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Piezosurgery versus Reciprocating Saw: Qualitative Comparison of the Morphology of Cutting Surfaces in Ex Vivo Human Bone

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Featured Application: In this study, the superiority of piezosurgical devices compared to the reciprocating saw is demonstrated on fresh human samples. Ultrasonic osteotomes showed superior performance, and their cutting features might provide better bone healing and remodeling.



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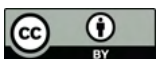
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Abstract: The aim of this study was to morphologically evaluate the differences in the cutting surfaces of bone segments obtained by reciprocating saw (RS) and two piezosurgical devices (Piezosurgery Medical—PM—and Piezosurgery Plus—PP) in ex vivo human fibulae. The ultimate goal was to identify the presence of debris, scratches, and microcracks on the cutting surface that might affect bone healing, a key aspect in oral and maxillofacial surgery. Ten patients who underwent a microsurgical reconstruction of the mandible with a free fibula flap were enrolled. The fibula segments usually discarded after surgery were cut using RS, PM, and PP, obtaining transverse sections to analyze under an environmental scanning electron microscope to perform a histomorphological qualitative evaluation. Bone surfaces cut with the RS presented several scratches, and haversian canals were frequently filled with bone debris/chips. On the contrary, PM and PP devices produced smoother and sharper cutting surfaces, with lower production of bone debris/chips, preventing vascular spaces' closure. Microcracks were found in both PM and PP cut specimens, and they could be associated with the triggering of bone remodeling, thus improving the formation of new bone, while their presence was rarely observable in RS cut samples. The use of piezosurgical devices showed superior performance, providing cleaner and smoother cutting surfaces that favor vascularization and bone remodeling; altogether, these processes could lead to accelerated bone healing, a fundamental goal in all surgical procedures that involve bone cutting.

Keywords: fibula; human bone; osteotomy; piezoelectric; reciprocating saw; environmental scanning electron microscope

1. Introduction

Bone healing is a contemporary topic that is becoming more and more interesting due to its clinical implications [1,2]. Traditional osteotomy devices, such as conventional rotary

osteotomes or reciprocating saws, have always been used for bone surgery. However, the use of these mechanical devices entails disadvantages, including bone overheating, bone fragmentation, formation of a 'smear layer' during osteotomy, and damage to adjacent tissues [3,4]. The piezoelectric bone-cutting osteotome was first introduced in orthopedic surgery in the late 1980s as an alternative bone-cutting instrument [5].

In oral, maxillofacial, vertebral, and hand surgery, as well as neurosurgery and aesthetic and reconstructive surgery, there is an increasing demand for precise and safe bone-cutting techniques [3,4]. Minimally invasive surgery is important to provide faster healing and to allow the preservation of delicate bony structures and adjacent soft tissues [6]. In recent years, significant steps have been made toward improving osteotomy devices and techniques. Among them, the development of ultrasound-based osteotomes has been a game-changer. Ultrasonic bone surgery, also called 'piezoelectric bone surgery', or simply 'piezosurgery', is a micrometric selective technique that uses a defined ultrasonic frequency, in a range between 24 kHz and 32 kHz, thus allowing a selective cut of bone [7,8]. Its mechanism of action is based on the ability of certain ceramics and crystals to deform when crossed by an electric current, resulting in micro-vibration at ultrasonic frequency [9]. The tip of piezosurgical devices cuts selectively mineralized tissues without cutting soft tissues, thereby limiting the risk of damage to blood vessels and nerves during bone surgery, which is essential in craniofacial surgery [10].

In order to introduce ultrasonic bone surgery in daily clinical practice, many studies have been performed, especially in the field of translational medicine. In fact, preclinical and clinical studies, combined with *in vitro* studies, have shown that piezosurgery produces clean and precise osteotomies with smooth surfaces and decreased bleeding [10,11]. These are key aspects, especially in those fields where precise and safe osteotomy cutting surfaces can also have an aesthetical impact on the result, such as oral, maxillofacial, and plastic surgical interventions. For these reasons, the use of piezosurgery has become the mainstay of pre-prosthetic and implant surgery. The presence of tips with different sizes and shapes determines excellent versatility, allowing the use of piezosurgery in several surgical fields [12,13]. Maxillary sinus floor elevation is a common application, as the sparing of bone tissue plays a key role in the success of this intervention [14]. Another frequent surgical intervention improved by the use of piezosurgery is bone grafting, where the reduction in bone damage during the harvesting phase allows the obtaining of tissue of higher quality [15]. Also interventions requiring high precision have benefited from this new technology, such as bone ridge augmentation and removal of fractured implants. The versatility of piezoelectric tips can help in implant site preparation in atrophic jaws because of an accurate site preparation with sparing of bone, maxillary sinus, and inferior alveolar nerve [16]. Moreover, precise mandibular implant site preparation using piezosurgery can be combined with pre-operative deep learning-based mandibular canal segmentation [1,17–19]. Finally, piezosurgery improved the safety of extreme interventions, such as inferior alveolar nerve lateralization, with a substantial impact on patients' post-operative quality of life [20]. All of these qualities have also been clinically demonstrated. For example, Pandey et al. evaluated the outcomes of alveoloplasty performed with piezosurgery compared with a classical technique with bone rongeur and bone file [21]. Arakji et al. focused on implant site preparation with a randomized controlled clinical trial-split-mouth design that assessed the superiority of piezosurgery compared to conventional drills in terms of bone quality and implant stability [22].

Moreover, it also demonstrated the effects and the advantages of piezosurgical devices over conventional rotary osteotomes in terms of bone healing in an animal model, which is indeed important to obtain suggestive data for clinical practice [2,10]. Following these experiments on animal models, it was decided to investigate the morphological effects of osteotomy instruments on human specimens for the first time *ex vivo*. It was decided not to investigate thermal damage effects in this study due to the lack of reproducibility in real clinical practice. In fact, heat production in *ex vivo* samples does not necessarily correlate to *in vivo* conditions. On the contrary, the morphological results related to the

different osteotomy devices used are clinically reproducible and can be associated with real surgical evaluations. Regarding the selected sample type, the diaphyseal fibula bone has been chosen due to its density, biomechanical properties, and practical implications since it is routinely used in major maxillofacial, plastic, and orthopedic reconstructive interventions [23–25]. Despite these features, there is a paucity of data on this topic, especially on the morphological aspects of the cutting surfaces obtained with piezosurgical osteotomies on human bone tissue. In particular, these morphologic modifications can play a key role in the success of implant site preparation. The use of *ex vivo* human specimens is critical, thus maximizing the real setting of the osteotomy procedure and lowering the risks of disadvantages for the patients. In this specific study, it has to be said that human fibula samples that were already collected from the patients and that would have been discarded after the preparation of a free fibula flap were used. A fibula flap is an osteoseptomuscular flap that can be harvested together with a skin paddle. The indications for surgery included oncological diagnosis, osteoradionecrosis (ORN), medication-related osteonecrosis of the jaw (MRONJ), pathological fractures, and atrophy of the jaws. The main consequence is that the patients involved did not experience any risk and/or adverse event. Likewise, it was possible to collect fresh human fibula samples to be cut and evaluated. To summarize, while the specimens were collected in a real clinical scenario, the osteotomy procedures were performed in a laboratory setting, thus enhancing the advantages of this human *ex vivo* experiment.

Here, there is a comparison between the use of piezoelectric bone-cutting devices and a reciprocating saw on human fibula segments harvested during the microvascular reconstruction of jawbone defects. This study aimed to qualitatively evaluate *ex vivo* the morphology of the cutting surfaces in human fibula obtained with different osteotomes using environmental scanning electron microscopy, allowing us to observe the whole surface with a tridimensional perspective. This approach would allow us to clearly identify the presence of debris, scratches, and microcracks on the cutting surface.

2. Materials and Methods

2.1. Study Design

A prospective, monocentric, observational study has been performed at the University Hospital of Modena, Italy (Azienda Ospedaliero-Universitaria di Modena). Eligibility criteria required individuals who had to undergo reconstructive surgery of the mandible and/or the midface by a microvascular fibula flap. A total of 10 patients (3 males and 7 females) met the inclusion criteria and were enrolled in the study between June 2018 and December 2019. The specimens were collected at the Cranio-Maxillofacial Surgery Unit, while the histomorphological analysis was performed at the Section of Human Morphology of the Department of Biomedical, Metabolic and Neural Sciences, University of Modena and Reggio Emilia.

The present research has been approved by the local ethical committee (protocol number 216/2018/DISP/AOUMO). A written consent has been obtained by the patients. The study was conducted according to the guidelines of the Declaration of Helsinki.

2.2. Flap Harvesting

After a proper study of the patients, an indication for a free fibula flap reconstruction was given. Using a two-team approach, the flap was harvested simultaneously with the resective procedure using classical lateral access and following our previously described technique [23,26]. There were no changes in the therapeutic strategy chosen for the patient in relation to this experiment. A minimum of an 8 cm long segment was left in place at each ending of the fibula, thus allowing for the joints' stability. After having finished the resective procedure, the bony component of the flap was modeled *in vivo* according to the real defect. The osteotomies were performed using a piezosurgical device, and when the flap was ready for the inseting procedure, the vascular pedicle was ligated. The proximal fibula segment that was already planned to be discarded was maintained in a sterile setting

each ending of the fibula, thus allowing for the joints' stability. After having finished the resective procedure, the bony component of the flap was modeled in vivo according to the real defect. The osteotomies were performed using a piezosurgical device, and when the flap was ready for the inseting procedure, the vascular pedicle was ligated. The fibula segment that was already planned to be discarded was maintained in a sterile container and immediately transferred to the experimental table for the dedicated procedures. A clinical example of the described osteotomies and segmentation of the fibula is shown in Figure 1, performed on a virtual surgical planning software. The same two operators have always performed the flap harvesting procedure and its modeling.

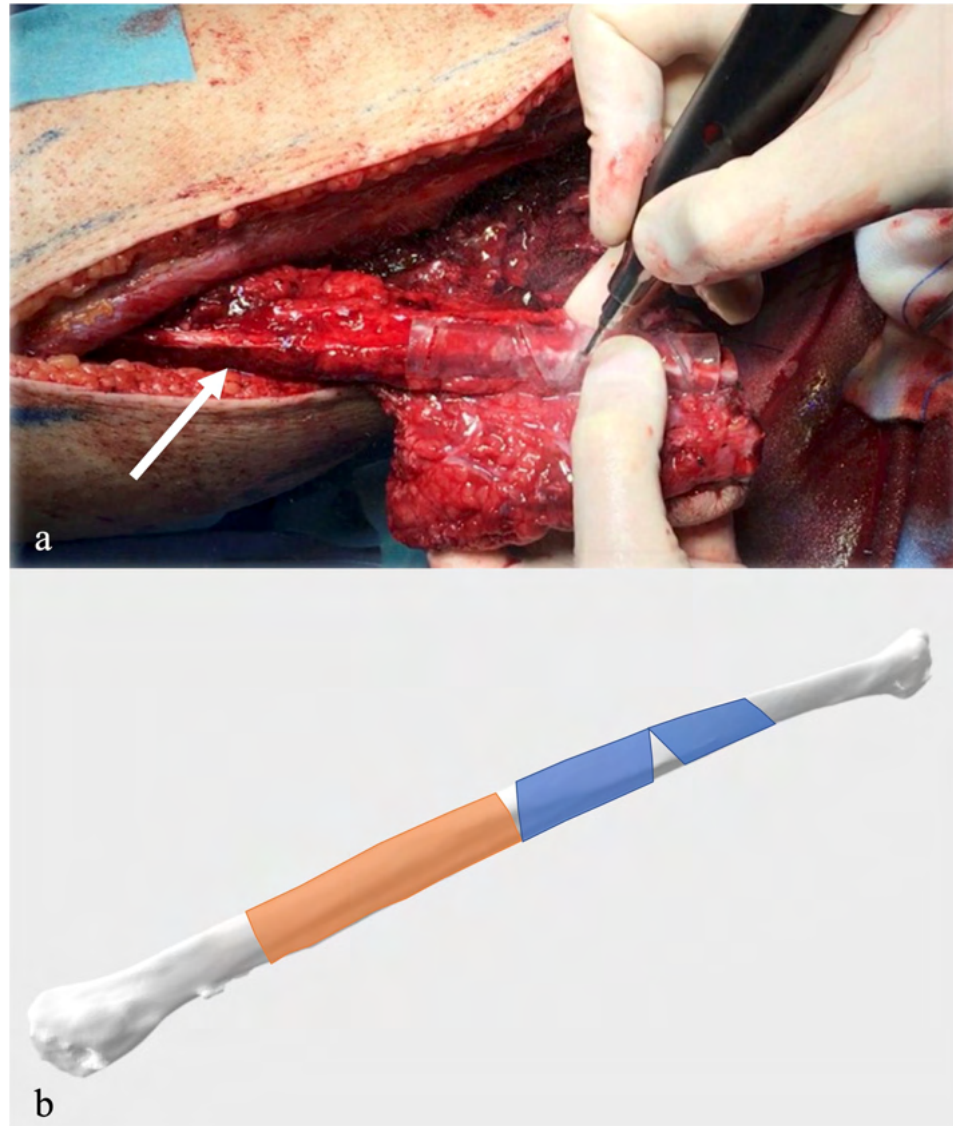


Figure 1. Clinical example of a microsurgical fibula flap reconstruction of the jaws. (a) Intraoperative picture of a free flap harvesting procedure performed with the PM device (Mectron S.p.A., Carasco (GE), Italy). The discarded fibula segment is indicated by the arrow. (b) Virtual surgical planning representation of a microsurgical fibula flap reconstruction of the jaws. In white, the proximal and distal segments of the fibula that are left in place in order to grant joints' stability. In blue, the segments that will be used for the reconstructive purposes. In orange, the proximal segment of the fibula that is usually discarded and that is analyzed and analyzed in this research.

2.3. Specimens' Collection

The fibula segment was collected from the surgical table and cut ex vivo. Transverse sections (3D samples with a 3 mm thickness) of human fibulae at the diaphyseal level were obtained with a reciprocating saw (RS) (16,000 cpm);

- Reciprocating saw (RS) (16,000 cpm);

- Piezoelectric device with an output power of 23 W (Piezosurgery® Medical=PM; Mectron Medical Technology, Carasco, GE, Italy);
 - Piezoelectric device with an output power of 75 W (Piezosurgery® Plus=PP; Mectron Medical Technology, Carasco, GE, Italy);
 - Piezoelectric device with an output power of 75 W (Piezosurgery® Plus=PP; Mectron Medical Technology, Carasco, GE, Italy).
- The RS was provided by MicroAire (Surgical Instruments LLC, Charlottesville, Charlottesville, VA, USA), while PM and PP were provided by Mectron Medical Technology (Carasco, GE, Italy). Each fibula sample was placed in a container filled with 4% paraformaldehyde in a 0.1 M phosphate buffer and was given a code number to maintain the patient's anonymity.

2.4. Environmental Scanning Electron Microscope Specimens' Evaluation

The qualitative assessment was carried out on the cortical bone cut surfaces since the amount of trabecular bone is irrelevant at the diaphyseal level. After 24 h of paraformaldehyde fixation, bone samples were dehydrated in an ascending ethanol series, and eventually critical point dried and sputter-coated with a 10 nm gold-palladium layer (Emitech K550, Emitech Ltd., Ashford, Kent, UK). The entire cut surfaces were observed with an environmental scanning electron microscope (ESEM) Quanta200 Scanning electron microscope at 80, 300, and 600× magnification in order to evaluate the presence of debris, scratches, and microcracks on the cutting surface. This observation was carried out by two blinded investigators.

3. Results

During the fibula harvesting and cutting procedures, no complications were encountered. The patients did not suffer any disadvantage or adverse event related to the sample collection.

3.1. ESEM Analysis—Conventional IRS

The bone sample surfaces cut with the RS show many scratches due to the blade, which are also visible in low magnification. Moreover, the bone cutting surfaces are frequently partially covered with bone debris/chips (Figure 2a) that do not completely fill the fissures canals (Figure 2b). Some areas of the bone surfaces appear extremely irregular with depressions and reliefs, showing a porous appearance (Figure 2a). Some canals are present only in a few specimens and clearly visible at high magnification (Figure 3b).

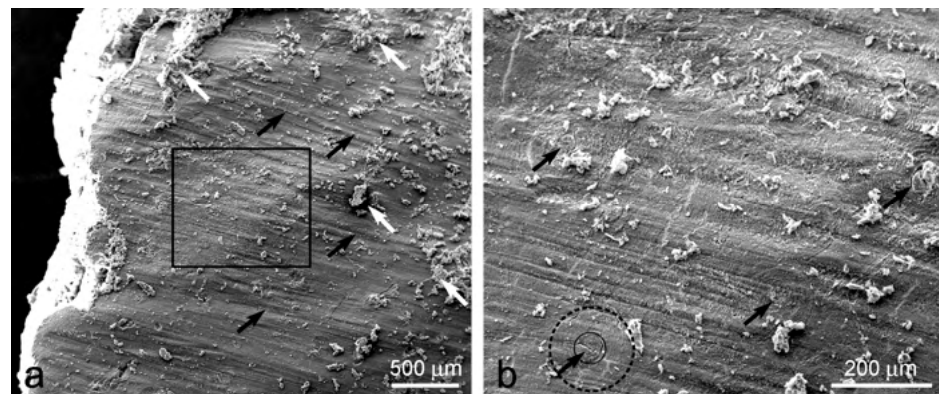


Figure 2. (a) ESEM micrograph of the surface of a bone disk cut with the RS showing many scratches (black arrows) and debris/chips (white arrows). (b) Enlargement of the squared area in (a) showing debris filling the Haversian canals (black arrows). As an example, an osteon is shown outlined by a circular dotted line, while the circular continuous line indicates the profile of the Haversian canal.

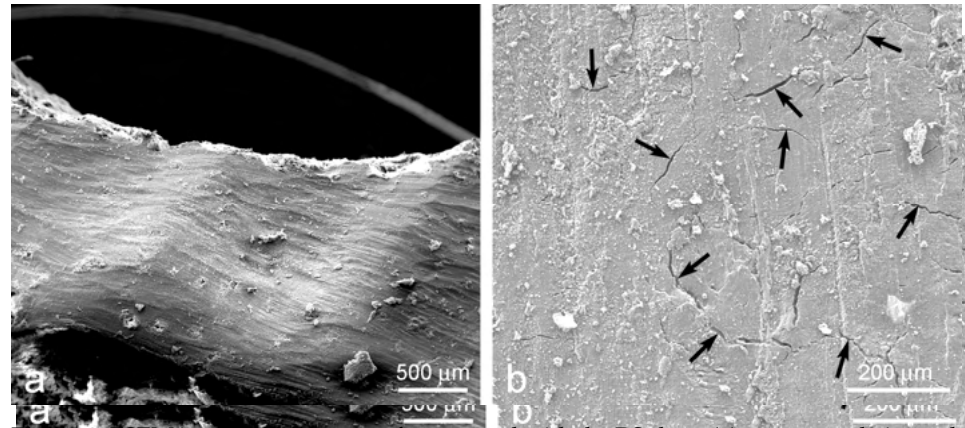


Figure 3. ESEM images of the cut surface created with the RS show (a) an extremely irregular surface with depressions and reliefs giving a wavy appearance and (b) some microcracks (arrows) visible only at higher magnification.

3.2. ESEM Analysis – PM and PP Devices

3.2.1. ESEM Analysis – PM and PP Devices
 The surfaces of bone specimens cut with the two piezoelectric devices (PM and PP) are smooth, regular, clean, and free of debris (Figure 4). Some indentations left by the tip of the device are (Figure 5) in some instances, of minor depth and they are not visible in bone samples cut with the PM device (Figure 6). On the contrary, they are not visible in samples cut with the PP device (Figure 7). In both cases, pores of the trabecular bone are (Figure 6) in the two piezoelectric devices are clearly visible (Figure 7). A lot of microcracks are present in all positions on the surface (Figure 8). At a lower magnification, this difference between the RS cutting (Figure 3) (Figure 8).

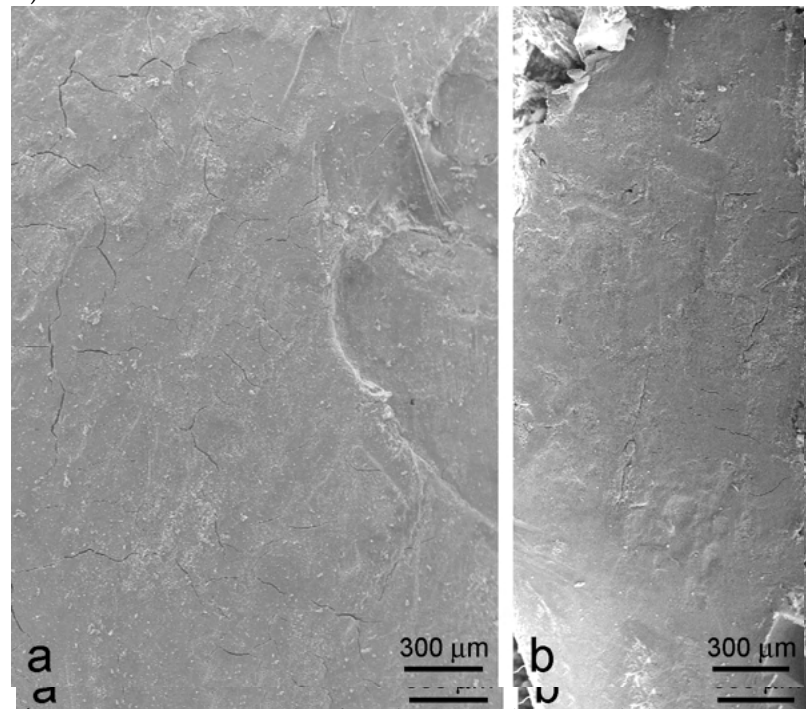


Figure 4. ESEM micrographs of two bone samples cut with the PM (a) and PP (b) show smooth and regular surfaces free from debris.

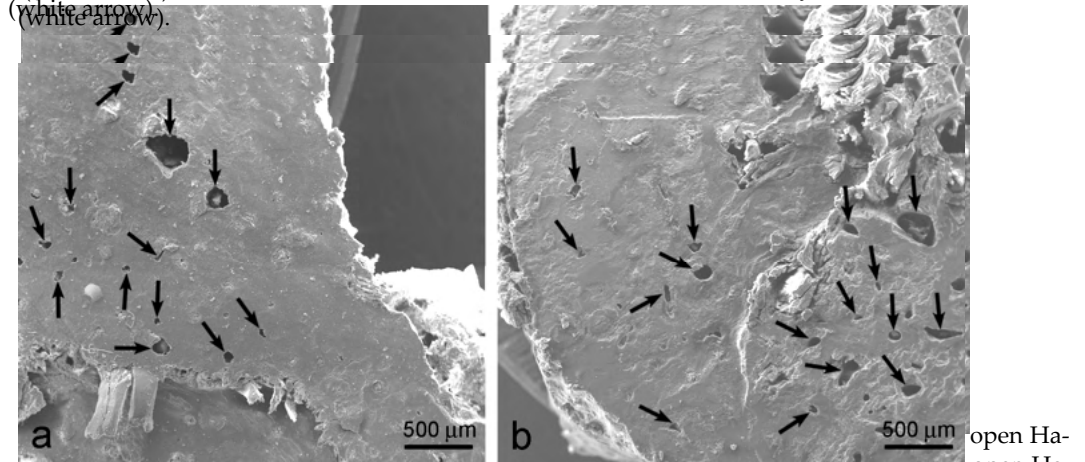
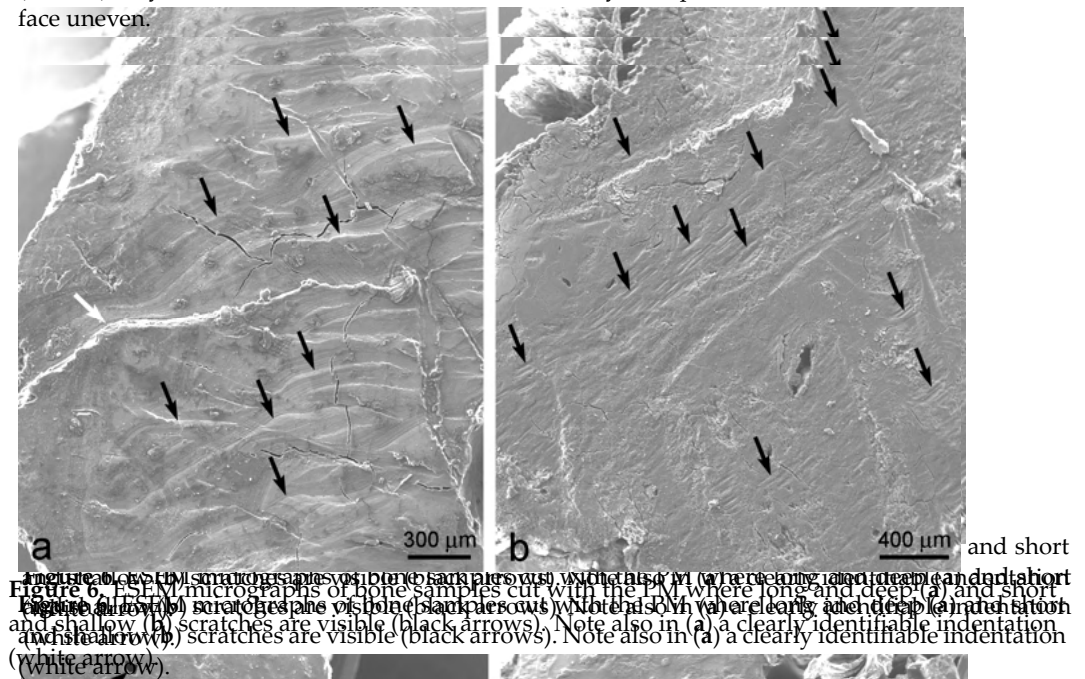
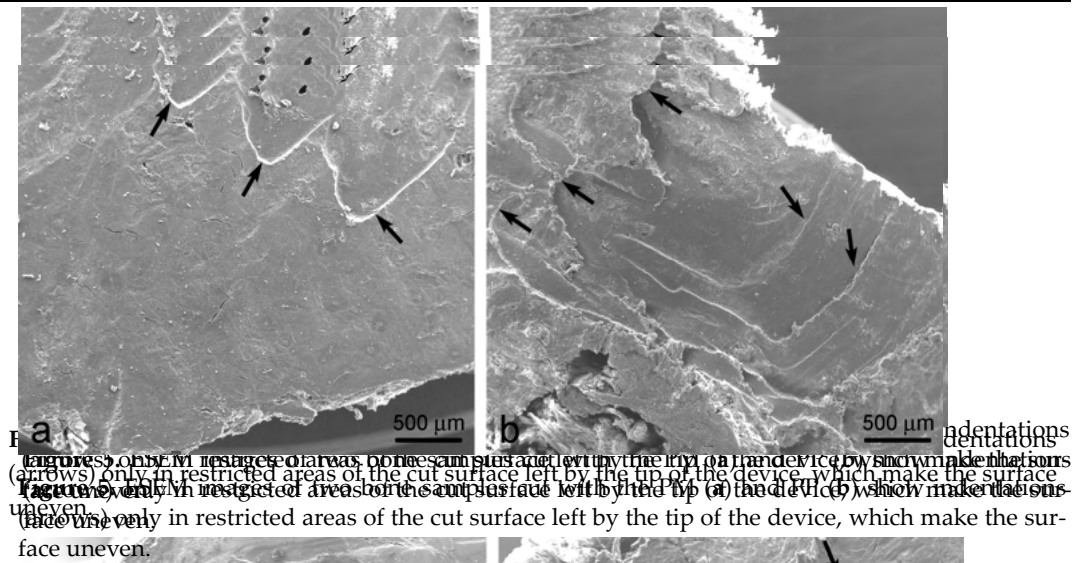


Figure 6. SEM micrographs of bone samples cut with the PM where long and deep (a) and short and shallow (b) scratches are visible (black arrows). Note also in (a) a clearly identifiable indentation (white arrow).
 Figure 7. SEM images of two bone samples cut with the PM (a) and PP (b) show many open Haversian canals free from debris (arrows).

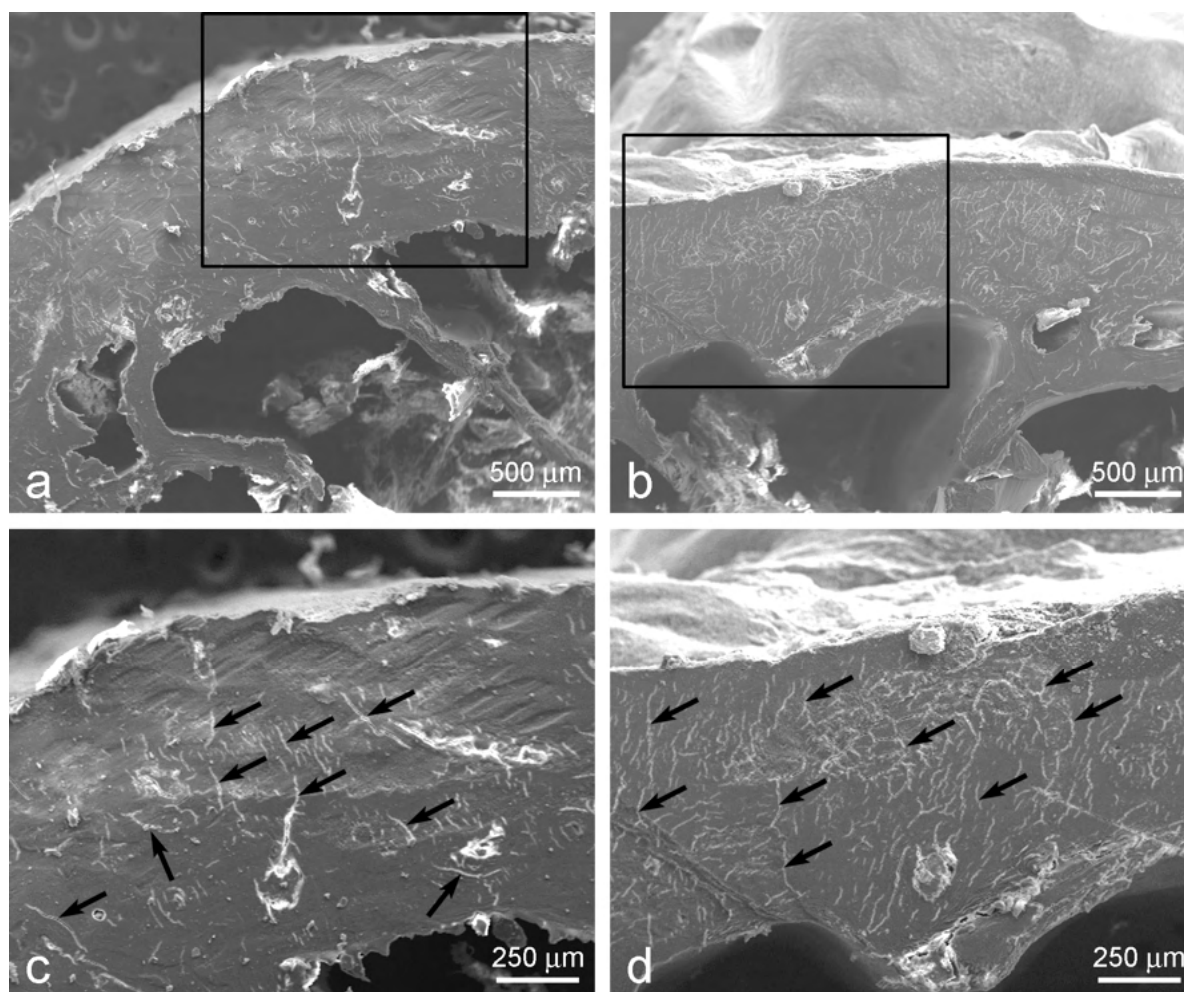


Figure 8. ESEM images of two bone samples cut with the PM (a) and PP (b). (c, d) Enlargements of the squared areas in (a, b) show abundant and well-identifiable microcracks (arrows).

4. Discussion

4. Discussion

Bone healing after surgery can be strongly influenced by the surface characteristics of the cut bone; in fact, the presence of debris and closed vascular canals can delay the process itself. Therefore, for skeletal tissue regeneration, it is important to verify which surgical device provides the best surface characteristics to optimize bone recovery. Different morphological aspects will be discussed, from the presence of debris, which makes the surface more or less contaminated and fills any cavities capable of allowing vascularization, to the appearance of microfractures that might facilitate rather than hinder regeneration. As mentioned before, the morphological evaluation of the different effects of osteotomy devices is crucial for ex vivo specimens due to their reproducibility in real clinical settings. This study has been designed in order to maximize the advantage of ex vivo evaluations (that have been performed on fresh human samples collected from the surgical table) to nullify the adverse effects for the patient population (bone samples have been collected from discarded fibula segments) and to allow the implementation and the strictness of laboratory experiments (all the osteotomy procedures have been performed by the same operator, in a laboratory setting) as well as the morphological analysis.

The observations under ESEM of the cutting surfaces of human fibulae using three different devices showed that both piezoelectric devices (PM and PP) make regular, smooth, and clean surfaces (Figure 4) compared to the RS, whose cutting surfaces appear irregular and dirty (Figures 2a and 3a). In particular, many scratches, depressions, and

line with the observations of different authors. Reside and coworkers [27] showed that more smooth shear margins were present in rat bones osteotomized with piezoelectric devices than those obtained with high-speed rotary devices. Simonetti and coworkers [28] showed a significant accumulation of bone chips on the surfaces of osteotomies of bovine ribs performed with the Lindemann bur, compared to those cut with the sonic and ultrasonic instruments, which showed more precise and clean-cutting surfaces, facilitating their alignment. Furthermore, the same authors point out that the Lindemann bur is the most irregular and traumatic of the three instruments tested, most likely due to the high kinetic energy used by the instrument and the need to apply more pressure during cutting. According to many authors, macro vibrations of saws and burs at high speed can cause trauma and damage to bone, producing heat and debris that can interfere with the healing response [29–34].

Another interesting finding to discuss is the presence of a ‘smear layer’ (i.e., bone debris) that fills the Haversian canals mainly in RS cutting surfaces (Figure 2b), while in both piezoelectrical devices, the vascular canals are often open and free from debris (Figure 7) since these instruments do not produce as much debris as the traditional RS. As reported by Simonetti and collaborators [28], in bone surfaces cut with the Lindemann bur, most of the vascular canals of the cortical bone are completely or partially filled with a smear layer. In fact, according to the authors, two types of debris can be observed on bone surfaces, i.e., detached debris, which produces a smear layer, and debris still attached to the bone surface. Other authors have also shown that bone debris, resulting from osteotomy and accumulated in the bony vascular spaces, is a common result after conventional osteotomies with drills and saws, and, consequently, blood perfusion may be limited by this mechanical obstacle [28,35–37]. On the other hand, sonic and ultrasonic instruments, by leaving a cleaner osteotomy surface free of debris, avoid the closure of vascular spaces [28,36]. In addition, clean surfaces can reduce inflammatory processes, and open vascular canals can improve tissue cell nutrition and facilitate bone healing [16,17,19,25].

A further aspect to be considered in this study is the presence of indentations in restricted areas of some specimens in both piezoelectric devices, probably due to the operator’s repositioning of the device tip during the cutting procedure (Figure 5). In addition to the indentations, scratches of different sizes and depths are observed only on the bone surfaces cut with the PM device, probably due to the roughness of the tip and the lower power of the PM (23 W) compared to the PP one (75 W) (Figure 6). In another experimental model (i.e., holes drilled in bovine cortical bone), Fugito et al. [38] described the presence of ‘slots’ after 30 consecutive drillings with the piezosurgical device on the bone surface.

Concerning the microcracks observed on bone-cutting surfaces, both piezoelectric devices have been shown to produce more microfractures compared to the RS (Figures 3b and 8). Interestingly, some authors described the presence of microcracks after the use of different cutting devices; they suggest that such microcracks might be related to compression of bone or excessive bone strain over certain threshold values [28,38]. Moreover, bone microfractures result from bone drilling and may also occur in physiological loading conditions and under excessive loads [39,40]. Some publications report that microcracks increase bone fragility, reducing the mechanical properties of bone tissue and leading to stress fractures [41,42]. On the contrary, in a 2017 review, Dittmer and Firth [43] reported that repetitive strain applied to the bone can cause microfractures that, in turn, trigger the process of bone remodeling, thus removing and repairing the same microcracks.

As it is well known, the bone remodeling that renovates the structure of skeletal segments for life is triggered by viable osteocytes [44–46] and is due to the coupled activity (both in spatial and temporal correlation) of osteoclasts and osteoblasts: initially, bone is eroded by osteoclasts and, on the same eroded surfaces, osteoblasts subsequently lay down new bone. With regard to osteocyte viability, it is very interesting to point out that in various papers [47,48], the histologic analyses on the cutting surfaces with piezoelectric devices showed the presence of live osteocytes with a normal size and morphology. In contrast

with the hypothesis that viable osteocytes are needed to trigger bone remodeling, Cardoso and coworkers [40] demonstrated that microdamage, induced by in vivo fatigue loading (in a model using ulnae of Sprague–Dawley rats), correlates with osteocyte apoptosis near the bone damage and the subsequent cortical bone remodeling process, suggesting that cell apoptosis plays a substantial role in activating and/or targeting osteoclastic resorption. In another paper by Firth and Poulos [39], the authors demonstrated in an equine model, in the neonatal period, that even habitual bone deformities (those below the microdamage threshold) cause microfractures in both cortical and trabecular bone; osteocytes close to microfractures become apoptotic, and subsequently, the early phase of the bone remodeling cycle takes place. In the present study, it is important to highlight that the numerous microcracks found in the samples cut with both piezoelectric devices should not be interpreted as a negative aspect. In fact, as described above, they can promote bone remodeling, thus leading to the formation of new bone, regardless of whether microfractures involve living/viable osteocytes or induce their apoptosis. In support of this, in a recent study [2,10], the authors showed that osteotomies of the adult rabbit cranial vault with piezoelectric devices heal faster than those with traditional rotating osteotomes, and in the bone samples cut with PM and PP devices, the number of osteoclasts is higher with respect to the traditional rotating one, suggesting greater bone remodeling activity. In addition, by immunohistochemistry analysis, Pereira and collaborators [49] showed that the bone formation and resorption responses were greater with piezosurgery than with conventional drilling, suggesting that the implant preparation with piezoelectric surgery favors cell viability, thereby improving bone healing.

The authors remark that the main advantage of the present study is related to the evaluation of human specimens, while previous papers mainly used animal bone. Nonetheless, the main limitation of this research is related to the lack of dynamic bone healing evaluation, which was not assessable in the present ex vivo setting but that the authors have extensively exploited in in vivo preclinical animal studies. The natural progression of this work will be to compare the effects of piezosurgical osteotomes and the reciprocating saw on in vivo human bone, thus also allowing both a static evaluation of the osteotomy procedure and a dynamic evaluation of short-term and long-term bone-healing process.

5. Conclusions

In conclusion, morphological observation via ESEM showed that piezosurgical devices provided cleaner and smoother cutting surfaces that prevent the closure of vascular spaces and favor cell nutrition with respect to the reciprocating saw. Moreover, the presence of microcracks in bone cut with piezosurgical devices could trigger and enhance bone remodeling, thus forming new bone.

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Institutional Review Board Statement: The present research has been approved by the local ethical committee (protocol number 216/2018/DISP/AOUMO, approved on 10 May 2018). The study was conducted according to the guidelines of the Declaration of Helsinki.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The datasets presented in this article are not readily available due to privacy reasons.

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