Primary stability of dental implants installed using osseodensification or bone expansion drilling systems: a comparative clinical study

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Abstract

Aim: Primary stability of dental implants is a prerequisite for osseointegration, and the osteotomy technique is one of the factors that may alter it. The aim of this study was to compare the primary stability of dental implants installed using osseodensification and bone expansion drilling systems.

Materials and Methods: This split-mouth comparative clinical study included 12 patients. Each patient received one implant for each of the tested systems, totaling 24 implants. Implants were installed in edentulous areas with space for two adjacent implants or in two similar contralateral areas for the installation of a single implant. The areas had to present medullar bone interposed between vestibular and palatal/lingual cortical bone. The primary outcome was the insertion torque.

Results: The average torque obtained with bone expansion was 37±14 N.cm, whereas the final torque equaled 46±10 N.cm with osseodensification (p=0.02). The average torque was also higher with osseodensification than bone expansion in cases of type IV bone, in the maxilla and in cases of narrow implants. Osseodensification reached 35N.cm or more in 91.7% of cases compared to 50% after bone expansion (p=0.02).

Conclusion: Primary stability is affected by the osteotomy technique. Dental implants installed after osseodensification presented higher levels of insertion torque than after a bone expansion system.

Keywords: Osseodensification. Dental implants. Dental instruments. Primary stability.

Introduction

Primary stability of dental implants can be defined as the mechanical interlock between the implant and the surrounding bone, being a crucial factor to osseointegration success (Coelho and Jimbo, 2014). The interlock is based on physical interactions between the bone (bone quantity and quality) and the macrogeometric aspect of the implant (Albrektsson *et al*., 1981), which overtime progresses to bone apposition and final osseointegration (Gomes *et al*., 2013).

In the practice of implant dentistry, in several situations, clinicians face conditions of low bone density during the drilling process for the installation of implants. Frequently, this can be made previously predicted through computed tomography evaluation, and, as an alternative to obtain greater primary stability, the use of the last drill indicated by the surgical drilling system is avoided, performing a sub-drilling instead. With this procedure, the discrepancy between the diameter of the preparation and the diameter of the implant to be installed is increased,

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resulting in a possible increase in the final insertion torque. It has been shown that the effects of surgical instrumentation methods are directly related to osseointegration, and studies point out that it can be accelerated by adjustments in the sequence of the drilling protocol, the speed and the drill design (Galli *et al*., 2015; Giro *et al*., 2011; Giro *et al*., 2013; Abboud *et al*, 2015).

Recently, a new drilling concept has been developed through a technique called osseodensification (Huwais, 2014; Huwais, 2013; Huwais and Meyer, 2016). This technique is centered on drill design, which permits the creation of an environment that increases primary stability through the densification of the walls at the osteotomy site through non-subtractive drilling (Lahens *et al*., 2016). The rationale to use this technique is that bone densification will not only result in higher degrees of primary stability due to physical interlocking (higher degrees of contact) between bone and implant, but also due to the acceleration of bone neoformation as has been demonstrated by the presence of active osteoblasts in the instrumented bone (Jimbo, 2014b). Then, the osseodensification procedure is used in order to develop the possibility of increased mechanical interlocking associated with the presence of condensed autograft bone around the spires of the implant, supposedly accelerating the osseointegration process.

The use of osteotomes have been introduced to increase local bone density and primary implant stability. It is suggested that, besides expanding atrophic ridges, osteotomes could also be used to preserve bone resulting in superior stability than conventional drilling (Summers, 1994). Despite these statements, its use is associated with side effects and negative reports from patients, mainly in relation to the mechanical impact of the surgical hammer causing discomfort and concussions, as well as benign paroxysmal positional vertigo (Penãrrocha-Diago *et al*., 2008; Lee and Anitua, 2006). In order to minimize this events, rotating osteotomes were developed to compress bone laterally, increasing bone density and achieving higher degrees of stability when installing implants (Kreissel *et al*., 2013).

Although the concepts of osseodensification and drilled bone expansion has direct and indirect plausibility, there is a lack of clinical studies evaluating these drilling systems. In addition, several drill systems developed specifically for osseodensification have been launched on the market without clinical comparisons between them. Thus, this study aimed to compare the primary stability of dental implants installed using osseodensification (OD) and bone expansion (BE) drilling systems.

Method and Materials

This comparative non-randomized split-mouth clinical study was developed at a professional training school of Periodontics and Implantology (Implanteperio Institute, São Paulo, Brazil). This study was approved by the Research Ethics Committee of São Leopoldo Mandic University (protocol number 3.449.375). All participants signed an informed consent form.

Patients seeking rehabilitation with dental implants in edentulous areas of molars and premolars were considered eligible for the study. To be included in the study, individuals should have edentulous areas comprising space for the installation of two adjacent implants or two similar contralateral areas for the installation of one implant. All patients should have good health without systemic disorders that could alter osseointegration and had never smoked. They should also present with periodontal health determined by pocket depths <4mm and bleeding on probing <10%.

Moreover, tomographic images of edentulous areas of interest were obtained before the study. Eligible areas should present sufficient amount of bone for the installation of implants without the need for bone augmentation. These areas should present bone type III or IV (Lekholm & Zarb, 1986) as determined by the presence of medullar bone interposed between vestibular and palatal/lingual cortices in the tomographic image.

Surgical procedures

All surgeries were performed by the same operator. All patients underwent a prosthetic treatment planning and a preparation of surgical models before the conduction of the surgical procedures.

After taking an initial photograph, intraoral antisepsis with a mouthwash of chlorhexidine digluconate 0.12% during 1 minute was conducted. Block anesthesia was performed with 2% mepivacaine with epinephrine 1:100,000 (DFL, Rio de Janeiro, RJ, Brazil). A full-thickness mucoperiosteal flap was elevated in cases where adjacent implants would be installed in the same area, and two isolated flaps in cases of contralateral areas. After this, drilling was initiated following the orientation and the drill sequence of each group according to the manufacturers' instructions according to the diameter and length of the selected implants.

Conical implants (Unitite Implant, S.I.N. Implant System, São Paulo, Brazil) were installed using a manual torque meter up to its final position. Implants with same length and diameter were installed for each group. Single sutures (Resolon 5.0, Resorba, Nuremberg, Germany) were applied to close the operated areas.

Post-operative care for all patients included amoxicillin 875mg every 12 hours during 7 days, ibuprofen 600mg every 6 hours during 4 days, and 0.12% chlorhexidine digluconate every 12 hours during 7 days after surgery. After 7 days, patients were recalled to remove the sutures. Three months after the installation of the implant, reopening surgery and installation of healing abutments were performed, and patients were then sent to final prosthetic rehabilitation.

Treatment groups

Two commercial drilling systems for the installation of implants were compared. In the osseodensification (OD) group, a world marketed system was used (Densah Burs, Versah, Jackson, Michigan, USA). This OD system has 13 drills with the following references: Pilot, VT1525, VT1828, VS 2228, VT 2535, VT 2838, VS3238, VT 3545, VT 3848, VS 4248, VT4555, VT4858, VS5258. Depth marks are 3mm, 5mm, 8mm, 10mm, 11,5mm, 13mm, 15mm, 18mm and 20mm.

According to the description of the manufacturer, the OD system has a variety of clinical applications (densification in medium and soft bone, densification in hard bone, expansion, sinus augmentation procedure) and different utilization protocols alternating speed (between 800-1500rpm and 150-200rpm for maxillary sinus graft compaction), motor rotation direction, sequence of drills according to characteristics of bone quality and therapeutic objective.

In the other group, a drilling system of bone expansion (BE) was used (Bone Expander, Maximus, Contagem, Brazil). This BE system has 14 drills with the following references: LC 150, ALO 16.TI, ALO18. TI, ALO 20TI, ALO 24.TI, ALO 26.TI, ALO 28.TI, ALO 30.TI, ALO 34.TI, ALO 36.TI, ALO 38.TI , ALO 40.TI , ALO 44.TI , ALO 46.TI. The depth markings are 3 mm, 5 mm, 7 mm, 9 mm 11mm and 13 mm. The manufacturer of the BE system guides the use of the same sequence of drills for all clinical circumstances with only one protocol ("bone enlargement"), alternating speed between 400-1250rpm, always with the engine in clockwise orientation.

In addition to their different characteristics regarding the number of drills and depth marks, drills of the two systems have visually different designs. While the drills of OD have their faces with oblique grooves, drills of BE have their faces with straight grooves. Grooves of the BE system are shallow, while the grooves of OD system are deep.

Figures 1 and 2 illustrate two cases treated in this study with the two drilling systems. Figure 3 shows pictures illustrating one bur of each tested system.

Outcomes

The primary outcome of this study was the primary stability measured in N.cm immediately after the implant installation using a manual torque meter marked from 5 N.cm to 60 N.cm. The final insertion torque was measured when the implant reached its final apical position and it was rounded to the lowest 5 N.cm.

In addition, adverse events were assessed after 7 days of implant healing. Edema, soft tissue necrosis and hematoma were evaluated.

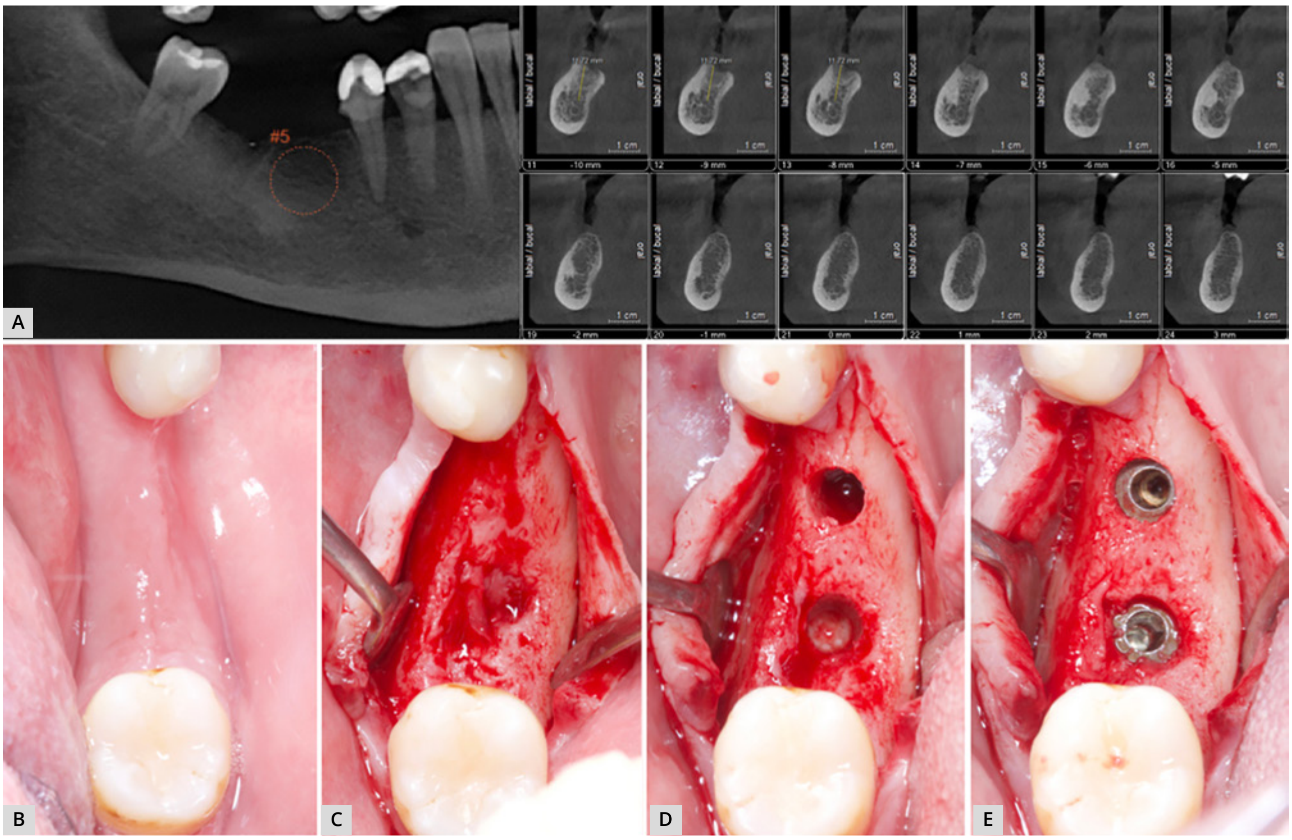

Figure 1. Clinical case depicting the systems in the mandible. (A) Tomography of the implanted areas. (B) Clinical photograph of the operated area. (C) Mucoperiostal flap of the operated area. (D) Prepared bone sites. (E) Implants inserted.

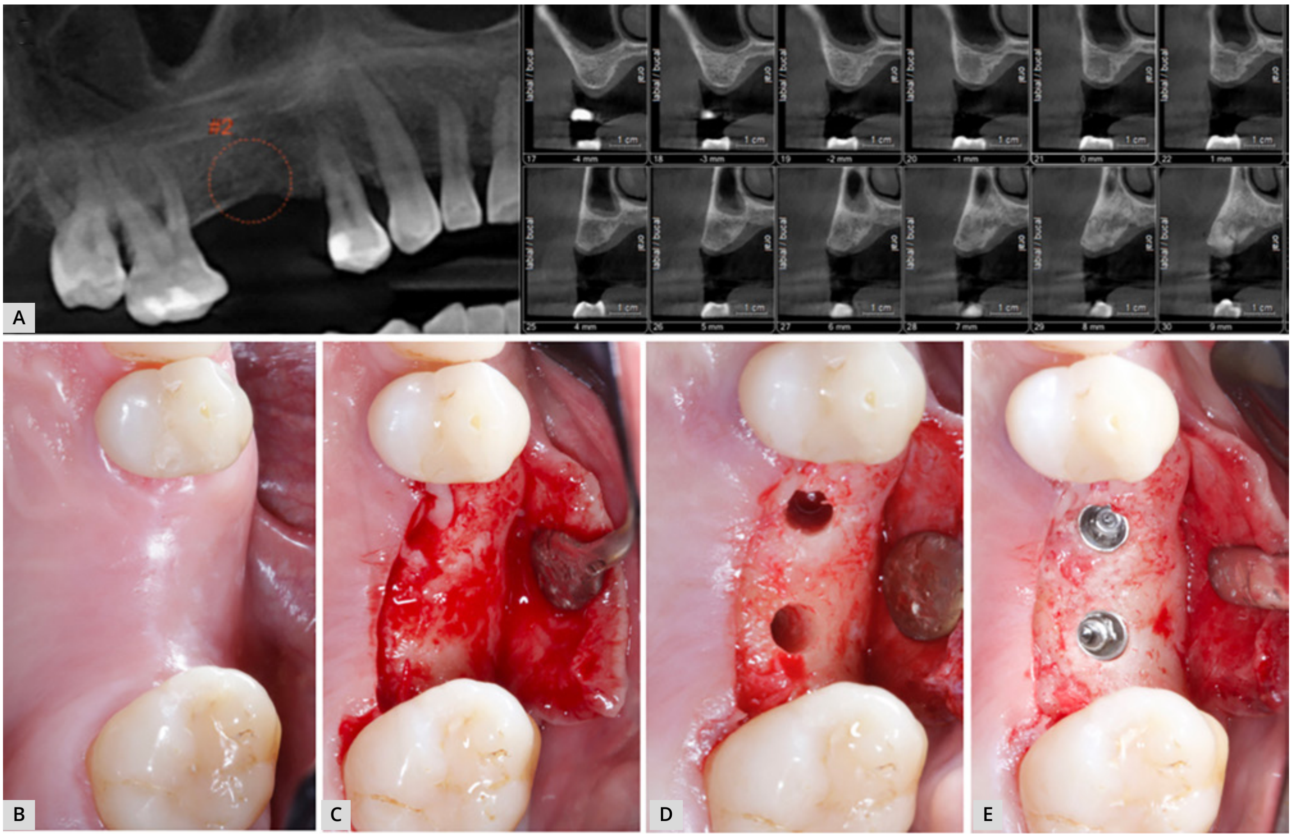

Figure 2. Clinical case depicting the systems in the maxilla. (A) Tomography of the implanted areas. (B) Clinical photograph of the operated area. (C) Mucoperiostal flap of the operated area. (D) Prepared bone sites. (E) Implants inserted.

Osseointegration success was evaluated 3 months after the implants' installation. The following success criteria were applied (Albrektsson *et al.*, 1986):

- Absence of implant mobility assessed during installation of healing abutments;
- Absence of radiolucency around the implants in a periapical radiograph;
- Absence of signs of infection such as suppuration and radiographic bone loss;
- Absence of pain, paresthesia and neuropathies reported by the patients.

Perceptions of the operator were registered during all the surgeries, which may include difficulties during drilling, bone characteristics after drilling, number of drills applied and bleeding.

Statistical analysis

Categorical variables were described with frequency distribution, while quantitative variables were presented using averages and standard deviation or 95% confidence interval. The comparison between the two groups in regard to torque was performed using the t test for dependent samples.

In addition, two dichotomous outcomes were used, considering cases that reached a maximum torque of 50 N.cm and ≥35 N.cm. The comparison between groups was made using the McNemar test. A secondary and descriptive analysis was made based on the difference in torque between the two groups, stratifying for torque predictor variables: bone type, arch and implant diameter. Statistical tests were not applied due to the exploratory character of the study and the small sample size in each stratum.

The significance level was established in 5%. The analytical unit was the individual. The software Stata (Stata 14, Stata Corp., College Station, Texas, USA) was employed for data analysis.

Results

In total, 12 patients were included in the study, and 24 implants were installed. No adverse events were observed during the initial healing period of 7 days in both groups. After 3 months of healing, all implants were osseointegrated without failures.

Table 1 shows the characteristics of the study sample. The average age of the participants was 45.7 years old, with half of them being men. Most of the implants were installed in the mandible and in type III bone. In approximately two thirds of the cases (66.7%), implants were installed side by side in a neighboring area. Most of the implants were of 4.3mm in diameter and 8.5mm in length.

Figure 3. Illustration of burs from osseodensification (silver) and bone expansion (gold) drilling systems.

Table 1. Characteristics of the sample.

Characteristic	Estimative
Age (years)	45.7±13.7
Sex	
Male	6 (50%)
Female	6 (50%)
Arch	
Maxilla	3 (25%)
Mandible	9 (75%)
Region of installation	
Contralateral	4 (33.3%)
Neighboring area	8 (66.7%)
Bone type	
III	9 (75%)
IV	3 (25%)
Implant diameter	
3.5	6 (50.0%)
4.3	6 (50.0%)
Implant length	
8.5mm	10 (83.3%)
10mm	2 (16.7%)

Figure 4 shows a comparison of the torque after using OD and BE systems. The final torque in the OD group was significantly higher than that reached in the BE group (p=0.02). The torque in the OD group was 46±10 N.cm compared to 37±13 N.cm in the BE group.

A total of 9 cases (75%) in OD group reached a maximum torque of 50N.cm (Figure 5). In the BE group, 5 (41.7%) cases reached this torque. The p-value for this comparison was equal to 0.22. When comparison was made regarding a final torque ≥35 N.cm, there was a significant difference between groups (p=0.02). The OD system reached 35 N.cm or more in 91.7% of the cases compared to 50% with the BE system.

The average torque was 9.6 N.cm higher in OD group than in BE group (Figure 6). This difference was numerically greater in cases of type IV bone, in the maxilla and in implants of narrower diameter.

Perceptions were registered using the two systems and were qualitatively analyzed. For the BE system, the following clinical findings were recorded:

- Necessity of applying excessive force during drilling.
- Larger sequence of drills for installing the implant.
- Difficulties while fitting and removing drills in the contra-angle after being used in more than one case, being necessary to apply force to the final fitting position.
- Constant chattering of the drills during bed preparation.
- During the sequence of use, drills presented bone fragments in its entire extension after removing it from the prepared site, requiring a vigorous cleaning after its use to remove the intimate contact of the bone fragments with the drill grooves.
- Greater bleeding at the prepared site in all surgeries, with an aspect of conventional drilling by bone subtraction.
- Absence of osseodensification characterized by bone removal during drilling and by the visual characteristics of the bed prepared, being visible the absence of autograft compacted in the bone walls prepared.

For the OD system, the following clinical findings were recorded:

- Application of controlled force.
- Lower sequence of drills for installing the implant.
- Ease of targeting when drilling the bed.
- After removing the drills from the surgical site, no bone particles were removed.
- Less bleeding in the prepared bed in all surgeries.
- Presence of osseodensification characterized by visible compacted autograft in the preparation walls.

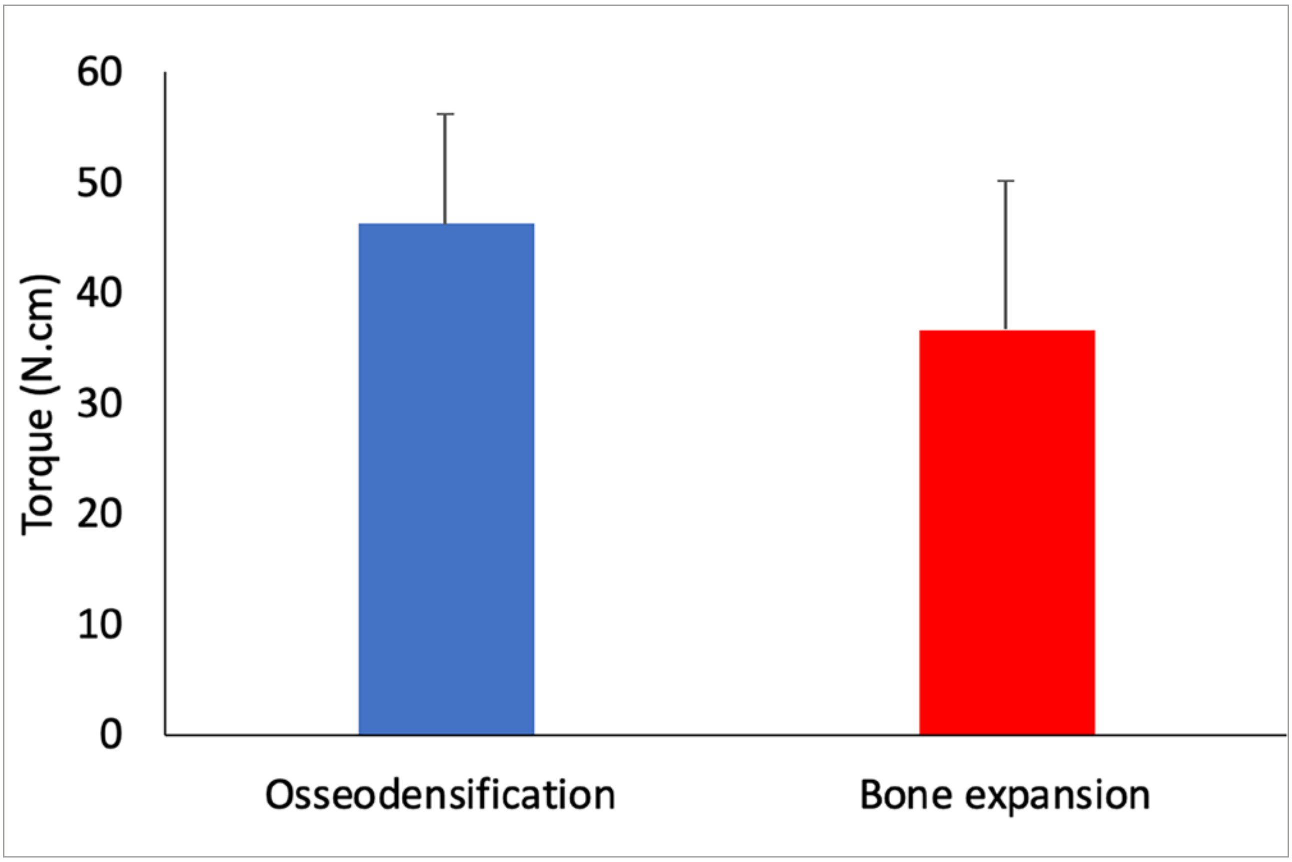

Figure 4. Maximum torque according to each group (p=0.02).

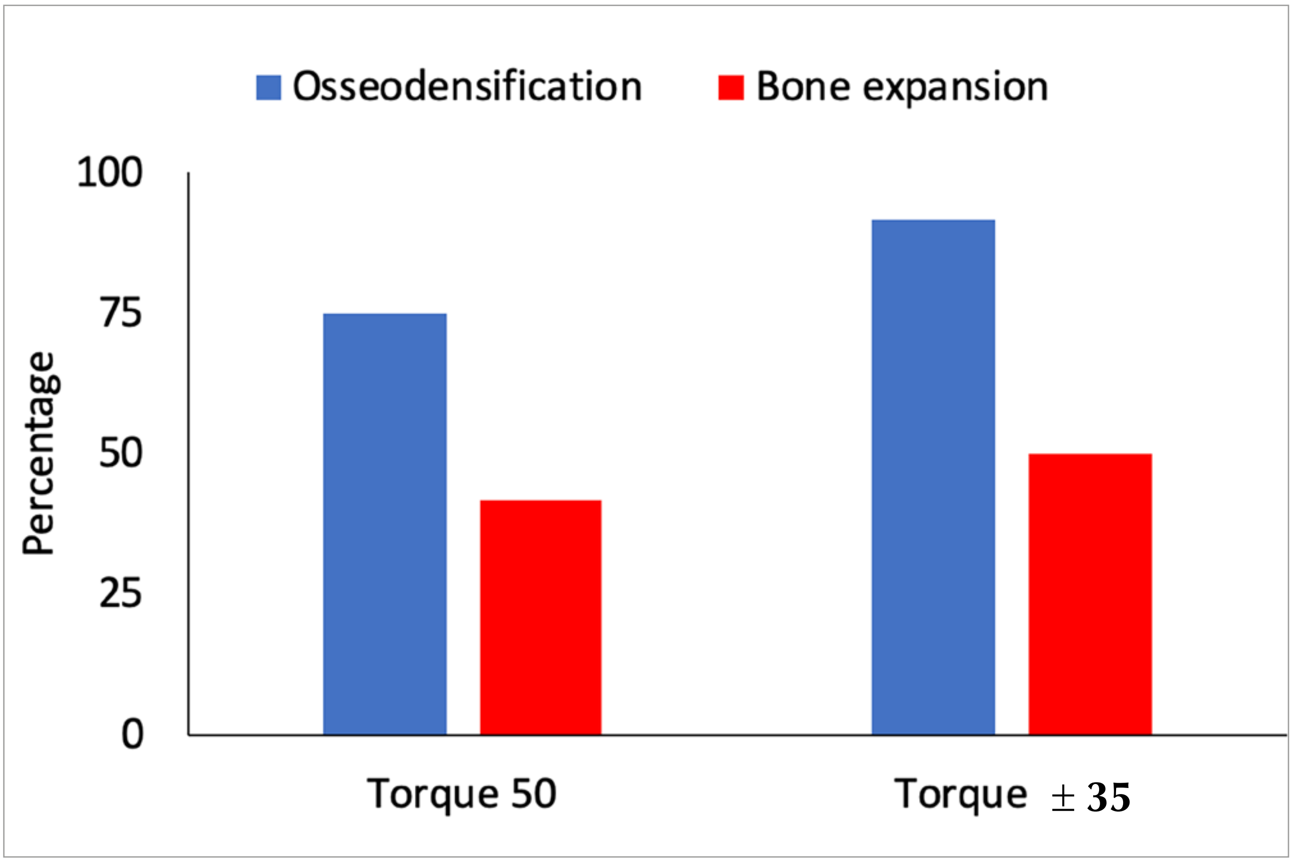

Figure 5. Frequency of cases with maximum torque of 50N.cm (p=0.22) and ±35N.cm (p=0.02).

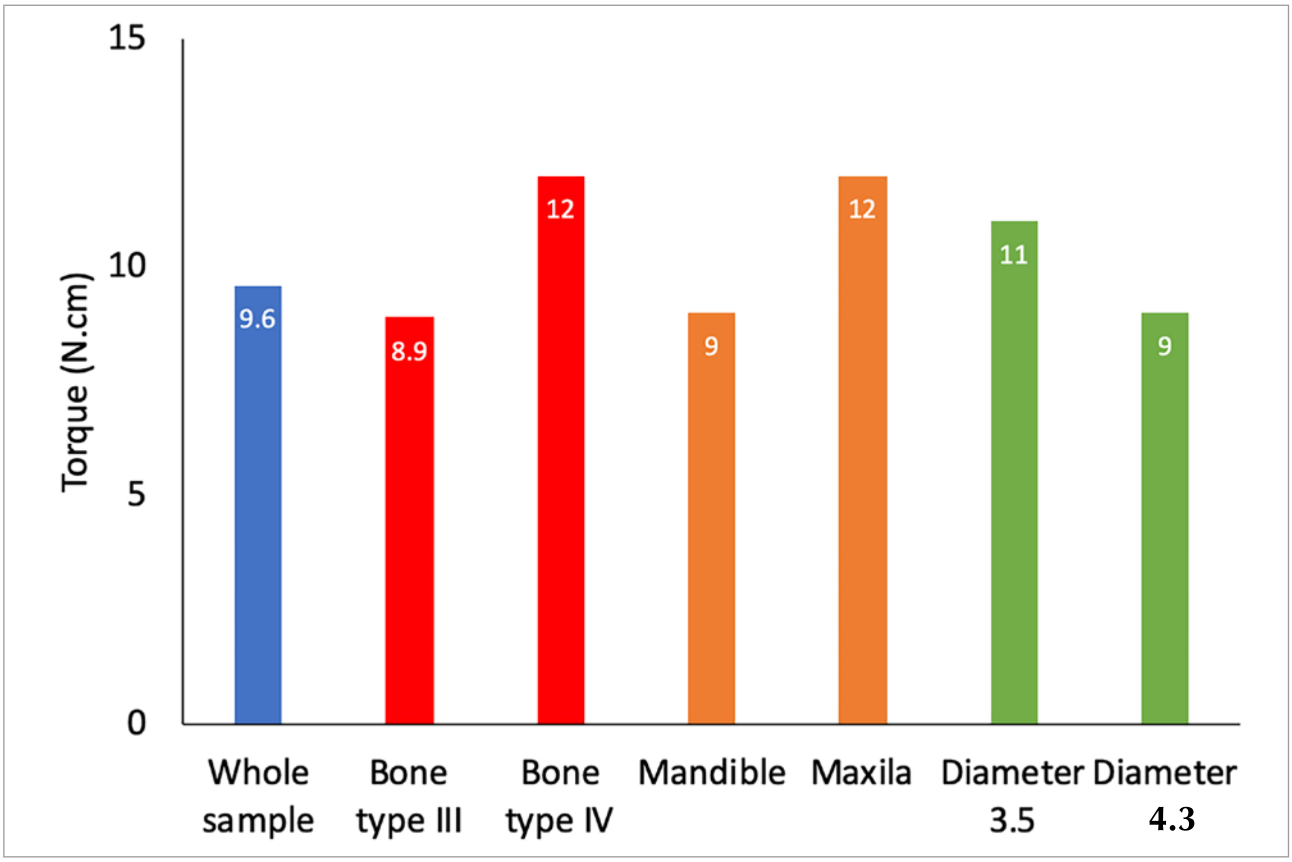

Figure 6. Differences in torque in favor of the osseodensification group for all the sample and according to bone type, arch and diameter of the implant.

Discussion

This study seems to be the first clinical study to compare two drilling systems that claim preparation according to osseodensification and bone-expansion principles. It was demonstrated that the final implant insertion torque in areas prepared with an OD system reached greater primary stability than a BE system.

The superiority of the OD system tested in this study has also been demonstrated when compared to conventional drilling in pre-clinical studies (Huwais and Meyer, 2017; Lahens, 2019; Oliveira *et al*., 2018). In a study with tibial plateau from porcine bone (low density bone) and implants of 4.1mm, the primary stability obtained with the osseodensification technique reached approximately 49 N.cm compared to 25 N.cm obtained with the standard drilling technique (Huwais and Meyer, 2017). In another study in sheep, the insertion torque registered for conventional drilling was approximately 10 N.cm, whereas the values increased significantly using clockwise osseodensification (above 50N.cm) and reaching 80N.cm after osseodensification in counterclockwise direction (Lahens, 2019).

Animal studies have also been conducted to compare osseodensification to other techniques that are also indicated for areas of soft and/or scarce bone. For instance, OD was compared to the osteotome technique, and increased insertion torque values were found for implants inserted in beds prepared with OD than those prepared with the osteotome technique in a porcine model (Tian *et al*, 2018). This finding was further supported by another animal study showing the highest bone-to-implant contact for osseodensification, followed by the Summers technique and conventional drilling, demonstrating that the surgical technique changes the original implant bed characteristics (Slete *et al*, 2018).

One single study using fresh pig ribs (Delgado Ruiz *et al*, 2020) did not find superior insertion torque with OD compared to conventional drilling. Nevertheless, they conducted under-drilling for bed preparation with the OD system, which decreases the spring back effect responsible for the benefits of osseodensification in terms of primary and secondary implant stability. Therefore, the above mentioned study should be interpreted with caution due to this methodological limitation. Moreover, a recent clinical study comparing the stability of dental implants placed in low-quality bone prepared with OD and a standard undersized drilling demonstrated that a wider surgical bed prepared by the OD technique allowed for the bone healing-chamber concept in soft bone allowing greater implant stability (Mello-Machado *et al*, 2021). Therefore, OD provides the balance between preserving bone bulk and producing higher implant stability (due to the spring back effect) without the need to create severely downsized "misfit" osteotomies (Bergamo *et al*, 2021).

Importantly, the primary outcome of this study has important clinical implications in implant dentistry. The role of primary stability in osseointegration is well consolidated in the literature (Javed *et al*.,2013; Calandriello *et al*., 2003, Galluci *et al*., 2014). Besides, it is crucial in protocols requiring immediate loading during rehabilitations with multiple implants and immediate provisionalization in single implants. For those protocols, it is essential that stability levels are as high as possible, avoiding fibrous encapsulation and implant loss (Del Giudice *et al*., 2019). Successful osseointegration of implants has been shown in cases immediately loaded after using an initial insertion torque >32 N.cm, while implants placed with reduced insertion torque (20 N.cm) often fail (Ottoni *et al*., 2005). Data suggest that failure in osseointegration can be reduced by 20% for every 9.8 N.cm increase in the initial torque (Ottoni *et al*., 2005). In this study, the final insertion torque was 9.6 N.cm higher in the OD than in the BE group, which may suggest a possible increase in success rates of implants receiving immediate loading or provisionalization.

A systematic review showed that the minimal insertion torque used as a parameter for placing implants in edentulous patients is of 30 N.cm (Papaspyridakos *et al*., 2014) or >35 N.cm (Schimmel *et al*., 2014), and in partially edentulous patients is of >30 N.cm (variation of 15 N.cm to 45 N.cm) (Schrott *et al*., 2014). Other studies refer to criteria of necessary stability for immediate loading protocols as greater than 30 N.cm (Degidi e Piattelli, 2003; Lorenzoni *et al*., 2003). Another recent review (Huynh-Ba *et al*. (2018) showed that, despite the scarcity of comparative data, immediate placement and loading of implants in the edentulous space of a single tooth seems to be a well-accepted treatment modality in the perspective of patients, and is worth of consideration in clinical practice. Considering these data, it is important to highlight that a total of 9 cases (75%) in the OD group reached maximum torque of 50N.cm, whereas in the BE group only 5 (41.7%) cases reached this torque. Despite not reaching statistically significant difference ($p = 0.22$) due to a small sample size, it is important to emphasize that these results can have relevance in daily clinical practice, since only a quarter of the patients treated with OD system did not reach maximum torque, while less than half of the implants installed with BE system reached the same result. Future studies with larger sample sizes may consolidate these findings.

In view of the need to reach torque values ≥35N.cm for immediate loading, a comparison between the two groups was performed using this threshold as an outcome. This analysis demonstrated a significant difference between the tested groups. While OD system reached 35 N.cm or more in 91.7% of cases, BE system reached this torque in 50% of cases. Then, it should be taken in consideration that most of the patients treated with OD could be submitted to installation protocols of immediate temporary crowns. Contrarily, half of the patients treated with the BE system would need temporary prostheses with supports on adjacent teeth and/or temporary removable prosthesis. In the patient's perspective, these outcomes have relevant importance for the decision on which drilling system to be used.

Another descriptive data of this study that should be discussed was the greater insertion torque of OD compared to BE in specific critical situations of daily practice. In maxillary posterior regions, type IV bone, and when is necessary to use an implant of reduced diameter, OD system reached a torque of approximately 12 N.cm higher than BE system. This fact demonstrates that in these scenarios, the results may be improved with the increase of the torque that is directly related to a reliable osseointegration pattern. These findings corroborate those from a recent clinical study demonstrating that OD outperformed conventional drilling for pairwise comparisons of arches (maxilla and mandible) and areas operated (anterior and posterior), diameters and lengths of the implants, except for short implants (Bergamo *et al.* 2021).

To the best of the authors' knowledge, there are no previous clinical studies similar to the present one. As a consequence, the uniqueness of this study is one of its strengths. Nevertheless, the results of this study must be also interpreted considering its methodological limitations. This was a comparative non-randomized, open-label, clinical study. Randomization and blinding were not possible because the study was developed in the setting of a private clinical care. Also, the sample size may not provide analytical power for some of the comparisons. On the other hand, the split-mouth design provides less variability, improving the comparability of treatments even in a small sample. In addition, this study provides data with clinical relevance for the development of future clinical studies about osseodensification.

It can be concluded that primary stability is affected by the osteotomy technique. Dental implants installed with an osseodensification system presented higher levels of insertion torque, being superior than a system using bone expansion drills.

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