

**“COMPARATIVE EVALUATION OF CRESTAL BONE LOSS
FOLLOWING TITANIUM IMPLANT PLACEMENT BY
OSTEOTOMY AND OSSEODENSIFICATION TECHNIQUE”**

Dissertation

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**BABU BANARASI DAS UNIVERSITY
LUCKNOW, UTTAR PRADESH**

In the partial fulfillment of the requirements for the degree

of

MASTER OF DENTAL SURGERY

In

PROSTHODONTICS, CROWN & BRIDGE

By

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Under the guidance of

DR. SWATI GUPTA

Head of the Department

**DEPARTMENT OF PROSTHODONTICS
BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES,
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I hereby declare that this dissertation entitled “**COMPARATIVE EVALUATION OF CRESTAL BONE LOSS FOLLOWING TITANIUM IMPLANT PLACEMENT BY OSTEOTOMY AND OSSEODENSIFICATION TECHNIQUE**” is a bonafide and genuine research work carried out by me under the guidance of **DR SWATI GUPTA**, Professor & Head, Department of Prosthodontics, Crown & Bridge, Babu Banarsi Das College of Dental Sciences, Lucknow, Uttar Pradesh.



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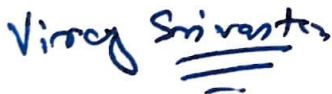


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*“A mother is she who can take the place of all others
but whose place no one else can take.”*

DEDICATED TO MY MOTHER

SULEKHA

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LIST OF ABBREVIATIONS

CBCT	Cone -beam Computed tomography system
BIC	Bone to Implant Contact
OPG	Orthopantomogram
R	Regular drilling
OD-CW	Osseo densification-Clockwise
OD-CCW	Osseodensification-Counterclock wise
BAFO	Bone area formation
IOPA	Intra-oral peri-apical radiographs
RVG	Radio Visio Graphy

Aim: The present study was done to evaluate and compare the crestal bone loss following titanium implant placement by osteotomy and Osseo densification technique.

Setting and Design: In vivo comparative study

Materials and Methods:

The study was conducted on twenty patients divided into two groups: Group A and Group B.

In Group A, ten implants were placed in patients by osteotomy technique (Conventional drilling) and in Group B, the remaining ten implants were placed in patients requiring implants in Maxilla by Osseo densification technique. The crestal bone loss was evaluated and compared in both groups using an RVG sensor with an IOPA grid by paralleling technique at different time periods of one month and third month of implant placement and the same was compared with that of radiograph taken at baseline.

Statistical Analysis used:

The data obtained were subjected to an independent t-test (for comparing two groups) and paired t-test (for intragroup comparison)

Results

The data obtained from the intra-group comparison in the Osseo densification technique showed no appreciable bone changes in the first and third months when the same was compared with that of the baseline. Whereas the intra-group comparison in the Osteotomy technique showed crestal bone loss, though statistically, it was insignificant.

CONCLUSION

Within the limitations of this study, it was concluded that no significant difference in crestal bone loss was seen between Osseo densification and Osteotomy technique at the first three months of implant placement when compared using an Independent t-test as $p > 0.05$

The concept of Osseointegration introduced by Branemark has led to the foundation of implant dentistry for replacing teeth in edentulous spaces of the jaw without compromising the health of the adjacent tooth¹. This two-phase surgical-prosthetic innovation has shown its success and longevity through conventional drilling protocol in thick cortical regions of the jaw but has failed to attain the same in thin trabecular regions with poor bone density.

With years of research, Huwais introduced Osseo densification, an autografting method of osteotomy utilizing bones property of Visco elasticity and plastic deformation². Unlike conventional drilling protocol which excavates bone during implant placement, Osseo densification compacts the bone chips between the thin trabecular regions which on itself acts as an autograft for bone mineralization³. Hence, creating a promising bone-implant contact by improving the healing rate at the implant site of low bone density regions of the jaw.

The radiographic analysis of bone at the implant site by the dental surgeon decides the type of technique to be followed for implant placement. Thus, proper diagnosis and treatment planning and precise knowledge of various drilling protocols regarding when and where to apply is also an essential determinant for the success of any treatment.

The present study dealt with radiographically analyzing the efficacy of Osseo densification over conventional drilling protocol in managing crestal bone loss in a single implant procedure in thin trabecular regions of the jaw.

AIM

The aim of this study was to evaluate and compare crestal bone loss around titanium implants placed with Osteotomy and Osseo densification techniques using an RVG sensor with an IOPA grid by paralleling technique

OBJECTIVES

1. To evaluate crestal bone loss at the third month of implant placement by osteotomy technique and radiographically compare the same with that of radiograph taken at first month and baseline.
2. To evaluate crestal bone loss at the third month of implant placement by Osseo densification technique and radiographically compare the same with that of radiograph taken at first month and baseline.
3. To compare the crestal bone loss in osteotomy and Osseo densification technique and evaluate the procedure of minimal crestal bone loss using RVG sensor with IOPA grid by paralleling technique.

A structured review of scientific publications in English literature related to the dissertation topic “**COMPARATIVE EVALUATION OF CRESTAL BONE LOSS FOLLOWING TITANIUM IMPLANT PLACEMENT BY OSTEOTOMY AND OSSEODENSIFICATION TECHNIQUE**” was done.

Adell et al (1981)⁴ studied annual bone loss around Osseointegrated implants within a time period of 15 years (1905-1980). Within this time period, 2768 fixtures were done in 410 edentulous jaws. It was observed that 81% of the maxilla & 91% of the mandible were stable throughout supporting the fixtures. The studies observed bone loss of 1.5mm in the first year followed by 0.1mm bone loss annually.

Albrektsson et al (1986)⁵ reviewed a study on the long-term efficacy and success of currently used dental implants using diverse implant systems and concluded that only Branemark Osseo integrated screw and Small Trans osteal staple was shown to be accepted with a long-term success rate of more than ten years with an acceptable vertical bone loss of 0.2mm or less annually.

The criteria as described:

1. The mean vertical bone loss is less than 0.2mm annually after the first year of service.
2. No persistent pain, discomfort, or infection is attributable to the implant.
3. The implant design does not preclude the placement of a crown or prosthesis with an appearance that is satisfactory to the patients and dentist.
4. By these criteria, a success rate of 85% is seen at the end of a 5-years and an 80% success rate is seen at the end of 10 years which are considered as minimum levels for success.

Albrektsson T et al (1987)⁶ stated that periapical radiograph represents a generally accepted method to assess the long-term evaluation of interproximal crestal bone changes of Osseointegrated implants; however, the sensitivity for detecting small changes in bone level is low. Although the optical resolution of standard radiographs is too small to detect fibrous encapsulation or osseointegration, ongoing bone loss over time can be an indication of peri-implant infection. Therefore, radiographic results have been incorporated into most definitions of success.

Bragger et al (1998)⁷ evaluated the crestal bone loss adjacent to non-submerged dental implants radiographically within the follow-up period of one year. The study was conducted in 128 patients with known reference points as implant dimension. Radiographically using Hollander & Rockler film holding system, crestal bone loss was calculated from the implant shoulder to the alveolar crest on the mesial and distal side at baseline and one year. The results showed mean crestal bone loss of -0.78mm on the mesial side (at baseline 2.07mm) and mean crestal bone loss of -0.85mm on the distal side (at baseline 2.19mm) during a follow-up period of one year.

Bragger (2000)⁸ studied the assessment of changes in peri-implant bone height and concluded that increased peri-implant radiolucency with time can lead to implant mobility and subsequent failure of implants. The radiograph was mounted on slides and projected on the screen. The accepted criteria as suggested from his studies suggest a mean crestal bone loss of 0.9mm to 1.6mm is accepted during the follow-up period of one year and mean crestal bone loss of 0.05mm to 0.13mm is accepted annually for implant longevity and success.

Bryant, Zarb (2003)⁹ studied crestal bone loss around the implant in two groups: older (60 to 74 years old) and young adults ((29 to 49 years old) with a follow-up period of four years. The peri apical radiographs were measured from the vertical distance in millimeters from the apical edge of the implant collar to the most apical initial point of contact between the implant and bone. The results concluded that mean bone levels at loading were 1.4 mm below the collar in both groups and mean annual crestal bone loss after the first year of loading was 0.04 mm/y in both groups.

Davies (2003)¹⁰ studied the peri-implant bone formation during implant placement histomorphologically in trabecular and cortical bone. He enlightened on the fact that D4 bone has a high surface area and hence is in close proximity to the bone marrow which is rich in mesenchymal cells, osteoclasts, and high vascularity. Thus, though D4 is considered as the poor density bone, its ability for new trabecular bone formation is comparatively faster than the cortical bone

AC Kritika et al (2007)¹¹ studied the compatibility of dental X-ray grids using 0.3ml of Radiosensitive Iodine based water soluble dye. The dye was spread between the canvas and the grid and then a radiograph was made using paralleling technique. It was observed from the studies that the grid does not absorb the dye or made the image opaque, instead, it formed a layer between the mesh and framework producing good contrast to the image. One other added advantage of the grid was discussed such that during image distortions like elongation or shortening, the values of the grid as 1mm remains the same, thus reducing the chances of repeated exposure

Cochrane et al (2009)¹² observed that the bone loss is maximum in the first five years of implant placement ‘i.e.,’ from the time of implant placement to the time of placement of the definite prosthesis. He studied a five-year follow-up period of 592 implants placed on 192 patients using peri apical and panoramic radiographs and observed that the reason behind the bone loss may be an interruption in vascular supply during drilling procedures causing inflammatory responses at the implant site. This further causes loss of trabecular or cortical bone thereby delaying bone healing and ultimately bone loss. Studies have shown that about 2.84-1.63mm of bone loss occurs within the first five years which constitutes about 86% of total mean bone loss. This decrease in bone loss after implant loading over five years implies the importance of proper bone healing around the implant site is the key factor to the success of the prosthesis.

Padmanabhan & Gupta (2010)¹³ studied the crestal bone loss and implant stability in two groups, one with the conventional procedure and the other with the osteotome technique in the maxillary anterior region of five patients with a follow-up period of six months. The radiographic evaluation of crestal bone loss was done with reference points as implant shoulder and alveolar crest using Radio Visio Graphy taken with RINN X-ray holders (Rinn Corp Com, Dentsply, Elgin, Ill) by paralleling long-cone technique. The mean difference of this reference point was measured on the mesial and distal aspect and the study reported that a significant difference was found in the level of the crestal bone loss after 6 months of surgery between both groups ($P=0$; $n=5$) with less crestal bone loss in the conventional technique. The mean crestal bone loss for conventional and osteotome techniques was 0.99 mm and 1.19 mm respectively.

Lang NP et al. (2011)¹⁴ According to the consensus meeting of the European Federation of Periodontology, a radiograph should be obtained at the time of prosthetic loading to determine alveolar bone levels after physiologic remodelling. This recorded baseline data should be the reference from which the peri-implant disease can be recognized in subsequent microscopic examinations. One should understand, however, that the time of loading is dependent on the surgical and prosthetic treatment protocols. When peri apical baseline radiographs were taken after prosthesis placement, the initial bone remodelling may already have taken place and consequently, the measured bone loss excludes the bone lost during the initial remodelling. Thus, a baseline radiograph is an essential reference to determine bone remodelling and, osseointegration. Moreover, if adequate osseointegration is not achieved, then to determine the possibility of periapical diseases.

Ghoveizi et al (2013)¹⁵ studied crestal bone loss and bone density through computer radiographic comparison in the posterior maxillary region of twenty patients. A total of ten implants were placed in twenty patients. By longitudinal radiographic assessment technique, crestal bone loss and bone density of single Osseointegrated implants were evaluated through progressive and conventional loading with a follow-up period of two, four, six, and twelve months. From the studies, it was observed that there is comparatively less crestal bone loss in the progressively loaded group (0.19mm) than in conventional loading (0.36mm) with an increased bone density in crestal, middle, and apical regions of the progressively loaded implant.

Bruschi et al (2014)¹⁶ studied crestal bone loss around the implant during delayed loading using a peri apical radiograph with long cone paralleling technique. A total of 137 implants were placed on 120 patients with three constant references as keratinized gingiva, 2mm implant collar, and implant orientation to the occlusal plane. The study was done in the premolar and molar regions of the jaw and the crestal bone loss was evaluated at the time period of baseline, one-year, third year, and five years. Within the time period of one year, it was observed that there is bone loss of 1.5 ± 0.62 mm and in a three-year study, it was observed a bone gain of 1.20 ± 0.49 mm which was statistically significant. During the follow-up period, it was observed that within the time range of 9.71 ± 4.88 years, there is a success rate of 97.76%.

Deshpande and Bhargava (2014)¹⁷ studied on the accuracy of the Gridded Intra Oral Periapical Radiograph with that of CBCT with the superior cortex of the inferior alveolar canal as the reference. The study was done on the same patient for pre-implant evaluation of the mandibular posterior region. The distance measured from the superior cortex of the alveolar canal to the crest of the alveolar ridge was calculated using the grid and was found to be 15.4mm and than CBCT was found to be 15.6mm with an accuracy of 9.7%. The grids accuracy and advantages over CBCT are that it is less technique sensitive, affordable, decreased scattered radiation, and has a precise linear calculation of a two-dimensional image.

Sang Y Kim et al (2015)¹⁸ studied the magnitude of crestal bone loss and factors associated with it using peri apical radiographs. The longitudinal study was done among eighty-four subjects where a total of 148 implants were placed. Changes in crestal bone were calculated by measuring a ratio of the actual implant length divided by the measured radiograph i.e., implant length on peri apical radiographs. The results concluded that within the time period of 15 to 2057 days, there was a mean crestal bone loss of 2.1 ± 1.5 mm, and 66.1% implants showed a mean crestal bone loss of >1.5 mm in the first year.

park et al (2015)¹⁹ studied the correlation between systemic diseases and crestal bone loss in 157 patients (Male:52, and Female:85) within a follow-up period of one year. The study was done using a peri apical radiograph in paralleling technique with IMPAX (AGFA, Belgium) program among 30 patients with various systemic diseases like Diabetes Mellitus (n=10), Hypertension(n=2), Cardiovascular Disorder (n=2) and without any systemic diseases (n=67). The crestal bone loss evaluated within the follow-up period of one year showed crestal bone loss of 0.42mm(Sd=0.530) for patients with no systemic diseases, 0.32 mm(Sd=0.31) of crestal bone loss for cardiovascular patients, 0.62mm(Sd=0.84)for Diabetes Mellitus patients and 1.58 mm(Sd=1.80) for Hypertensive patients. Though the amount of crestal bone loss was comparatively higher in patients with hypertension, no statistical difference was found among each group.

Rajput et al (2016)¹ reviewed on the chronology from ancient 1600-2015 and recent developments that led to the advancements in dental implantology. He emphasized the late 1980s when Brandmark studied the unique ability of titanium to Osseo integrate with bone which led to the development of implantology. The article also highlighted the recent advancements in dental implantology with the introduction of zirconia implants by Blaschkcet which has been ported to have osteointegration properties, cosmetic results, and better soft tissue response when compared with that of Titanium implants.

Vikhe et al (2016)²⁰ studied crestal bone loss at the peri-implant region on two different dental implant systems before prosthetic loading. The study was conducted in the mandibular posterior region (fourth quadrant) of the jaw among twenty patients divided into two groups of Noble BioCare and Lifecare implant systems. The study was radiographically compared at six months of implant placement using OPG. The results of the six-month study observed mean crestal bone loss of 1.6mm and 1.8mm on the mesial and distal sides respectively for the Noble BioCare system. On the other hand, radiographic evaluation of the life care system proved a comparatively less crestal bone loss of 0.7mm and 0.6mm. Thus, the study concluded that the smooth collar design of implants shows more bone loss when compared with rough collar designs.

Wang et al (2016)²¹ discussed soft tissue recovery around dental implants during various time periods. He described that the blood clot around the dental implant initiates neo-vascularisation after twenty-four hours by the host's immune response. This is replaced by mesenchymal cells by the fourth day converting itself to osteoblasts. Hence the calcification starts at around the first week of implant placement. By one month, the process of contact osteogenesis and distant osteogenesis proceeds to complete lamellar bone formation around the peri-implant area forming a peri mucosal seal around the implants.

He also described the relevance of connective tissue (1-1.5mm) and junctional epithelium(2mm) around dental implants, hence forming 3mm of mean biological width. Thereby, it was also observed that if the biological width around dental implants is reduced due to the immune response of the host or any other factors, the same will lead to marginal bone loss around implants.

Nancy Singla, Sandeep Kumar, Shashikala Jain, Sunita Choudhary, Navleen Dandiwal, and Kulashakar R Nandalur (2018)²² radiographically evaluated the crestal bone loss in two groups, one with flap & other with the flapless technique. The study was done using intraoral periapical & orthopantomography with a follow-up period of three months intervals of baseline, first, and third month. In the flapless method, (flapless method); the mean loss at 0 months was 1.99 mm, at 1 month, it was 2.02 mm, and at 3 months, it was 2.11 mm. Whereas in the flap method, it was observed that; the mean loss from 0 months was 1.74 mm, at 1 month, it was 1.89 mm, and at 3 months, it was 2.19 mm. The study concluded that the crestal bone around the implant was reduced in both groups; with comparatively lesser crestal bone loss in the flapless technique. Furthermore, it was observed that for most of the flapless cases, the bone loss settled at 1st thread or just below the implant collar after 3 months.

Kanathila and Pangi (2018)² reviewed the newer innovation of Huwais, the Densah burs, and the Osseo densification technique. The densah burs work in both clockwise and anti-clockwise directions at a speed of 800-1500rpm. The clockwise direction movement removes bone, while the anti-clockwise direction compacts the removed bone towards the implant bed. It has been reported that the saline irrigation along with the inward-outward movement creates a hydrodynamic action thereby compacting the bone laterally along the walls of the implant site with reduced heat production when compared to other traditional drilling protocols. This helps in improving bone mineral density.

Randolph R. Resnik, in Misch's Avoiding Complications in Oral Implantology, (2018)²³ reported about the density of the maxillary posterior region of the jaw and its subsequent complications on implant loading. Misch classified the bone according to its density into various categories, out of which the maxillary posterior region is D4 with fine trabeculae and poor bone density when compared to all other bone quality of the oral cavity. Since the elastic modulus of the posterior maxilla is higher than the Titanium implant under loading, the stress pattern transfers more force towards the apical area of the implant leading to decreased % BIC (Bone Implant Contact) followed by bone loss and implant failure

Gasper et al (2018)²⁴ studied Osseo densification in Maxilla by placing a total of ninety-seven implants in forty-one patients. The study was done among four groups: Group A with reduced bone width (3.2 -5mm), where bone expansion and Osseo densification were done with Guided Bone Regeneration. Osseo densification with sinus Augmentation was done in Group B patients with a reduced bone height of 2.9-6.1mm. Group C with immediate loading of implants & Full mouth Rehabilitation cases in Group D. The results after the follow-up period showed 99.6% successful osseointegration with insertion torque >45N in all four groups of Osseointegration with 1.6mm bone deposition coronally in Group A, 5.8mm increase in bone height in Group B patients.

Pikos and Miron (2019)²⁵ highlighted various cases like lateral sinus augmentation, crestal sinus augmentation, and socket shield technique in the aesthetic zone where Osseo densification was a primary requirement for the success of the implant prosthesis. It was studied that Osseo densification when compared to traditional drilling produces a smaller osteotomy site due to the viscoelastic property of bone. Thus, due to this reason, Osseo densification is indicated for maxillary posterior regions of the jaw. Osseo densification if performed in a dense cortical bone without caution or adequate knowledge in an anti-clockwise direction will lead to bone necrosis at the site. The osseodensification technique utilizes the bone's inherent property of viscoelasticity and plastic deformation, thereby compacting the removed bone at the bone-implant site itself. Hence here the host's autogenous bone itself acts as a graft and increases the primary stability, bone mineral density, and longevity of implant prosthesis.

Witek et al (2019)³ studied Histomorphologic analysis of BIC (Bone Implant contact) and BAFO (Bone Area Fraction Occupancy) in low bone density sites of sheep using three drilling techniques: R (Regular drilling), OD-CW (Osseo densification Clockwise), OD-CCW (Osseo densification Counter Clockwise) techniques. The samples were analyzed using histology micrographs and image analysis software (ImageJ, NIH, Bethesda, MD). The study highlighted that the bone chips are formed within the trabeculae and proximity areas of bone drilled with OD-CCW when compared to R and OD-CW samples. It was further concluded that these act as nucleating sites for osteogenesis leading to increased Bone ingrowth, vascularisation, and Bone Remodelling, and BIC% ($p>0.05$) and BAFO ($p=0.036$) in OD samples were comparatively higher than when compared to R samples.

Anitua and Alkhraisat (2019)²⁶ study on the longevity of short dental implants and its associated marginal bone loss with a follow-up period of 15 years. The study was done on fifty patients aged 59 +/- 10 years old. Kaplan–Meier method was used to assess the implant survival rate. A total of seventy-five implants were placed, 30 in the maxilla and 45 in the mandible. Within a time period of 15 years, it was found that though the success of implants was 93.9%, the amount of crestal bone loss irrespective of implant position was found to be more in the maxilla when compared with that of the mandible.

Sultana et al (2020)²⁷ conducted a clinical-radiographic study of crestal bone loss and implant stability of implants placed using Osseo densification and traditional drilling protocol in the anterior maxillary region of the jaw in 20 patients.

The study was divided into two groups, Group 1 for traditional drilling & Group 2 Osseo densification technique which was used for narrow ridges with a follow-up interval of baseline, six- and eight-months using Cone Beam Computed Tomography (CBCT). ADIN Touareg spiral implants were used for the study. CBCT reports showed bone growth of 36.90% was seen in group 2 when compared to Group I with bone growth of only 29.84% in eight months. In the comparison of crestal bone levels between OD and traditional drilling, no statistically significant difference was found between the two groups ($P < 0.05$). The results of statistical analysis using t-test concluded variations in intragroup only with $P < 0.05$

Hassan et al (2021)²⁸ studied a comparison between Osseo densification & Traditional drilling technique in split-mouth design in the Bilateral Edentulous Posterior Maxillary region of the jaw in which one side of the same patient's jaw Osseo densification was done & another side of the same patient's jaw traditional drilling was performed. A CBCT evaluation was done at the interval of baseline, seven, and twelve months and the results concluded Osseo densification group showed enhanced bone density and less bone loss (2.46 ± 1.05) when compared to the conventional group. The Osseodensification group showed variation in marginal bone by 1.148 ± 0.35 to 2.46 ± 1.05 at baseline and at twelve months, whereas in traditional drilling, it was observed as 1.22 ± 0.54 to 2.45 ± 0.60 at baseline and twelve months respectively. The statistical analysis of intergroup comparison shows reduced variation in the given time period with a statistically significant difference observed in bone density of the osseodensification group immediately after surgery.

Afsheen Tabassum (2021)²⁹ studied the radiographic comparisons of mean crestal bone levels around implants placed with low-speed drilling and standard drilling protocols within three months follow-up period. The radiographs for the study were evaluated with phosphor plates (Henry-Schein Supplies ScanXTM) and X-ray film-holders (Rinn-holder with 1 mm-Biolon-Dentamid, Dreve) using the long-cone paralleling technique. It was observed from the results that the mean crestal bone loss of implants placed with standard drilling and low-speed drilling protocols was 1.01 ± 0.49 mm and 0.74 ± 0.62 mm, respectively and statistically no significant differences could be recorded between the two groups ($p = 0.206$).

Mullings et al (2021)³⁰ performed histomorphometric analysis on the conventional drilling technique and Osseo densification on low-density bones & observed that Bone Implant contact and Osseointegration are higher in the Osseo densification than Conventional drilling group ($P < 0.05$). It was concluded from the studies that the microcracks formed in the trabeculae during the drilling procedure resulted in further crestal bone loss due to delayed healing time. Whereas in Osseo densification, the trabecular microcracks are compacted by autogenous bone leading to decreased crestal bone loss.

Siddhant Aloorker, Manoj Shetty, and Chethan Hegde (2022)³¹ studied the effect of Osseo densification on Bone Density and Crestal Bone Levels. The study was done in ten patients wherein the maxillary posterior region of the same patient was divided into two categories, the left side with osteotomy and the right side of the same patient with Osseo densification technique with a follow-up period of baseline, three and six months. In the osteotomy group, crestal bone level changed from 8.401(baseline) to 7.860mm at three months, whereas in the Osseodensification group, it was observed a change from 8.664(baseline) to 8.963mm at the third month respectively.

It was also found through a CBCT study that the bone density at the Osseo densification site tends to increase from 8.664% to 9.189% when compared to the osteotomy site which showed decreased bone width from 8.4 to 8.1. The results concluded that there is no statistical difference between the levels of the crestal bone in an Osseo densified site as compared to a conventional osteotomy site ($p=0.124$)

Nasr and Eltohami (2022)³² discussed various advantages and considerations of Osseo densification and concluded that Osseo densification via Densah burs doesn't excavate bone, instead, this technique helps to deposit and compact bone along the walls of the implant site. Thus, here the host bone itself acts as an autograft which increases the rate of Osseointegration when compared to the traditional drilling technique.

Osseo densification helps in a plastic expansion of the alveolar ridge by deforming and condensing bone osteotomy fragments in an outward strain, thereby improving the integrity of the ridge. Moreover, this dense layer of autografted bone formed along the walls helps in increased Bone Implant Contact, better stability, and rapid osseointegration thereby decreasing the loading time of implants.

The study was conducted in the Department of Prosthodontics and Crown & Bridge, at Babu Banarasi Das College of Dental Sciences, Lucknow, to compare and evaluate radiographically the crestal bone loss following Titanium implant placement by Osteotomy and Osseo densification techniques.

Study Sample and size

- Group A: Osteotomy Technique - 10
- Group B: Osseo densification Technique – 10

Partially edentulous patients reporting to the Department of Prosthodontics, desiring replacement of missing teeth, and willing for implant treatment were selected for the study as per the inclusion and exclusion criteria. They were provided with a written consent form and a written explanation regarding the nature of the study, treatment procedures, and the benefits of the follow-up protocols.

The study was approved by the ethical Committee of Babu Banarasi Das College of Dental Sciences, BBD University, Lucknow, Uttar Pradesh.

The number allotted to the study is IEC CODE:38

SELECTION CRITERIA

Inclusion criteria

1. Patients with good oral hygiene and willing to undergo restoration with a dental implant.
2. Healthy patients with no systemic disease.
3. Male and female patients aged 18 years and above.
4. Patients with good periodontal health.
5. Short or long-span edentulous area.
6. Patients with an adequate amount of bone volume and bone quality for implant placement.

Exclusion Criteria

1. Patients unable to maintain proper oral hygiene.
2. Patients with para-functional habits.
3. Patients with uncontrolled systemic disease.
4. Patients with insufficient inter arch space.
5. Patients who are current smokers or consume any form of tobacco
6. Patients going through radiotherapy.

ARMAMENTARIUM

The materials and instruments that were used during the course of this study.

A. Equipment

1. Implant kit† (**Figure 1**)
2. Physiodispensor £ (**Figure 2**)
3. Densah burs (**Figure 3**)
4. IOPA Grid¥ (**Figure 4**)
5. Periapical radiograph machine©
6. Panoramic radiograph machine®
7. Film positioning device€

B. Materials

1. Intraoral Periapical Radiographic films (size 21X41mm) °
2. Panoramic dental films (size 15X30 cm) yˆ
3. Chromatic Alginate Impression Material±
4. Clear self-cure acrylic resinµ
5. Lidocaine topical aerosol≠
6. 2% Xylocaine with adrenaline (1:80,000) Ψ
7. Povidone Iodine Solution (5 w/v) Ъ
8. Saline (sodium chloride, I.P. 0.9% w/v) Ÿ
9. Suture materials

C. Miscellaneous instruments needed during the surgical and prosthetic procedures.

COMPANY NAMES

£ NSK Surgic AP, Japan

† Adin Implant Private Ltd

© Planmeca Prostyle intraoral X-ray machine

® Planmeca Pm 2002 Cc Proline

€ Dentsply India

¥ X-ray mesh gauge, Dentech Corporation, Japan

◦ Kodak @ Ekta speed film

Y Kodak T-MAT GIRA

± DPI, Dental Products, Mumbai, India

μ Dental Products of India, Gurgaon India

≠ Nummit Spray

Ψ Xicaine ICPA health products Ltd. India

‡ Wockhardt ltd., India

Ÿ Wockhardt ltd., India

Φ Ethicon, Johnson & Johnson Ltd. India

METHODOLOGY

The patients reporting to the Department of Prosthodontics and Crown AND Bridge, Babu Banarsi Das Dental College, Babu Banarasi Das University, Lucknow for restoring the edentulous site with implants were evaluated radiographically and clinically and were categorized into two: Osteotomy and Osseo densification.

As per the eligibility criteria mentioned above, the patients requiring implants in the maxilla were categorized in Osseo densification and the rest 10 were categorized for osteotomy technique.

<u>GROUP</u>	<u>TECHNIQUES USED FOR STUDY</u>	<u>NUMBER OF SAMPLES</u>
A	OSTEOTOMY	10
B	OSSEODENSIFICATION	10

Table 1: Number of samples and techniques

PROCEDURE

- Impression & surgical guide fabrication

An alginate impression of both the arches was made and a surgical template was fabricated on the cast at the implant site using a clear acrylic resin for the accurate orientation of burs through the bone. **(Figure 5)**

- Pre-operative radiographic evaluation

An intraoral radiograph of the edentulous site was taken before the surgery using an RVG with a dental grid, which was further used as a reference **(Figure 6)**

- Antibiotic prophylaxis

The patient was prescribed to take premedication of Tab Augmentin one gram one hour before surgery.

- Surgical procedure

The patient was asked to rinse and gargle the mouth with a 5% povidone-iodine solution for forty seconds.

Stage 1 surgery

- The appropriate Local anesthesia technique should be used to anesthetize the implant site. A cotton swab dipped in 5% povidone-iodine is used to swab extra oral regions. The procedure starts with a pilot drill being made with the help of a surgical template (**Figure 7**) The surgical guide was then removed and the osteotomy or Osseo densification procedure as per the indication of the implant site was done with proper saline irrigation with the help of pilot drills in a sequential manner (**Figure 8**). Sterile cold saline irrigation should be done during the drilling procedure at a flow rate of 50ml/min
- The osteotomy site is prepared to the desired depth, 2 to 3mm short of the final planned implant length as evaluated from the radiograph. The orientation was checked with the paralleling pin using a radiograph.
- Once acquiring the desired implant depth, the implant was carried from the packaging to the site using the disposable carrier provided by the manufacturer. It was then screwed in or tightened using the hand/Torque ratchet and was made sure that a minimum torque of 35Nm - 45Nm is obtained while torquing the implant and the implant was placed (**Figure 9**)
- This is followed by placing a cover screw (**Figure 10**)

Post implant placement, all patients were kept on antibiotics and analgesics for the next 5 days, along with chlorhexidine 0.2% mouth rinse twice daily for 2 weeks.

- Post-operative medications

Tab Augmentin 625mg, 1tab BD (Amoxicillin 500mg+Clavulanic acid 125mg)

Tab Diclomol 375mg, 1tab BD (Diclofenac 50mg + Paracetamol 325mg)

Tab Pantop 40mg, 1 tab OD half an hour before food (pantoprazole 40mg)

Cap Nutrolin B, 1tab BD (lactic acid bacillus +Vitamin B)

- Post operative Injections

Inj. Dexona 4mg/2ml stat

Inj Voveran 75mg/1ml

RADIOGRAPHIC EVALUATION

Radiographically, the implant site was evaluated using a peri apical radiograph with the grid by paralleling cone technique with a positioning device. The study was done during a time period of the first and third month and the same is compared with the radiograph taken at the baseline. (**Figure 11 to Figure 13**)

The distance from the mesial and distal margins of the implant abutment junction to the first point of bone-to-implant contact (BIC) was measured on an mm scale. The implant health status and complications were also evaluated clinically.

ANALYZING RADIOGRAPHS

Intraoral peri-apical radiographs were taken for all the implant sites of the selected patients. To compensate for magnification and image distortion errors, a lead grid with a 1 square mm grid pattern was affixed to the sensor. The radiographs were standardized by using the standard long cone paralleling technique with a film positioning device.

Considering the coronal surface of the implant fixture as the reference point, two perpendicular lines are drawn from the mesial and distal side of the implant to the first point of implant bone contact as seen radiographically on the grid. The difference is measured using a divider and scale in mm at the first and the third month of implant placement and the same is compared with that of the baseline.



Figure 1: Implant kit



Figure 2: Physio dispenser with handpiece

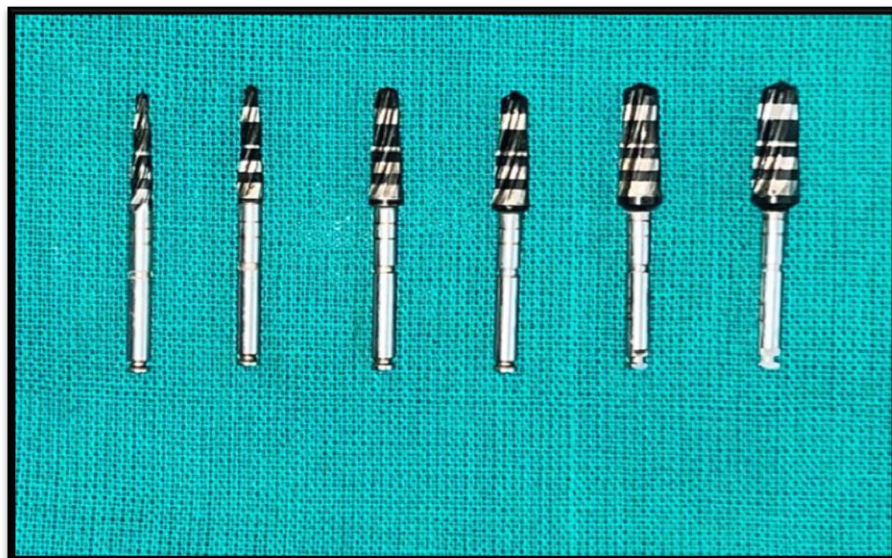


Figure 3: Densah Burs



Figure 4: Dental X-Ray Mesh Gauge



Figure 5: Surgical template made of clear acrylic on the cast

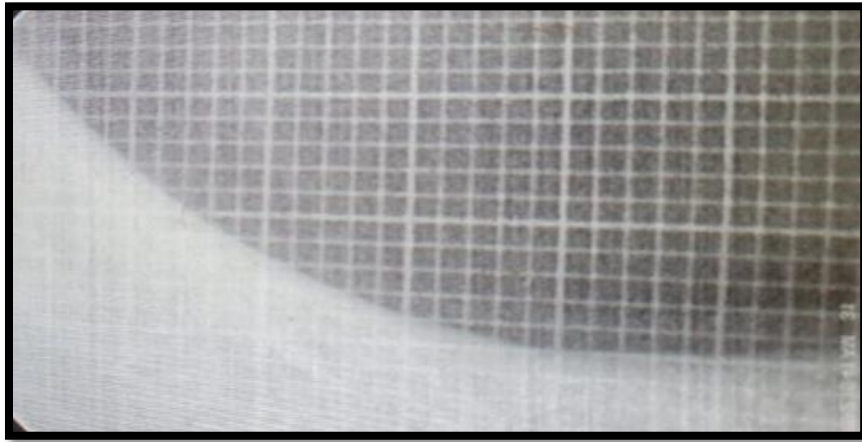


Figure 6: Pre-op radiograph with grid

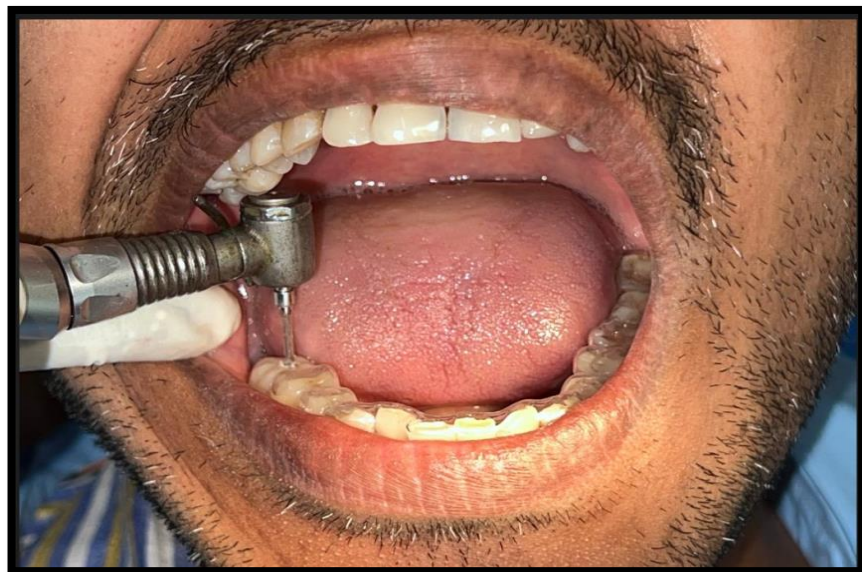


Figure 7: Pilot drill through the surgical template and acrylic teeth

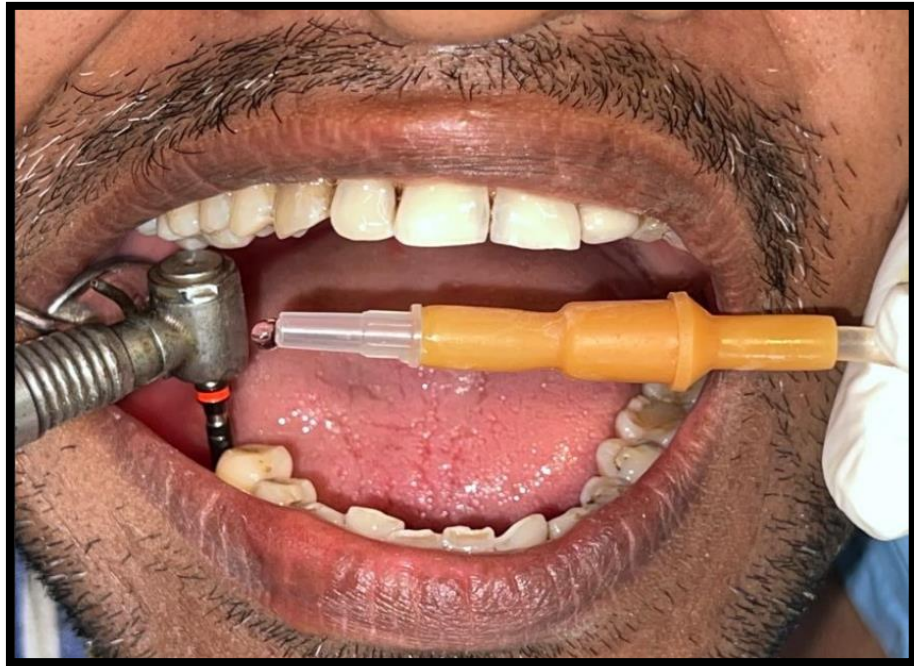


Figure 8: Saline irrigation throughout the procedure



Figure 9: Implant Placement using Torque ratchet



Figure 10: Implant with cover screw

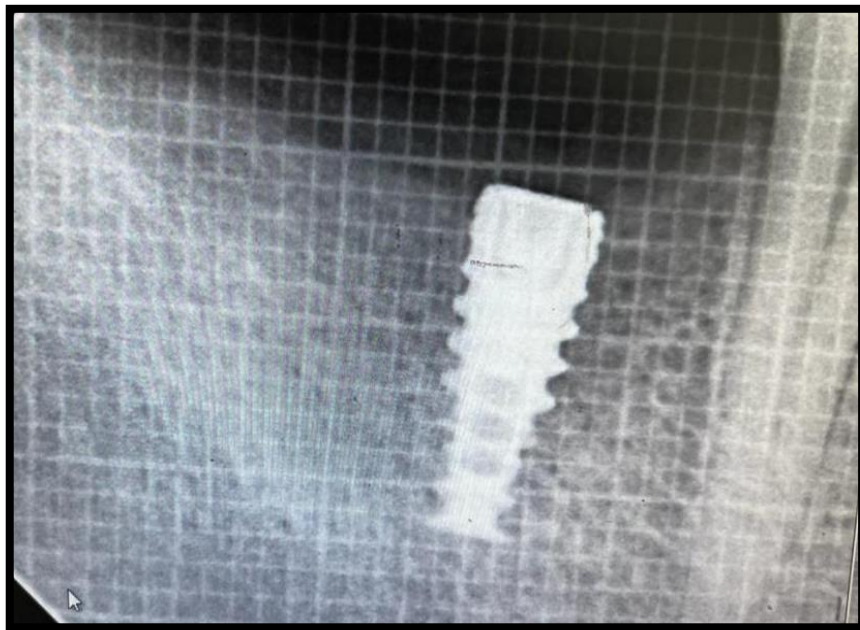


Figure 11: Post -op radiograph

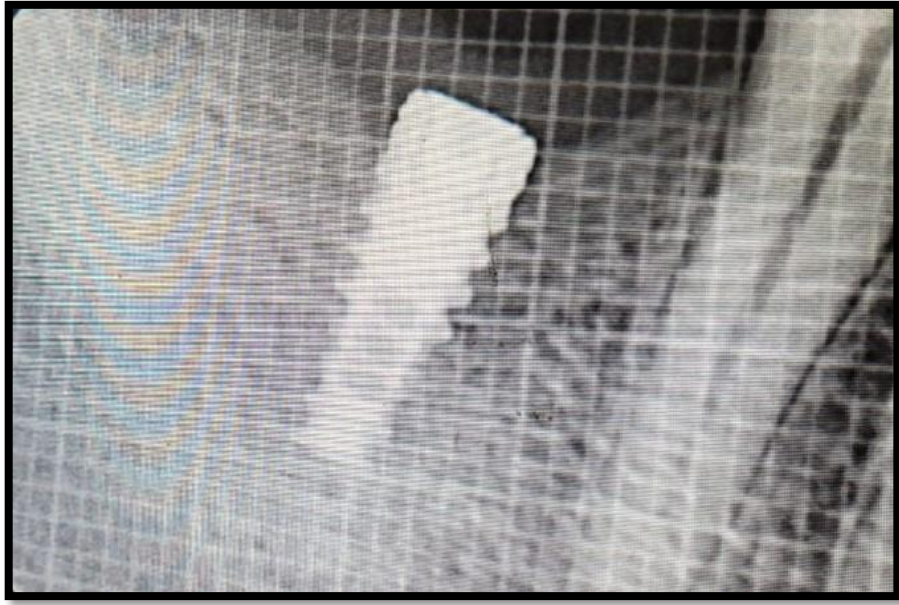


Figure 12: Radiograph at one month

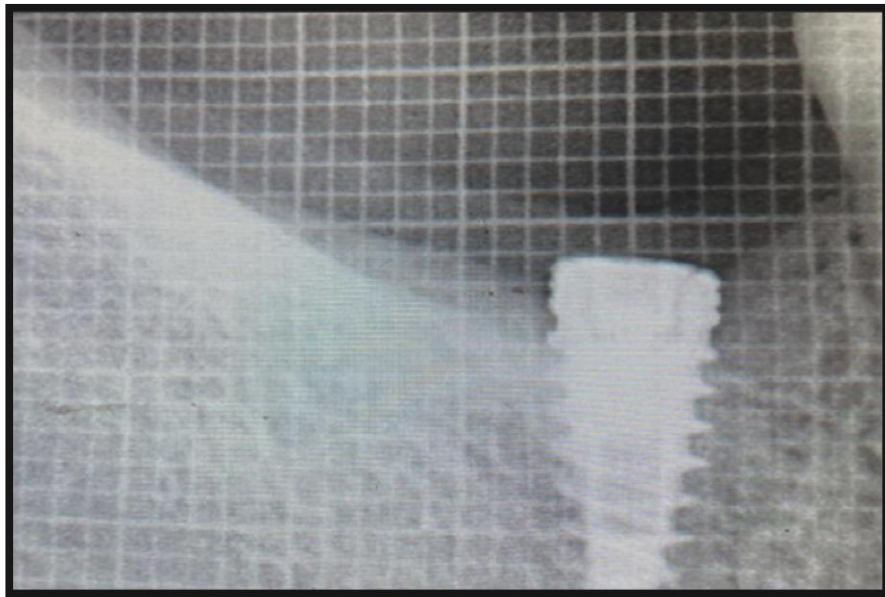


Figure 13: Radiograph at three months

Data analysis

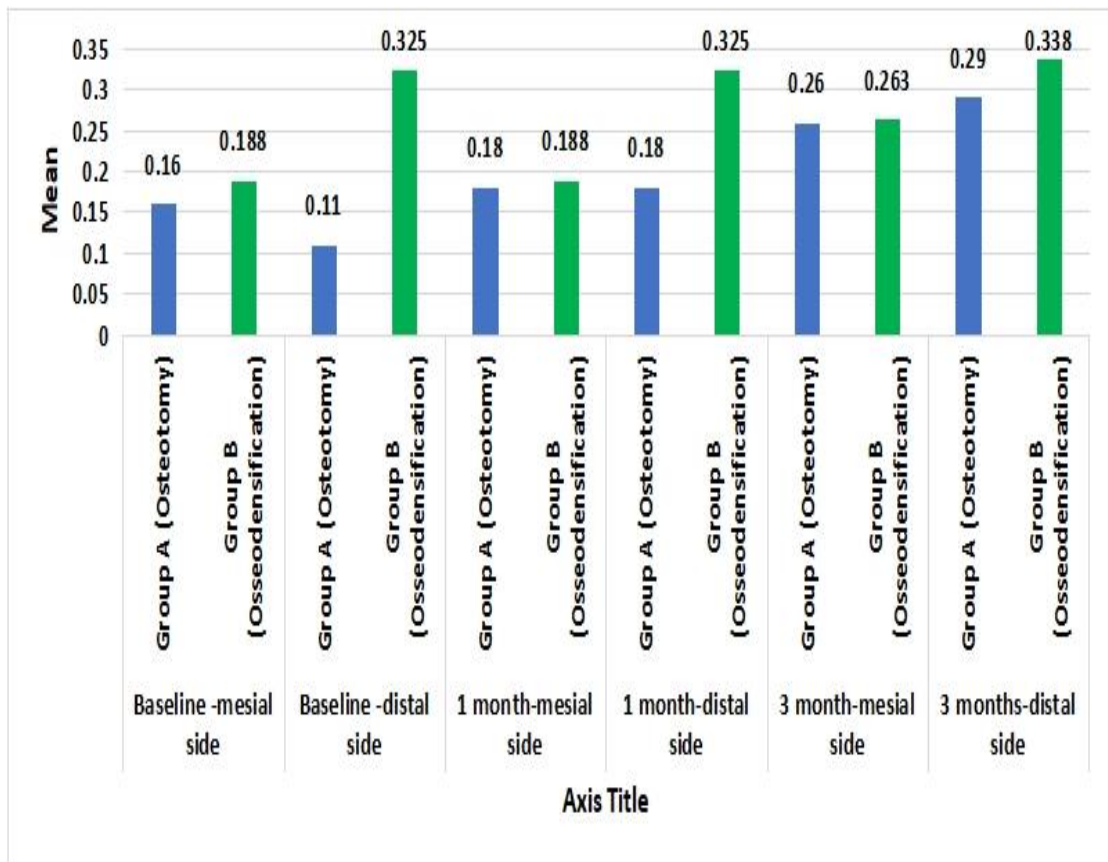
Data were entered into Microsoft Excel spreadsheet and was checked for any discrepancies. Summarized data was presented using Tables and Graphs. The data were analysed by SPSS (21.0 version).

Wilk test was used to check which all variables were following a normal distribution. Data were normally distributed, therefore; bivariate analyses were performed using the parametric tests i.e., independent-test (for comparing two groups), and Paired test or intragroup comparison level of statistical significance was set at a p-value less than 0.05

No significant difference was seen in crestal bone loss of Group A and Group B subjects on the mesial and distal side at baseline, 1 month, and 3 months when compared using an independent t-test as $p > 0.05$.

	Groups	Mean	Std. Deviation	Std. Error Mean	P VALUE
Baseline - mesial side	Group A (Osteotomy)	.160	.1838	.0581	0.840
	Group B (Osseodensification)	.188	.3720	.1315	
Baseline - distal side	Group A (Osteotomy)	.110	.1524	.0482	0.019
	Group B (Osseodensification)	.325	.1982	.0701	
1 month - mesial side	Group A (Osteotomy)	.180	.1751	.0554	0.955
	Group B (Osseodensification)	.188	.3720	.1315	
1 month - distal side	Group A (Osteotomy)	.180	.1619	.0512	0.106
	Group B (Osseodensification)	.325	.1982	.0701	
3 months - mesial side	Group A (Osteotomy)	.260	.1506	.0476	0.985
	Group B (Osseodensification)	.263	.3889	.1375	
3 months - distal side	Group A (Osteotomy)	.290	.1792	.0567	0.596
	Group B (Osseodensification)	.338	.1923	.0680	

TABLE 2: Intergroup comparison of mean crestal bone loss in the first three months of implant placement

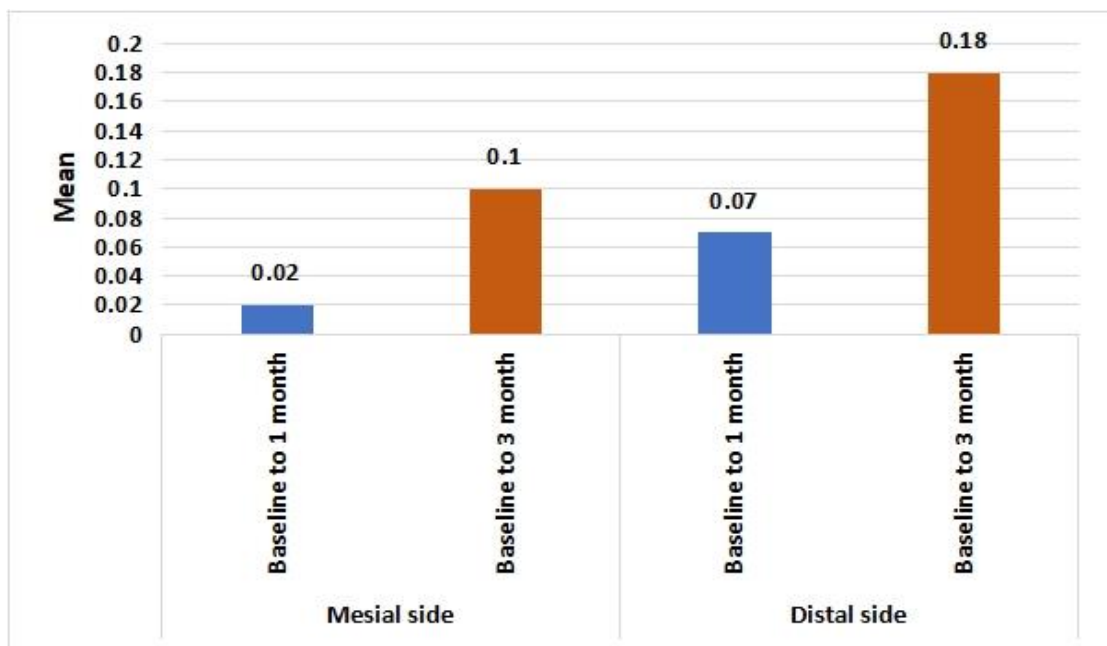


Graph 1: Axis title graph showing intergroup comparison of mean crestal bone loss in the first three months of implant placement

Intragroup comparison of crestal bone loss among Group A subjects showed significant differences on the mesial side from 0-3 months only whereas on the distal side significant difference was seen in mean crestal bone loss from 0-1 month or 0-3 months.

The difference in crestal bone loss from		Paired Differences					t	df	P value
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Mesial side	Baseline to 1 month	-.020	.0632	.020	-.0652	.0252	1.000	9	.343
	Baseline to 3 months	-.100	.1054	.0333	-.1754	-.0246	3.000	9	.015*
Distal side	Baseline to 1 month	-.070	.0675	.0213	-.1183	-.0217	3.280	9	.010*
	Baseline to 3 months	-.180	.1317	.0416	-.2742	-.0858	4.323	9	.002*

Table 3: Intragroup comparison of crestal bone loss in Group A subjects

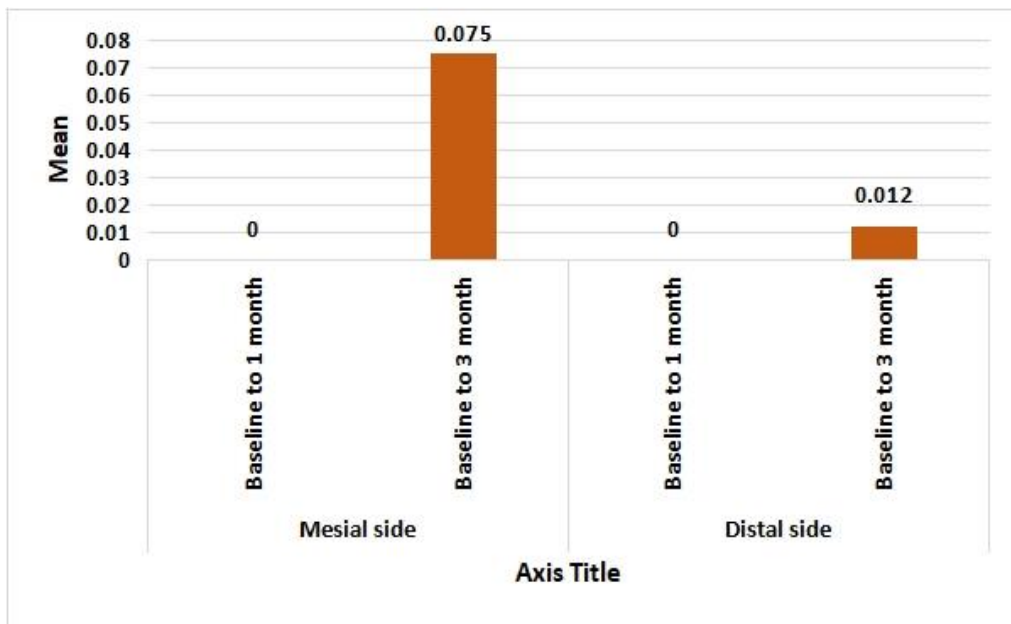


Graph 2: Intra-group comparison of mean crestal bone loss in Group A subjects

Intragroup comparison in Group B subjects showed no significant differences in crestal bone levels from 0-3 months whereas, from 0-1 month, no change in crestal bone level was appreciated.

	Paired Differences	T	df	P value					
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference	Lower	Upper			
Mesial side	Baseline to 1 month	-	-	-	-	-	-	-	-
	Baseline to 3 months	-.0750	.1753	.0620	-.2215	.0715	-1.210	9	.265
Distal side	Baseline to 1 month	-	-	-	-	-	-	-	-
	Baseline to 3 months	-.0125	.0354	.0125	-.0421	.0171	-1.000	9	.351

Table 4: Intragroup comparison of crestal bone loss in Group B subjects



Graph 3: Intragroup comparison of crestal bone loss in Group B subjects

The concept of Osseointegration ‘i.e.,’ the formation of bone to the titanium oxide layer of the implant was introduced by Branemark which was a milestone in the field of implantology¹. To achieve successful osseointegration, the two phases of implant dentistry namely: surgical and prosthodontics must be executed with utmost precision and care.

In the surgical phase, conventional drilling protocol has proven its efficiency for implant placement in edentulous areas of dense cortical bone, but it failed to attain the same in the thin trabecular region of the jaw, especially the maxillary posterior region. The posterior region of the maxilla (D4, Misch’s classification) has fine trabeculae and poor bone density when compared to all other regions of the jaw, due to which the elastic modulus of the posterior maxilla is higher than the Titanium implant under loading. Thus, the stress pattern transfers more force towards the apical area of the implant leading to decreased % BIC (Bone Implant Contact) followed by bone loss and implant failure. This leads to increased morbidity of implants placed in the posterior maxilla²³. Since then, various kinds of research have been done so far to improve the efficiency of osteotomy in poor bone density regions of the jaw which led to the development of a newer approach in implantology- Osseo densification.

The novel approach in implant dentistry Osseo densification was introduced by Huwais in 2015 where specially designed Densah burs are used. These burs in their counter-clockwise movement with a negative rake angle condense the excavated bone laterally towards the implant bed thus improving bone mineral density². The viscoelasticity and plastic deformation of bone enhance the Osseo densification procedure by condensing the bone fragment which itself is an autograft at the implant site thus creating a smaller osteotomy site when compared with that of traditional drilling protocol²⁵.

The current study was done to evaluate the crestal bone loss around Titanium implant placement by Osteotomy & Osseo densification at different time periods of the first and third month and compare the same with that of baseline. The time period is a significantly important factor to consider in the assessment of the amount of bone formed or lost during osseointegration due to its healing pattern or peri-implant remodeling. Post-implant placement, within the first twenty-four hours inflammatory cells namely, Neutrophils act at the implant site as the first line of defense. For two to four days, macrophages and monocytes release cytokines and growth factors at the implant site and remove debris. By the fourth day, the blood clot is gradually replaced by mesenchymal cells which convert themselves to osteoblast and collagen matrix. Thus, the process of calcification initiates in one week. By one-month, new bone will be formed at the implant site by means of contact osteogenesis and Distant osteogenesis. Hence it takes approximately three months (8 to 12 weeks) for the peri-implant site to completely remodel to lamellar bone forming a peri mucosal seal²¹

The study used peri apical radiographs for analyzing crestal bone loss as has been documented by various authors ^{13,16,19,29}. The accuracy of the grid used in the study is insignificantly lesser than that of CBCT as per study done by Deshpande and Bhargava¹⁷ Moreover radiographic grid was used as it is economical and easily available with the added advantage of scatter rejection. The grid absorbs scattered radiation before reaching the film thus producing the exact reproduction of proportions. Even though in cases of radiographic angulation errors like image elongation and shortening, the dimension of the grid as 1mm square remains the same, thus reducing the requirement of re-exposure to radiation. Though CBCT is used currently for most cases it has a few disadvantages of scattering implant images and beams hardening artifacts which can reduce the diagnostic quality of images^{11,17}

From the current evaluation of the study, it was observed that crestal loss was more in the mesial side of the osteotomy group in a few cases though statistically, it was insignificant. This may be due to an interruption in vascular supply during traditional drilling which would have formed microcracks in between the trabeculae thereby initiating an inflammatory response and delaying wound healing at the implant osteotomy site^{12,30}. Moreover, traditional drilling excavates bone from the implant site and thus bone remodeling takes almost twelve weeks or more depending upon the host immune response for bone remineralization at the implant site²¹.

Studies have shown that the proximity of thick cortical bone to bone marrow is comparatively less than the thin trabecular regions of the jaw¹⁰ increasing the time period for the formation of peri mucosal seal²¹.

Osseo densification group showed no variation in crestal bone when compared to osteotomy. This may be due to the formation of bone chips between the trabeculae which themselves act as nucleating sites along the wall of the implant site thus initiating bone mineralization and osseointegration. The densah burs in counterclockwise movement condense the bone fragments in an outward strain forming an auto graft layer at the peri-implant site and improving bone integrity³². D4 bone has a high surface area and hence is in close proximity to the bone marrow which is rich in mesenchymal cells, osteoclasts, and high vascularity. Thus, though D4 is considered as the poor density bone, its ability for new trabecular bone formation is comparatively faster than the cortical bone¹⁰

The clinical-radiographic study by Sultana et al ²⁷ on Osseo densification and traditional drilling protocol in the anterior maxillary region through a Cone Beam Computed Tomography (CBCT) showed bone growth of 36.90% was seen in osseodensification when compared to osteotomy group with bone growth of only 29.84% in eight months. The results of statistical analysis using t -test concluded variations in intragroup only with $P < 0.05$ which was statistically insignificant.

This study is in accordance with the study done by Siddhant Aloorer, Manoj Shetty, and Chethan Hegde³¹. The CBCT results of his study showed that the bone density at the Osseo densification site tends to increase from 8.664% to 9.189% when compared to the osteotomy site which showed decreased bone width from 8.4 to 8.1. The results of his study concluded that there is no statistical difference between the levels of the crestal bone in an Osseo densified site as compared to a conventional osteotomy site ($p = 0.124$).

The CBCT studies of other research on crestal bone loss by comparing osseodensification and osteotomy have also shown statistically insignificant results³¹. Though significant changes were observed in other research as well¹⁶ on a five-year study, bone loss in the first year was 1.5-0.62mm, and bone gain of 1.20+0.49mm when observed in the third year with a success rate of 97.76% in the fifth year. This decrease in bone loss after implant loading over five years implies the importance of proper bone healing around the implant site is the key factor to the success of the prosthesis¹²

The viscoelastic property and plastic deformation of bone is enhanced in Osseo densification which compacts the bone chips in between the thin trabecular regions of the jaw, which on itself acts as an autograft at the implant site. Thus, when compared to traditional drilling protocol, Osseo densification improves the nucleating sites for osteogenesis, thereby promoting bone-implant contact and bone mineralization. whereas, over-compression of thick cortical regions of the jaw by Osseo densification can lead to bone necrosis and implant failure²⁵. Hence precise knowledge of the technique should also be considered for the success and longevity of the implant prosthesis.

From various researches done by many so far, it can be observed that Osseodensification has been shown to improve bone density in thin trabecular regions of the jaw provided we analyze crestal bone formation with proper healing time. Hence the healing time to assess crestal bone formation is an important determinant to consider the amount of bone formed or lost²¹.

The results from the study indicate no statistically significant changes in crestal bone between Osteotomy and Osseo densification at the first three months of implant placement as the accepted criteria as suggested from various studies suggest a mean crestal bone loss of 1.5mm in the first year⁴, 0.2mm or less annually⁵, 0.9mm to 1.6mm is accepted during the follow-up period of one year and mean crestal bone loss of 0.05mm to 0.13mm is accepted annually for implant longevity and success⁸.

The radiographic evaluation of bone mineralization at the implant site to determine its success requires a precise long-term follow-up at regular intervals. More research is yet to be done in human trials to accurately determine the crestal bone loss at the implant site.

LIMITATIONS

- Limited sample size.
- Placement of implants is not confined to one region of the jaw.

FUTURE SCOPE OF STUDY

- Longer observation interval
- Larger sample size
- Evaluation of post-prosthesis crestal bone loss is required to analyze crestal bone changes around implants.

The present in-vivo study radiographically assessed the crestal bone levels of Osteotomy and Osseo densification for a period of three months

The conclusion is as follows:

- No significant difference was seen in crestal bone loss of Osteotomy and Osseo densification subjects at baseline, 1 month, and 3 months when compared using an independent t-test as $p > 0.05$.

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**BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES
(FACULTY OF BBD UNIVERSITY), LUCKNOW**

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled “**Comparative Evaluation of Crestal Bone Loss Following Titanium Implant Placement by Osteotomy & Osseodensification Technique**” submitted by **Dr Rakhi Raveendran** Post graduate student from the **Department of Prosthodontics and Crown & Bridge** as part of MDS Curriculum for the academic year 2020-2023 with the accompanying proforma was reviewed by the Institutional Research Committee present on **11th October 2021** at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.



Prof. Vandana A Pant
Co-Chairperson



Prof. B. Rajkumar
Chairperson

Babu Banarasi Das University
Babu Banarasi Das College of Dental Sciences,
BBD City, Faizabad Road, Lucknow – 226028 (INDIA)

Dr. Lakshmi Bala
 Professor and Head Biochemistry and
 Member-Secretary, Institutional Ethics Committee

Communication of the Decision of the IXth Institutional Ethics Sub-Committee

IEC Code: 38

BBDCODS/04/2022

Title of the Project: Comparative evaluation of crestal bone loss following titanium implant placement by osteotomy & osseodensification technique.

Principal Investigator: Dr Rakhi Raveendran **Department:** Prosthodontics and Crown & Bridge

Name and Address of the Institution: BBD College of Dental Sciences Lucknow.

Type of Submission: New, MDS Research

Dear Dr Rakhi Raveendran,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 07th April, 2022.

- | | | |
|----|--------------------------------------|--|
| 1. | Dr. Lakshmi Bala
Member Secretary | Prof. and Head, Department of Biochemistry, BBDCODS,
Lucknow |
| 2. | Dr. Amrit Tandan
Member | Prof. & Head, Department of Prosthodontics and Crown &
Bridge, BBDCODS, Lucknow |
| 3. | Dr. Rana Pratap Maurya
Member | Reader, Department of Orthodontics, BBDCODS, Lucknow |
| 4. | Dr. Akanksha Bhatt
Member | Reader, Department of Conservative Dentistry & Endodontics,
BBDCODS, Lucknow |

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.

The comments were communicated to PI thereafter it was revised.

Decisions: The committee approved the above protocol from ethics point of view.

Forwarded by:

Lakshmi Bala

(Dr. Lakshmi Bala)
 Member-Secretary

IEC
Member-Secretary
Institutional Ethics Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

Puneet Ahuja

(Dr. Puneet Ahuja)
 Principal

PRINCIPAL BBDCODS
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 (Babu Banarasi Das University)
 BBD City, Faizabad Road, Lucknow-226028

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Consent Form (English)

Title of the Study **COMPARATIVE EVALUATION OF CRESTAL BONE LOSS FOLLOWING TITANIUM IMPLANT PLACEMENT BY OSTEOTOMY AND OSSEODENSIFICATION TECHNIQUE**

Study Number.....

Subject's Full Name.....

Date of Birth/Age

Address of the Subject.....

Phone no. and e-mail address.....

Qualification

Occupation: Student / Self Employed / Service /

Housewife/ Other (Please tick as appropriate)

Annual income of the Subject.....

Name and of the nominees(s) and his relation to the subject.....(For the purpose of compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document dated.....for the above study and have had the opportunity to ask questions. OR I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.

2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

3. I understand that the sponsor of the project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.

4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

5. I permit the use of stored sample (tooth/tissue/blood) for future research. Yes / No

6. I agree to participate in the above study. I have been explained about the complications and side effects, if any, and have fully understood them. I have also read and understood the participant/volunteer's Information document given to me.

Signature (or Thumb impression) of the Subject/Legally

Acceptable Representative.....

Signatory 's Name..... Date

Signature of the Investigator..... Date.....

Study Investigator 's Name..... Date.....

Signature of the witness..... Date.....

Name of the witness.....

Received a signed copy of the PID and duly filled consent form

Signature/thumb impression of the subject or legally

Date...

.....

Acceptable Representative

Participant Information Document (PID)

Study title: **COMPARATIVE EVALUATION OF CRESTAL BONE LOSS FOLLOWING TITANIUM IMPLANT PLACEMENT BY OSTEOTOMY AND OSSEODENSIFICATION TECHNIQUE**

You are being invited to take part in a research study, it is therefore important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully. Ask us for any clarifications or further information. Whether or not you wish to take part is your decision. The purpose of this study is to assess the prognosis of dental implants. Crestal bone levels will be evaluated for a period of three months post implant placement.

You have been chosen for this study as you are fulfilling the required criteria for this study. Your participation in the research is entirely voluntary. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. During the study you still are free to withdraw at any time and without giving a reason.. You need to follow the same precautionary methods as advised for usual implant patients. After the placement of the prosthesis on the implant, you will be required to come for follow up at first month and third month

In this study, participants radiographs with grid of dental implants will be taken at different time intervals of first and third months. The mesial and distal bone levels will be recorded and comparison will be made with conventional drilling and Osseodensification technique.

There are no side effects on patients of this study.

If additional information becomes available during the course of the research you will be told about these and you are free to discuss it with your researcher, your researcher will tell you whether you want to continue in the study. If you decide to withdraw, your researcher will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

This research study is organized by the academic institution. You do not have to pay for any additional procedures involved apart from the usual cost of treatment.

Signature of PI.....

Name.....

Date

MASTER CHART

SL NO:	Tooth.NO	OSTEOTOMY POST IMPLANT PLACEMENT					
		AT TIME		AFTER 1 MONTH		AFTER 3 MONTHS	
		MESIAL	DISTAL	MESIAL	DISTAL	MESIAL	DISTAL
1	46	0.1	0.1	0.1	0.1	0.2	0.3
2	46	0.1	0.1	0.1	0.2	0.3	0.2
3	47	0.5	0.2	0.5	0.2	0.5	0.2
4	37	0.5	0.5	0.5	0.6	0.5	0.7
5	35	0.1	0	0.1	0.1	0.3	0.3
6	36	0	0.1	0	0.1	0.1	0.2
7	44	0.1	0	0.1	0.1	0.1	0.3
8	34	0.1	0	0.1	0	0.1	0
9	35	0	0	0.2	0.2	0.3	0.4
10	37	0.1	0.1	0.1	0.2	0.2	0.3

MASTER CHART

SL NO:	Tooth.NO	OSSEODENSIFICATION :POST IMPLANT PLACEMENT					
		AT TIME		AFTER 1 MONTH		AFTER 3 MONTHS	
		MESIAL	DISTAL	MESIAL	DISTAL	MESIAL	DISTAL
1	25	0	0.5	0	0.5	0.5	0.5
2	11	0	0.2	0	0.2	0	0.2
3	14	0.5	0	0.5	0	0.6	0
4	15	1.0	0.5	1.0	0.5	1.0	0.5
5	23	0	0.5	0	0.5	0	0.5
6	26	0	0.2	0	0.2	0	0.2
7	16	0	0.5	0	0.5	0	0.5
8	25	0	0.2	0	0.2	0	0.3
9	21	0	0.1	0	0.2	0	0.1
10	16	0	0.5	0	0.5	0	0.5

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Swati
30/1/23

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