The accuracy of computer-guided piezocision: a prospective clinical pilot study


Abstract. Computer-guided piezocision can be used to overcome the disadvantages of corticotomy in accelerating orthodontic tooth movement. The aim of this clinical pilot study was to determine the accuracy of this technique. STROBE guidelines were followed. Ten patients were selected and treated. Using new dedicated planning software, the piezocision cuts were properly positioned in virtual models. A surgical guide was designed and printed with slots to guide the scalpel blade first and then the piezoelectric micro-saw. The slots limit the cortical incisions coronally and apically, and also limit the depth of penetration of the piezoelectric micro-saw. The patients underwent CBCT before and immediately after surgery, and the pre- and postoperative images were matched. Using software, the planned piezocisions were compared to the actual piezocisions, and the entry point and depth deviations were measured. Descriptive statistics, kappa statistics, and the t-test were used for the data analysis. The mean deviation at the entry point was 0.67 mm (range 0.06–1.44 mm, standard deviation 0.31). The mean depth deviation was 0.54 mm (range 0.17–0.80 mm, standard deviation 0.21). The limits of the use of computer-guided piezocision are set by the maximum deviation observed; thus a safety distance of 1.5 mm should be considered, which confirms that this innovative technique is clinically applicable.

Corticotomy is an effective technique to accelerate orthodontic tooth movement, but it is characterized by significant post-operative discomfort1–4. The original technique requires the elevation of mucoperiosteal flaps and a long surgical time, resulting in a reluctance to employ this technique among both patients and the dental community.5

To overcome the disadvantages of the corticotomy, Dibart et al. introduced the concept of ‘piezocision’6,7. This procedure is characterized by small mucoperiosteal vertical incisions, minimal piezoelectric osseous cuts to the buccal cortex only, and bone or soft tissue grafting6,7. Even more recently, an innovative, minimally invasive, flapless procedure combining piezoelectric surgery cortical micro-incisions with the use of a three-dimensionally printed computer-aided design and computer-aided manufacturing (CAD/CAM) surgical guide has been reported in the literature (computer-guided piezocision)8–11. This computer-guided piezocision procedure offers ‘static’ guidance via a surgical guide that prevents changes to the surgical plan at the time of surgery12,13.

Key words: computer-guided surgery; accuracy; accelerated tooth movement; CAD/CAM; piezocision; accelerated orthodontics; minimally invasive surgical procedure.

Accepted for publication 24 February 2017 Available online 20 March 2017
dentist, provide a guide representing the planned proper positions of the virtual piezocision cuts. When the planned piezocision is incorporated into the computed tomography (CT) images, the planning can take into account both the jawbone anatomy and the roots of the teeth. Using this technique it is possible to decrease the length of time of orthodontic treatment without periodontal tissue damage. The limited deterioration in postoperative oral health-related quality of life (OHRQoL) and the effectiveness of computer-guided piezocision are encouraging and may prompt the more widespread clinical use of this technique; however, the accuracy of this technique has not yet been evaluated. In computer-guided surgery, the risk of deviation (transfer error from the software planning stage to the surgical field) is significant. As in computer-guided implantology, computer-guided piezocision involves a sequence of diagnostic and therapeutic events, and errors can be introduced at different stages.

The primary objective of this clinical pilot study was to determine the deviations in 3D directions between the virtual planned piezocisions and the actual piezocisions using the computer-guided technique (i.e., its accuracy). The frequency of surgical complications and unexpected events was also recorded in order to assess the application of this static computer-guided technique in clinical practice. It was hypothesized that a deviation would exist between the planned piezocisions and actual piezocisions, but that the accuracy measurement would allow an appropriate safety distance to be determined. It was also hypothesized that there would be no surgical complications or unexpected events.

Materials and methods

This prospective clinical pilot study was conducted in the department of orthodontics of the study institution in Rome, Italy, between March 2015 and July 2016. Two hundred and thirty patients were assessed for eligibility. Two hundred and twenty patients were not eligible, as they did not meet the inclusion criteria, detailed below. Thus, 10 patients were assigned to receive corticotomy-facilitated orthodontic treatment using computer-guided piezocision. The first patient was enrolled on 9 March 2015, and the final patient was enrolled on 1 June 2016. No patient was excluded at any stage of the study. The STROBE guidelines were followed in this study (Strengthening the Reporting of Observational Studies in Epidemiology). Written consent was obtained from each participant. The investigation was reviewed and approved by the local ethics committee.

The eligibility criteria were as follows: systemically healthy patient; no clinical evidence of dental caries; good oral hygiene; skeletal and molar class I relationships; crowding of both arches (4 mm or more of discrepancy); willingness to participate in the study.

Dedicated software and a modified 3D-printed CAD/CAM surgical guide were used in the present study, as described below.

Planning phase

First, a preliminary impression of the dental arches was taken. A customized impression tray was manufactured, and a second impression was then taken. Using a thermoplastic impression compound in stick form to mould the border, the impression tray was extended as far as possible into the vestibular fornice. The final impression was taken using a silicone material (polyvinylsiloxane). The cast was poured and the model digitally acquired using a 3D scanner (Easy Optical 3D Scanner; Open Technologies, Rezzato, Italy). Written consent was obtained from each patient. The investigation was reviewed and approved by the local ethics committee.

Fig. 1. The radiological matching tray with radiopaque landmarks used to obtain a perfect overlap of the jaw and cast STL files.
BS, Italy). The cast scanner images were saved as stereolithography (STL) files and stored.

The patient then underwent cone beam computed tomography (CBCT) using a personalized radiological tray (radiological matching tray) with radiopaque landmarks to obtain a perfect overlap of the jaw and cast STL files (Fig. 1). Digital Imaging and Communications in Medicine (DICOM) images were acquired using software (Cortex; Media Lab, Milano, Italy), allowing the segmentation of 3D medical images. Images of the jaws were transformed into 3D models and saved as STL files. With the same software (Cortex; Media Lab, Milano, Italy) and using the radiological matching tray as reference, the STL files of the jaw and cast were matched.

Using the 3D planning software (Cortex; Media Lab, Milano, Italy), the piezocision cuts were appropriately positioned in the virtual models (Fig. 2). When the cast images were matched with the CT images, the planning took into account both the jawbone anatomy and the extension of the guide (Note: it is not possible to extend the surgical guide beyond the limits determined by the impression taken, i.e. beyond the limits of the fornx that the plaster cast defines). The software (Cortex; Media Lab, Milano, Italy) permitted a
view of the 3D model from different perspectives and planes with perfect rendering. The space between the roots of each tooth was evaluated from the right second molar to the left second molar, and corticotomy cuts were drawn with the longitudinal axis parallel to each root. Following the direction of this pre-determined longitudinal axis, a template was designed, characterized by the presence of guide slots of a predetermined height (Fig. 3).

The slots delimit a space of 1 mm and limit the cortical incisions coronally and apically. The width of the slot is proportional to the thickness of the piezoelectric cutting insert (0.55 mm).

The slots were designed to be 2 mm from the papilla (coronal limit preventing damage to the periodontal tissues) and 2 mm above the apex of the teeth (this apical limit is the minimum extension of the cortical bone incision required to achieve effective acceleration of orthodontic movement). The height of the slots was determined in order to allow the piezoelectric micro-saw to penetrate at most 10 mm into the slot, so that the depth of the piezocision would correspond to the virtual project.

A 3D model of the guide was then transformed (i.e., printed) into a surgical guide with the slots designed to guide the scalpel blade first and then the piezoelectric cutting insert (OT7). The 3D STL model of the surgical guide was printed using an Objet30 OrthoDesk 3D Printer for medical devices (Stratasys, Eden Prairie, MN, USA) (Fig. 4).

Surgical phase

Following the administration of plexus anaesthesia, the guide was positioned. The surgical guide covers the occlusal surface of molars and premolars and the margins of the canines and incisors, extending as far as possible into the vestibular fornx between the right second molar and the left second molar.

The surgical guide stability was checked by inviting the patient to bite. In order to reduce the possible positioning error, occlusal indices were added to further stabilize the surgical guide before surgery (Fig. 4). Gingival vertical incisions were made interproximally below the interdental papilla using a number 15 blade. The incisions crossed the periosteum, allowing the blade to come into contact with the alveolar bone (Fig. 5). The piezocision cuts were then performed through the gingival incisions. The slot limits the cortical incisions coronally and apically, while the depth control is achieved by introducing the micro-saw 10 mm into the surgical guide slots (Figs. 6 and 7). The procedure was then completed by suturing the vertical incisions.

The orthodontic treatment was started on the same day using clear aligners (Smiletech; Ortodontica Italia, Rome, Italy). Immediately after surgery the patients underwent CBCT. The CBCT device used was the same for all study patients (SCANORA 3D; Soredex, Tuusula, Finland). The postoperative CBCT was performed at the end of the surgical phase. The scanning protocol used was as follows:
14-bit grey density, 0.250-mm pixel size, 90-kV tube voltage, 0.25-mm nominal slice thickness, 15 mAs, and 40-s exposure time. DICOM images were acquired using Cortex software (Media Lab, Milano, Italy), which allows the segmentation of 3D postoperative images. Images of the jaws were transformed into 3D models and saved as STL files (Fig. 8) and the pre- and postoperative 3D images were matched using the same software (Fig. 9). The planned piezocisions were compared to the actual piezocisions using GOM software (GOM Italia Srl, Milan, Italy) (Fig. 10).

Taking into account that piezocisions are incisions affecting the cortical bone, the accuracy at the level of the entry point was assessed (Fig. 10). For each corticotomy, the discrepancy between the planned piezocision and the actual piezocision at the entry point was calculated for at least six points (Fig. 10). Furthermore, the depth deviation was determined by superimposing the planning images onto the postoperative images. The maximum depth extension of the planned incision was compared to that actually obtained using Cortex software (Media Lab, Milano, Italy) (Fig. 11).

Data analysis
In order to reduce the potential sources of bias, the same operator, who is highly experienced in orthodontics and computer-guided surgery, performed the planning and the surgical treatments (MC). To further reduce sources of bias, two researchers measured the discrepancy between the planned incisions and the actual incisions to evaluate the accuracy; these researchers were not involved in the clinical part of the investigation.

For the statistical analysis, descriptive statistics, including mean values and standard deviations (SD), were used. A database was created using Excel (Microsoft, Redmond, WA, USA), with appropriate checks to identify errors. Intra-examiner and inter-examiner reliability was determined. Kappa statistics were used to compute intra- and inter-examiner reliability. To determine intra-examiner reliability, the examiners measured and re-measured the discrepancy. The measurements were made 2 months apart. The intra-examiner kappa coefficients were 0.85 and 0.87. The inter-examiner kappa coefficient was 0.80.

The statistical analysis was conducted at the level of the piezocision cuts; the mean values recorded by a single examiner were used. Data were evaluated using SPSS version 17.0 software (SPSS Inc., Chicago, IL, USA). The t-test was used to compare the mean deviation values of the anterior and posterior cuts. Cuts in the canine and incisor areas were considered anterior, whereas cuts in the premolar and molar areas were considered posterior. The threshold for significance was set at $P \leq 0.05$.

Results
Ten patients received the computer-guided piezocision-facilitated orthodontic treatment. The mean age of the selected patients was 22 years (range 18–30 years, SD 6.28). The male to female ratio was 1:1. All patients were treated in both arches; the number of interventions was 20, which equaled the number of guides used. A total of 112 piezocision cuts were planned and 112 piezocision cuts were made.

Accuracy
All of the 112 piezocision cuts were available for the comparison of accuracy, matching the pre- and postoperative jaw images. The deviation at the entry point and the depth deviation were determined and analysed statistically.
Fig. 8. Postoperative DICOM images were acquired using Cortex software (Media Lab, Milano, Italy); the postoperative images of the lower jaw were transformed into a 3D model and saved as an STL file.

Fig. 9. Matching of planning and postoperative 3D images using Cortex software (Media Lab, Milano, Italy).
The mean deviation at the entry point for the anterior cuts was 0.69 mm (range 0.06–1.44 mm, SD 0.32) and the mean deviation at the entry point for the posterior cuts was 0.65 mm (range 0.08–1.29 mm, SD 0.30). The mean depth deviation of the anterior cuts was 0.55 mm (range 0.41–0.68 mm, SD 0.17) and the mean depth deviation of the posterior cuts was 0.54 mm (range 0.17–0.80 mm, SD 0.21). There was no statisti-
cally significant difference between the deviation values of the anterior and posterior piezocision cuts for either the entry point deviation ($P = 0.474$) or the depth deviation ($P = 0.988$).

**Unexpected events and complications**

Regarding surgical complications and unexpected events using computer-guided piezocision, no damage to the critical anatomical structures, such as the mental foramen, the maxillary sinus, or the roots of adjacent teeth, was recorded. No nerve injury, abnormal haemorrhage, or sinus pathology was seen in this sample. In no case was there a complaint of prolonged pain. Swelling was extremely rare. Mucosal lacerations did not occur, but mucosa and alveolar bone overheating injuries were recorded at 28 of the 112 prepared sites (Fig. 13). These lesions, diagnosed immediately after surgery, were characterized by erythematous and slightly white mucosal margins. They were associated with greater pain localized to the site involved, limited to the 7 days immediately following surgery. Although the pain disappeared rapidly, the healing process took about 2 months in some cases (nine out of 28 piezocision cuts), with soreness reported in the area affected by overheating (Fig. 14). Misaligned seating of the surgical template on the teeth, resulting in

![Fig. 12. The deviation data illustrated using box plots showing the median, quartile, and extreme values of deviation.](image)

![Fig. 13. Mucosa and alveolar bone overheating injuries in the posterior areas of the maxilla.](image)
Discussion

The first hypothesis of the present study was confirmed by the results. The second hypothesis of the present study was not confirmed by the results.

Computer-guided piezocision was designed to provide greater control and to eliminate the risks involved in piezocision. However, as in computer-guided implantology, the risk of deviation between the planned incision and actual incision and the possible occurrence of unexpected events or complications remains relevant.

Regarding accuracy, the results of the present study showed high levels of accuracy for computer-guided piezocision. However, when a technique is applied clinically, the maximum deviation should be taken into account, because the incidental contact of the piezoelectric micro-saw with tooth roots or any critical anatomical structure could result in significant complications. In this study, the mean deviation value at the entry point was 0.67 mm and the mean depth deviation was 0.54 mm, but the maximum deviation values between the planned and the actual piezocision cuts far exceeded these mean values. This indicates that although the use of a CAD/CAM surgical guide is an indispensable aid for minimally invasive piezocision, it is always advisable to observe a minimum safety distance from the limiting anatomical structures and tooth roots of at least 1.5 mm.

The surgical procedure was not complicated by poor access in the posterior quadrants because of the relatively long piezoelectric cutting insert and thinness of the surgical guide. The poor visibility in the posterior regions did not make it difficult for the surgeon to accomplish the appropriate depth of piezocision, which was confirmed by the absence of a statistically significant difference in accuracy values between the anterior and posterior areas.

Regarding the allowance of the micro-saw in the slot, the tolerance between the two components needs to be 0.2 mm to reduce excessive friction between them. This tolerance leads to an intrinsic error, which leads to a lack of precision inherent in the method. The presence of depth control is important to reduce the risk of complications and avoiding injuries to the surrounding anatomical structures, but a depth deviation is still present.

In order to maximize accuracy, careful attention must be paid to every stage of treatment, and the following steps must be checked: Regarding accuracy, the reproducibility and stability of the radiological ray position when the CT examination is performed and during plaster cast scanning, as well as the reproducibility and stability of the surgical guide during the surgery, are essential. Guide manufacturing (precision of the 3D printer, rigidity and physical properties of the material used for the template) is important. Proper guide positioning in the mouth should be improved using occlusal indices placed in a tripod formation.

With regard to the possible complications in computer-guided surgery, these can be classified as ‘early’ and ‘late’. Early complications can be further divided into planning and procedural complications. The procedural complications are the surgical complications. In the present study, no complications were observed when performing the planning procedure using the Cortex software (Media Lab, Milano, Italy), but during the piezoelectric cutting surgery, irritation was difficult due to obstruction of the surgical guide slots. Indeed mucosa and bone overheating injuries were recorded at 28 of the 112 piezocision sites (early surgical complications); greater pain was localized to the site involved, which was limited to 7 days immediately following the surgery (late surgical complications). Unlike the surgical guides initially used in the computer-guided piezocision technique, which were not equipped with depth control, the guides used in the present study are characterized by variable-height slots, which reduce the deviation at the entry point and also limit the depth deviation. These slots make it more difficult to cool the micro-saw, and greater attention to cooling the piezoelectric insert during surgery is required. This may be critical, especially in the posterior areas, as overheating of the bone and mucosa may occur. Overheating was in fact recorded in some cases treated in the present study, but only in the posterior areas (Fig. 13). Therefore additional attention should be paid to micro-saw irrigation and regular pauses, to minimize the risk of overheating, especially in the posterior areas.

Complications in computer-guided surgery can also be divided into those related to the technical procedure and those related to the hardware used. Errors in positioning the surgical guide and overheating during piezocision can be categorized as ‘procedure-related’, whereas the accuracy or stiffness of the surgical guide is ‘product-related’. Complications related to the rigidity and physical properties of the material used for the guide were not recorded in the present study. No template cracked with or without breaking.

The use of the piezoelectric micro-saw prevents any possible interference caused by the soft tissues. Tilted seating of the surgical guide was not recorded. In all cases the surgical guide was stable in its position due to the support of the teeth. However occlusal indices were used to increase the stability of the guide (Fig. 4).

In conclusion, the limits of the use of computer-guided piezocision are set by the maximum deviation observed between planning and the actual postoperative outcomes. Deviations may reflect the sum of...
all errors occurring from imaging to the transformation of the data into a guide, to the improper positioning of the latter during surgery\textsuperscript{16}. Thus, all errors, although seldom occurring, can be cumulative\textsuperscript{9}. A safety distance of 1.5 mm should be considered in order to avoid damage to the critical anatomical structures, such as the mental foramen, the maxillary sinus, or the roots of the adjacent teeth.

Concerning surgical complications and unexpected events, the most frequent and important complication is overheating of the soft and hard tissues, which was recorded in the present study. For this reason, the utmost attention is required when performing micro-saw irrigation, which is made more difficult by the obstruction of the surgical guide slots. This complication leads to a worsening of the postoperative course limited to the first 7 days. Profuse irrigation and regular pausing of the piezo-electric micro-saw are sufficient to reduce the frequency of this event.

Funding
None.

Competing interests
None.

Ethical approval
This study was reviewed and approved by the local ethics committee (Umberto I Policlinico di Roma “Corticotomy minimamente invasiva in ortodonzia, studio clinico randomizzato controllato” (Rif. 3730)).

Patient consent
Patient consent was obtained.

Acknowledgements. The authors thank Dr Alfonso Di Mambro and Dr Matteo Gian- santi for their valuable assistance in the evaluation of accuracy and in the statistical analysis. The authors gratefully ac- knowledge the editing help offered by Ms Alison Driver.

References

Address:
Michele Cassetta
Department of Oral and Maxillofacial Sciences
School of Dentistry “Sapienza University of Rome
V. le Cesare Pavese
00144 Rome
Italy
Fax: +39 06 5016612
E-mail: michele.cassetta@uniroma1.it