Comparative assessment of BMP-9 levels and clinical implant parameters in immediately restored implants using bone compaction drilling versus conventional drilling: a randomized controlled study.

ABSTRACT

Background-This study aimed to compare the effects of bone compaction drilling and conventional drilling techniques on bone marker BMP-9 and clinical implant parameters.

Materials and Methods: Forty-two participants were randomized into two groups (n = 21 each): OD and CD. Randomization was computer-generated with allocation concealment, and both participants and outcome assessors were blinded. Over a 6-month follow-up, peri-implant crevicular fluid (PICF) levels of bone morphogenetic protein-9 (BMP-9), implant stability, and crestal bone loss were evaluated.

Results: At 2 weeks, the CD group exhibited significantly higher BMP-9 levels (177.67 ± 8.24 pg/mL) than the OD group (150.43 ± 4.96 pg/mL; $p < 0.05$). By 16 weeks, the OD group showed greater BMP-9 expression (440.90 ± 33.57 pg/mL vs. 423.62 ± 15.58 pg/mL). Implant stability was consistently higher in the OD group at all time points, with ISQ values initially declining at 2 weeks and increasing thereafter in both groups. The OD group also demonstrated significantly less crestal bone loss at each follow-up interval *($p <.05$).*

Conclusion:

Bone compaction drillingor osseodensificationusing Densah burs demonstrated enhanced secondary healing, as indicated by increased BMP-9 levels, along with improved implant stability and reduced crestal bone loss compared to conventional drilling. These findings indicate a potential biomechanical advantage for implant placement.

Keywords: BMP-9;Crestal bone loss; Immediate restoration; Implant; Implant stability; Osseodensification

INTRODUCTION

Dental implants have completely transformed the realm of oral rehabilitation with a well-documented success rate typically ranging between 90%- 95% after 10 years of follow-ups.[1,2] However in the maxillary arch, there's often a deficiency in both the quality and quantity of bone, because of which achieving successful osseointegration of implants is particularly challenging. Insufficient bone surrounding implants may adversely affect implant stability, percentage of bone-to-implant contact (BIC) and bone volume (BV), which consequently delays osseointegration.[3]

In the past, undersizing the osteotomy,[4]osteotome technique by Summer’s[5] and implant site preparation using peizosurgery[6] have been introduced to improve osseointegration in low bone density areas. However major drawbacks like increased mechanical strain on the bone leading to bone compression and ischemia, increased marginal bone loss and risk of overheating associated with ultrasonic devices reduced the clinical implications of these techniques.[6,7,8] Also use of wider, longer implants with a reverse buttress, larger thread depth, narrow pitch and a self-tapping design were reported to be beneficial in compromised bone sites.[9]

Huwais in 2013[10] developed an innovative osteotomy preparation method known as osseodensification (OD). This bone compaction drilling technique sparked a significant change in the methods used for implant site preparation, being a non-subtractive drilling technique. Osseodensification technique is indicated where there is insufficient quantity or quality of bone. Relying on the elastic and plastic properties of bone, the osseodensification (OD) technique aids in preserving the bone bulk, increasing the density at the implant preparation site and also accelerate the formation of new bone.[11]

Various animal studies[12-16]have reported that the use of osseodensification or bone compaction drilling compared to conventional drilling has resulted in higher insertion and removal torque values, improved primary and secondary implant stability, higher BV and BIC. This favours and rationalizes the use of bone compaction drilling technique. Although numerous studies on animal models exists, its clinical impact in humans during bone healing remains limited. Also, our understanding of the molecular mechanisms involved in the process and its impact on crestal bone loss is lacking.

Various bone turnover markers act on the regulation of molecular and biological events leading to osseointegration. Bone morphogenetic proteins (BMPs) belong to the transforming growth factor beta (TGF-β) family. They play a crucial role in the formation of bone and differentiation of stem cells. BMP-9, alternatively referred to as Growth Differentiation Factor 2 (GDF2), is recognized as one of the most potent osteogenic bone morphogenetic proteins.[17] The levels of BMP-9 during the early and late stages of peri-implant bone healing may reflect the biological advantages conferred by osteogenic differentiation[18]Additionally, implant stability and crestal bone loss (CBL) remain critical indicators of long-term implant success.

This study aims to compare bone compaction drilling and conventional drilling techniques using both molecular (BMP-9 expression) and clinical (implant stability, CBL) parameters. The null hypothesis posits that there is no significant difference between the two techniques.

MATERIALS AND METHODS

A two yearstudy was carried out in a tertiary hospital setting. Ethical approval (XIV-PGTSC-IIA/PII) was obtained and registration in the Clinical Trial Registry of India (ICMR-NIMS) (CTRI/2023/03/050409)was done prior to the commencement of the study. The study followed a randomized controlled design (computer-generated random numbers) with participants and outcome assessor blinding following the CONSORT (Consolidated Standards of Reporting Trials) guidelines.[19] Allocation of treatment was concealed using opaque sealed envelope. Sample size of 21 participants in each group was calculatedbased on the minimum difference d = max (σ1, σ2), considered to be clinically significant.Type I error $\alpha = 5\%$ corresponding to 95% confidence level, Type II error $\beta = 10\%$ for detecting results with 90% power of study.[17]

Participants visiting prosthodontics clinic for rehabilitation of a single edentulous space in the maxillary arch that could be restored with an implant supported single unit crown were screened as per predetermined inclusion and exclusion criteria (Figure 1). Participants aged 18-60 years of both genders, capable of comprehending and signing an informed consent, with a bounded edentulous space in the maxillary arch post-extraction for at least 3 months were included. Keratinized tissue >2 mm from mid crest to mucogingival junction, simplified oral hygiene index of 0-3 indicating good to fair oral hygiene and adequate bone for optimal implant placement and a safe distance (≥2 mm) from vital tissues and an opposing dentition with a stable occlusion were assessed and included in the study.

Participants with history of systemic conditions or under medications, presence of any local risk factor,history of treated periodontitis, smoking,any parafunctional habits, pregnant or lactating women were excluded. Also participants fulfilling any criteria either group 1 or 2 according to second ITI (International Team of Oral Implantology) Consensus report were excluded from the study.[20]The participants underwent comprehensive clinical examination, laboratory investigations, and radiological assessment before being enrolled in the study.

All patients were prescribed prophylactic antibiotics before implant surgery. Drilling technique for bone compaction drilling or osseodensification group (OD) was using Densah Burs (Versah International, USA) (Figure 2 and3) and for CD group was using the conventional drills supplied by the manufacturer corresponding to the implant (Figure 2and 4). MIS implants (MIS Implants Technologies Ltd, Israel) were used which have an SLA treated surface with V shaped design, pitch of 1.0 mm, thread depth of 0.5 mm and an internal hexagonal connection. Implants were placed 0.5 mm subcrestal into the prepared osteotomy with the rate of 30 Ncm, and tightened using a torque wrench.Following implant placement with either technique, immediate restoration was done with provisional poly methyl methacrylate (PMMA) crown fabricated using CAD/CAM within 1 week withprosthesis held out of occlusion.[21]Afollow-up program of six months was designed for all participants. Final implant prosthesis was fabricated after appropriate healing time (6 months) abiding by the principles of implant protected occlusion.

Samples for the assessment of BMP-9 levels were collected at 2 weeks, 8 weeks and 16 weeks post-implantation. Samples were collected prior to clinical measurements to minimize blood contamination. Area around implant was isolated with the help of cotton roles and any layer of supragingival plaque, if present was removed carefully. After air drying the area, sterile absorbent paper points were inserted in the sulcus until light resistance was felt and held steady for 30 seconds. For each implant site, four samples were collected per time point and were transferred into a single Eppendroff tube containing 100μl of phosphate buffer solution.(Figure 5A).Visibly contaminated samples with blood were discarded and recollected after ensuring haemostasis. Samples were centrifuged at

1000 rpm for 10 minutes and stored at -80°C. While PICF volume was not measured directly, standardization was ensured by consistent sampling time and PBS dilution. BMP-9 levels were quantified using sandwich ELISA technique (E0051Hu, Bioassay Technology Laboratory, Zhejiang, China) and expressed in picogram/millilitre.

Primary implant stability was assessed immediately after implant placement. Smart Peg (MIS Implants Technologies Ltd, Israel) specific to the implant system and the restorative platform diameter was utilized and subsequently resonance frequency analysis (RFA) was conducted using Osstell (Integration Diagnostics, Savedalen, Sweden)). Average of three readings was recorded in terms of implant stability quotient (ISQ). Secondary stability was recorded in similar way in terms of ISQ values assessed at 2 weeks, 8 weeks and 16 weeks. (Figure 5B).

Standardized periapical radiographs were captured using the long-cone paralleling technique, with individualized sensor holders employed for consistent and reproducible positioning. The acquired images were analysed using ImageJ software (National Institutes of Health, Bethesda, MD, USA). Dimensional calibration of the images was performed using the known length of the inserted implant to correct for any magnification errors.

Crestal bone loss was measured by subtracting the baseline measurements recorded at the time of provisional prosthesis delivery frommeasurements taken at 2 weeks, 8 weeks, 16 weeks, and 6 months postoperatively (Figure 5C). Radiographic analysis was conducted independently by two calibrated investigators. To assess intra- and inter-examiner reliability, 20% of the radiographs were randomly selected and re-evaluated after a two-week interval. Intra-class correlation coefficients (ICCs) were calculated, and values above 0.85 were considered acceptable, indicating high reliability. To determine the method error, duplicate measurements were analysed using Dahlberg’s formula, and the standard error of measurement (SEM) was calculated. This ensured that any reported differences in bone loss between groups exceeded the magnitude of measurement error, thereby supporting the validity of the statistical findings.

Sample size was calculated based on the variation in BMP-9 levels among the study groups,using the appropriate formula which is

$$n = k\frac{\left(z_{\alpha}+z_{\beta}\right)^{2}\left(\sigma_{1}^{2}+\sigma_{2}^{2}\right)}{d^{2}}$$

Where n = number of samples to be collected

σ1 = 300, The SD of BMP-9 in first group with reduced torque, σ2 = 250, The SD of BMP-9 in second group with conventional torque.[33] The data were analysed with a statistical software package (IBM SPSS Statistics, v26.0; IBM Corp) (α =.05).[22] Unpaired t test, repeated measures ANOVA followed by Bonferroni post hoc analysis and Pearson's correlation were the statistical tools used.

RESULTS

The OD group had notably lower levels of BMP-9 after 2 weeks compared to the CD group (OD group: 150.43±4.96 and CD group: 177.67±8.24) which was statistically significant*($P<0.05$)*.However, the levels of BMP-9 were higher at 8 weeks (OD group: 274.19 ±12.16 and CD group: 267.24±14.50) and 16 weeks (OD group: 440.90±33.57 and CD group: 423.62±15.58) in the osseodensification group with the difference being statistically significant at 16-week(*$P<0.05$*). There was a consistent upward trend in BMP-9 levels from the 2nd week to the 16th week in both the groups indicating increased formation of bone during this period. (Table 1)

The mean ISQ values at baseline (OD group: 75.19±4.92 and CD group: 64.90±6.80), at 2 weeks (OD group: 69.24±7.74 and CD group: 61.43±8.26), at 8 weeks (OD group: 72.76±5.12 and CD group: 62.95±8.40) and at 16 weeks (OD group: 74.62±4.57 and CD group: 64.57±4.17) indicated that the implant stability of the OD group was more than the CD group which was statistically significant *(P<0.05)* at every time point. There was a decrease in the ISQ values at 2 weeks when compared to the baseline and subsequently showed a gradual increase in both the groups. (Table 2)

There was evidence of significant difference *(P<0.05)* in the crestal bone loss of both the OD and CD groups at all the time intervals. The mean values of crestal bone loss in mm at 2 weeks (OD group: 0.07±0.01 and CD group: 0.10 ±0.03), at 8 weeks (OD group: 0.24±0.03 and CD group: 0.29±0.05), at 16 weeks (OD group: 0.37±0.05 and CD group: 0.45±0.07) and at 6 months (OD group: 0.58±0.09 and CD group: 0.67±0.08) indicated that the crestal bone loss of the CD group was significantly more than the OD group. (Table 3)

Pearson's correlation analysisshowed that there was a significant *(P<0.05)*correlation between BMP-9 and implant stability in the OD group and between BMP-9 and crestal bone loss in the both the OD and CD group (Supplementary Table 1 and2)

DISCUSSION

Over the past two decades, significant advancements in implantology have positioned endosseous implants as the preferred method for replacing missing teeth.Despite their widespread success, implant failures do occur, with rates reaching 8.16% and 4.93% in the maxillary and mandibular arch respectively.[22]Thiebotet al[23] noted that in most cases of implant failures, the bone involved was classified as type III or IV. Ko et al[24]showed that the cortical bone thickness is least in the anterior and posterior maxilla, elucidating why 83% of the failures identified in Thiebot et al 's study occurred in the maxilla, as also observed in Kern et al's5-year follow-up investigation.[25]

The osseodensification technique, introduced by Huwaisin 2013[10]utilizes specially designed Densah burs to preserve and compact bone rather than removing it. This method promotes dense autografted bone formation around the implant, improving bone-implant contact and increasing insertion torque, thereby ensuring primary implant stability.[11]

The demographic analysis confirmed no significant influence of age or gender between the groups, ensuring homogeneity. The central biological marker evaluated in this study was bone morphogenetic protein-9. BMP-9 plays a pivotal role in osteoblast differentiation and bone tissue formationby activating the SMAD-dependent signalling pathway.[26]Studies by Nieet al[27], Kawecki F[28], Haimov H[29] and others have enumerated the recent applications of BMP-9 ranging from alveolar bone healing to coatings on titanium implants.

BMP-9 levels increased progressively across all time points in both groups, with significantly higher levels observed in the OD group at the 8- and 16-week follow-ups. These findings align with the known osteoinductive properties of BMP-9, which peak during thelate stages of bone remodelling.[30] The lower levels observed in the OD group at 2 weeks may reflect the delayed inflammatory and resorptive phase due to early bone compaction.[14] By 8 and 16 weeks, healing chambers created by OD likely served as active sites for osteogenesis, accounting for elevated BMP-9 expression.[31,32]

Implant stability values both primary and secondary were significantly higher in the OD group compared to the CD group. These results which are in alignment withother animal and human studies,[13,15,33,34, 35]reinstate that OD promotes a biomechanical environment conducive to immediate and long-term implant success.

Additionally, crestal bone loss was significantly lower in the OD group at all follow-ups. This can be attributed to increased bone volume, higher bone density, and reduced micromovement due to superior primary stability. Although some previous studies have reported no statistically significant difference in crestal bone loss between drilling techniques, they were often limited by smaller sample sizes or restricted anatomical locations.[36, 37]

Importantly, this study found a positive linear correlation between BMP-9 levels and implant stability, which was statistically significant in the OD group. This supports the biological rationale that increased osteogenic activity, as signalled by BMP-9, contributes to enhanced implant anchorage and stability over time.

The study also found a positive correlation between BMP-9 and crestal bone loss, which may appear contradictory given BMP-9's role in bone formation. However, this relationship likely reflects a reactive biological response rather than a direct causative one. As bone remodelling intensifies (indicated by higher BMP-9 levels), localized bone turnover may transiently elevate, especially in regions subject to biomechanical stress, surgical trauma, or inflammatory response. Given the multifactorial nature of crestal bone loss, which includes biological, biomechanical, and surgical influences, this correlation should not be interpreted as BMP-9 causing bone loss. Instead, it suggests that elevated BMP-9 may co-occur with active bone remodelling processes, some of which could contribute to marginal bone alterations.

This study rejects the null hypothesis and confirms that bone compaction drilling enhances peri-implant bone healing, increases implant stability, and reduces crestal bone loss, supported by the levels of bone marker and clinical parameters.

Limitations of this study include the relatively small sample size, limited follow-up duration, and the unicentric design, which may introduce Berksonian bias. Future research with broader populations and longer observation periods is needed to validate these findings further. Additionally, more detailed exploration of the temporal relationship between BMP-9 expression and specific bone remodelling phases may provide deeper insights into peri-implant healing dynamics.

CONCLUSION

Within the limitations of the present study, it can be concluded that the bone compaction drilling technique demonstrated a superior biological response compared to conventional drilling, as evidenced by elevated BMP-9 levels. Additionally, clinical parameters, including improved implant stability and reduced crestal bone loss, further support the efficacy of osseodensification as a favourable technique for implant placement.

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TABLES

Table 1. Comparison of levels of BMP-9 in OD and CD groups

BMP Levels	Group	N	Mean (pg/ml)	Std. Deviation	Std. Error Mean	p-value
2 wk	OD group	21	150.43	4.96	1.083	0.000[a]
	CD group	21	177.67	8.24	1.798	
8 wk	OD group	21	274.19	12.16	2.653	0.100
	CD group	21	267.24	14.50	3.164	
16 wk	OD group	21	440.90	33.57	7.326	0.039[a]
	CD group	21	423.62	15.58	3.400	

Values are presented as mean±standard deviation

CD- conventional drilling, OD- osseodensification drilling

[a)]Statistically significant difference

Table 2. Comparison of implant stability in OD and CD groups

Implant Stability	Group	N	Mean (ISQ)	Std. Deviation	Std. Error Mean	p-value
Baseline	OD group	21	75.19	4.92	1.074	0.000[a]
	CD group	21	64.90	6.80	1.484	
2 weeks	OD group	21	69.24	7.74	1.688	0.003[a]
	CD group	21	61.43	8.26	1.802	
8 weeks	OD group	21	72.76	5.12	1.116	0.000[a]
	CD group	21	62.95	8.40	1.834	
16 weeks	OD group	21	74.62	4.57	0.996	0.000[a]
	CD group	21	64.57	4.17	0.909	

Values are presented as mean±standard deviation

CD- conventional drilling, OD- osseodensification drilling

[a)]Statistically significant difference

Table 3. Comparison of crestal bone loss in OD and CD groups.

Crestal bone loss	Group	N	Mean (mm)	Std. Deviation	Std. Error Mean	p-value
2 weeks	OD group	21	0.071	0.011	0.0025	0.000[a]
	CD group	21	0.104	0.026	0.0057	
8 weeks	OD group	21	0.244	0.028	0.0060	0.001[a]
	CD group	21	0.287	0.049	0.0107	
16 weeks	OD group	21	0.367	0.055	0.0120	0.000a
	CD group	21	0.469	0.070	0.0152	
6months	OD group	21	0.584	0.094	0.0205	0.002[a]
	CD group	21	0.675	0.080	0.0174	

Values are presented as mean±standard deviation

CD- conventional drilling, OD- osseodensification drilling

[a)]Statistically significant difference

Figure 1: CONSORT flow diagram.

Figure 2. Preoperative Computed Tomography scan. (A) Osseodensification (OD) group. (B) Conventional drilling (CD) group.

Figure 3. Osseodensification (OD) group. (A) Preoperative site. (B) Implant site preparation using Densah bur drills. (C) Prepared osteotomy.

Figure 4. Conventional drilling (CD) group. (A) Preoperative site. (B)Preparated osteotomy using conventional drilling technique.

Figure 5. Assessment of outcomes. (A) BMP-9 using PICF (peri-implant crevicular fluid). (B) Implant stability using RFA (Resonance Frequency Analysis). (C)Crestal bone loss using IOPA (intraoral periapical radiographs).