Implant stability changes in dental implants installed by osseodensification and conventional methods: A randomized controlled study

Abstract

Aim
To evaluate the effect of implant site preparation in low-density bone using osseodensification (OD) drilling technique in terms of implant stability changes during the osseous healing period, insertion torque (IT), and preparation time and compare them to the conventional drilling technique.

Materials and Methods
In this randomized controlled clinical study, a total of 40 dental implants (DI) were randomly divided into two groups: A study group of implants installed after using the OD drilling technique, and a control group of implants installed using the conventional drilling technique. The outcome variables included implant stability measured immediately following implant insertion as well as 6 and 12 weeks postoperatively using resonance frequency analysis and recorded as implant stability quotient (ISQ), IT measured as Ncm, and preparation time in minutes.

Results
There was no statistically significant difference in primary stability between the groups (P-value 0.216). In contrast, at 6 weeks and 12 weeks postoperatively, the control group showed higher ISQ values (P-values 0.002 and 0.005, respectively). There was no significant difference in the (IT) between the groups (P-value 0.627). The preparation time was significantly longer in the study group compared to the control group (P-value 0.0001).

Conclusion
The OD drilling technique did not show a more favorable outcome regarding the implant stability changes, IT, and preparation time over that of the conventional approach and resulted in a significant drop in stability after 6 weeks postoperatively, making OD use for early loading questionable.

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INTRODUCTION

Osseointegration is a process that involves a biological connection between the host bone and the dental implant (DI) surface, various treatment approaches and methods have been attempted to speed up the production of bone tissue and osseointegration after implant placement (1).
One of the most crucial elements for the successful osseointegration of DI is the primary implant stability attained by the mechanical attachment of the external implant surface to the walls of the recipient osteotomy site, enhancing primary stability depends on bone density, surgical technique, and implant design (2). Following the installation of DI, a sequence of bone modeling and remodeling actions occur that begin with bone turnover at the interface, followed by fast regeneration (3).
As the transition from primary stability to secondary stability occurs during the osseous healing phase, there is a physiological decline in implant stability within 1-4 weeks of the healing process, this drop is caused by the resorption of bone tissue that is immediately lateral to the implant (4).
Numerous surgical techniques have been developed over the last few decades to improve the primary stability of DI when inserted into the low-density bone (5). Among these techniques is osseodensification (OD), a non-subtractive drilling technique that compacts bone at the osteotomy walls by rotating counterclockwise (6), OD also causes narrow alveolar bone to expand without fenestration or dehiscence, enabling the simultaneous installation of DI (7).
Studies have shown that OD has a better outcome than traditional drilling approaches (6, 8); however, its clinical effect on stability changes during the healing phase is not clear. Therefore, this study aimed to evaluate the effect of OD on implant stability changes during the osseous healing phase, insertion torque (IT), and preparation time and compare them with the conventional one. The null hypothesis was that there is no difference in the outcome of interest between the two groups.

MATERIALS AND METHODS

This randomized clinical study was conducted during the period extending from December 2021 to December 2022 at the Department of Oral and Maxillofacial Surgery, College of Dentistry, University of Baghdad. The study was conducted in accordance with the Declaration of Helsinki guidelines and was approved by the local ethics committee (protocol number 397121). The study followed the CONSORT (Consolidated Standards for Reporting Trials) guidelines and was registered at ClinicalTrials.gov (ID number: NCT05390996)

A total of 20 patients who fulfilled the eligibility criteria participated in this study. The inclusion criteria were patients over 18 years of age having single or multiple missing teeth in the maxilla and/or mandible with healed edentulous sites of at least 6 months after extraction (delayed implant placement protocol), sufficient vertical and horizontal dimensions of the alveolar ridges with bone density of the proposed implant site of less than 850 Hounsfield units (HU) which corresponds to D3-D5 bone density according to Misch bone classification based on CBCT findings (9).
Patients were excluded from the study when they showed signs of infection in the proposed implant zone, had signs of parafunctional habits such as bruxism and clenching, had a history of radiotherapy to the head and neck, had a history or were currently under treatment with bisphosphonates or other drugs that may alter bone metabolism, patients who were heavy smokers or presented with severe periodontitis or had local limitations such as inadequate inter-ridge distance. Also, patients who presented with bone density at the proposed implant site of more than 850 HU which corresponds to D1 or D2, or needed augmentation of the implant site, were excluded from the study.
The patients received 40 DI (NucleOSS™ T6, Izmir, Turkey). These were randomly assigned into 2 groups using an online Randomization tool at https://www.graphpad.com: A study group of DI installed through the OD drilling technique, and a control group of DI inserted by conventional drilling technique.
A preoperative CBCT was taken to determine the appropriate width and length of the proposed implant and to ensure that the average bone density of the cancellous bone of the proposed area was less than 850 HU by using OnDemand™ 3D software (Cybermed Inc., Seoul, Korea), a virtual implant was placed in the planned implantation site, and by using the "Bone Density Graph" tool, bone density inside the proposed implant fixture was determined as (HU).

Surgical procedure

All procedures were performed under local anesthesia. After reflection of a full-thickness mucoperiosteal flap, the implant bed was prepared through sequential drilling, and the implants were inserted about 0.5 mm subcrestally. DI used in this study were 3.5, 4.1, and 4.8 mm in diameter and 8, 10, and 12 mm in length. The implants were standardized for insertion in the upper then lower jaw, right then left side, and posterior to anterior position in case of multiple implants.
The drilling protocol for the study group, (OD group) started with a 1.7 mm Pilot drill of Densah® Burs (Versah Co., LLC., USA) that was inserted with a drill speed of 800 rpm to the desired depth in a clockwise direction under copious saline irrigation,

the preparation proceeded in the densification mode through the sequential stepped drilling with the Densah® Burs in a counterclockwise direction with copious irrigation. The diameter of the final drill inserted was 0.5 mm smaller than the implant diameter according to manufacturer instructions.
For the control group (conventional drilling group), the preparation of the implant bed was done using NucleOss T6 surgical kit. Beginning with the pilot drill followed by sequential drilling until reaching the final drill size which was equivalent to fixture size under copious saline irrigation in a clockwise direction. For both groups, the total preparation time was recorded from the beginning with the pilot drill until the final one.
The DI was installed into the implant site using the

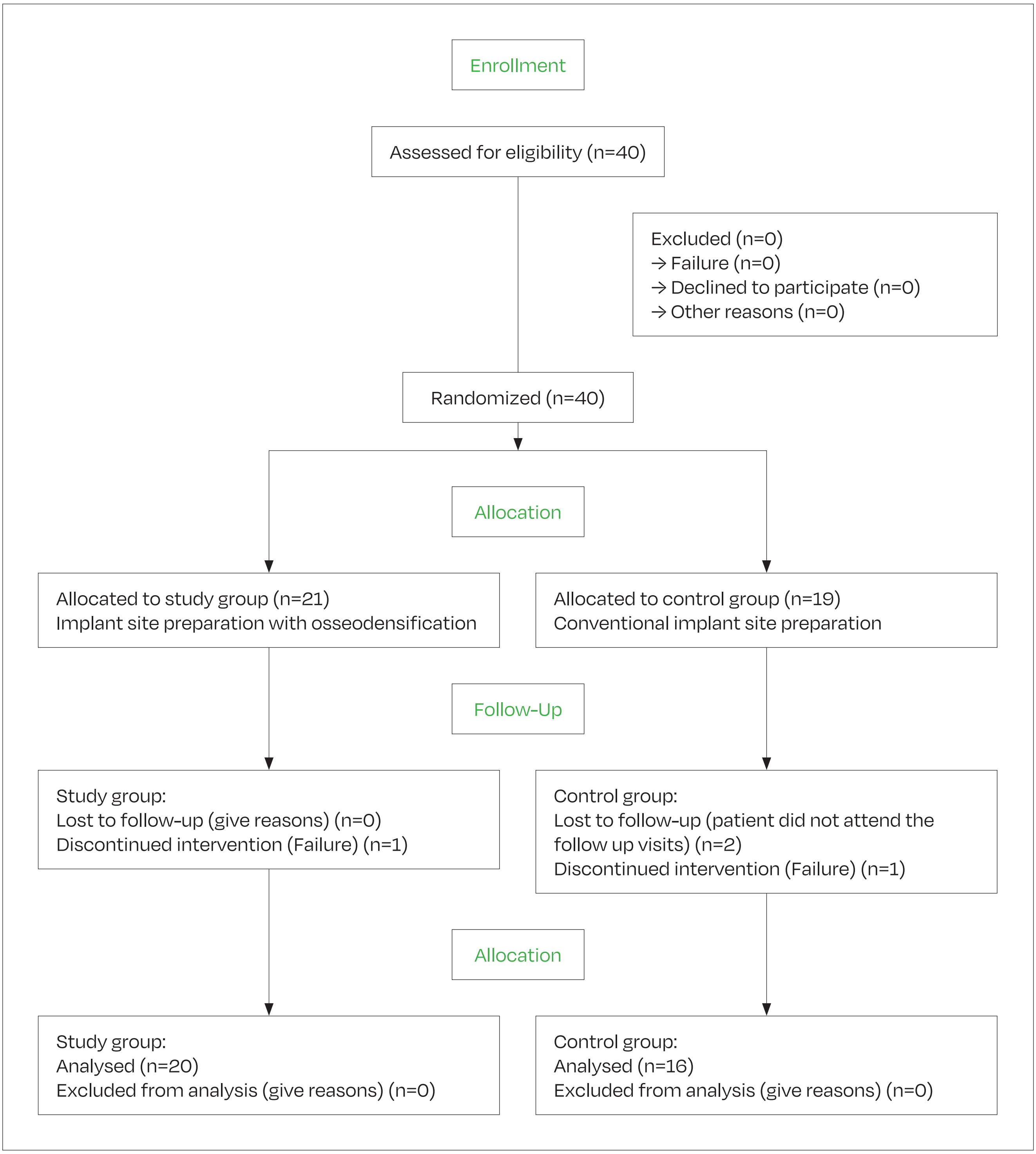

Fig. 1 Flow diagram of the basic steps of the study.

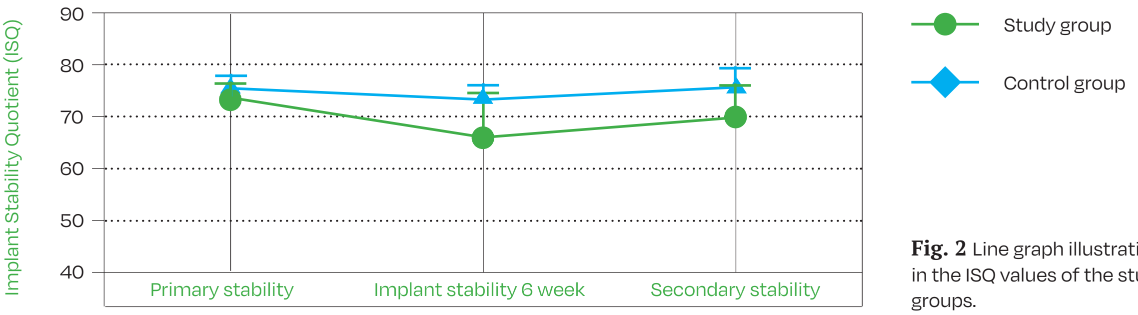

Fig. 2 Line graph illustrating the differences in the ISQ values of the study and control groups.

motorized method with the engine set at 50 rpm and the torque that was initially set at 20 Ncm to drive the implant into the requisite depth in which the platform of the implant was about 0.5-1 mm below the bone level, when the requisite depth of the implant could not be achieved, the torque was increased incrementally to 30, 40 and 50 Ncm. When the final seating of the implant could not be completed with the motorized method the implant was seated manually using a ratchet and the IT was recorded as more than 50 Ncm. Immediately after insertion of DI, primary stability was measured by using the Osstell Mentor (Göteborg, Sweden) with its smart pegs® type 6, and was recorded as implant stability quotient (ISQ). The measurements were repeated 2 times for each implant, with buccolingual and mesiodistal directions, and the mean of these measurements was recorded. Implant stability was also measured after 6 weeks, at the time of healing abutment placement, and after 12 weeks (secondary stability) in the same manner.

Study variables

The predictor (independent) variable in this study was the implant site preparation using either the OD technique or the conventional drilling technique.

The outcome (dependent) variables included; implant stability measured immediately after insertion (primary stability), at 6 weeks, and 12 weeks postoperatively (secondary stability) and recorded as ISQ, the insertion torque recorded as Ncm, and the preparation time measured in minutes.

Another outcome variable was the success and failure rate. The clinical success was determined by the lack of mobility, the lack of any signs and symptoms of infection, and a radiographic bone adaptation to the interface (3).

Other variables (covariates) included the recipient jaw, bone density in HU, and implant dimensions (diameter and length) in mm.

Statistical analysis

The statistical analysis was performed using GraphPad Prism version 6 for Windows (GraphPad Software, La Jolla, CA, USA). The descriptive statistics included means (standard deviations, SD) and median of the numerical data and frequency, and percentages for the categorical data. The Shapiro-Wilk normality test was used to determine the normality of the distribution of the numerical data. The inferential statistics included the use of Fisher's exact test and the Chi-square test for the categorical data, and the use of the unpaired t-test and repeated measure ANOVA test for the normally distributed numerical data, and the use of the Mann-Whitney test and the Friedman test followed by Dunn's multiple comparisons test for not normally distributed numerical data. The differences were considered significant at $P<0.05$.

RESULTS

This study included 20 patients with an age range of 21-60 years and a mean (SD) of 45.4 (10.8) and a median of 48 years, they consisted of 13 females (65%) and 7 males (35%). The patients received 40 DI with a mean number of DI per patient of 2.

The study group included 21 DI of which 1 failed during the early postoperative period, while the control group included 19 DI of which 1 failed during the early postoperative period, furthermore 1 patient who received 2 DI was lost to follow up. So the number of DI that were available for statistical analysis was 20 in the study group and 16 in the control group (Figure 1).

There were statistically non-significant differences between the two groups with respect to the covariates (Table 1) indicating that none of these factors acted as a confounding factor that may affect the outcome of the study.

There was a statistically non-significant difference in primary stability ISQ values between the two groups, while at 6 and 12 weeks postoperatively, the control group showed higher stability values (Table 2). The changes in implant stability values between the 2 groups are shown in Table 3, the drop in implant stability at 6 weeks compared to the primary stability was significantly more in the OD group than the control group. This significant difference was also observed in the differences in the values of primary and secondary stability (Figure 2).

In the OD group 10/20 (50%) DI were inserted with an IT > 50 Ncm, while the remaining DI were inserted with an IT ⩽ 50 Ncm with a median of 30 Ncm. In the conventional group 8/16 (50%) DI were inserted with

Variables	Control group (n=16)	Study group (n=20)	P value
Recipient jaw/number (%)			
Mandible	13 (81.3)	10 (50)	0.083 *
Maxilla	3 (18.7)	10 (50)	
Bone density, mean (SD), median/HU	269.6 (150.8), 270	221.1 (155.5), 202.6	0.121 †
Implant width (mm)/number (%)			
3.5	2 (12.5%)	8 (40%)	0.185 ‡
4.1	12 (75%)	10 (50%)	
4.8	2 (12.5%)	2 (10%)	
Implant length (mm)/number (%)			
8	2 (12.5%)	4 (20%)	0.539 ‡
10	13 (81.25%)	13 (65%)	
12	1 (6.25%)	3 (15%)	
SD, Standard deviation; HU, Hounsfield unit; *Fisher's exact test; † Mann Whitney test; ‡Chi-square			

Tab. 1 The differences in covariates between the two groups

Implant stability/ISQ	Study group (n=20)				Control group (n=16)				
	Mean	SD	Median	Range	Mean	SD	Median	Range	P-value
Primary	73.65	2.95	74.00	69-78.5	74.94	3.17	75.25	68-80	0.216 *
Primary	73.65	2.95	74.00	69-78.5	74.94	3.17	75.25	68-80	0.216 *
6 weeks	66.50	8.50	69.25	46-75	73.62	2.36	73.80	68-78	0.002 †
Secondary	70.43	6.42	72.25	51-77	75.63	4.01	75.75	67-83	0.005 †
SD, Standard deviation; ISQ, Implant stability quotient; *Unpaired t test; †Mann Whitney test;									

Tab. 2 Comparison of implant stability values between the two groups

Changes in implant stability	Control group/mean (SD), median ISQ	Study group/mean (SD), median ISQ	P value
Primary stability vs. Implant stability 6 weeks	1.319 (4.108), 0.9500	7.150 (8.869), 3.250	0.021 *
Implant stability 6 weeks vs. Secondary stability	-2.006 (3.701), -1.950	-3.925 (6.652), -3.000	0.300 †
Primary stability vs. Secondary stability	-0.6875 (5.385),-2.500	3.225 (6.586), 1.750	0.033 †
SD, Standard deviation; ISQ, Implant stability quotient; *Unpaired t test; †Mann Whitney test.			

Tab. 3 Changes in implant stability between the 2 groups

Preparation time/minute	Mean	SD	Median	Range	P-value
Study group	2.58	1.04	2.70	1.28-4.46	0.0001*
Control group	1.41	0.35	1.29	1.10-2.33	
SD, Standard deviation; * Mann-Whitney test					

Tab. 4 The difference in implant site preparation time between the two groups.

an IT > 50 Ncm while the remaining DI were inserted with an IT ⩽ 50 with a median of 35 Ncm. There was a non-significant difference between the two groups with respect to the DI that were installed with an IT ⩽ 50 or > 50 Ncm (p-value 0.627).
Regarding the preparation time, there was a statistically significant difference between the two groups, where the study group demonstrated longer preparation time than the control group (Table 4).
At the end of the healing period of 12 weeks, 20 out of 21 DI in the study group were stable and successfully osseointegrated, producing a survival rate of 95.2%, while 16 out of 17 DI in the control group (2 DI were lost to follow-up) were stable and successfully osseointegrated with a survival rate of 94.1%. The difference between the two groups was statistically

not significant P-value (1.0000)

DISCUSSION

In most implant systems, the typical expectation after DI placement for healing is that implant stability would change throughout healing/ osseointegration. Stability would go from primary higher stability to slightly decreased stability due to physiologic bone modeling/ remodeling, then back to ISQ values close to those observed initially (10).

In this study, the implants in the conventional drilling group maintained their high stability (> 70 ISQ) throughout the study period. They attained a significantly higher mean ISQ value for secondary stability than the OD group. The mean primary implant stability ISQ values seen in this study, in both groups, are regarded as high (11). The lack of a significant difference between the two groups suggests that the surgical technique did not affect the primary stability, possibly because there was enough bone volume present, as a requirement for inclusion in the study.

Almutairi et al (12) observed that there was no statistically significant difference in the Periotest readings for the implants placed in either the OD or the regular osteotomies and that the implants placed in regular drilling osteotomies had significantly better primary stability than the implants placed in OD osteotomies. As a result, the authors concluded that OD is not necessary in cases where there is good bone quality and quantity.

In the current study, the OD group experienced a significant drop in implant stability at 6 weeks after surgery when compared to the primary stability (mean difference 7.15 ISQ), whereas the decrease in implant stability for the control group (mean difference 1.32 ISQ) was not significant. This result is consistent with an earlier observational study (13) that was carried out at the same institution and investigated the impact of OD on implant stability change during the osseous healing period. In that study, the authors showed that the OD technique produced high primary stability followed by a significant decline in implant stability during the first six weeks postoperatively.

Other clinical studies, on the other hand, presented different results; Bergamo et al. (14) demonstrated that DI installed after OD showed higher overall ISQ values compared to the conventional subtractive drilling technique during the first six weeks for both arches and areas operated, they also reported that the OD presented higher insertion torque values than the conventional drilling technique with approximately 41% difference. It is worth noting that the latter study was a multicenter study that included 3 implant systems with narrow, regular, and wide implant diameters (3 mm to ⩾5 mm) and short, regular, and long implant lengths (> 6 mm to ⩾ 13 mm), it also included different bone mineral densities [D2-D4]. Whereas the current study was a randomized controlled study that included a single implant system with regular implant diameter and length and D3-D4 bone mineral density, this may explain the different results obtained in this study.

Also, Mello-Machado et al (15), in a randomized clinical study, compared OD drilling with standard undersized drilling in D3-D4 bone, and They concluded that OD enabled the concept of a bone healing chamber in low-quality bone without affecting implant stability or success rates.

The significant difference in stability between the two groups at 6 weeks may be attributed to the effect of condensation on the peri-implant bone that Wang et al (16) investigated in an animal study, the authors noted that condensation increased peri-implant bone density but did not improve implant stability, creating high interfacial strains and microdamage that led to prolonged periods of resorption and delayed secondary stability.

Heat generation also needs to be considered; Huwais and Meyer (6) demonstrated that implant site preparation using OD resulted in a 6 °C temperature rise compared to 3 °C with conventional drills. According to reports, heat produced during implant site preparation can inhibit the development of bone tissue at the bone/implant contact, which lowers the likelihood of osseointegration (17), It may result in osteocytic degeneration, hyperemia, necrosis, fibrosis, and an increase in osteoclastic activity (18).

Another factor that may be relevant to the difference in implant stability course throughout the study period between the two groups is the difference in geometry between the OD drills and the DI used. Implants implanted into implant beds prepared with drills of differing geometry offer less stability than implants inserted into beds with drills of similar geometry, as this inaccuracy may cause less initial bone-to-implant contact and empty spaces in certain places surrounding the implant body (19).

The biomechanical and histomorphometric outcomes of implants placed by the OD technique were investigated in a systematic review and meta-analysis (20) where the authors reviewed 9 animal trials and concluded that the scant information suggests that OD outperformed conventional drilling in terms of main implant stability, bone-implant contact, and bone area frequency occupancy. To offer stronger proof, they advised conducting further laboratory and clinical investigations. Another comprehensive study and meta-analysis that assessed the utility of the OD technique (21) included 8 animal studies and 3 human studies, and the authors concluded that the available studies do not allow for performing an objective assessment of the advantages of this technique; nevertheless, they demonstrated that OD is a valuable method to obtain high IT and bone to implant contact.

They also recommended more randomized clinical studies to support this evidence.

On the other hand, many other studies have shown that there was no significant difference between OD and conventional drilling methods as Sultana et al (22), in their clinical study, found no statistically significant difference in implant stability and crestal bone levels despite the small sample size and a short period of investigation. Also William et al (23), In a comparative histological study, concluded that throughout the experiment the OD technique using the Densah Bur did not differ significantly from the conventional drilling method in terms of bone area fraction, bone-implant contact, or bone mineral density around dental implants.

The primary stability measured by ISQ and IT values in this study showed similar results demonstrating non-significant differences between the two investigated drilling techniques. Both higher IT and ISQ values are positive markers for implant stability as well as lower micromotion, which can be crucial for early loading and later enhanced osseointegration (14).

Monje et al (24), in a systematic review, maintained that both ISQ and IT depend on the modulus of elasticity of the bone and that some relationship between them should exist. However, the authors suggest that higher IT values do not necessarily translate to higher ISQ values in some clinical cases, especially those related to undersizing of the osteotomy for an implant in porous cancellous bone. Other studies, on the other hand, demonstrated that IT and RFA are independent and incomparable methods of measuring primary stability with no relationship between them (25, 26).

The current study showed a non-significant difference in insertion torque between the OD and the conventional techniques. This finding contradicts most previous studies that observed a higher IT with OD technique (6, 14,27). In their systematic review and meta-analysis, Inchingolo et al (21) concluded that the OD drilling technique was regarded as an effective drilling technique for increasing implant IT in low bone density regions. Also, Bhargava et al (28), in an ex-vivo study, demonstrated that implants inserted following the OD protocol exhibited the highest IT values outperforming piezo devices, conventional drills, and osteotomes.

Implant site preparation time

There was a statistically significant difference in the preparation time between the two groups, where the OD group demonstrated longer preparation time than the control group, with a mean difference of about 1.2 minutes per single implant site preparation. Although this difference can be considered clinically not significant for a single implant site preparation, it may be clinically relevant for multiple implant site preparation. Prolonged operation time is a significant risk factor for postoperative complications in oral surgery patients (29).

Multiple implant placement may be a time-consuming procedure that may result in prolonged patient discomfort and prolonged tissue exposure, which may, in turn, amplify the inflammatory response and increase the risk of postoperative infection due to prolonged exposure to the oral environment [30]. Also, there is a direct relationship between the time of drilling and the amount of frictional heat generated indicating that as the time of drilling increases, the bone temperature is elevated (31).

The limitations of the study

The result of this study needs to be interpreted after considering its main limitations, which are related to the small sample size and the fact that no formal sample size calculation was conducted. Also, the researcher was not blinded to the allocation of the DI to the groups or the assessment of the variables.

CONCLUSIONS

Within the limitation of this study, it may be concluded that the OD drilling technique did not show a more favorable outcome regarding the implant stability changes, IT, and preparation time over that of the conventional technique and resulted in a significant drop in stability after 6 weeks postoperatively compared with that of conventional technique.

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