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ORIGINAL ARTICLE

The clinical efficacy of deproteinized bovine bone mineral with 10% collagen in conjunction with localized piezosurgical decortication enhanced orthodontics: A prospective observational study

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Abstract

Background: Evidence exists on the clinical efficacy and safety of periodontally accelerated osteogenic orthodontics (PAOO) with "Piezocision"—a minimally invasive, flapless alternative to corticotomy for alveolar bone augmentation. Allograft has been extensively studied for alveolar bone augmentation in Piezocision; however, the use of deproteinized bovine bone mineral with 10% collagen (DBBM-C) in Piezocision for PAOO has not been investigated.

Methods: This study is a prospective, observational, cohort study of 19 patients of Angle Class I malocclusion with a total of 692 teeth assessed for maintenance of health of the periodontal attachment apparatus. Patient-centered pain, sensitivity, and satisfaction outcomes, digital photographs and radiographs, and changes in probing depth, clinical attachment level, width of keratinized tissue, percussion sensitivity, pulp vitality tests, radiographic pathology, and root-crown-ratio were all recorded.

Results: Overall treatment was significantly faster (5 to 7 days between clear aligner tray changes), periodontal parameters remained stable, and alveolar bone loss was not observed. Visual analog score for healing, sensitivity/duration, bleeding/duration, swelling/duration, appearance, and inflammation, demonstrated no significant differences between DBBM-C and control (no bone graft) groups. Patient-centered outcomes revealed high levels of satisfaction with Piezocision. Piezocision-treated teeth with DBBM-C tended to exhibit less root resorption, although it was not statistically significant ($P = 0.074$).

Conclusions: Within the limits of the study, our results show that the use of DBBM-C with piezosurgically enhanced orthodontics is effective and safe. This study was not designed to demonstrate equivalence with other materials that might be used in Piezocision. To understand whether there is an advantage to using DBBM-C, additional studies may be required.

KEYWORDS

bone graft(s), bone regeneration, malocclusion, orthodontics, periodontal surgery

1 | INTRODUCTION

Emerging evidence exists with regard to the innovative and minimally invasive technique called "Piezocision", a piezoelectric alveolar decortication approach that uses a tunneling flapless technique for the placement of freeze-dried bone allograft.[1]

Murphy et al. described the surgical technique for the established clinical procedure, known as periodontally accelerated osteogenic orthodontics (PAOO).[2] With PAOO, corticotomy-facilitated orthodontics was used with the addition of alveolar bone augmentation to the procedure. It has been reported that the use of PAOO would result in shorter treatment times, increased post-treatment stability, increased alveolar bone width, and decreased apical root resorption.[2]

The rationale for the acceleration of orthodontic treatment by surgical pretreatment appeared to be due to a cascade of healing events that occurred following the induction of surgical wounds in osseous tissue as described originally by Frost.[3,4] Lee et al. concluded that by the use of both osteotomies and corticotomies, different alveolar bone reactions were induced and both of these reactions, osteotomy-induced distraction osteogenesis, and corticotomy-induced regional accelerated phenomenon, could be "exploited for tooth movement."[5]

Sebaoun et al. reported that surgical injury to the alveolus induced a significant increase in tissue turnover by week 3 and that this increase dissipated to a steady state by week 11.[6] The impact of the injury was determined to be localized to the area immediately adjacent to the decortications injury.[6] Cho et al. concluded that following cortical activation, rapid initial tooth movement was possible. However, after 6 months of this cortical activation, cell number, and activity in the periodontal tissues were decreased.[7]

Vercellotti et al. compared the wound healing in dogs following osseous surgery with three different instruments.[8] A piezoelectric instrument, carbide bur, and diamond bur were all shown to have increased bone level and regeneration of cementum and the periodontal ligament at day 28. However, by day 56, the carbide bur and the diamond bur groups were shown to have bone loss, while the piezoelectric group had bone gain. As such, the piezoelectric instrument provided favorable osseous repair and remodeling and was regarded as efficacious in performing osseous surgery.[8]

While both demineralized freeze-dried bone allografts (DFDBA) and freeze-dried bone allografts (FDBA) have been used in augmentation procedures, it has been suggested that DFDBA and FDBA have inconsistent osteoinductive properties.[9] While allograft alveolar augmentation strategies in PAOO have been reported,[10] the use of bovine xenograft with its osteoconductive and resorption-slowing properties as a source for alveolar augmentation in Piezocision has not been recorded in the literature. Deproteinized bovine bone mineral with 10% collagen (DBBM-C)* is formable, trimmable, and therefore, easier to handle than granular bone graft material. It should be noted that there is both regulatory impediment and cultural resistance in some countries to the use of human derived allograft.

This observational study was designed to investigate whether DBBM-C could be used as the grafting material with similar safety and outcomes to those reported for allograft in Piezocision with a clear aligner orthodontic technique.† This study tested the hypothesis that the DBBM-C grafting material would ensure the stability and health of attachment apparatus from 6 weeks to 18 months.

2 | MATERIALS AND METHODS

This study was a prospective observational cohort study with one investigator (TM). One periodontist (TM) performed surgical procedures and recorded surgical measurements and all other clinical assessments. Written informed consent was obtained from each patient before any study-related procedures. The study protocol was reviewed and approved by Creighton University Institutional Review Board (IRB) committee as following the guidelines according to the Helsinki Agreement. The study followed the patients for efficacy for up to 18 months after their surgical treatments. Screening took place no more than 32 days before the first treatment and included the clinical assessments required to confirm eligibility.

Patients were required to meet the following inclusion criteria to be eligible for the study: 1) patient read and signed the IRB approved consent form before treatment signifying that he/she understood the procedure, alternative treatments available, and possible complications; 2) patient was aged 19 to 60 years; 3) patient was of Angle Class 1 occlusal relationship; 4) patient's orthodontic needs met the indications for clear aligner orthodontic treatment; and 5) patient was willing and able to follow study procedures and instructions.

A patient with any of the following issues was deemed not to be eligible for the study: 1) participating (currently or within 30 days before enrollment) in other clinical trials involving therapeutic intervention (either medical or dental); 2) poor oral hygiene as indicated by an initial score of >50% on the O'Leary plaque index;[11] 3) presented with a systemic condition, which would preclude periodontal treatment including, but not limited to, uncontrolled diabetes; 4) presented with acute infectious lesions in the areas intended for treatment; 5) taking chronic (i.e., >2 weeks) therapeutic doses of medications known to affect bone metabolism such

* Bio-Oss Collagen, Geistlich Pharma, Wolhusen, Switzerland.

† Invisalign, Align Technology, San Josè, CA.

as non-steroidal anti-inflammatory drugs or bisphosphonates. Prophylactic aspirin (≤325 mg daily) for cardiovascular indications were permitted in patients; 6) currently on any chronic antibiotic or steroidal therapy; 7) currently taking medications associated with the development of drug-influenced gingival enlargement, for example, calcium channel-blockers; 8) presented with radiographic evidence of pathology; 9) presented with tooth mobility exceeding a mobility score of class 2 (Miller classification); 10) presented with parafunctional habits and were not wearing a bite guard; and 11) presented with insufficient attached gingiva facial to study teeth.

The preliminary phase of the study comprised of the completion of medical and dental histories, signing of consent forms, obtaining radiographs and photographs, performing screening assessments to confirm eligibility, and instruction in oral hygiene techniques. The patient-centered outcomes recorded with visual analog scale (VAS) assessments used a graduated scale of 0 to 100. Other clinical assessments included: patient pain/discomfort questionnaire, change in probing depth, change in clinical attachment level, change in width of keratinized tissue, change in sensitivity to percussion, change in pulp vitality tests, and change in radiographic pathology. Digital photographs were obtained at each study visit and radiographs of the test sites were made at the baseline and final visits.

2.1 | Orthodontic protocol

The orthodontic treatment began 1 week following the surgery by using clear aligners. Before the surgical procedure, polyvinyl siloxane impressions of the maxillary and mandibular arches were taken and sent to the clear aligner company manufacturer to create clear aligners at the referring general dental practice offices. Each aligner was replaced with a new aligner every 5th to 7th day for a 6-month time period from the date of Piezocision surgery. Clinical judgment was used to determine if the placement of DBBM-C should be rendered or not at the time of surgery, which was based on the proposed direction of orthodontic tooth movement and position of the teeth in relationship to the gingival phenotype. It should be noted that the clinical judgment was made by the referring general dentists/periodontist team who performed the orthodontic treatment.

2.2 | Surgical protocol

Patients received periodontal surgery as described in the original protocol for the Piezocision technique.[1] Vertical gingival incisions were made interproximally, apical to the interdental papilla, with a no. 15 blade. The incisions crossed the periosteum, allowing the blade to contact the alveolar bone. Interproximal corticotomy cuts were extended through the entire thickness of the cortical layer, fully penetrating the medullary bone, in the areas of vertical gingival incisions. The design of the vertical cuts was aimed at maximizing marrow penetration and bleeding. The vertical cuts for the corticotomy were performed using a piezoelectric device.* A periosteal elevator was used to prepare a flapless tunnel connecting the vertical gingival incisions on the facial surfaces of the teeth which were to receive a bone graft material. Xenograft DBBM-C was placed on the facial surfaces of selected teeth, when prescribed clinically by the referring general dentist who performed the orthodontic treatment, through a flapless tunneling technique. The surgical site was assessed for osseous and root surface anomalies by the surgeon. The procedure was then completed by suturing the vertical incisions with 4.0 plain gut suture.†

2.3 | Radiographic analysis protocol

All radiographs were taken with the same digital x-ray imaging device. The measurement of the dental full-mouth series radiographs were performed as follows: All root and crown measurements were taken in each radiograph and measured by investigators masked in a random sequence at the discretion of the investigator. The radiographs used in the full-mouth series were obtained using a Rinn paralleling device. Thus, projection or magnification errors could not be eliminated. To compensate, the relationship between the vertical root length and crown length was used for examination. This technique has been described in another investigation.[12] Taking under consideration the pre- and post-treatment root and crown lengths, the individual root-crown-ratio (RCR) was calculated for each tooth and, therefore, the relative changes of RCR (rRCR). An rRCR of 100% indicated no change in the pretreatment root length relative to the post-treatment root length. A decrease of rRCR indicated a reduction of the root length during treatment.

2.4 | Statistical methods

Insufficient clinical experience on how this new procedure will affect change in either visual assessment or stability of the attachment apparatus currently exists. In addition, no estimates comparing similar procedures for PAOO have been reported in the literature. However, based on clinical experience, an average difference in groups or change from baseline in periodontal probing depth or recession between 0.5 and 1.0 mm with an estimated standard deviation of 1.0 mm would be clinically meaningful. Calculations at 5% significance level for a two-tailed paired *t* test indicate that 19 evaluable patients are needed to detect a difference of 0.7 mm difference in the change in periodontal probing depth or recession depth with

* Variosurg, NSK, Tokyo, Japan.

† Ethicon, Inc., Johnson & Johnson, Cincinnati, OH.

80% power and assuming a within-patient variation (standard deviation estimated from previous studies with similar inclusion/exclusion criteria) of 1.0 mm.

A total of 22 patients will be enrolled to assure ample power for the primary measures, as shown above, and to account for potential loss to follow-up.

Summary statistics were calculated for all patient-level mean periodontal outcomes (probing depth, recession, clinical attachment level, mobility, and furcation), all patient-level mean bone measures (CEJ-to-crestal bone, CEJ-to-apex bone, and CEJ-to-CEJ bone), and all patient-level mean healing measures. For the latter, the following investigator-determined criteria were used: a healing visual analog scale (0 to 100), bleeding (1 = none to 4 = severe), swelling assessment (1 = none to 4 = severe), soft tissue texture (1 = less firm versus 2 = equally or more firm), soft tissue color (1 = more red versus 2 = less or equally red), and inflammation (0 to 4). The following patient-determined criteria were used for patient-level mean healing measures: pain visual analog scale (0 to 100), sensitivity (1 = none to 4 = severe), and satisfaction with appearance (1 = very satisfied to 5 = very dissatisfied).

Summary statistics for patient-level duration of sensitivity, duration of bleeding, and duration of swelling (in days) were also calculated. Paired *t* tests were used to test for changes in clinical measures over time for patient-level means. Percent root resorption also was calculated over time with frequencies tabulated for the distribution of percent root resorption at second visit and at third visit on an observation level. Distributions of healing measures on an observational level were also tabulated. Continuous and ordinal healing data were analyzed using the method of generalized estimating equations to accommodate lack of independence among observations. Number of measured tooth types, mean, and standard deviation of RCR% for every tooth by bone graft (with versus without) was analyzed.

3 | RESULTS

3.1 | Patient characteristics

Twenty-two patients (eight males and 14 females) aged 43.9 ± 12.8 years were included in the study with a total of 692 teeth. Three patients discontinued participation in the study due to geographic relocation. The mean observation duration from initial visit to final visit was 1.28 years.

3.2 | Periodontal outcomes

All periodontal parameters remained stable before and after treatment throughout the study. No statistically significant changes in patient-level means of periodontal measures were noted from baseline to the final visit (Table 1). No significant change in *t* tests for gingival measures was noted.

A post-hoc power analysis was conducted and demonstrated the following: Based on the changes in periodontal measures in this study, we had 90% power to detect an average increase in periodontal probing depth of at least 0.5 mm, we had 87% power to detect an average increase in recession of at least 0.25 mm, we had 86% power to detect an average increase in clinical attachment loss of at least 0.6 mm, 67% power to detect an average overall increase in mobility of 0.2, and 40% power to detect an average increase in molar furcation of 0.2.

3.3 | Radiographic outcomes

Increase in bone loss was not observed in the study from baseline to the final visit. Table 1 shows summary statistics for patient-level means for bone measures for baseline, final visit, and change in bone measures with corresponding *t* tests for change in bone measures from baseline to the final visit. No statistically significant change in mean bone measure was noted from baseline to the final visit.

Increase of root resorption was observed from baseline to the final visit with considerable individual variations in root resorption values among the participants; however, only total root resorption values reached statistical significance. Similar distributions of root resorption were observed (Tables 2 and 3). Piezocision-treated teeth with DBBM-C tended to be less likely to experience root resorption (Table 4).

3.4 | Patient-centered outcomes

Patient-centered outcomes including healing from visual analog scale, sensitivity (from 1 = none to 4 = severe), sensitivity duration (in days), bleeding (from 1 = none to 4 = severe), bleeding duration (in days), swelling (from 1 = none to 4 = severe), swelling duration (in days), appearance (from 1 = very satisfied to 5 = very dissatisfied), and inflammation (0 to 4) with adjustment for sex and age demonstrated no significant differences in both groups (no bone graft versus use of DBBM-C). It should be noted that data suggested there was a significant difference in adjusted mean pain from visual analog scale (greater pain in use of DBBM-C). Table 5 shows summary statistics for patient-level mean healing variables. There were no statistically significant associations between bone graft and either soft tissue texture or soft tissue color (Fig. 1).

4 | DISCUSSION

To our knowledge, this is the first report of the use of DBBM-C as part of the Piezocision procedure. In this prospective

TABLE 1 Periodontal measures over time for PAOO patients at baseline, final visit, and change from baseline to final visit (probing depth, recession, and CAL) and summary statistics for bone measures at baseline and final visit and change in bone measures from baseline to final visit (all measures in mm)

	n	Mean	SD	Median	Min	Max	*P*
Probing depth – baseline	22	2.64	0.62	2.78	0.44	3.33	
Probing depth – final visit	19	2.70	0.45	2.56	2.15	3.74	
Change in probing depth at final visit	19	0.06	0.66	−0.11	−0.90	2.22	0.709
Recession – baseline	22	0.31	0.46	0.24	−0.38	1.30	
Recession – final visit	19	0.30	0.45	0.21	−0.71	1.33	
Change in recession at final visit	19	0.00	0.39	0.04	−0.81	0.67	0.988
CAL – baseline	22	2.96	0.78	2.94	0.89	4.43	
CAL – final visit	19	3.00	0.74	2.79	2.19	5.07	
Change in CAL at final visit	19	0.08	0.83	0.04	−1.46	2.11	0.682
Average mobility – baseline	22	0.26	0.27	0.19	0.00	0.92	
Average mobility – final visit	19	0.24	0.25	0.15	0.00	0.74	
Change in average mobility at final visit	19	0.01	0.39	0.00	−0.56	0.71	0.938
Average furcation – baseline	22	0.05	0.12	0.00	0.00	0.56	
Average furcation – final visit	19	0.15	0.44	0.00	0.00	1.89	
Change in furcation at final visit	19	0.10	0.31	0.00	−0.11	1.33	0.176
Average CEJ to crestal bone – baseline	19	1.59	0.59	1.40	0.91	3.04	
Average CEJ to crestal bone – final visit	19	1.73	0.69	1.53	1.11	3.70	
Average change in CEJ to crestal bone at final visit	19	0.13	0.36	0.17	−0.75	0.80	0.093
Average CEJ to apex bone – baseline	19	15.40	1.94	15.56	12.51	20.24	
Average CEJ to apex bone – final visit	19	14.94	1.81	15.33	11.06	17.58	
Average change in CEJ to apex bone at final visit	19	−0.52	1.36	−0.13	−2.83	1.74	0.153
CEJ to CEJ Bone – baseline	19	1.66	0.25	1.74	1.21	2.24	
CEJ to CEJ Bone – final visit	19	1.61	0.25	1.57	1.26	2.21	
Change in CEJ to CEJ bone at final visit	19	−0.04	0.24	0.01	−0.50	0.34	0.353

TABLE 2 Number of measured teeth, mean, and standard deviation of RCR% for every tooth

Tooth number	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**
n	18	15	14	18	17	18	18	18	18	15	18	19
Mean	100.4	101.4	96.4	95.8	95.3	96.7	96.0	98.9	98.3	100.7	102.6	96.4
SD	14.2	14.2	15.8	9.7	10.9	10.5	8.0	11.6	14.2	12.1	16.2	16.0
Tooth number	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**
n	17.0	18.0	15.0	18.0	17.0	19.0	18.0	17.0	17.0	16.0	17.0	15.0
Mean	98.3	97.8	94.6	94.2	96.4	96.9	95.0	98.0	97.2	100.7	101.4	95.5
SD	13.6	13.1	9.4	9.6	14.4	12.7	13.0	13.9	14.4	20.1	19.2	14.9

observational study, overall treatment was faster (5 to 7 days between tray changes) as compared with the conventional clear aligner protocol recommended by the manufacturer. Furthermore, our data indicated that 1) the overall periodontal parameters remained stable before and after treatment, 2) alveolar bone loss was not observed from baseline to the final visit, 3) the Piezocision-treated teeth with DBBM-C tended to be less likely to experience root resorption, and 4) patient-centered outcomes demonstrated no significant differences in both groups (no bone graft versus use of DBBM-C). Based on the data, the clinical outcomes with bone graft use appear to be similar to outcomes with no bone graft use; however, this remains to be demonstrated and the comparison of outcomes with other bone substitutes would be a logical extension of this study. To our knowledge, this is the first study to demonstrate the clinical efficacy and safety of piezoelectric alveolar decortication approach with a tunneling flapless technique when clear aligner orthodontics is used for Angle class 1 cases with the comprehensive treatment rendered by periodontist/general dentist team.

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TABLE 3 Number and percentage of teeth presenting relative changes of RCR (rRCR) ≥100% (no RR), rRCR between 90 and 100 (slight RR), rRCR between 80 and 90 (moderate RR), rRCR ≤80 (severe RR)

rRCR (%)	No. of teeth	%
≥100	209	44.8
90 ≤ X < 100	139	29.8
80 ≤ X < 90	77	16.5
<80	42	9.0
Total	467	100.0

RR, Root Resorption.

TABLE 4 Number and percentage of teeth presenting relative changes of RCR (rRCR) ≥100% (no RR), rRCR between 90 and 100 (slight RR), rRCR between 80 and 90 (moderate RR), rRCR <80 (severe RR) by bone graft (bone graft versus no bone graft)

rRCR (%)	Bone Graft	No Bone Graft
≥100	51.1% (92/180)	40.8% (117/287)
90 ≤ X < 100	24.4% (44/180)	33.1% (95/287)
80 ≤ X < 90	15.6% (28/180)	17.1% (49/287)
<80	8.9% (16/180)	9.1% (26/287)

$P = 0.074$ for "bone graft" versus "no bone graft" for comparison of "no root resorption" versus "root resorption," based on Rao-Scott Chi-squared test with adjustment for clustering of teeth. No statistically significant difference in root resorption between teeth with bone grafting versus those without bone grafting, although those with bone grafting tended to be less likely to exhibit root resorption.

Various grafting materials have been reported for the purpose of PAOO. Gantes et al. did not use bone graft augmentation with their corticotomy-facilitated orthodontics and demonstrated that the corticotomy caused minimal changes in the periodontal attachment apparatus.[13] Use of DFDBA has been successfully used and recorded in the literature to facilitate corticotomy-facilitated orthodontics.[10] Nowzari showed that the PAOO procedure could be performed with the use of an autogenous bone graft, using bone harvested from the rami and exostosis.[14] Furthermore, it has been demonstrated that minimally-invasive/few osteoperforations of the buccal cortical plate have been demonstrated to suffice proper cytokine-recruiting osteoclastic potential for accelerated tooth movement, suggesting a similarly fine-tuned and favorable molecular ecological environment of the alveolar bone by Piezocision, as opposed to corticotomy-facilitated orthodontics.[15] In this study revealing the efficacy of DBBM-C as part of the Piezocision procedure, our data demonstrated that all periodontal parameters remained stable and alveolar bone loss was not observed in both groups (no bone graft versus use of DBBM-C).

Data demonstrated and confirmed the absence of clinically significant root resorption as a result of the procedure. This finding was consistent with extensive reports in previous literature which established that no clinically significant apical root resorption occurred with Piezocision. In a randomized controlled trial of conventional orthodontics versus Piezocision, Charavet et al. reported the absence of an increase in root resorption in both groups.[16] Dibart et al. revealed no histological evidence of an increase in root resorption in rats undergoing Piezocision-assisted tooth movement.[17] Abbas et al. reported decreased canine root resorption in adults undergoing Piezocision-facilitated rapid maxillary canine retraction when compared with contralateral control sides.[18] This study was the only study which incidentally evaluated root resorption of maxillary canines in patients with Angle Class II division I malocclusions following extraction of maxillary first premolars and subsequent Piezocision or corticotomy-facilitated-orthodontics therapies. Although the study reported a decrease in mean canine root resorption in Piezocision and corticotomy groups in comparison with control groups with conventional orthodontics, the presence of minimal amounts of root resorption was observed with little clinical significance. However, the nature of the treatment sequence involving inflammatory environmental trauma to adjacent alveolar bone following extraction of maxillary first premolars, in addition to the malocclusion scheme of the patients, could have had significant influence on subsequent maxillary canine apical root resorption data in the study, causing global increases in inflammatory apical root resorption rates in all data points. Furthermore, Taner et al. reported that Angle Class II division I malocclusion patients undergoing orthodontic treatment following the extraction of maxillary first premolars have been shown to have statistically significant intergroup differences with higher mean root resorption rates of anterior teeth when compared with Angle Class I patients.[19] Only one study has specifically reported the effect of Piezocision on root resorption associated with orthodontic force.[20] Patterson et al.[20] reported a 110% more volumetric root loss on Piezocision teeth when compared with average control teeth. This value is potentially misleading because the recorded iatrogenic root damage/cratering on the teeth (five out of the 14 samples) from incorrect Piezocision technique was summated with root resorption data to create a total 110% more volumetric root loss figure.

The study reported that there were considerable individual variations in root resorption values among the participants; however, only total root resorption values reached statistical significance. The summation method in achieving statistical significance does not accurately analyze inflammatory root resorption from orthodontic forces. In addition, the difference in mean total resorption per tooth (mm^3) from the Piezocision and the non-Piezocision control teeth (0.435 and 0.302 mm^3, respectively) was calculated in the report as 0.133 mm^3, which was reported with statistical significance, but has little to no clinical significance. In addition, difficulties in user error with Piezocision technique occurred during the study, including reported inadequate visual access which impaired the surgical procedure.

TABLE 5 Summary statistics for patient-level mean healing variables and tooth-level distribution of sensitivity, bleeding, swelling, appearance, soft tissue texture, soft tissue color, and inflammation

Healing measures	n	Mean ± SD (median)	Range
Pain VAS	21	38.4 ± 23.4 (36.7)	5 to 72.4
Healing VAS	21	90.9 ± 29.7 (90.0)	45 to 150
Average sensitivity	22	1.70 ± 0.79 (1.50)	1 to 3.67
Average bleeding	22	1.67 ± 0.42 (1.85)	1 to 2.32
Average swelling	22	2.51 ± 0.77 (2.35)	1 to 4
Satisfaction with appearance	22	1.68 ± 0.96 (1.32)	1 to 4
Average soft tissue texture	22	1.76 ± 0.38 (2.00)	1 to 2
Average soft tissue color	22	1.67 ± 0.35 (1.79)	1 to 2
Average inflammation	22	0.88 ± 0.71 (0.85)	0 to 2.32
Duration of sensitivity (in days)	11	3.06 ± 2.07 (3.48)	0 to 7
Duration of bleeding (in days)	15	1.37 ± 0.70 (1.00)	0.75 to 3.5
Duration of swelling (in days)	19	2.99 ± 1.88 (3.00)	0 to 7

Healing measures	% (Frequency)
Sensitivity	
None	58.7% (345/588)
Mild	20.6% (121/588)
Moderate	18.5% (109/588)
Severe	2.2% (13/588)
Bleeding	
None	37.8% (222/588)
Mild	60.2% (354/588)
Moderate	2.0% (12/588)
Swelling	
None	25.0% (147/588)
Mild	22.3% (131/588)
Moderate	40.0% (235/588)
Severe	12.8% (75/588)
Appearance	
Very satisfied	55.9% (329/589)
Satisfied	34.0% (200/589)
Neither	6.3% (37/589)
Unsatisfied	0.0% (0/589)
Very dissatisfied	3.9% (23/589)
Soft tissue texture	
Less firm	22.4% (132/589)
Equally or more firm	77.6% (457/589)
Soft tissue inflammation	
More red	27.0% (159/589)
Equally or less red	73.0% (430/589)
Inflammation	
None	42.8% (252/589)
Mild	45.0% (265/589)
Mild-to-moderate	2.9% (17/589)
Moderate-to-severe	6.8% (40/589)
Severe	2.5% (15/589)

FIGURE 1 **A**) Pretreatment clinical photo at date of surgery. **B**) Pretreatment clinical photo at date of surgery. **C**) Clinical photo at completion of surgery and placement of sutures. Deproteinized bovine bone mineral with 10% collagen (DBBM-C) was placed using tunneling technique from the area of tooth #22 to tooth #27. **D**) Clinical photo at final visit for patient who completed surgical treatment with DBBM-C

Yet, despite the evidence which established no clinically significant root resorption as a result of Piezocision, one fundamental major risk factor influencing orthodontists to prescribe longer-duration conventional orthodontic treatment over Piezocision is the potential for iatrogenic injury to the periodontium and increased likelihood of root resorption. Increased duration of orthodontic treatment is considered an important factor that may influence root resorption.[21] The reduced time factor of accelerated Piezocision-facilitated orthodontics, versus longer-duration conventional orthodontics, is a possible component of decreased likelihood of root resorption.

Furthermore, our analysis of root resorption data suggests that the addition of DBBM-C with Piezocision may provide an additional protective effect against root resorption compared with Piezocision alone. There was no statistically significant difference in root resorption between teeth with bone grafting versus those without bone grafting, although those Piezocision-treated teeth with DBBM-C tended to be less likely to experience root resorption (Table 4). DBBM-C can potentially be used as a drug delivery carrier in the periodontium in further experimental efforts to supplement assurance of root resorption stability such as reported successfully with prostaglandin E_2 (PGE_2) agonists.[22] Seifi et al. demonstrated the administration of exogenous PGE_2 and calcium stabilizes root resorption while accelerating tooth movement in rats.[23] There is a possibility that the clinical effect of DBBM-C in relationship to the osteoinductive and osteoconductive components of bone formation plays a role in the prevention of tissue necrosis of the root surface via mitigation of inflammation.

Future studies with a larger sample size are needed using DBBM-C as a drug delivery medium with Piezocision to evaluate the effect on root resorption during accelerated tooth movement. Such procedures designed to create a transient controlled biological environment through the use of DBBM-C could provide an opportunity for minimally invasive biological fine-tuning of the periodontium and a potential medium for drug delivery to favor accelerated orthodontic tooth movement while ensuring stabilization of root structure.

Additionally, the authors could not rule-out a possible influence of trauma to the periosteum as an influential component to reduced root resorption seen in the Piezocision-treated teeth with DBBM-C. Stimulation of pluripotent cells from the inner layers of periosteum toward the osteoblastic phenotype following periosteal tearing during mucogingival surgery has been reported.[24] In essence, it may not have been the intrinsic property of DBBM-C which limited root resorption, but rather the difference in the technique required to place the DBBM-C, which required lifting of the periosteum.

Limitations of this current study include: 1) the number of the study population is somewhat limited, which may not provide strong power. 2) The periapical radiographic data in this study present a limitation regarding the accuracy of measurements as compared with a CT scan analysis. 3) No objective clinical criterion was used, rather subjective clinical judgement of general dentists who performed the orthodontic therapy, was used to determine if the placement of DBBM-C should be performed or not. 4) Because the investigator was also the examiner in this study, the investigator may have unintentionally been biased toward making better clinical periodontal measures with teeth where DBBM was used. Since the radiographic measures were conducted by a masked observer, no such bias exists for the radiographic measures. To eliminate observer bias in future studies, all measures should be conducted by an observer masked to treatment, if at all possible.

CONCLUSION

To our knowledge, this is the first study which demonstrated the clinical efficacy and safety of Piezocision, when clear aligner orthodontics was rendered for Angle class 1 occlusion cases by a periodontist/ general dentist team. In this study, we introduced a new protocol of 5 to 7 days per clear aligner tray as compared with conventional protocol recommended by manufacturer. Piezocision appeared to be effective and safe in accelerating orthodontic tooth movement. Furthermore, our data revealed the use of DBBM-C as part of the Piezocision is effective and safe. The overall periodontal parameters remained stable before and after treatment and alveolar bone loss was not observed. It should be noted that our data revealed the trend that Piezocision-treated teeth with DBBM-C tended to be less likely to experience root resorption. Our data agree with a previous randomized controlled trial for Piezocision-facilitated orthodontics[16] and the patient-centered outcomes revealed a high level of satisfaction with the Piezocision. Future studies are necessary to determine the relationship between root resorption outcomes in Piezocision-treated teeth with or without additional DBBM-C bone grafting.

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