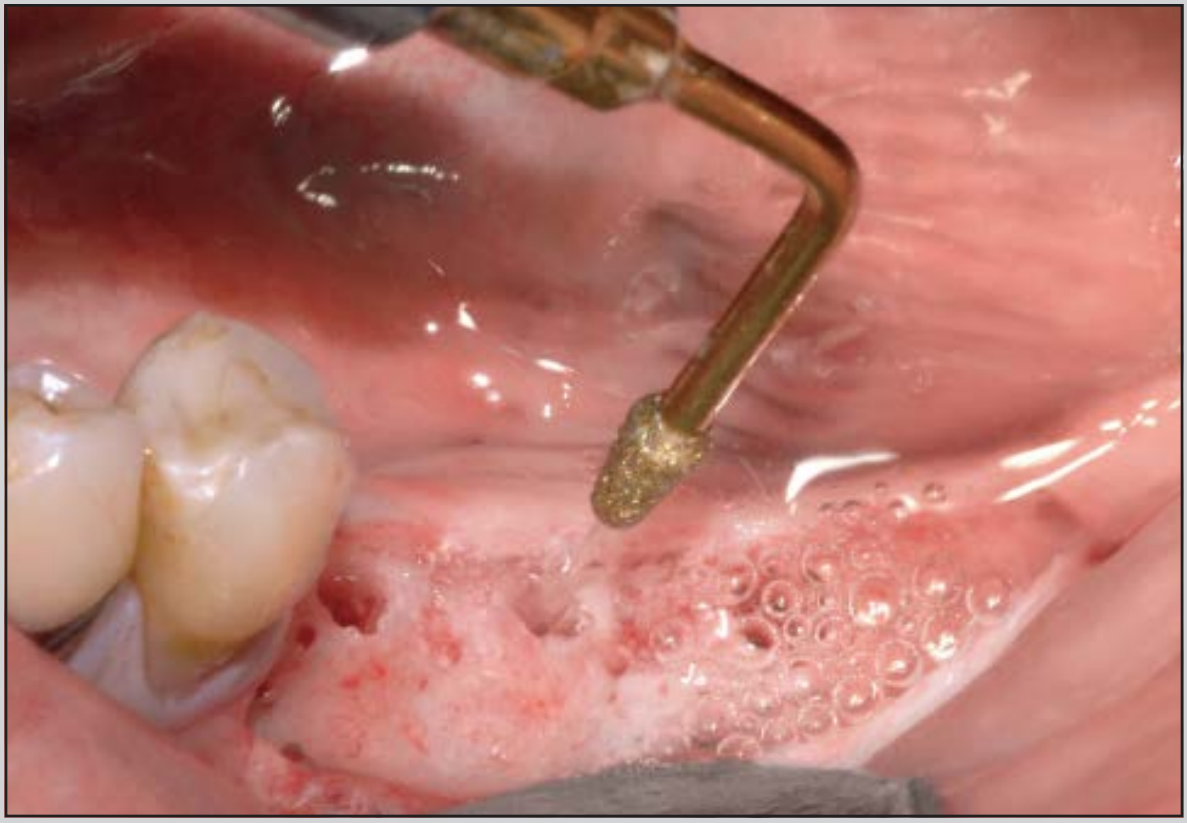

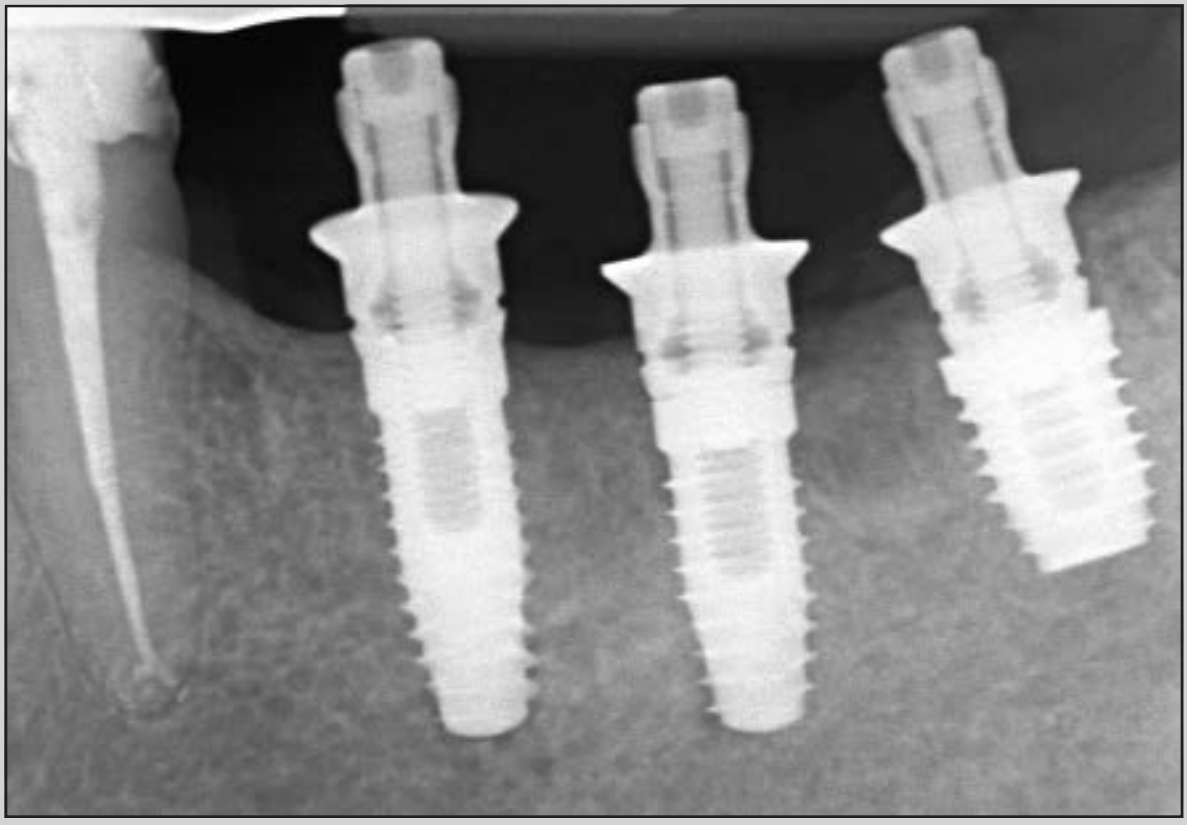

Ultrasonic Implant Site Preparation Using Piezosurgery: A Multicenter Case Series Study Analyzing 3,579 Implants with a 1- to 3-Year Follow-Up

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This multicenter case series introduces an innovative ultrasonic implant site preparation (UISP) technique as an alternative to the use of traditional rotary instruments. A total of 3,579 implants were inserted in 1,885 subjects, and the sites were prepared using a specific ultrasonic device with a 1- to 3-year follow-up. No surgical complications related to the UISP protocol were reported for any of the implant sites. Seventy-eight implants (59 maxillary, 19 mandibular) failed within 5 months of insertion, for an overall osseointegration percentage of 97.82% (97.14% maxilla, 98.75% mandible). Three maxillary implants failed after 3 years of loading, with an overall implant survival rate of 97.74% (96.99% maxilla, 98.75% mandible).
(Int J Periodontics Restorative Dent 2014;34:11–18. doi: 10.11607/prd.1860)

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Surgical preparation of the implant site and implant characteristics are crucial points for success in implant therapy. To date, the research has mainly focused on the improvement of the macro- and microgeometry of the implant, with the aim of enhancing primary stability and promoting quicker secondary stability.[1–5] However, little attention has been dedicated to implant site preparation and its influence on clinical outcomes. The most widespread surgical protocol involves the use of handpiece and twist drills with a rotating speed in the range of 700 to 2,000 rpm.[1] The drilling action takes advantage of mechanical macrovibrations, which, although providing a very effective result, are limited in regard to intraoperatory control. This, in the presence of reduced bone volume, can be an additional surgical difficulty.[6,7]

Despite the fact that minimally traumatic preparation of the implant site is recognized to have an important influence on osseointegration, very few studies have analyzed the relationship between site preparation technique and bone healing response. Indeed,

variables related to twist drills, such as heat generation,[8] irrigation,[9] and osteotomes,[10] have been analyzed but apply only to low-density bone. To the best of the authors' knowledge, there are no publications describing new site preparation protocols able to overcome the limits of traditional drilling techniques.

The last decade has witnessed the introduction of piezoelectric bone surgery,[6] opening new perspectives for osteotomies with ultrasonic surgical systems. The micrometric cut of ultrasounds provides a precise, controllable action[11] and has been adopted in a variety of fields, eg, oral[12–14] and maxillofacial surgery,[15,16] otorhinolaryngology,[17] orthopaedics,[18] and neurosurgery.[19] Moreover, piezoelectric devices for osseous surgery work selectively on hard tissues,[20] and both histologic and biomolecular observations suggest that there appears to be a more favorable bone healing response after ultrasonic osteotomy than after bone surgery performed with traditional rotary instruments.[21,22]

Therefore, to take advantage of the possible benefits this new approach offers to osseous surgery, specific piezoelectric inserts were designed for implant site preparation. The aim of this multicenter case series study is to introduce an innovative ultrasonic implant site preparation (UISP) technique and to evaluate outcomes, such as implant survival, in daily clinical practice.

Method and materials

Study design

The study was designed in such a way so as to reflect daily clinical reality, with very broad inclusion criteria: partially or totally edentulous patients necessitating a fixed implant-supported rehabilitation who were 18 years or older, with the ability to understand and sign a written informed consent form, who had any quantity or quality of bone in any location, and who were smokers. Clinicians were allowed to insert implants in adequate bone volume or to associate implant placement with any regenerative option such as sinus elevation, ridge expansion, bone grafting, or guided bone regeneration (GBR). Immediate postextractive, immediate-delayed, or delayed placement; immediate, early, or delayed loading; submerged or nonsubmerged placement; and implant brand were left to the operators' discretion. Bone volume was assessed with preoperative radiographs, orthopantomography, computed tomography (CT), cone beam CT (CBCT) scans, and clinical examination.

Exclusion criteria included general contraindications for implant surgery; subjects who were immunocompromised or had immunosuppression; previous irradiation treatment in the head and/or neck area; uncontrolled diabetes; poor oral hygiene and motivation; untreated periodontal disease; illegal drug or alcohol abuse; psychiatric problems or unrealistic expectations; those who could not commit themselves to a follow-up of at least 1 year; and any subjects previously treated with or currently taking intravenous aminobisphosphonates.

The principles outlined in the Declaration of Helsinki (2000) on clinical research involving human subjects were adhered to. All patients were given a thorough explanation as to the aim of the study, including procedures, follow-up evaluations, and any potential risks, and were asked to sign a written informed consent form. All patients were recruited and treated by 12 clinicians with various levels of experience in traditional and ultrasonic implant therapy, and all follow-up visits were performed at the respective treating centers.

Surgical protocol

UISP

The patients were given prophylactic antibiotic therapy: 2 g of amoxicillin (or clindamycin 600 mg if allergic to penicillin) 1 hour prior to surgery and rinsing for 1 minute with 0.2%. chlorhexidine. After local anesthesia and flap elevation, UISP protocol was performed in all cases.

A Piezosurgery 3 device (Mectron) and UISP-dedicated inserts of increasing diameter (IM1, IM2, Pilot 2–3, IM3, Pilot 3–4, IM4) (Figs 1 and 2) were used with a power setting in IMPLANT mode. The manufacturer's standard implant site preparation procedures were used. Briefly, an IM1 insert was used to prepare cortical access and initial implant

Fig 1 *Piezosurgery device.*

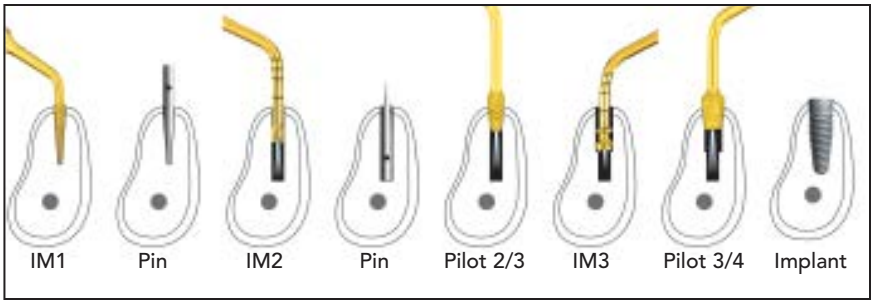


Fig 2 *Piezosurgery inserts for UISP.*

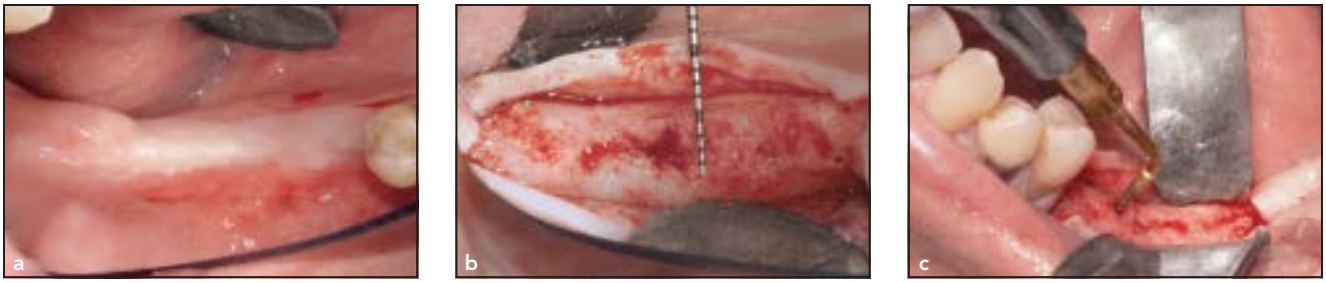


Fig 3 (a and b) *Clinical aspects.* (c) *IM1 insert, with the first surgical perforation to a maximum depth of 10 mm, determining the initial preparation axis.*

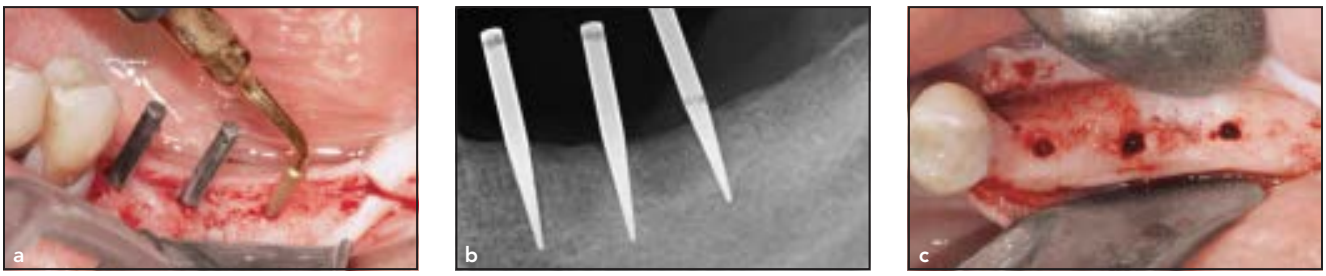
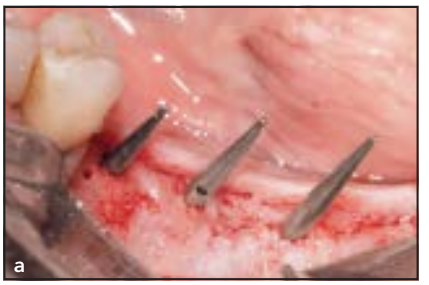


Fig 4 (a) *The parallel pins inserted from the cone-shaped portion to ensure the correct initial axis of preparation;* (b) *radiograph;* (c) *the cortical crestal view after the first bone surgical perforation using the IM1 insert.*

osteotomy, followed by an IM2 insert (2-mm diameter) to the programmed working length, and then Pilot 2–3 was used to prepare the cortical bone for the following insert. Lastly, an IM3 (3-mm diameter) was used for the entire depth. A cortical countersink with Pilot 3–4 was used for cortical bone, and an IM4 insert (4-mm diameter) for large-diameter implants. The preparation axis was controlled, step by step, with the use of dedicated directional pins, and corrections were made when deemed necessary (Figs 3 to 8).

Fig 5 *The second IM2 insert, cylinder-shaped with a 2-mm diameter. The internal cooling fluid distributed by the insert tip produces a cavitation effect inside the bone.*



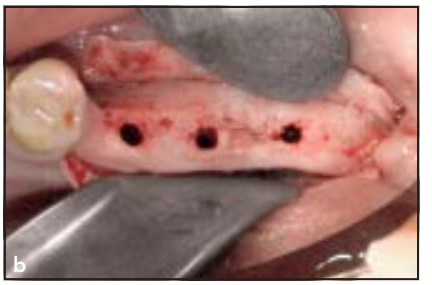


Fig 6 (a) *Parallel pins inserted from the cylinder-shaped portion to check the axis of the 2-mm-diameter perforation.* (b) *The cortical crestal view after the second bone surgical perforation using the IM2 insert.*

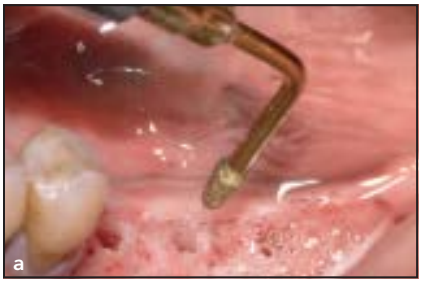
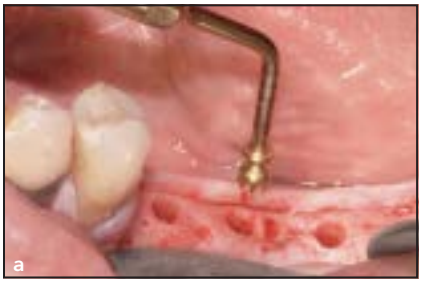
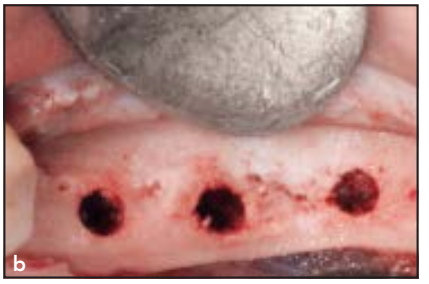


Fig 7 (a) *Pilot 2–3 truncated cone-shaped tip with diamond-coated surface* (b) *used to enlarge the implant site width in the cortical crest from 2 to 3 mm.*





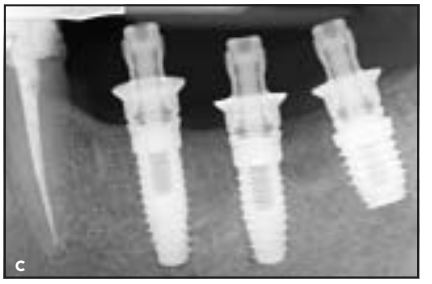


Fig 8 *IM3, cylinder-shaped with a 3-mm diameter.* (a and b) *The insert expands the diameter of the pilot osteotomy in spongy bone from 2 to 3 mm and completes the site preparation for implants with a diameter of approximately 4 mm;* (c) *radiograph.*

Once implant insertion had been completed, the clinicians dealt with any associated regenerative procedures and sutured flaps with synthetic monofilaments. The patients were prescribed nonsteroidal anti-inflammatory drugs for as long as required and instructed to use chlorhexidine 0.2% mouthwash for 1 minute twice daily for 2 weeks and to avoid brushing and trauma on the surgical sites. A 6-day postoperative antibiotic therapy was prescribed for patients who had bone augmentation procedures (amoxicillin 1 g twice daily or clindamycin 300 mg twice daily for patients allergic to penicillin). All patients were examined and sutures removed within 10 days.

All implants were loaded within 6 months postsurgery, and all materials, techniques, and timeframes for implant prosthetic rehabilitation were determined on an individual basis according to clinical requirements. The patients were enrolled in an oral hygiene program with recall visits planned every 3 to 6 months for the entire study period.

Outcome measurements

The outcome measurements were as follows. *(1)* Implant survival rate (primary outcome measure) taken as a whole, stratified per year (2007, 2008, 2009) and by implant

location (maxilla, mandible). Implant failure was defined as implant mobility and/or any infection dictating implant removal. The stability of each implant was measured manually by tightening the abutment screw or by assessing the stability of the crown using the handle of two instruments. *(2)* Any complications and/or adverse events were recorded and reported.

Statistical analysis

A statistical analysis was performed to determine the 1-year failure rate for all implants. Each risk estimate was calculated with a 95% confidence interval (CI).

Table 1 **Implant brands**

Astra Tech, Mölndal, Sweden
Exacta, Biaggini Medical Devices, Arcola, Italy
BioHorizons, Birmingham, Alabama, USA
Biomet 3i, Palm Beach Gardens, Florida, USA
Biotech, Salon de Provence, France
Camlog, Basel, Switzerland
Henry Schein Krugg, Buccinasco, Italy
Implant Direct, Calabasas, California, USA
Lifecore, Keystone Dental, Burlington, Massachusetts, USA
Nobel Biocare, Zurich, Switzerland
Shakleton, Brescia, Italy
Straumann, Basel, Switzerland
Sweden and Martina, Due Carrare, Italy
Endopore, Sybron, Orange, California, USA
Zimmer, Carlsbad, California, USA

Results

Between January 2007 and December 2009, 1,914 patients were consecutively enrolled and treated in 12 clinical centers. A total of 29 patients (1.5%) dropped out within 1 year of implant insertion. A 1- to 3-year follow-up was carried out on 1,885 patients (876 men and 1,009 women, age range: 19 to 77 years with a mean age of 58.2 ± 9.6 years). A total of 3,579 implants (2,060 in the maxilla and 1,519 in the mandible) were inserted following the UISP protocol. Fifteen different cylindric or tapered implant brands, 7 to 18 mm in length and 3 to 5 mm in diameter, with moderately rough surfaces were used (Table 1). No surgical complications related to the UISP protocol were reported for any of the implant sites. Seventy-eight implants (59 in the maxilla and 19 in the mandible) failed within 5 months of implant insertion; there was an overall percentage of osseointegration of 97.74%. According to year of insertion, the osseointegration rate was 98% in 2007, 97.4% in 2008, and 97.8% in 2009.

Table 2 **Implant failures per year and location**

	Implants (n)	Failure 1 y (n)	%	95% CI
Overall	3,579	81	2.26	(1.82–2.80)
Year				
2007	924	18	1.95	(1.24–3.06)
2008	1,237	32	2.59	(1.84–3.63)
2009	1,418	31	2.19	(1.54–3.09)
Dental arch				
Maxilla	2,060	62	3.01	(2.35–3.84)
Mandible	1,519	19	1.25	(0.80–1.95)

CI = confidence interval.

Three maxillary implants failed after 3 years of loading; there was a 97.82% overall implant survival rate (96.99% in the maxilla, 98.75% in the mandible) at the 1- to 3-year follow-up, with a 2.40-fold increase in the relative risk of failure (95% CI: 1.45 to 4.01) (Table 2). Although the failure risk trend remained

constant for the implants over the 3-year period, the failure rate for maxillary implants was higher than for mandibular implants.

Discussion

The postimplant healing process involves an acute inflammatory response in the peri-implant bone, leading to the generation of vascularized granulation tissue and the proliferation of pluripotent mesenchymal cells that have the capacity to differentiate into osteoprogenitors. There is a direct relationship between the intensity of the inflammatory process and surgical trauma, which, in turn, influences bone resorption around the implants: any excessive inflammation may lead to a significant loss of primary stability in the early healing phases.[23]

The introduction of piezoelectric bone surgery has led to a reduction in the trauma that accompanies twist drills when performing osteotomies. The cutting action of piezoelectric microvibrations takes advantage of ultrasonic shock waves that strike the bone with low force and high frequency.[7] Therefore, the bone fragments are both micronized and simultaneously removed by the cavitation effect of the saline solution, minimizing damage to the cortical and trabecular bone, while, at the same time, favoring enhanced cleansing, cooling, and disinfection of the site.[24] The cleansing action effectively removes bone debris and tissue remnants from the osteotomy, exposing marrow spaces and favoring a rapid migration of osteoprogenitor cells into the fresh wound. In vitro studies have shown that an ultrasonic bone cut is associated with the preservation of the original bone microarchitecture,[11] a factor that plays an important role in enhancing new bone formation.[25,26]

Furthermore, a recent biomolecular study[27] found lower cellular levels of Hsp70 (an oxidative stress marker) after ultrasonic surgery than after traditional bone surgery with rotary instruments.

In vivo findings seem to reflect the results of basic research: a preclinical canine study[21] that compared diamond burs, carbide burs, and piezoelectric inserts in periodontal osseous surgery demonstrated that the ultrasonic bone cut provided more favorable osseous repair and remodeling. Preti et al[22] compared UISP to traditional implant site preparation in an animal model, demonstrating a higher concentration of inflammatory cells in samples taken from the drilled sites. It was demonstrated that there was an earlier increase in bone morphogenetic-4 and transforming growth factor-β2 proteins and a reduction in pro-inflammatory cytokines in the implant bone site prepared by the ultrasonic technique.

A human radiologic study compared piezoelectric surgery to rotary protocols in implant site preparation using bone densitometry.[28] It was observed that there was a better promotion of bone density and osteogenesis around the implant sites prepared with UISP than in those prepared with rotary protocols. A recent randomized clinical controlled trial showed that ultrasonic implant site preparation leads to a limited decrease in implant stability quotient in the early phases of healing and in a faster shifting from a decreasing to an increasing stability pattern when compared with the traditional drilling technique.[29]

The goal of this multicenter case series was to evaluate the outcome of the UISP protocol in daily practice by using this surgical technique in a large number of patients and in a broad range of clinical situations. A total of 3,579 implants were inserted with the ultrasonic technique by 12 operators of different surgical experience over a 3-year period. No surgical complications related to the UISP protocol were reported for any of the implant sites. The overall osseointegration rate and implant survival rate (SR) up to 3 years (97.74%) were comparable with data reported in recent reviews analyzing the clinical outcomes of implants inserted with rotary instruments in native bone (SR, 94% to 98%),[4,30] in locally compromised sites treated with regenerative procedures (immediate implants into fresh extraction sockets [SR, 98% to 99%]),[31,32] in augmented maxillary sinuses (SR, 96% to 97%),[33,34] or in combination with GBR procedures (SR, 90% to 100%).[35,36]

These findings support the hypothesis that ultrasonic implant site preparation might be a viable alternative to the traditional drilling technique, with similar results

in terms of osseointegration and implant survival. However, properly designed case/control studies and randomized clinical trials are necessary to confirm and generalize these preliminary results, and further analyses are necessary to enhance understanding of the clinical impact of ultrasonic implant site preparation and to focus on outcomes in specific clinical applications.

Conclusions

The results of this multicenter case series study on a large number of patients show that ultrasonic implant site preparation could be a reliable alternative to traditional drilling protocols.

Acknowledgment

The authors reported no conflicts of interest related to this study.

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