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Clinical Assessment of Dental Implants Placed in Low-Quality Bone Sites Prepared for the Healing Chamber with Osseodensification Concept: A Double-Blind, Randomized Clinical Trial

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Abstract: The present study aimed to compare the stability of dental implants placed in low-quality bone prepared for the healing chamber with osseodensification technique and a standard undersized drilling. Sixteen subjects presenting D3 or D4 bone density according to Misch's classification were randomly distributed to receive dental implants following either osseodensification (G1: $n = 29$) or standard undersized drilling (G2: $n = 26$) preparation techniques. Implant insertion torque (IT) and implant stability quotient (ISQ) were measured immediately after implant placement. Implant survival and secondary stability (ISQ) were evaluated after six months. The G1 group showed higher IT (39.0 $\pm$ 6.4 Ncm) than G2 (32.0 $\pm$ 3.4 Ncm) ($p < 0.001$). ISQ values were similar ($p > 0.05$) at the implant insertion (67.1 $\pm$ 3.2 and 65.5 $\pm$ 2.7 for G1 and G2, respectively). After six months healing, implant survival was equally comparable in both groups ($p > 0.05$), and ISQ values were higher than those of implant insertion ($p < 0.001$) but similar ($p > 0.05$) for both groups (74.0 $\pm$ 3.6 and 73.3 $\pm$ 3.2 for G1 and G2, respectively). Within the limitations of this study, the present RCT demonstrated that a wider surgical bed prepared by osseodensification instrumentation allowed for the bone healing-chamber concept in low-quality bone without any reduction in implant stability and success rate.

Keywords: osseodensification; clinical trial; bone chamber healing; clinical assessment; bone–implant interactions

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1. Introduction

The survival of dental implants depends on the bone's ability to remodel at the bone–implant interface [1,2]. This process requires the mechanical engagement of the dental implant with bone at the point of insertion clinically defined as primary stability [3]. The newly formed bone at the implant surface produces the secondary stability which consolidates the osseointegration [3,4]. In a recent study, osseointegration was defined as a direct and functional connection between bone and an artificial implant [5]. Nevertheless, adequate primary stability is necessary to predict the survival of dental implants. This has led to the practice of under-preparing the implant bed to be significantly narrower in diameter than the thread diameter of the implant, especially in soft bone. This is associated with the self-tapping screw implant design, which guarantees a close fit of the dental implant and

bone [6,7]. Although this widely used surgical technique can achieve high insertion torque (IT) or implant stability quotient (ISQ) values, it can produce excessive strain on the bone, which causes transient necrosis in the surrounding bone and may delay or impair bone remodeling [8,9]. Further, friction between the dental implant and bone could damage the implant surface owing to the release of titanium particles [10]. Thus, the under-preparation of the implant bed produces high primary stability; however, it increases peri-implant remodeling and subsequent stability loss during the short-term healing [11].

In contrast, it has been hypothesized that larger osteotomies (where the implant-bed diameter is slightly wider than the implant core diameter) can create a "healing chamber" at the bone–implant interface [6,7,12,13]. Recently, this was also defined as a "healing gap" [14]. In this hypothesis, the space at the bone–implant interface is fulfilled by the coagulum which favors bone healing at the interface while ensuring that instrumented bone to remodel away from the surface of the implant. Although significantly lower final IT and implant stability quotient (ISQ) values are associated with this approach, it facilitates faster biological healing since the healing gaps are rapidly filled with woven bone at the initial stages [13]. However, in low-quality bone, the reduced initial contact of the implant with bone may not guarantee adequate primary stability, negatively affecting osseointegration, especially if immediate loading or provisionalization is desired.

Recently, a new surgical instrumentation approach called osseodensification has been developed [15], which is a non-extraction drilling technique that leverages controlled bone expansion through plastic bone deformation and compaction autografting to produce an implant bed without excavating bone tissue. As a result, an increase in the implant's primary stability has been reported due to the densification and the compaction autografting of the implant bed walls [15,16]. This denser bone interface would minimize the need to undersize the osteotomy to achieve adequate primary stability, and it may even allow the use of healing chamber in low-quality bone.

Although osseodensification has been reported to enhance the clinical outcomes of implants in several clinical scenarios, with a high implant stability and survival rate in both short- and long-term studies [16–22], it is important to investigate if the use of this technique to use the healing chamber concept leads to a more predictable outcome for the immediate loading of implants. Therefore, the purpose of this study was to evaluate the primary and secondary stability of dental implants placed in low-quality bone sites prepared for the healing chamber concept with osseodensification compared to a standard undersized drilling protocol.

2. Materials and Methods

2.1. Study Design

A prospective parallel-arm randomized controlled trial (RCT) was conducted at the Oral Implantology clinic at Unigranrio University (Rio de Janeiro, Brazil) between March 2019 and September 2019. The study adhered to the ethical values of the Declaration of Helsinki and was approved by the local ethics committee (#7021401700005283). All participants were informed of the study's procedure and objectives and were included only after providing informed written consent. To ensure the quality and transparency of this randomized clinical trial, the authors followed the CONSORT statement [23,24].

2.2. Sample-Size Calculation and Randomization

A priori power analysis (two-tail t-test between two independent samples with equal group sizes) was used for sample size estimation, based on the results of a pilot study. Previously, it was reported that the osseodensification technique improves implant stability by approximately 25% [25]; thus, an effect size of 25% on implant stability was assumed. A sample of at least 17 dental implants in each group would be required to achieve 0.80 power at a significance level of 0.05 (SPSS version 22.0; IBM Corporation, Armonk, NY, USA). Considering an expected drop-out rate of 30%, a minimum sample size of 23 implants was selected in the present study. Opaque envelopes were used as a randomization

method to assign each implantation site to receive one of two bone preparation techniques: osseodensification drills with healing chamber (test group—G1) or standard undersized drilling (control group—G2).

2.3. Inclusion and Exclusion Criteria

The complete medical and dental history of each participant was collected. Participants older than 18 years of age, requiring oral rehabilitation of the upper jaw were included [24]. Excluded criteria were: insufficient bone for implant therapy; a visible lack of primary stability at the time of implant insertion (low primary stability was considered when <30 Ncm or ISQ value < 60 for immediate loading [26,27]); decompensated metabolic diseases; motor difficulties that impeded or hampered hygiene; pregnancy; periodontal disease without previous treatment; and a history of smoking, radiotherapy, or the use of bisphosphonates.

Bone quality was assessed in the preoperative cone-beam computed tomographic (CBCT) images. A standard CBCT (5i-CAT® Cone Beam 3-D Imaging System, Imaging Sciences International, Hatfield, PA, USA) was used with standard exposure parameters set and operated by the same technician to minimize variation in the intensity of the voxel values between the patients [28,29]. The DICOM images were loaded into the Blue Sky Plan software (version 4.2.5; Blue Sky Bio, Grayslake, IL, USA), and a virtual implant was positioned in each implantation site. Next, using the "density value measure (Hu)" tool [30–33], the bone density (BD) at the implantation site was determined by the mean of the voxels' grey values for trabecular bone in the cervical, body, and apical regions (Figure 1). Following Misch's classification to determine bone quality [34], only implantation sites presenting BD values of 150–350 and 350–850, corresponding to D4 and D3 bone qualities, respectively, were included in the present study [35,36]. The CBCT evaluations of each implantation site were performed by an independent expert (CFABM) who had no contact with the patients.

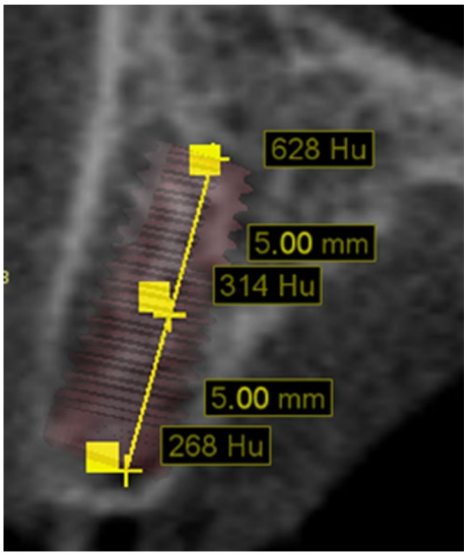

Figure 1. The bone density at the implantation site was determined as the mean of the grey values (Hu) of trabecular bone from cervical, body and apical regions.

2.4. Surgical Procedures

In the osseodensification group (G1), bone preparation was performed using tapered multifluted burs (Densah Bur; Versah, MI, USA) at 1200 rpm counterclockwise rotation under saline irrigation (Figure 2A). The drilling sequence is shown in Table 1. The burs compact bone at the interface and the final diameter of 3.8 mm (VT2838, information from the manufacturer) allow the formation of a healing chamber between the implant (3.5 mm diameter) and bone interface (Figure 3).

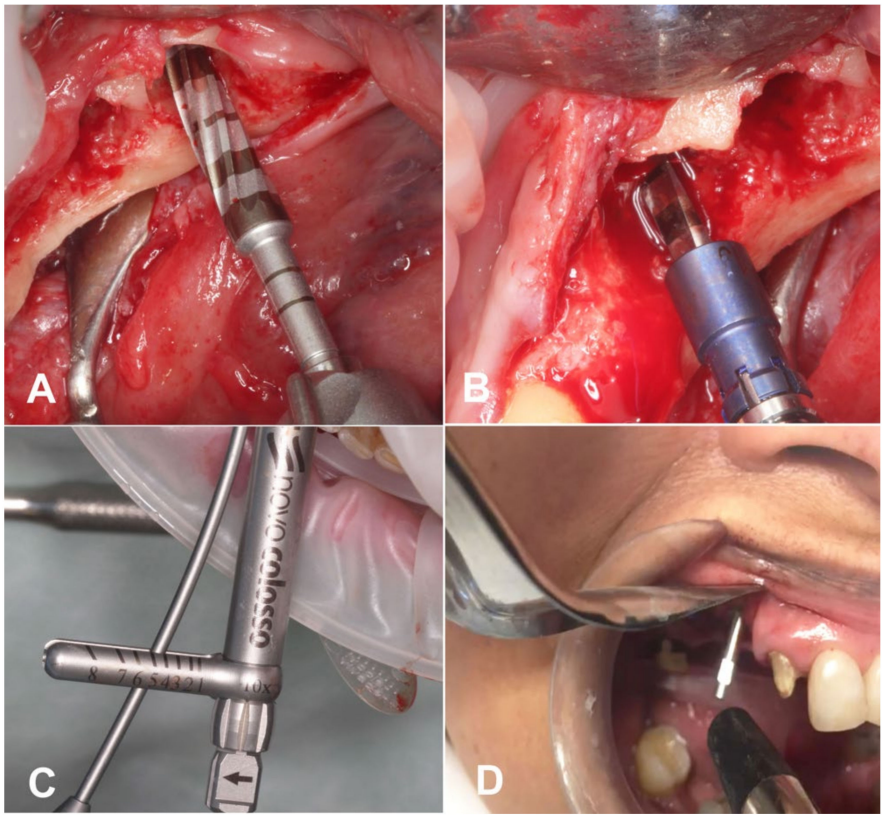

Figure 2. (**A**) Surgical procedure using osseodensification technique; (**B**) standard drill for undersized preparation; (**C**) clinical evaluation utilizing the torque wrench; (**D**) measurement of the stability quotient value using an implant Osstell ISQ device.

Table 1. Drilling sequence, with respective diameter and manufacturer code, used to prepare the implant bed in each group.

Drilling Sequence	Osseodensification with Healing Chamber GROUPS	Standard Undersized Group
1	Ø1.6 mm Pilot (G3)	Ø2.0 mm Pilot (BALD-2021)
2	Ø2.3 mm (VT1828)	Ø2.5 mm (BHED-2025)
3	Ø3.0 mm (VT2535)	Ø2.8 mm (BHED-2528)
4	Ø3.3 mm (VT 2838)	

The standard undersized drilling group (G2) received a final osteotomy diameter of 2.8 mm, as recommended by the manufacturer for placing 3.5 mm implants in low-quality bone (Emfils, Sao Paulo, Brazil) (Figure 2B). It was used 1200 rpm clockwise rotation under saline irrigation

All osteotomies received a 3.5-mm implant (morse platform) with a length of 10–13 mm (Figure 3A,B) (Emfils, Sao Paulo, Brazil). According to the manufacturer of the dental implants, the implants were placed approximately 2.0 mm subcrestal. The implant placement was conducted in an operating room under aseptic conditions. A postoperative panoramic X-ray was mandatory. All the surgical procedures were performed by an experienced oral surgeon (RCMM), whose work was calibrated prior to the study using polyurethane models (Sawbones, Pacific Research Laboratories, Washington, DC, USA).

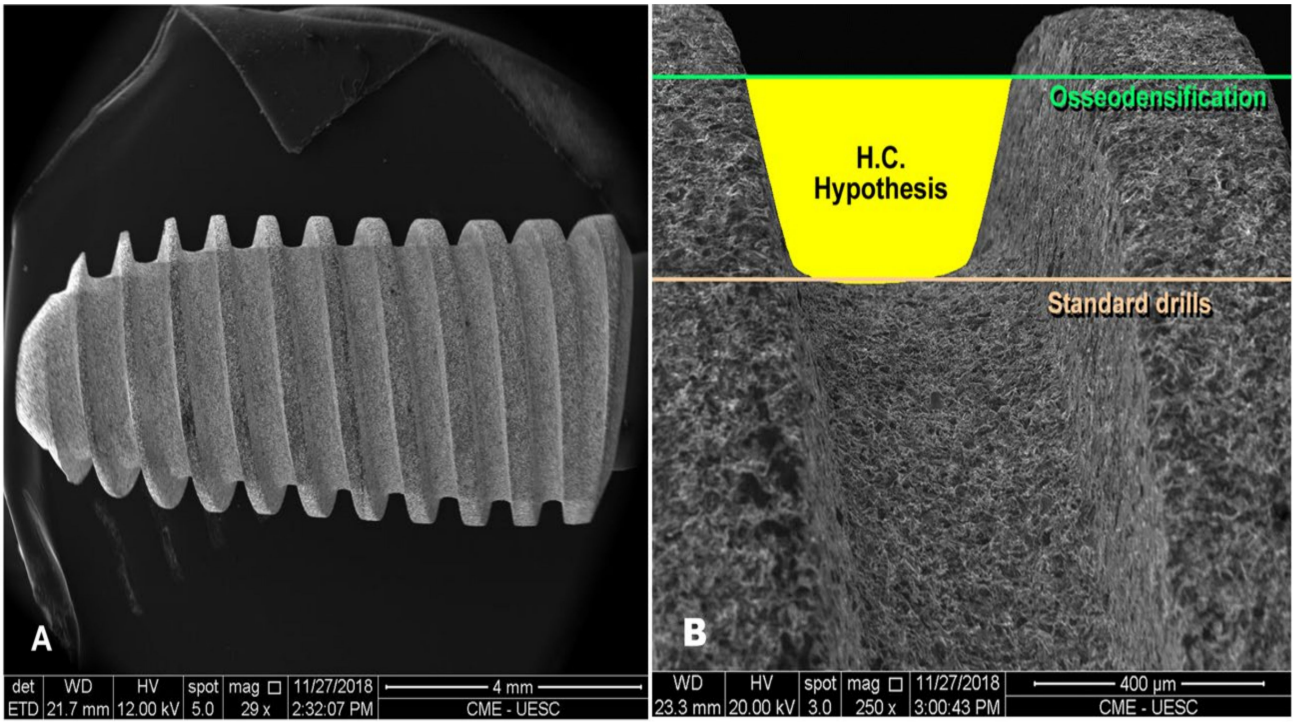

Figure 3. (**A**) Dental implant geometry and threads visualized using scanning electron microscopy (SEM) (×29) (Quanta 250, FEI Company, OR, USA); (**B**) SEM of the dental implant surface (×250)—space between the implant and bone interface exemplifying the "healing chamber" (H.C.) hypothesis with the wider implant bed preparation via osseodensification.

Immediately after implant insertion, the IT was measured using a manual torque wrench (Emfils) (Figure 2C), and the ISQ value was recorded as the mean of the buccal, lingual, mesial, and distal readings using the Osstell ISQ device (Osstell, W&H, Gothenburg, Sweden) (Figure 2D). The implants that reached a >30 Ncm of IT and >60 of ISQ were restored with an immediate provisional crown without any occlusal contacts. Those implants with IT values lower than 30 Ncm were replaced by wider implants and were excluded from the study.

Ibuprofen (400 mg, Advil, Pfizer, São Paulo, Brazil) was prescribed every six hours in case of pain. Chlorhexidine gluconate 0.12% oral mouthwash (Perioxidin, Laboratório Gross, Rio de Janeiro, Brazil) was also prescribed twice daily for two weeks. After ten days, the sutures were removed without removing the provisional crowns. After six months of healing, the survival of the implants was verified and the secondary stability was measured though ISQ values, and a final ceramic prosthesis was manufactured.

2.5. Statistical Analysis

The Shapiro–Wilks test was used to check for normality of the data distribution. The t-test was used to compare bone quality and IT variables. Immediate and final ISQ values were analyzed using a paired t-test. The chi-square test was used to compare the survival data of both groups. The significance level was set at 5% (SPSS, v.20, IBM, New York, NY, USA).

3. Results

The sample of recruited participants (March to September 2019) was composed of 30 participants, and a total of 55 dental implants were placed, a similar mean age of 50.0 ± 6.9 and 51.7 ± 9.3 for G1 and G2, respectively ($p > 0.05$). The distribution and sites were presented in Table 2. The mean grey values in each region of the implantation site are shown in Table 3. It is possible to see a homogeneous distribution of BD values in both groups ($p > 0.05$).

Table 2. Socio-demographic data of the patients included in the study.

Participants (*n* = 30)	**Groups**	
	G1 (*n* = 14)	G2 (*n* = 16)
Gender		
Male	4	3
Female	10	13
Age (years), mean ± SD		
	50.0 ± 6.9	51.7 ± 9.3
Implant placement (*n* = 55)		
First premolar	3	6
Second premolar	7	3
Canine	6	7
Central incisor	13	10
Education Level		
High school diploma	8 (6 Female and 2 Male)	9 (8 Female and 1 Male)
Bachelor's degree	6 (4 Female and 2 Male)	7 (6 Female and 1 Male)

SD = Standard deviation.

Table 3. The number of patients and implants in each group with respective mean bone density (± sd) at cervical, body, and apical regions of implantation sites.

Group	**Patients**	**Implants Areas**	**Bone Density**			
			Cervical	**Body**	**Apical**	**Mean**
Osseodensification + healing chamber	14	29	529 ± 226	389 ± 255	433 ± 207	450 ± 171
Standard undersized	16	26	483 ± 181	410 ± 213	481 ± 198	458 ± 115
***p*-value**			0.420	0.744	0.398	0.852

No significant difference was identified between the groups ($p > 0.05$).

The CONSORT chart of participant flow is shown in Figure 4, from the 55 implants, four implants in G2 had low IT and were excluded from the study since they were replaced by wider implants. In G1, one implant was excluded due to the same reason. The implant survival after six months was 100% for both groups ($p > 0.05$); however, considering the implant-stability parameters to allow immediate restoration, the osseodensification group (G1) exhibited 96.6% success, and the standard drilling group (G2) exhibited 86.6% success ($p < 0.001$). There was no change in the original trial outcomes and no postoperative complications (such as wound dehiscence and infection) occurred during the follow-up period in both groups.

Even with larger final diameter osteotomy of G1, higher IT values (39.0 ± 6.4 Ncm) were observed when compared to the standard undersized drilling protocol (32.0 ± 3.4 Ncm) ($p < 0.001$). Although ISQ values after 6 months healing were higher than those at the time of implant insertion for both groups ($p < 0.001$), no significant difference was identified when comparing both groups at each time point ($p > 0.05$) (Figure 5).

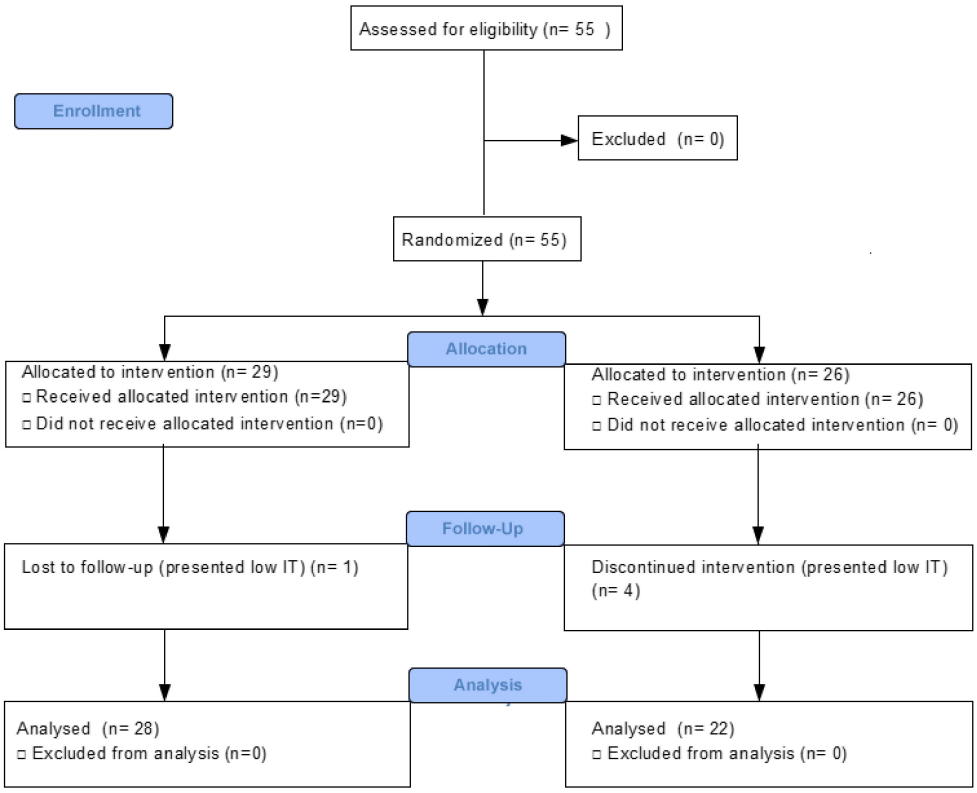

Figure 4. Flowchart (CONSORT) illustrating the implant placements of the clinical trial.

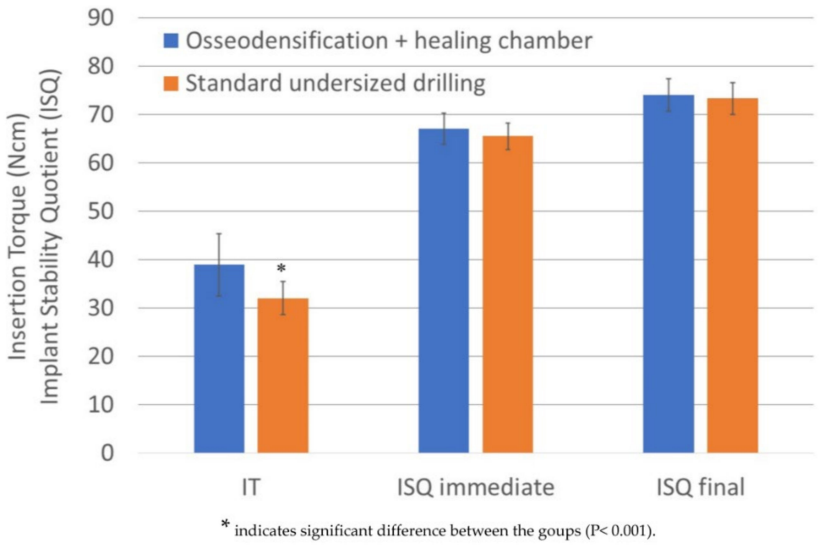

Figure 5. IT (Ncm) and ISQ values of osseodensification + healing chamber and standard undersized drilling groups.

4. Discussions

One factor that should be considered for implant stability is the influence of the interaction between the implant macrogeometry and the prepared bone bed [4,28]. When analyzing these two factors, it is suggested that a high insertion torque is desirable to improve implant stability during the osseointegration process, and to reduce implant micromovement [36]. In the present study, whether osseodensification allows for the use of wider implant beds to create healing chambers without jeopardizing implant stability was investigated.

The most widely accepted parameters to assess clinical implant stability are IT and ISQ [37,38]. While IT measures the frictional resistance of implant rotation into the bone, ISQ measures the implant stability during the healing process using the resonant frequency [38]. There is some debate regarding this relationship, but IT and ISQ can be considered to be independent methods to measure implant stability [39] and, therefore, no correlation analysis was performed. Higher IT and ISQ values are considered to be strong indicators for low implant micromotion, high stability for immediate loading, and osseointegration [40–42]. It was possible to identify higher IT values when using osseodensification instrumentation protocol.

Bone is a dynamic tissue that responds to stimuli—the surgical procedure and the interaction between the macrogeometry of the implant and its associated osteotomy drilling dimensions, in this case. Several studies have suggested that high values of IT do not necessarily indicate a higher degree of secondary stability and stabilized healing process [41,43]. A previous study demonstrated that a protocol undersized by no more than 10% is sufficient to improve the primary stability of the implant in regions of poor bone density [3], composed of weak bone trabeculae surrounded by a thin layer of lamellar bone [26]. However, in many clinical scenarios (as is the case in this study), it is necessary to use a final 2.8 mm standard drill to place a 3.5 mm implant in order to optimize implant stability. This represents a downsizing method to achieve higher IT and ISQ values to allow immediate provisional restoration without loading [27,28,41]. For comparison, in G1, wider osteotomies were established to create a healing chamber at the implant and bone interface, and this still produced higher IT values. Although ISQ values were similar in both groups, the osseodensification instrumentation prevented the need for undersizing the osteotomies and provided the requisite microgap for bone-chamber healing without reducing implant stability.

Both in vitro and in vivo studies have demonstrated up to a three-fold increase in primary stability when leveraging osseodensification [17,21,22,44–46] In the present study, osseodensification allowed the use of a wider diameter (3.8 mm) implant bed to place a 3.5 mm diameter implant with adequate stability. In addition, a previous in vitro histological study [46] reported that osseodensification does not reduce primary stability during bone healing due to the compacted autograft that promotes osteoblast activity—early osteoid tissue formation with osteons present at the implant bed, which act as nucleating surfaces for the osteoblasts around the implant [47]. Further, the compaction autografting produced by osseodensification would produce higher BIC values [47]. However, in the present study, both groups exhibited similar stability after 6 months of healing.

Other authors [12,40,47–49] have noted that implant stability also depends on the geometry of the threads. Larger implant threads with higher pitches contact more bone trabeculae and have improved bone-chip compaction. In the present study, the implant geometry had a square thread profile with a large pitch, observed through SEM, and exhibited adequate primary stability for both drilling protocols. These data agree with that of previous studies, which showed that large and self-cutting implant threads have higher primary stability than implants with small-thread designs in regions of poor-density bone [47–50].

The clinical assessment of bone density usually relies on analyzing tomographic images since histomorphometric and densitometric evaluations, which provide accurate bone-density measurements, cannot be applied routinely [49]. CBCT is used for maxillofacial imaging because of its advantages over medical computed tomography (CT), such as lower effective radiation doses, lower cost, and simpler image acquisition [29,30]. Bone density is proportional to the degree of X-ray attenuation, standardized as Hu in CT, and represented as grayscale (voxel values) in CBCT [29]. Although the CBCT software used in the present study refers to the density value as Hu, it is recorded as the voxel value.

The voxel values can differ depending on the CBCT equipment used, exposure parameters, the position of the measurement in the field of view [51] (centrally vs. peripherally), and the amount of mass inside and outside the FOV [34,51,52]. Although this variability could be considered to be a limitation regarding the use of voxel values to measure bone density in CBCT, previous studies reported that the voxel value could be used for

the estimation of bone density [51,52] with a high degree of agreement in comparison to medical CT analysis [53,54]. In the present study, the diagnosis of D3 and D4 bone sites was made using the same CBCT equipment to mitigate interequipment variability. A similar approach was previously reported to clinically evaluate the bone density clinically using the "Hu measurement" tool [28,31].

In the present RCT were possible to observe some limitations, and they can be answered with future studies. The OD group had a wider diameter than the standard drilling group. It allowed the creation of the healing chamber with good primary stability. However, other clinical effects suggested by the OD process require further research, such as the spring-back effect presented by Huwais and Meyer, 2017 [15]. Thereby the bone–implant contact and the size of the healing chamber can modify according to the implant design. The correlation between the drilling process and the implant macrogeometry should also be studied in future in vitro and in vivo studies.

Therefore, OD is a potential alternative technique to improve the implant bed for implant dentistry. However, new RCTs should be conducted in the future to evaluate the "healing chamber" hypothesis combined with osseodensification, especially with a long-term follow-up to evaluate marginal bone remodeling. Histological analysis should be encouraged to describe bone healing using this combination.

5. Conclusions

Within the limitations of this study, the present RCT demonstrated that a wider surgical bed prepared by osseodensification instrumentation allowed for the bone healing-chamber concept in low-quality bone without any reduction in implant stability and success rate.

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

Data Availability Statement: Data is contained within the article.

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