimental and control groups.

Time points	T1-T0		T2-T1		T3-T2		T4-T3	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Groups								
Control(12)	-0.073	0.049	-0.057	0.047	-0.064	0.064	-0.029	0.016
Piezotome-corticision (14)	-0.094	0.035	-0.0731	0.064	-0.047	0.026	-0.028	0.026
P value	0.188		0.600		0.967		0.559	

*P<0.05, significant.

NS, P>0.05, Not Significant.

Table IV. Pain scores in the experimental and control groups.

Time	VAS score				P Value
	Control (12)		Piezotome-Corticision (14)		
	Mean	SD	Mean	SD	
Immediately	7.21	9.88	18.49	23.84	NS (0.261)
1 Hour	12.34	14.37	25.40	22.23	NS (0.121)
12 Hours	21.40	19.20	28.79	21.79	NS (0.409)
7 Days	7.44	9.45	12.98	16.47	NS(0.636)

NS, Not Significant.

Table V. Data from the second questionnaire.

Questions	Control(12)		Experimental (14)		VAS Score				P Value
					Control (12)		Experimental (14)		
	Yes	No	Yes	No	Mean	SD	Mean	SD	
Did you Take any pain medication?	6 50%	6 50%	10 71%	4 29%					NS(0.263)
Are you satisfied with your treatment?					6.29	15.15	10.87	19.98	NS(0.438)
How easy was the procedure to you?					5.97	8.73	9.16	10.29	NS(0.345)
Would you undergo this procedure again?	10 83%	2 17%	13 93%	1 7%					NS(0.449)
Would you recommend this procedure to a friend?	11 92%	1 8%	13 93%	1 7%					NS(0.910)

NS, Not Significant

APPENDICES

Appendix I. Medical Conditions that exclude subjects from the study:

1. Hyperparathyroidism
2. Osteoporosis
3. Hypoparathyroidism
4. Vitamin D deficiency
5. Osteomalacia
6. Subjects taking NSAID's
7. Subjects taking Bisphosphonates
8. Subjects taking Corticosteroids
9. Fibrous dysplasia
10. Paget's disease
11. Multiple Myeloma
12. Osteogenesis Imperfecta
13. Bone metastasis
14. Hyperthyroidism (Graves Disease)
15. Hypothyroidism (Hashimoto Thyroiditis)
16. Uncontrolled diabetes
17. Smoking
18. Subjects using Nicotine patch
19. Subjects taking Opioids
20. Subjects taking Estrogen supplements
21. Subjects taking growth hormone

22. Subjects taking Relaxin
23. Subjects taking Tacrolimus after organ transplant or for treating Ulcerative Colitis
24. Asthmatic controlled with corticosteroids
25. Autoimmune diseases treated with NSAID's or Corticosteroids
26. Subjects taking anti-coagulants
27. Subjects with compromised immune system

Appendix II. The first questionnaire

How much pain/discomfort did you have at the following time points?

1. Immediately after your first wire placement
2. 1 hour after your first wire placement
3. 12 hours after your first wire placement
4. 7 days after your first wire placement

Appendix III. The second questionnaire

1. Did you take any type of pain medication after your treatment? If yes, when?

Indicate which one of the following pain killers?

- ☐ Salicylate NSAIDs (Example: Aspirin, Diflunisal, etc.)
- ☐ Propionic NSAIDs (Example: Ibuprofen/Motrin/Advil, Naproxen, etc.)
- ☐ Aniline analgesic (Example: Acetaminophen/Tylenol)
- ☐ Opioids (Example: Codeine, Hydrocodone, Morphine, etc.)
- ☐ Combination drugs (Example: Vicodin/ Acetaminophen and Hydrocodone)
- ☐ Other

If other, please write the name of the medication below:

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2. Are you satisfied with your treatment?

3. How easy was the procedure to you?
4. Would you undergo this procedure again?
5. Would you recommend this procedure to a friend?