ORIGINAL RESEARCH

Comparative Evaluation of Osseodensification vs Conventional Osteotomy Technique on Primary and Secondary Implant Stability in Rabbit Model Split Body RCT

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Received on: 04 September 2024; *Accepted on*: 30 October 2024; *Published on*: 27 January 2025

Abstract

Aim and objective: To measure and contrast primary stability metrics, such as insertion torque values and implant stability quotient (IQS) at the time of implant placement, and secondary stability metrics, such as ISQ three months post-implant insertion, between implants inserted in osteotomy sites prepared with conventional drills and osseodensification drills (OD) in the femoral condyles of female New Zealand white rabbits, which are characterized by low-density D4 type bone.

Materials and methods: Eight female New Zealand white strain rabbits, each 14 weeks old and weighing approximately 2.5 $\pm$ 0.3 kg, were utilized for this study. Using aseptic techniques and local anesthesia, a 3.1 $\times$ 8 mm implant was inserted into the rabbit's left femoral condyle using conventional drills (group I) from the Zimmer surgical kit. Similarly, using Densah drills (group II), a 3.1 mm $\times$ 8 mm implant was inserted into the rabbit's right femoral condyle. Primary implant stability was evaluated using insertional torque and ISQ values during insertion of implants using a torque wrench and radiofrequency analyzer, respectively. Secondary implant stability was evaluated by measuring ISQ values three months after implant placement.

Results: Group I had a mean insertional torque of 31.13 $\pm$ 1.727 Ncm, while group II had 33.00 $\pm$ 1.309 Ncm. ISQ during insertion was 63.63 $\pm$ 5.927 in group I and 63.62 $\pm$ 7.615 in group II. After three months, ISQ was 67.25 $\pm$ 6.45 in group II and 75 $\pm$ 6.85 in group II. Significant differences were found in insertional torque ($p = 0.028$), ISQ after three months ($p = 0.0353$), and ISQ changes over time ($p = 0.001$), but not in ISQ at the time of implant placement.

Conclusion: The investigation demonstrated that implants placed using the OD exhibited superior initial stability and subsequent stability progression compared to those placed using conventional drilling techniques in a rabbit model.

Clinical significance: Primary and secondary implant stability are critical factors for successful implant treatment in clinical practice. Osseodensification demonstrates a higher insertional torque and implant stability quotient by enhancing bone density and volume surrounding implants. This enhanced stability can lead to improved osseointegration and reduced healing times, ultimately benefiting patients with compromised bone quality.

Keywords: Bone implant contact, Conventional drill, Densah drill, Implant stability quotient, Insertional torque, Osseodensification.

The Journal of Contemporary Dental Practice (2024): 10.5005/jp-journals-10024-3751

Introduction

Tooth loss due to illness and injury is a constant and unchanging element of human life. This vast history of tooth replacement is surprising. Archeological findings indicate that ancient societies made efforts to restore lost teeth by affixing artificial tooth substitutes to existing teeth using metal. In 1807, Maggiolo implanted gold and platinum into alveolar bone sockets, pioneering the idea of implant beds. Younger et al. introduced the concept of creating implant beds by transplanting teeth into artificial bone cavities. Greenfield later described "secondary stability," referring to the bone-implant interface. In the 1940s, animal tests showed that titanium was promising, leading Leventhal to recommend it for bone fracture stabilization. Strock used cobalt-chromium-molybdenum alloys for tooth replacement in 1937, but the early clinical success was inconsistent.[1] Today, dental implants are a dependable choice for replacing missing teeth.[2,3] The use of dental implants as substitutes for absent teeth has been progressively increasing, likely because of their good predictability and survival rates, as shown by several studies.[4,5] However, the importance of the number of failures persists, and it remains a challenging endeavour to reduce these failures in modern implant research.[6]

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How to cite this article: Arpudaswamy S, Ali SSA, Karthigeyan S, *et al*. Comparative Evaluation of Osseodensification vs Conventional Osteotomy Technique on Primary and Secondary Implant Stability in Rabbit Model Split Body RCT. J Contemp Dent Pract 2024;25(11): 1052–1059.

Source of support: Nil

The stability of the implant serves as an indirect measure of osseointegration.[7] The stability may be evaluated at two distinct levels: Primary stability and secondary stability. Primary stability is mechanical, resulting from friction between the implant and bone. Secondary stability involves new bone cell formation, leading to biological stability.[8] Achieving adequate initial stability is believed to lead to suitable secondary stability.[9] The main goal of implant surgery is to achieve adequate primary stability, which is strictly related to bone quality and quantity, implant design, and implant site preparation characteristics.[10,11] The degree of implant stability can be objectively assessed using insertion torque (IT) values obtained via surgical hand pieces or subjectively measured using implant stability quotients (ISQ) derived from resonance frequency analysis. Insertion torque values exceeding 35 N.cm and/or ISQ values above 68 are considered acceptable thresholds for predictable osseointegration and early loading. These values should not only be attained after implant placement, but also ideally sustained throughout the initial phase of osseointegration.[12]

Furthermore, in 2013, Huwais et al.[13] proposed a bone condensing procedure termed osseodensification, which uses specific densifying burs known as Densah burs to prepare bones for dental implant insertion. Conventional drilling entails the excision and extraction of osseous tissue. Utilizing Densah burs facilitates the creation of an environment that improves early primary stability by compacting the osteotomy site walls without removing material. The Densah burs have a distinctive design, characterized by several flutes and a pronounced negative tilt angle. These noncutting edges enhance bone density by enlarging the osteotomy and spinning anticlockwise at 800–1200 rpm.[14,15] In addition, preclinical, biomechanical and histological investigations have shown that OD exhibits a much higher insertion torque and ISQ than conventional drilling.[16,17] The OD method indicate both short- and long-term efficacy in many clinical scenarios, thereby improving the primary and secondary stability of implants.[18–20] However, few studies have assessed IT and ISQ levels for primary stability during implant insertion using OD and conventional drills, as well as the development of secondary stability in D4 bone, and have produced inconsistent and obscure results.

Conflict of interest: Dr Rahul M shetty is associated as the Section Editor of this journal and this manuscript was subjected to this journal's standard review procedures, with this peer review handled independently of these Editorial board members and their research group

Therefore, this study sought to evaluate the efficacy of osseodensification-drill (OD)-inserted implants relative to conventional drill-inserted implants in low-density bone. The study aimed to assess primary stability by measuring IT and ISQ values at insertion, and secondary stability by calculating the ISQ value after three months, comparing implants inserted with conventional drill designs and osseodensification (OD) drills in the femoral condyles of New Zealand White rabbits (Oryctolagus cuniculus), which represent low density bone. Thus, the study postulated the null hypothesis that there is no significant difference in primary and secondary stability metrics between implants placed using a conventional drill and those implanted using an OD.

Materials and Methods

Eight female New Zealand white rabbits (Oryctolagus cuniculus), were used in this split-body randomized clinical trial, CONSORT is shown in Figure 1. The study was conducted between January and April 2023. The study was conducted at Skanda Life Sciences Pvt. Ltd., in collaboration with the Sree Chitra Tirunal Institute for Medical Sciences and Technology Medical Sciences and Technology in Thiruvananthapuram. The research protocol was approved by the IAEC Committee of Skanda Life Sciences (IAEC number IAEC-SLS-2022-076). This study was conducted in accordance with the ethical standards established by the CPCSEA Guidelines for Animal Welfare. All experimental rabbits were housed in stainless-steel cages measuring (Length 76 cm × Width 51 cm × Breadth 46 cm). The cages were equipped with pellet food storage and a bottle with a stainless steel sipper tube for drinking water. All rabbits were provided potable drinking water and certified standard pelleted laboratory animal food from Krishna Agro Industries Ltd., Pune, India. The temperature and relative humidity in the animal room

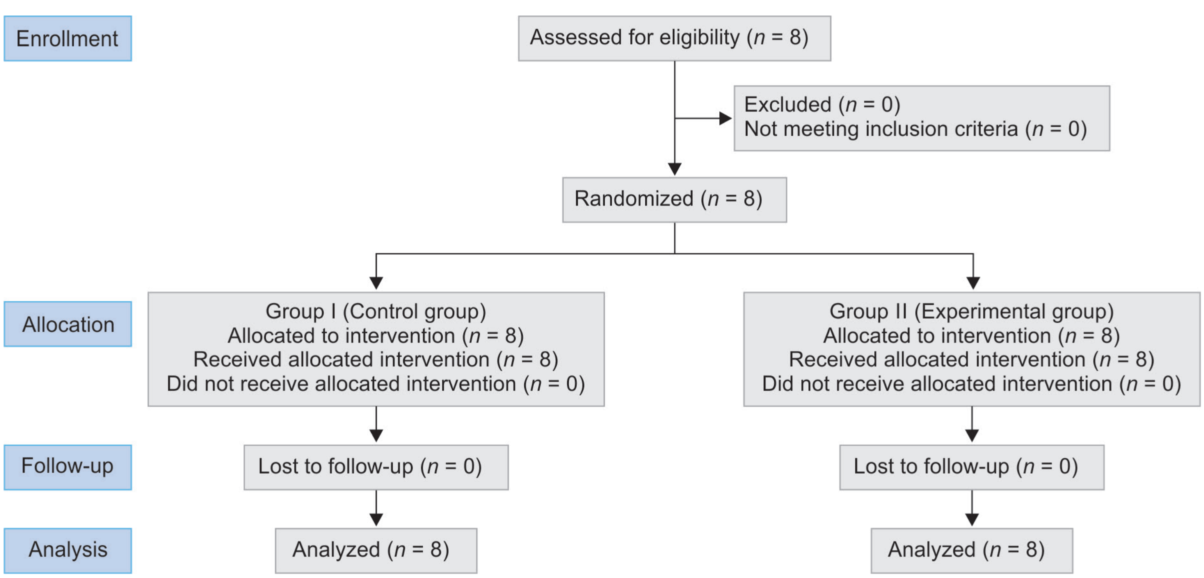
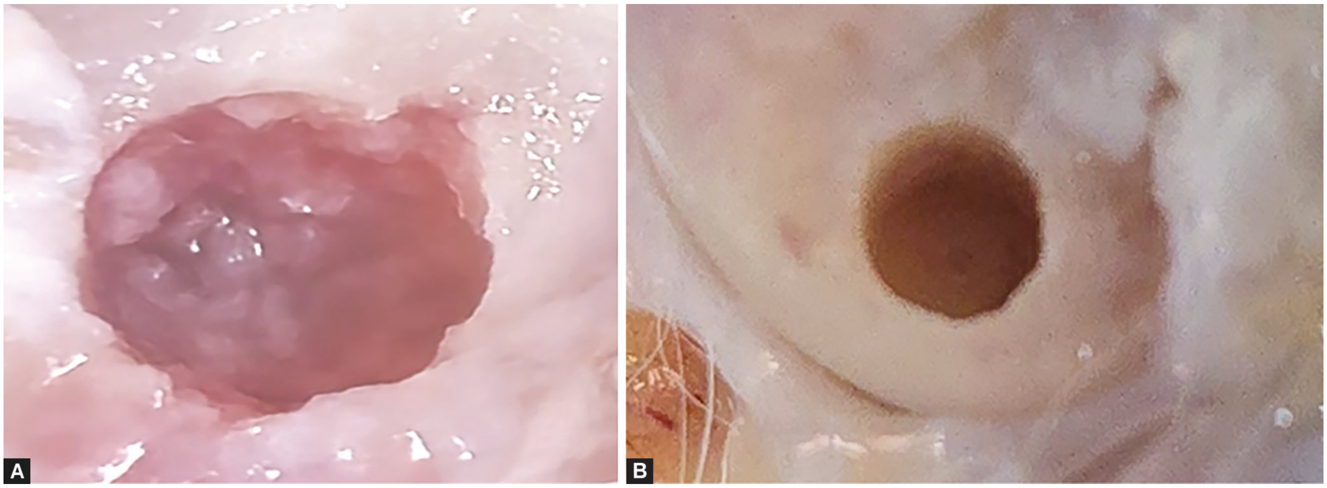


Fig. 1: CONSORT flowchart showing the progression through phases of a split-body randomized controlled trial



Figs 2A and B: Clinical photographs showing complete exposure of femoral condyle and prepared osteotomy site: (A) Conventional drill; (B) OD drill

were maintained at 20 ± 3 C° and 30–70%, respectively. Lighting was regulated to provide 12-hour periods of light and 12-hour periods of darkness within a 24-hour timeframe. The room was equipped with an air conditioner and was provided with fresh air with a minimum of 12 air changes per hour.

Only female rabbits, aged 14 weeks, with excellent general health, showed no signs of underlying medical conditions or physical deformities and were free from infections or diseases that met the inclusion criteria for the study. All the rabbits that satisfied the selection criteria were randomly selected. The left femoral condyle of the rabbits was classified as group I ($n = 8$), where the osteotomy site was prepared using conventional drills, and the right femoral condyle of the rabbits was classified as group II ($n = 8$), where the osteotomy site was prepared using an OD.

The surgical procedure was conducted under general anesthesia using intramuscular injections of a mixture of 0.2 mg/kg Xylazine and ketamine (1 mg/kg) using the technique described by Duan R et al.[21] Post-anesthesia, the surgical sites were shaved, cleaned with iodine, and covered with sterile drapes. A longitudinal skin incision of 3 cm was made on the lateral femoral condyle. The femoral condyle was exposed following reflection of the entire overlying periosteum. Subsequently, drilling was performed on the right femoral condyle using a Densah drill and on the left femoral condyle using a conventional drill (Fig. 2). To prevent heat generation and potential bone necrosis, the surgical site was first drilled the surgical site at a low speed (800 rpm) with a pilot drill, supplementing it with continuous external irrigation with a cold, sterile 0.9% sodium chloride solution. After the pilot drill, the osteotomy in group I was executed using a conventional drill (Implant Drills-Zimmer System, Zimmer Dental, USA) with a 2.4 mm drill bit, achieving a precise depth of 8 mm in the rabbit's left femoral condyle. In group II, the osteotomies were performed to a depth of 8 mm using Densah drills (Versah, Jackson, Michigan, USA), utilizing a two-step osseodensification technique for soft bone. The operation began with a clockwise operation of the pilot drill, followed by an anticlockwise operation of the VT1525. The surgically established osteotomy sites received a 3.1 × 8 mm implant (Zimmer Mtx, Biomet Dental, USA) in both cohorts.

The implants were manually threaded into the osteotomies in both groups to the bone level. The final insertion torque was measured for groups I and II using a calibrated torque wrench at this point. Osstell Beacon resonance frequency device (Osstell, Gothenburg, Sweden) was used to monitor implant stability. The SmartPeg was placed in the Mount. The SmartPeg was attached to the implant by manually screwing the SmartPeg Mount with a force of 4–6 Ncm. The ostell device instrument tip was brought close to the top of the SmartPeg without touching it, positioned at a 45-degree angle relative to the SmartPeg. An audible sound from the ostell device signalled the initiation of the measurement, and the measured data was displayed on the upper screen of the device along with a colored light indication below the tip which suffices the readings. The ISQ values was recorded and tabulated for group I and group II. After completing the measurements, the SmartPeg was removed. All measurements were performed by the same experienced clinician. After implant placement, the surgical site was closed with Trusilk (braided non-absorbable suture material), and the wound was dusted with Nebasulf antiseptic powder. The animals were placed under incandescent light for 45 minutes–1 hour, to maintain the body temperature during their recovery from sedation. Enrofloxacin 5%–5 mg/kg and Meloxicam 5 mg/mL, 0.1–0.2 mg/kg were administered 7–5 days respectively to control postoperative pain. For the assessment of ISQ after three months of implant placement, all previously indicated surgical protocols were reiterated, and the normal methodology for assessing ISQ was also repeated; ISQ was assessed 3 months post-implant implantation. The surgical site was closed as previously detailed.

All the measurements thus obtained from the study were tabulated and subjected to statistical analysis using SPSS version 23. The data of the study was subjected to a normalcy test using the Shapiro–Wilk test, which showed a normal distribution of the data with a p-value ≥ 0.05. Hence, parametric tests were applied for the study. The independent t-test was used to compare the means between the groups. The dependent t-test was used to compare the means within the group. Karl Pearson product movement correlation was used to correlate the findings.

Results

In group I, the mean torque applied during implant insertion was 31.13 ± 1.727 Ncm (mean ± SD). In group II, the mean torque applied during implant insertion was 33.00 ± 1.309 Ncm (mean ± SD). A statistically significant difference was noted between the groups

Table 1: Comparison of mean insertion torque measured during placement of implants between the two groups using independent *t*-test

Groups	*Mean ± S.D*	*Mean diff*	*p-value*
Group I ($n = 8$)	31.13 ± 1.727	−1.87	0.028*
Group II ($n = 8$)	33.00 ± 1.309		

*$p \leq 0.05$ will be considered as statically significant

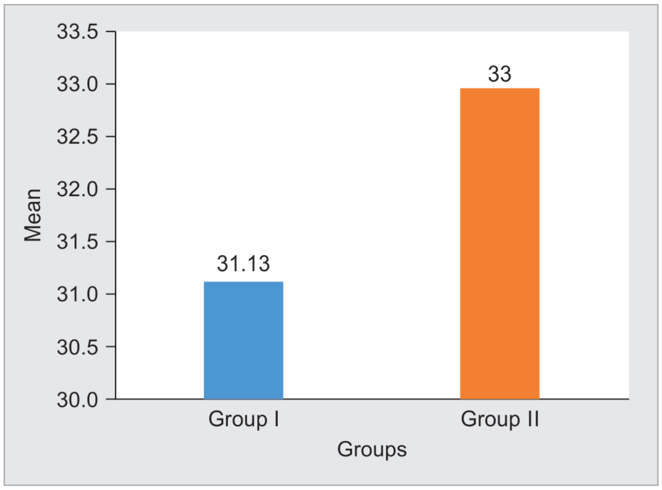


Fig. 3: Depicting the comparison of mean insertional torque measured during placement of implants between the two groups

Table 2: Comparison of mean implant stability quotient measured during placement of implants between the two groups using independent *t*-test

Groups	*Mean ± S.D*	*Mean diff*	*p-value*
Group I ($n = 8$)	63.63 ± 5.927	0.00	1.00*
Group II ($n = 8$)	63.62 ± 7.615		

*$p \leq 0.05$ will be considered as statically significant

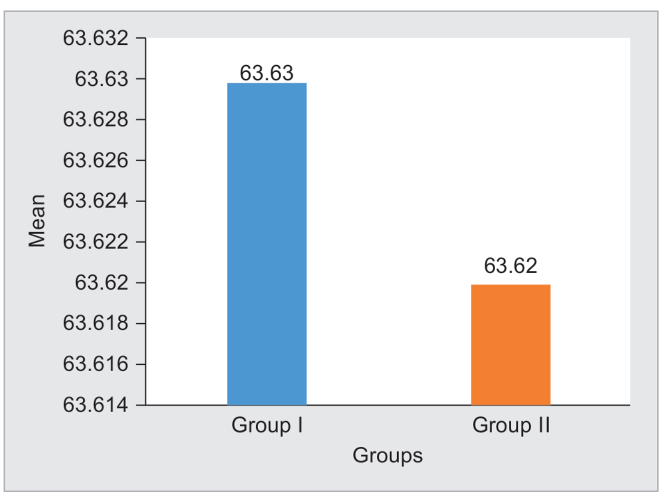


Fig. 4: Depicting the comparison of mean stability of the implant stability quotient measured during placement of implants between the two groups

Table 3: Comparison of mean implant stability quotient measured after three months of placement of implants between the two groups using an independent *t*-test

Groups	*Mean ± S.D*	*Mean diff*	*p-value*
Group I	67.25 ± 6.45	−7.75	0.0353*
Group II	75 ± 6.85		

*$p \leq 0.05$ will be considered as statically significant

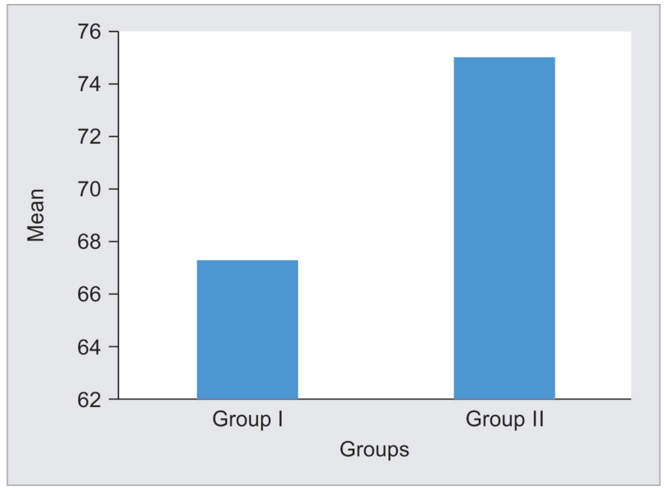


Fig. 5: Depicting the comparison of mean implant stability quotient measured after 3 months of placement of implants between the two groups

Table 4: Comparison of ISQ scores during insertion of implants and after 3 months of placing implants in group I and group II by dependent *t*-test

Groups	*Time*	*Mean*	*SD*	*p-value*
Group I ($n = 8$)	At insertion of implants	63.63	5.93	0.0001*
	After 3 months of insertion of implants	67.25	6.45	
Group II ($n = 8$)	At insertion of implants	63.62	7.61	0.0001*
	After 3 months of insertion of implants	75.00	6.85	

*$p \leq 0.05$ will be considered as statically significant

with a *p*-value of 0.028, as seen in Table 1 and Figure 3. The mean ISQ measured during insertion of the implants in group I was 63.63 ± 5.927 (mean ± SD), whereas in group II, ISQ was 63.62 ± 7.615 (mean ± SD). The groups, when compared, showed no statistically significant difference between the groups, as the *p*-value was 1.00, as shown in Table 2 and Figure 4. After 3 months of implant placement, the mean ISQ in group I was 67.25± 6.45 (mean ± SD), whereas in group II ISQ was 75 ± 6.85 (mean ± SD). A statistically significant difference was noted between the groups with a *p*-value of 0.0353, as shown in Table 3 and Figure 5. When comparing ISQ using a dependent *t*-test within the groups, specifically at insertion and after three months of implant insertion, there was a statistically significant difference between the ISQ intervals in groups I and II, with *p*-values of 0.0001 and 0.0001, respectively, as indicated in Table 4 and Figure 6.

The Karl Pearson product movement correlation, when performed, showed a statistically significant, very strong positive correlation between ISQ during insertion and ISQ after three

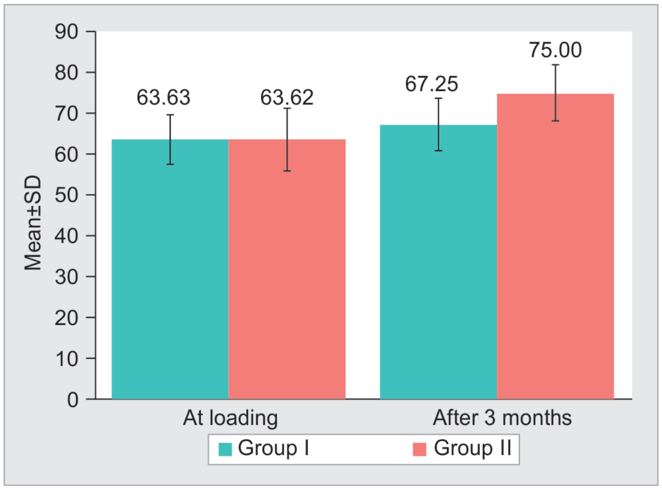


Fig. 6: Depicting the comparison of ISQ scores during insertion of implants and after 3 months of placing in groups I and group II

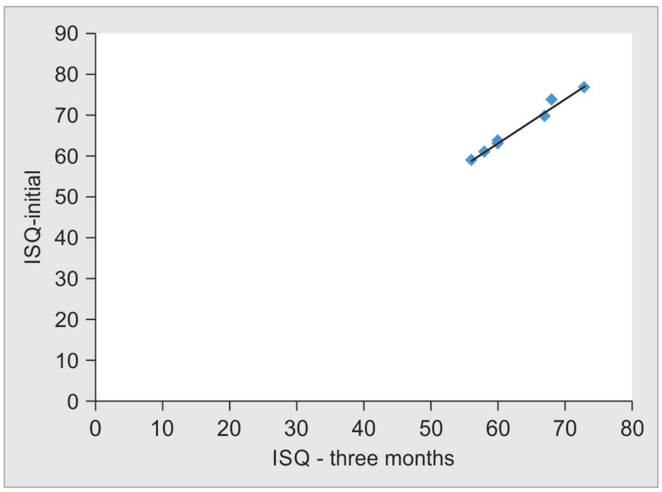


Fig. 7: Depicting correlation between ISQ during insertion of implants and after 3 months of placing implants using conventional drill

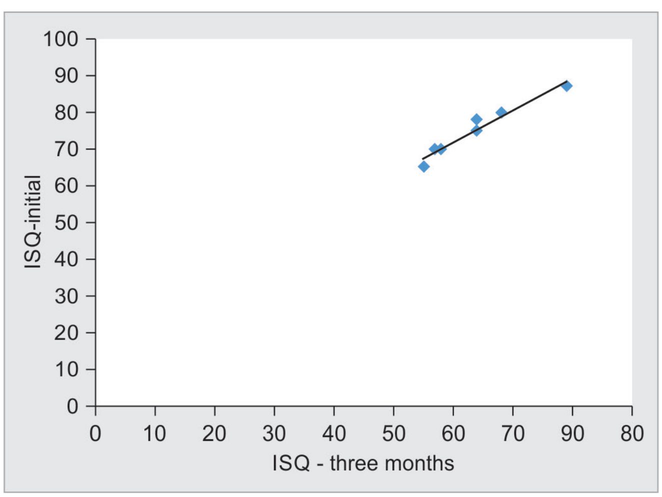


Fig. 8: Depicting correlation between ISQ during insertion of implants and after 3 months of placing implants using osseodensification drill

months of implant insertion in group I ($r = 0.9889$, $p = 0.0001$, Fig. 7), as well as in group II ($r = 0.9730$, $p = 0.0001$, Fig. 8). A fair positive correlation was also seen between ISQ during insertion of the implant and insertional torque ($r = 0.5732$), which was not statistically significant. A negative correlation was also noted between insertional torque and ISQ during insertion of implants ($r = -0.6229$, $p = 0.0990$), insertional torque and ISQ after three months of insertion of implants ($r = -0.5416$, $p = 0.1660$), in group I only. However, these negative correlations were not statistically significant.

The study's findings suggest that implants implanted using OD exhibited significant superior primary stability and secondary stability when compared to implants implanted using conventional drills.

Discussion

To achieve successful osseointegration, it is vital to choose surgical equipment that improves implant stability in native bone. This is especially true in situations where bone availability and quality are not optimum.[22–24] Historically, calculated curves of primary vs secondary stability development indicate that a stability drop often occurs 2–4 weeks post-implantation.[25] To overcome the inherent limitations of conventional drill procedures, which eliminate bone particles, researchers have developed an alternate technique known as OD, which compacts these particles into the osteotomy wall to preserve bone.[14]

An effective osteotomy for dental rehabilitation ensures the precise preparation of the implant bed through a series of drills, preventing tissue damage from overheating.[24] In clinical practice, it is crucial to reach high levels of biomechanical stability to keep up with early loading schedules, especially for bone types with low density.[26] OD drilling has been shown to improve bone quality as the osteotomy size increases, ensuring superior levels of physical interlocking at the implant interface, particularly in difficult situations.[27–29] In preclinical animal models of OD, histomorphometric studies have revealed an increased bone mineral density zone around and apex to the osteotomy wall as a result of compacted autograft particles acting as starting points for new bone formation, which speeds up the osseointegration process.[30–32] This method has also shown that it can seal and bridge spaces between threads and, at the same time, reverse the compression caused by the bone spring-back effect, which is caused by the residual elastic strain created during osteotomy.[33]

Implant IT and ISQ are two recognized methodologies that are assessed using a torque wrench and a radiofrequency analyzer (RFA), respectively. Elevated IT and ISQ values indicate favorable implant stability and reduced micromotion, which are crucial for quick loading and enhanced osseointegration.[10,11] Animal studies suggest that osseodensification enhances bone density, primary stability, and the proportion of bone-implant contact. Studies have shown that an insertion torque of 30–60 Ncm is best for implant osseointegration.[34] Trisi et al.[35–37] found that 45 Ncm is best for immediate placement in low-density bone. Other studies have recommended early loading of implants at 45 cm or higher.[38,39] In contrast, Duyck et al.[36] discovered that an insertion torque greater than 45 N resulted in an elevated likelihood of bone microfractures. This, in turn, triggers a more pronounced bone resorption response at both the molecular and cellular levels, ultimately leading to a substantial decrease in bone stability during the first three weeks of the healing process. In randomized clinical trials, high insertion torque (50 N) has been shown to have a higher rate of marginal bone loss and soft tissue recession than normal torque (<50 N).[37] However, recent systematic studies have not found significant differences between bone loss around implants inserted with high torque and those with normal or moderate torque.[38]

Animal studies have indicated that implants inserted into low-density bone using the osseodensification surgical approach had significantly higher insertion torque values than traditional osteotomies, irrespective of implant area.[39]

Several studies have shown that the assessment of implant stability using RFA is reliable, noninvasive, and useful at any point after implant placement and during the follow-up period.[40,41] According to previous studies, there is still no clear definition of the normal range of ISQ values for properly osseointegrated implants when used as a single method.[27,28] However, higher ISQ values are often associated with more stable implants in the healing phase. A significant disagreement persists to date. However, Aragoneses et al.[42]conducted a clinical experiment, which revealed average implant stability quotient (ISQ) values of 69.62 for 3.7 mm implants, 72.02 for 4.0 mm implants, and 69.67 for 4.3 mm implants. Another study by Sadeghi et al.[43] found that the primary ISQ for implants placed using conventional and OD) techniques was 67.4 $\pm$ 10 and 71, respectively. Yet another, study by Bafijari D et al.[44] has shown that primary stability ranges from 63.89 $\pm$ 6.99 units, with a considerable rise to 70.25 $\pm$ 9.30 units seen during the first and third months. Numerous studies indicate that implants placed using OD drills consistently provide superior ISQ values both during insertion and after three months compared to those placed with conventional drills.[45] Hassan et al.[46] separate research, using a split-mouth design with 14 implants, demonstrated that the osseodensification technique enhances the healing process and maintains the integrity of the surrounding bone after placing dental implants. This research design differed methodologically in terms of the sample size, factors examined, implant placement, measurement methods, and follow-up duration.[47] The current study was a split-body trial. Eight 14-week-old New Zealand white strain rabbits were used in the trial for comparison with conventional drills using the Zimmer surgical kit to place implants in the left femoral condyle and Densah drills (OD drills) to place implants in the right femoral condyle. The study tested both groups to determine the IT value during insertion, ISQ value during insertion, and ISQ value three months after implant insertion.

This study showed that implants inserted with OD drills had a higher mean insertion torque value than those inserted with conventional drills. However, the IT values in both groups were lower than the optimal range described by Trist P et al.[32] The increase in insertional torque values in implants loaded with Densah drills compared to conventional drills is in accordance with the studies of Lahens et al.,[31] Alifarag et al.,[16] and Oliveira et al.[17] in sheep models. This increase in the present study may be attributed to the shape of drills conventional drills typically have three flutes with cutting edges to remove bone during drilling; in contrast, densah burs have four or more flutes with noncutting edges these noncutting edges compress the bone towards the osteotomy wall.[14] Further, the increase in insertional torque values in the densah drill technique in the present study may also be attributed to anticlockwise (CCW) directed densitometry drilling, which resulted in an increase in bone density around the osteotomy site.[32]

In the present study, the mean ISQ measured at the time of implant insertion showed no difference in ISQ value between the conventional and densah drill strategies. However, the current study showed a statistically significant difference pertaining to the ISQ values of implants placed using the conventional drill method and implants placed using the OD drill approach 3 months after implant insertion. The study results showed that osseodensification was more successful in achieving secondary stability than the traditional technique. These findings align with those of previous studies conducted by Aboelnaga et al.[45] in sheep models, which also reported increased levels of secondary stability in OD drills compared to standard drills. The lack of difference in ISQ during implant insertion between the conventional drill method and the Densah drill approach in this study could potentially be attributed to the level of inter-operator reliability and repeatability of RFAs procedures, as well as the micromobility of implants and the density of bone.[48–54] Furthermore, the research demonstrated that secondary implant stability, assessed as ISQ three months post-implantation, was considerably higher than primary stability, measured as ISQ during implantation, in both the conventional and OD drill groups. There was a strong positive correlation between the primary and secondary magnetic RF values in both the conventional ($r = 0.9889$, $p = 0.0001$) and OD drill groups ($r = 0.9730$, $p = 0.0001$). Findings from this study show that obtaining sufficient primary stability (ISQ values above 60) leads to good secondary stability development, regardless of the drilling method used. Baldi et al.[49] and Degidi et al.,[50] showed a positive correlation between ISQ and insertion torque. In contrast, studies by Da Cunha et al.[51]and Açil Y et al.[52] revealed no correlation between ISQ and insertion torque. The current study demonstrated a significant positive correlation between the ISQ during implant insertion and insertional torque as well as between insertional torque, and ISQ after three months for implants placed using OD drills. This study's findings is significant since both variables (Ncm and ISQ) are independent and represent distinct facets of fundamental stability, but they behave in a way that is related.[53]

The study's findings showed a statistically significant difference in primary and secondary stability between implants placed with conventional drills and OD drills (densah drills). Consequently, the null hypothesis is rejected. The results of this study suggest that interfacial stress and the peri-implant tissue strain that come from the frictional forces created by the interaction between osteotomy and macro geometry during implant placement control the mechanical interlocking that is needed for better primary stability and a better bone healing response.[22–24] Furthermore, it can be inferred that the bone tissue can tolerate certain levels of compressive strain, even beyond the yield point, without hindering osseointegration. This elasticity improves physical contact at the bone implant interface, resulting in higher IT and ISQ values.[54] When the strain level significantly exceeds the yield threshold, plastic deformation and micro crack production may trigger considerable interfacial bone remodeling, leading to reduced initial stability and a shift from primary to secondary stability.[24]

The omission of radiographic indicators for assessing BIC and the lack of evaluation of biological markers that regulate bone metabolism, and which may be involved in the bone repair process, constrain this research. The study demonstrated that OD drilling implants outperformed conventional drilling in terms of secondary stability, especially in instances of lower bone density.

Notwithstanding the approach's positive results, it is essential to conduct more meticulously designed prospective cohorts and long-term clinical studies in humans to validate the biological response of peri-implant bone and determine the therapeutic effectiveness of this technique.

Conclusion

Osseodensification signifies a notable achievement in dental implantology. This method aids in the conservation of existing bones, thereby reducing the likelihood of dehiscence or fenestration. This research has shown that the osseodensification approach enhances bone density and improves volume around implants, likely due to improved bone-to-implant contact and stability. Due to its capacity to enhance bone-to-implant contact, it may enhance the durability of dental implants in clinical situations with low-density bone.

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