Changes in Implant Stability Using Different Site Preparation Techniques: Twist Drills versus Piezosurgery. A Single-Blinded, Randomized, Controlled Clinical Trial

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ABSTRACT

Purpose: The objective of the present investigation was to longitudinally monitor stability changes of implants inserted using traditional rotary instruments or piezoelectric inserts, and to follow their variations during the first 90 days of healing.

Materials and Methods: A randomized, controlled trial was conducted on 20 patients. Each patient received two identical, adjacent implants in the upper premolar area: the test site was prepared with piezosurgery, and the control site was prepared using twist drills. Resonance frequency analysis measurements were taken by a blinded operator on the day of surgery and after 7, 14, 21, 28, 42, 56, and 90 days.

Results: At 90 days, 39 out of 40 implants were osseointegrated (one failure in the control group). Both groups showed an initial decrease in mean implant stability quotient (ISQ) values: a shift in implant stability to increasing ISQ values occurred after 14 days in the test group and after 21 days in the control group. The lowest mean ISQ value was recorded at 14 days for test implants (97.3% of the primary stability) and at 21 days for the control implants (90.8% of the primary stability). ISQ variations with respect to primary stability differed significantly between the two groups during the entire period of observation: from day 14 to day 42, in particular, the differences were extremely significant ($p < .0001$). All 39 implants were in function successfully at the visit scheduled 1 year after insertion.

Conclusions: The findings from this study suggest that ultrasonic implant site preparation results in a limited decrease of ISQ values and in an earlier shifting from a decreasing to an increasing stability pattern, when compared with the traditional drilling technique. From a clinical point of view, implants inserted with the piezoelectric technique demonstrated a short-term clinical success similar to those inserted using twist drills.

KEY WORDS: clinical trial, implant site preparation, implant stability, piezosurgery, resonance frequency analysis

INTRODUCTION

Osseointegration is a biologic response leading to a direct structural connection between living bone and the surface of an implant under functional loading. Implant stability is one of the fundamental prerequisites for achieving successful osseointegration and must be maintained for the entire healing period in order to avoid micro-movements, which could lead to fibrous tissue formation around the fixture. Specifically, literature suggests that there is a critical threshold of micromotion above which fibrous encapsulation prevails over osseointegration (50–150 μm).[1–3]

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Implant stability, over time, can be considered a variable combination of primary and secondary stability. Primary implant stability is a mechanical phenomenon influenced by factors related to implant (design and dimensions of the fixture), patient (quality and quantity of bone), and operator (surgical technique): it is highest just after implant placement, because of mechanical compression of the fixture on bone walls, and it decreases with time. Secondary stability is the progressive increase in stability related to biologic events at the bone-implant interface such as new bone formation and remodeling[4]: it is absent at the time of implant placement and increases with time.

Different clinical methods for monitoring implant stability at various stages have been proposed, such as Periotest® (Siemens AG, Bensheim, Germany), Dental Fine Tester® (Kyocera, Kyoto, Japan), and Osstell Mentor® (Osstell AB, Göteborg, Sweden). However, Periotest and Dental Fine Tester have been the subject of criticism as a result of their poor sensitivity and because their measurements are significantly influenced by variables such as the vertical measuring point on the implant abutment, the handpiece angulations, and the horizontal distance of the handpiece from the implant.[5–7]

Osstell Mentor determines implant stability using magnetic frequencies between a transducer screwed to the implant (a magnetic peg) and a resonance frequency analyzer.[8,9] The magnet on the top of the peg is excited by a magnetic pulse, and the wave feedback is interpreted as a numerical value (0–100), which is linearly related to the degree of micro-motion of the implant. By means of resonance frequency analysis (RFA), implant stability can be quantitatively assessed and followed over time as a function of the implant's stiffness in bone. The main factors influencing RFA measurements are bone structure (the most important is cortical thickness) and, to a lesser degree, implant length.[10–12] Implant stability quotient (ISQ) values seem not to be affected by instrument positioning: especially if two-directional readings are performed, results are reliable and sensitive.[13]

The arising of secondary stability is strongly influenced by fixture characteristics and surgical technique. In the last 20 years, many experimental investigations have demonstrated that the bone healing process was modulated by implant surface topography[14,15]: in particular, moderately rough surfaces promote a faster and more efficient osseointegration than smooth surfaces.[16,17] In addition, recent data support the role of bioactive surfaces, suggesting that critical steps in osseointegration can be enhanced by nanoscale modifications obtained by chemical and physical treatments of the implant surface.[18–24]

Although a wide and comprehensive mass of studies focuses on the effectiveness of diverse fixture characteristics, very few works analyze relations between site preparation technique and bone healing response, despite the fact that atraumatic preparation of the recipient bed has been always considered an important factor in influencing osseointegration. These studies consider factors related to twist drills (heat generation,[25,26] type of irrigation,[27] effects of wear[28,29]) and osteotomes,[30–32] whose application is, however, limited to medium-low density bone.

The introduction of piezoelectric bone surgery[33,34] paved the way to new possibilities in performing osteotomies utilizing an ultrasonic surgical system. Currently, the effect of ultrasounds is being widely investigated in various fields of medicine: in orthopedics, they are used to accelerate healing of bone fractures and ligament damage by promoting cell proliferation and bone matrix synthesis.[35–37] Other experimental studies have postulated an ultrasound influence in promoting angiogenesis[38] and in stimulating odontoblasts to produce reparative dentin, simultaneously activating dental pulp stem cells to differentiate into odontoblasts.[39] Multidisciplinary clinical reports on the application of ultrasounds in bone surgery obtained promising results in terms of precision and safety.[40–49] Moreover, two recent animal pilot studies concluded that piezosurgery appears to be more effective than drills in favoring bone healing in periodontal and implant surgery: an ultrasonic cut induces an earlier increase in BMP-4 and TGF-β2 levels, controls the inflammatory process, and stimulates faster bone remodeling.[50,51]

The objective of the present investigation was to longitudinally monitor stability changes of implants placed in sites prepared with twist drills and piezoelectric inserts, and to follow variations during the first 90 days after insertion. The null hypothesis of this study is that there are no differences in implant stability during the early phases of healing between implants inserted using rotating instruments and implants inserted with the piezoelectric technique.

MATERIALS AND METHODS

Study Population

This randomized, controlled pilot trial included 20 adult patients needing two adjacent implants in the maxillary premolar area. It was required that edentulous areas had at least 6 months of healing, without any grafting procedure performed at the time of, or after, teeth extraction. Patients were requested not to wear any kind of removable prosthesis. General exclusion criteria were the following: acute myocardial infarction within the past 6 months; uncontrolled coagulation disorders; uncontrolled metabolic diseases (i.e., diabetes mellitus and bone pathologies); radiotherapy to the head/neck district within the past 24 months; present or past treatment with intravenous bisphosphonates; psychological or psychiatric problems; heavy smoking (>10 cigarettes/day); and alcohol or drug abuse. Local exclusion criteria were the following: the presence of uncontrolled or untreated periodontal disease; insufficient bone volume to insert implants without augmentation procedures (a crest of at least 10 mm in height and 6 mm in width was required); and insufficient mesio-distal crestal space to properly insert two adjacent implants of 4 mm in diameter (a minimum edentulous crestal space of 14 mm was required).

The study protocol was approved by the Ethics Committee of the University of Trieste, and all subjects signed a written consent form.

At the initial visit, all subjects underwent a clinical and occlusal examination, and panoramic radiographs were evaluated. Then, a prosthetic assessment with diagnostic waxing was carried out, and a computed tomography scan with a template was performed in order to study the programmed implant sites. The sites were randomly assigned to the test or control group by a computer-generated table, which was prepared using a balanced, randomly permuted block approach.

Treatment

All of the implants were inserted by a single operator, familiar with both traditional and piezoelectric surgical techniques. Patients were premedicated with two tablets of amoxicillin/clavulanate potassium (875 + 125 mg) (Augmentin, GlaxoSmithKline, Brentford, UK) 1 hour prior to the surgery. Under local anesthesia (articaine HCl 40 mg/mL with epinephrine 1:100,000 – Alfacaina, Weimer Pharma, Rastatt, Germany), a full thickness mucoperiostal flap was elevated, and the underlying alveolar bone was exposed for osteotomy. After flap reflection, the randomization envelope was opened, and the assigned treatment was revealed to the surgeon. Two adjacent implant sites were prepared in each patient during the same surgery: the control site (group A) was performed with drills (Biomet 3i, Palm Beach Gardens, FL, USA); the test site (group B) was performed with specific piezoelectric inserts (Piezosurgery, Mectron, Carasco, Italy) (Figure 1). Manufacturer recommendations were followed for sequence of drills and piezoelectric inserts in preparing implant sites. Each drill and piezoelectric insert was used to prepare no more than six implant sites (in three following patients). The last instrument used was 3 mm in diameter, in both groups, and no bone tapping was performed in any site. Immediately after the insertion of the implants (Biomet 3i, NanoTite Parallel Walled Certain 4.0 × 10 mm), a blinded operator recorded in triplicate ISQ values from mesio-distal, disto-mesial, bucco-lingual, and

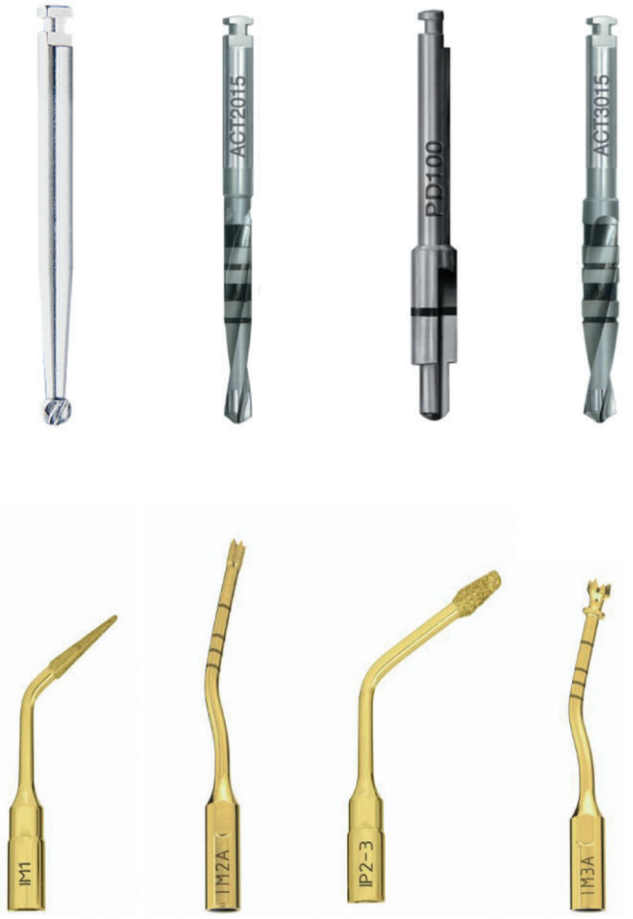

Figure 1 Type and sequence of rotating and piezoelectric instruments used for implant site preparations in this study.

linguo-buccal directions. Disposable transducers (SmartPeg, Osstell AB) and an Osstell Mentor instrument were used. Instrument calibration was verified before and after each patient visit, using an implant fixed in an epoxy resin block.

As an additional record, surgical time from the first perforation of the cortical bone to the moment in which the implant reached the final position was registered for each implant inserted with both techniques.

The flaps were then sutured with polyamide pseudo-monofilament (Supramyd 5/0, Butterfly Italia, Cavenago Brianza, Italy); the implants were left unsubmerged and connected with healing abutments of appropriate length (10 N/cm torque). Patients were prescribed with ibuprofen 600 mg tablets (Brufen, Abbott Laboratories, Abbott Park, Chicago, IL, USA), when needed, and chlorhexidine 0.2% 1-minute rinses, twice a day (Corsodyl, SmithKline Beecham, Brentford, UK).

Sutures were removed 7 days after surgery. A blinded operator collected ISQ measurements following the previously described protocol after 7, 14, 21, 28, 42, 56, and 90 days. In addition, each implant was evaluated at all visits for mobility, pain, and signs of infection.

After 5 months, all implants were restored with custom abutments and luted metal-ceramic crowns. All patients were followed for at least 1 year after implant insertion.

Statistical Analysis

Stability of each implant was described at each time interval with a single ISQ value (mean of 12 measurements), and the Kolmogorov-Smirnov test was applied to assess data normality. The outcomes were longitudinally analyzed, within the same group, using the analysis of variance (ANOVA) test for repeated measures, while the comparison between the two groups was performed using the *t*-test for unpaired samples (R Software version 2.6.2, R Foundation for Statistical Computing, Wien, Austria). The level of significance was set at $\alpha = 0.05$.

RESULTS

Twenty patients (12 males, 8 females – age range from 41 to 81 years – mean 59.7 ± 13.6) received 40 identical implants in the maxillary premolar area. No dropouts occurred during the entire period of observation. Ninety days after the insertion, 39 out of 40 implants were osseointegrated (one failure in group A after 21 days).

TABLE 1 Mean ISQ Values at Different Time Points

	Mean ISQ Value	
Time Point	Drills	Piezoelectric
Baseline	72.2 ± 5.8	70.5 ± 5.8
7 days	68.5 ± 7.1	69.3 ± 6.2
14 days	66.7 ± 7.4	68.6 ± 6.5
21 days	65.6 ± 7.2	68.8 ± 5.8
28 days	66.1 ± 6.7	69.4 ± 5.2
42 days	66.4 ± 7.2	69.6 ± 4.5
56 days	67.3 ± 6.2	70.1 ± 3.6
90 days	69.2 ± 5.5	71.0 ± 2.9
Significance	$p < .0001$	$p = .1142$

Repeated measures analysis of variance performed within each group showed that ISQ variations among the drills column were significantly greater than expected by chance ($p < .0001$), while ISQ variations among the piezoelectric column were not ($p = .1142$).
ISQ = implant stability quotient.

Except for the failed implant, no other evidence of adverse local or systemic side effects was observed in any site throughout this study.

ISQ measurements, collected in triplicate, showed a high degree of repeatability (less than 2% variation for single-implant measurements). Differences in the mean ISQ at the time of placement between group A (mean ISQ 72.2 ± 5.8) and group B (mean ISQ 70.5 ± 5.8) were not statistically significant ($p = .3215$). Maximum and minimum ISQ values recorded at the baseline in groups A and B were 84–58 and 83–56, respectively. Mean ISQ values at different times with relative statistical significance are reported in Table 1 and visualized in Figures 2–4.

A repeated measures ANOVA performed within each group showed that ISQ variations in the drills group were significantly greater than expected by chance during the entire period of observation ($p < .0001$), while ISQ variations among implants inserted with the piezoelectric technique were not statistically significant ($p = .1142$).

Both groups showed a decrease in ISQ values during the first period after implant insertion. The lowest peak was recorded at 21 days for group A implants (mean ISQ 65.6 ± 7.2 – 90.8% of primary stability) and at 14 days for group B implants (mean ISQ 68.6 ± 6.5 – 97.3% of primary stability). After the third week, values increased constantly in both groups: group B implants, at the 90-day mark, surpassed their baseline ISQ values. ISQ

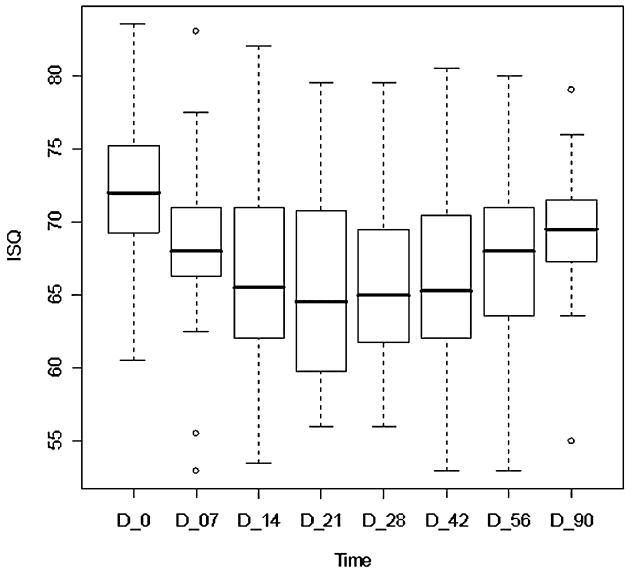

Figure 2 Implant stability quotient (ISQ) levels in the drills group at different time points. Significant differences were observed when performing a repeated measures analysis of variance ($p < .0001$).

range recorded 90 days after implant insertion varied from 79 to 55 in group A, and from 80 to 64 in group B.

Stability loss analysis (mean ISQ percentage of decrease compared with primary stability) resulted in a statistically significant difference between the two groups during the entire period of observation: from day 14 to day 42, in particular, the difference was extremely significant ($p < .0001$). Table 2 reports ISQ percentage variations for both groups at different time points with relative statistical significance. Figure 5 depicts a visual description of stability pattern trends.

Mean surgical time registered from the first perforation of the cortical bone to the moment in which the implant reached the final position was 6.00 minutes (95% confidence interval [CI] 5.45, 6.55) for the drills procedure and 7.15 minutes (95% CI 6.74, 7.56) for piezoelectric surgery. The difference between the groups was statistically significant ($p < .01$).

All 39 implants were in function successfully at the visit scheduled 1 year after insertion.

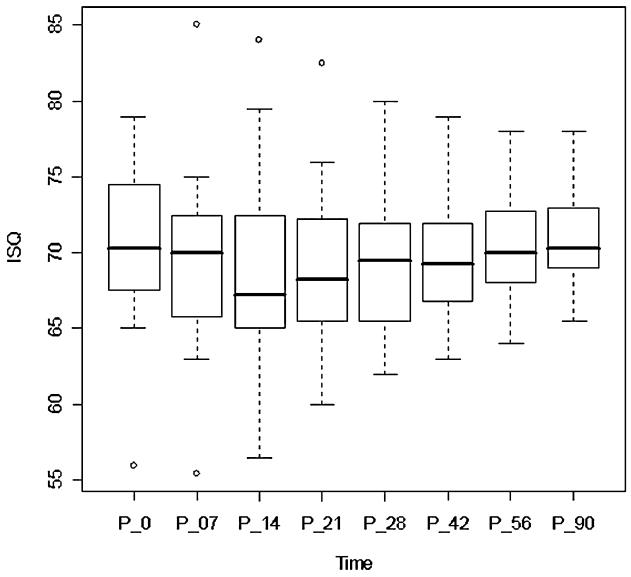

Figure 3 Implant stability quotient (ISQ) levels in the piezoelectric group at different time points. No significant differences were observed when performing a repeated measures analysis of variance ($p = .1142$).

DISCUSSION

The aim of this study was to longitudinally evaluate changes in stability of implants inserted in sites prepared with rotary and ultrasonic surgical techniques.

In this work, we tried to minimize all of the factors influencing implant primary stability[11,12] in order to focus our attention on the impact of surgical technique over the healing process. We used implants identical in diameter, length, macrotopography, and microtopography (a bioactive surface, which is very efficient in promoting fast bone formation[19,20]). Surgical site choice (upper premolar area) and operating technique (single operator and the same final diameter of the osteotomies in both groups) were standardized as much as possible in order to minimize subjective final outcomes.

RFA was chosen as a noninvasive and reliable method to assess variations in implant stability over time.[9,52] RFA registrations are directly related to the stiffness of the implant in the surrounding bone: during healing, an increase in ISQ values presumably reflects new bone apposition at the implant-bone interface.

Mean ISQ values of both groups registered in this study, at the time of implant placement and after 90 days, are in line with other clinical studies conducted with parallel-walled implants of different brands.[11,12,53–55]

Stability of both groups, starting at the baseline from comparable ISQ values ($p > .05$), decreased during the first period of healing. Many studies demonstrate that bone modeling and remodeling adjacent to the implant surface lead to a decrease in ISQ values within the first 3 weeks.[11,12,56–59] These findings suggest the existence of a time interval between primary and secondary stability during which the mobility of the implant may

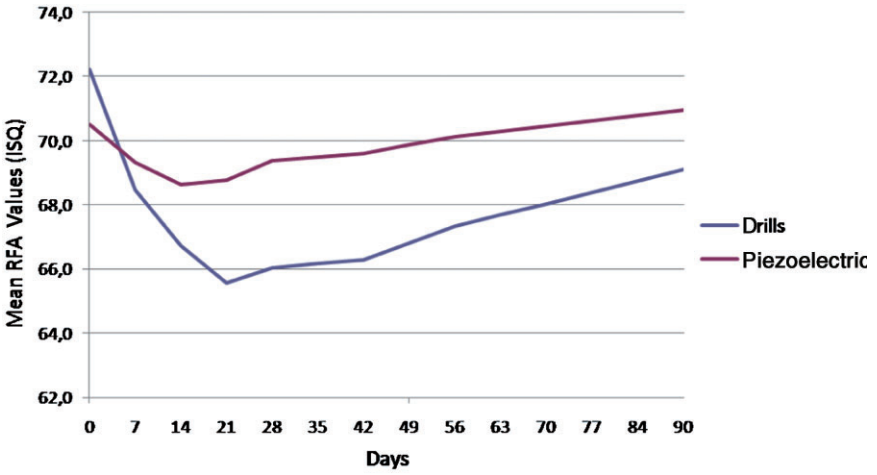

Figure 4 Changes in mean implant stability quotient (ISQ) values of both groups during the first 90 days after implant insertion. The lowest peak was registered at 14 days for the piezoelectric group and at 21 days for the drills group. (RFA = resonance frequency analysis.)

TABLE 2 Loss of Implant Stability during Early Phases of Healing

	Loss of Stability (%)		Significance
Days	Drills	Piezoelectric	*p* Value
7	−5.2	−1.7	.0296
14	−7.6	−2.7	.0006
21	−9.2	−2.5	<.0001
28	−8.5	−1.6	<.0001
42	−8.2	−1.3	<.0001
56	−6.7	−0.5	.0020
90	−4.3	+0.6	.0179

Stability loss analysis (mean implant stability quotient percentage of decrease compared with primary stability) resulted in a statistically significant difference between the two groups during the entire period of observation: from day 14 to day 42, in particular, the difference was extremely significant ($p < .0001$).

increase. Berglundh and colleagues,[60] in studying the sequence of wound healing events surrounding dental implants, demonstrated that in areas of primary mechanical stability at the pitch of the implant threads, osseointegration occurred after bone-resorptive processes, which can jeopardize mechanical stability for a short period of time. The transition point from decreasing to increasing implant stability suggests a change in bone metabolism from mainly resorptive to mainly appositional.

In the present study, control group implants had their lowest ISQ peak at 21 days (9.2% decrease from primary stability), according to the observations of a number of other clinical studies conducted with traditional site preparation.[11,12,56–60] In the test group, ISQ values began to increase after 14 days: a 2.7% ISQ

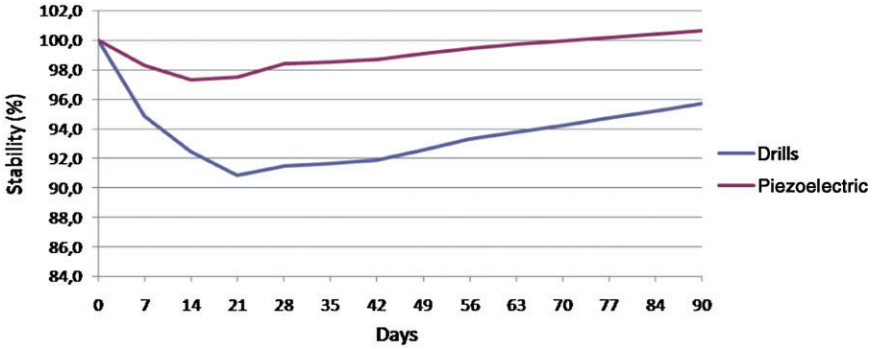

Figure 5 Implant stability quotient percentage of decrease in both groups during the first 90 days after implant insertion. The maximum loss of stability was recorded at day 14 for the piezoelectric group (−2.7% compared with primary stability) and at day 21 for the drills group (−9.2% compared with primary stability).

decrease from primary stability was the lowest dip for implants inserted with piezosurgery.

Moreover, the longitudinal changes of the ISQ values during the entire period of observation did not differ significantly in the test group ($p = .1142$); on the contrary, variances are statistically significant in the control group ($p < .0001$). Analyzing these data, we must reject the null hypothesis of this study: in other words, differences in implant stability between the two groups are statistically significant for the entire period of observation. In particular, the limited initial decrease and the early increase of ISQ values in piezoelectric sites suggest a lower surgical trauma to the bone, with a shorter inflammatory phase and little resorption, when compared with sites prepared with drills.

These findings are in line with a recent human comparative study,[61] which showed, using bone densitometry, that piezoelectric implant site preparation results in healing with a higher bone density and enhanced osteogenesis around dental implants with respect to traditional rotary instruments.[61]

The classical bone repair cascade comprised of an acute inflammatory response and cell chemotaxis, leading to the generation of a vascularized granulation tissue and the proliferation of pluripotent mesenchymal cells with a capacity to differentiate into osteoprogenitors. In the early phase of healing, macrophages and polymorphonucleated cells remove bone debris, which, after drilling procedures, is compacted on the osteotomy walls, leaving little or no access to marrow spaces.[62,63] A possible interpretation of our results could derive from the cleaning effect of piezosurgery[40,64]: micro-vibrations and the cavitation effect of saline solution could result in effectively removing bony debris and tissue remnants deriving from site preparation, exposing marrow spaces and favoring a rapid migration of osteoprogenitor cells into the fresh wound.

It is important to note that the findings of this pilot trial must be evaluated with caution because of some limitations of the present study. Variables such as the single operator's surgical technique, the limited numerosity of the sample, and the choice of the surgical site (limited to the lateral maxilla) must be taken into account when generalizing these results. Furthermore, it remains to be determined if a difference in stability of some ISQ points will be regarded as clinically relevant. Similarly, the drills procedure was significantly faster than piezosurgery but allows for a clinically nonrelevant reduction of total surgical time (about 1 minute).

In any event, the outcomes of this study should be considered as a trend: the repeatability of the results and their high statistical significance must encourage new and extensive investigations in order to clarify the potentials and limits of "ultra-osseointegration."

CONCLUSIONS

The findings from this pilot study suggest that ultrasonic implant site preparation seems to have the potential to modify biologic events during the osseointegration process, resulting in a limited decrease of ISQ values and in an earlier shifting from a decreasing to an increasing stability pattern, when compared with the traditional drilling technique. Further clinical trials and additional long-term studies are necessary to evaluate and completely understand the bone healing process after ultrasonic surgery, and the possible clinical advantages of this approach in immediate and early loading protocols for dental implant therapy.

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