COMPARISON OF THE PRIMARY AND THE FINAL DENTAL IMPLANT STABILITY PLACED BY CONVENTIONAL DRILL AND DENSAH BUR IN SUBOPTIMAL DENSITY BONE

Dissertation

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In the partial fulfillment of the requirements for the degree

Of

MASTER OF DENTAL SURGERY

In

ORAL AND MAXILLOFACIAL SURGERY

By

Dr. Hrishijit Saikia

Under the guidance of

Prof. (Dr.) Hemant Gupta

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BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

(Faculty of Babu Banarasi Das University)

BATCH: 2018-2021

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"COMPARISON OF THE PRIMARY AND THE FINAL DENTAL IMPLANT STABILITY PLACED BY CONVENTIONAL DRILL AND DENSAH BUR IN SUBOPTIMAL DENSITY BONE"** is a bonafide and genuine research work carried out by me under the guidance of ***Prof. (Dr.) Hemant Gupta***, Professor and Head, Oral and Maxillofacial Surgery, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

Date: 07/07/21

Place:

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Dr. Hrishijit Saikia

CERTIFICATE BY THE GUIDE

This is to certify that the dissertation entitled **"COMPARISON OF THE PRIMARY AND THE FINAL DENTAL IMPLANT STABILITY PLACED BY CONVENTIONAL DRILL AND DENSAH BUR IN SUBOPTIMAL DENSITY BONE"** is a bonafide work done by **Dr.Hrishijit Saikia,** under my direct supervision and guidance in partial fulfillment of the requirement for the degree of M.D.S. in Oral and Maxillofacial Surgery.

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CERTIFICATE BY THE CO-GUIDES

This is to certify that the dissertation entitled **"COMPARISON OF THE PRIMARY AND THE FINAL DENTAL IMPLANT STABILITY PLACED BY CONVENTIONAL DRILL AND DENSAH BUR IN SUBOPTIMAL DENSITY BONE"** is a bonafide work done by **Dr. Hrishijit Saikia,** under our direct supervision and guidance in partial fulfillment of the requirement for the degree of M.D.S. in Oral and Maxillofacial Surgery.

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This is to certify that the dissertation entitled **"COMPARISON OF THE PRIMARY AND THE FINAL DENTAL IMPLANT STBILITY PLACED BY CONVENTIONAL DRILL AND DENSAH BUR IN SUBOPTIMAL DENSITY BONE"** is a bonafide work done by **Dr. Hrishijit Saikia,** under direct supervision and guidance of **Prof. (Dr.) Hemant Gupta,** Professor and Head, Department of Oral and Maxillofacial Surgery, Babu Banarasi Das College Of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

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Dedicated to my family

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Dr. Hrishijit Saikia

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LIST OF ABBREVIATION

ASA :	Anaethesiologist Classification
RFA :	Resonance frequency analysis
BIC :	Bone implant Contact
ISQ :	Implant Stability Quiescent
RVG :	Radiovisiography
CBCT :	Cone-beam computed tomography
IOPARs :	Intraoral periapical radiographs
OPGs :	Orthopantomograms
BAOSFE :	Bone added osteotome sinus floor elevation
CT :	Computed tomography
OSFE :	Osteotome sinus floor elevation
tSFE :	Transcrestal sinus floor elevation

Abstract

INTRODUCTION

Dental implant has transmogrified the dental rehabilitation. The prime requisite for successful implant treatment is osseointegration. Inadequate quality and quantity of bone in posterior maxilla is a challenge in achieving primary stability, which is an imperative factor for a successful osseointegration. In the last two decades many techniques have been developed to increase the primary stability of dental implants; some of the most advocated techniques are the Summer's osteotome technique,[8] under-sized osteotomy and bicortical fixation. Despite the success of these techniques, they have considerable complications and have a steep learning curve. The recent technique of osseodensification introduced by Huwais in 2014[11] allows the increase in primary stability by autografting and compacting in an outward direction while expanding the osteotomy. The pumping motion creates a rate-dependent stress to produce a rate-dependent strain and allows saline solution to induce outward pressure to the osteotomy walls. This combination facilitates increased bone plasticity and bone expansion. The present was conducted to compare the osseo-densification (OD) technique with the traditional osteotomy preparation by drilling.

AIM AND OBJECTIVES

To clinically evaluate and compare the primary and final dental implant stability and radiographically measure the %BIC and crestal bone loss between implants placed by OD technique and conventional technique.

METHOD AND METHODOLOGY

A randomized single center study was conducted on 14 implants to clinically and radiographically compare the primary and final dental implant stability by RFA, crestal bone loss and percentage of bone-to-implant contact.

RESULTS

No implant failures were observed after 6 months of implant placement in both the groups. The % BIC was statistically significantly higher in the test group than the control group. The mean ISQ value of the test group (OD) was also higher, but it was more significant from 3rd to 6th month period between both the groups. The difference in the crestal alveolar bone height resorption was not significant, between the test (OD) and the control group (Conventional drill), as evaluated radiographically.

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CONCLUSION

Osseodensification technique by Densah bur is a biomechanical site preparation for implant placement which increases implant primary stability, by increasing the peri-implant bone density. It was found to be a superior technique of osteotomy preparation, especially in sub-optimal density bone. OD preserves bone bulk and increases the peri-implant bone density by autografting along with compaction of bone tissues along the osteotomy walls as it expands to the desired size. This compact autografted walls also increases the %BIC, thus increases the secondary stability along with faster healing. The overall patient satisfaction was high in both the groups, but the OD was found to be a superior technique that provides not only enhanced primary stability, but also greater % BIC as compared to conventional osteotomy technique.

Introduction

Introduction

The concept of osseointegration of dental implants in the field of dentistry resulted in a paradigm shift that affected almost every aspect of dental rehabilitation. It not only restores the function and esthetic of a partially edentulous patient, but also provides a sound framework for treating complete edentulism, with meager complications. However, as more dentists and patients started choosing implants as restorative option, more complications and adverse events began to surface. One of the most important factors that affect osseointegration is the primary stability of the implant which in turn is affected mostly by the surgical procedures and the quality and volume of the peri-implant bone[1]. Dental implants inserted at the posterior region of maxilla exhibit the lowest success rates as the inadequate quantity and low density bone in this area often jeopardize rigid fixation of the endosteal implants,[2] leading to inferior osseointegration.[3] Besides, tooth loss, old age, and removable or unsuitable removable dentures inevitably lead to alveolar bone resorption both in height and width.[4] Many surgical techniques have been developed to increase the primary stability of an implant placed in low density bone such as bi-cortical fixation of the implant,[5] undersized preparation of the implant bed[6,7] and bone condensation by the use of Summer's osteotomes[8,9] technique. Specially designed implants, with different micro- and macro-geometry, for implant placement in structurally compromised areas were developed, but the results were not consistent. It's still remains a challenge to achieve adequate implant stability in these areas.[11] Standard drills remove and excavate bone during implant site preparation. Osteotome technique introduced by Summers et al [12] in 1994 is one of the alternatives of osteotomy site preparation for low-density bone, particularly the maxilla. Using osteotomes of increasing size in a controlled, sequential manner compresses the trabecular bone, laterally and apically, to expand the osteotomy site with minimal trauma, and bone volume preservation. But this technique induces fractures of the trabeculae that require long remodeling time and hence delays the secondary implant stability.[12] Moreover the pressure exerted on the crestal cortical bone could result in greater degree peri-implant marginal bone loss. The resultant prolonged healing period will eventually decreases secondary stability. Undersizing the osteotomy is a common practice, especially in maxilla to achieve increase in the primary stability but by doing so it eliminates the healing chamber and creates a high degree of bone mechanical strain, thus adversely effecting the stability and the process of osseointegration.[13]The difference in the modulus of elasticity of the bone and the metallic implant leads to a higher fracture rates in cases where bicortical fixation was used as an alternative to enhance the primary stability in low-density areas. OD, a non extraction technique, was developed by Huwais in 2013[14] and made possible with specially designed burs, called Densah burs, to increase bone density as they expand an osteotomy and in turn increases Implant Mechanical Stability.[13] Unlike traditional bone drilling technologies, osseodensification does not excavate bone tissue. On the contrary, it preserves bone bulk, so bone tissue is simultaneously compacted and autografted in an outwardly expanding direction to form the osteotomy.[14] The OD technique of osteotomy preparation uses universal compatible drills to expand the osteotomy, bone densification, and indirect sinus lift; and also to achieve bone expansion at different sites of compromised bone quality. The rationale behind this process is the densification of the bone in immediate contact to the implant results in higher degree of primary stability due to the formation of a denser bone interface and a significantly higher bone-to-implant contact ratio, thus enhancing the mechanical engagement and decreasing the micro-motion between the implant and the bone walls of the implant bed.

The present study attempts to assess the use of Densah bur as a drilling technique in comparison to the use of conventional drilling in implant placement in terms of initial and final implant stability in suboptimal density bone.

Aim and objective

AIM

The aim of this study is to compare the primary and the final dental implant stability placed by conventional drill and Densah bur in suboptimal density bone.

OBJECTIVES

The objectives of the present study are

- To evaluate the primary dental implant stability placed by conventional drills and Densah burs.
- To evaluate the implant stability placed by conventional drills and Densah burs after 3 months and 6 months, postoperatively.
- To evaluate the Bone-to-implant contact (BIC) percentage after 6 months, post-operatively in both the groups.
- To assess crestal bone loss radiographically at 3 months and 6 months, postoperatively in both the groups.
- To compare both the groups.

Review of literature

- **Scahalhorn (1972)**[16] in a study found that the most common allograft used is deminaralized freeze-dried bone allograft (DFDBA). It was observed that DFDBA is a rich source of type I collagen, which comprises most of the organic component of bone.
- **Albrektsson et al (1981)**[17] studied ultrastructural analysis of long term functioning osseointegrated implants and the interface zone between bone and implant using X-rays, scanning electron microscopy (SEM), transmission electron microscopy (TEM) and histology in man. The SEM study revealed a very close spatial relationship between titanium and bone. Dense lamellae type bone, forming well organized concentric lamellae was visualized under TEM. They concluded that osseointegration is a reliable cement free bone harbor for permanent prosthetic tissue substitutes.
- **Adell et al (1981)**[18] evaluated the outcome of osseointegrated implants in the treatment of edentulous jaws. Elective removable bridges were provided to all patients and were examined continuously at one year intervals for 5-9 years. The stability and the crestal bone loss values were very encouraging. They concluded that osseointegrated implants, in all aspects, fulfils and even exceeds the criteria set by the 1978 Harvard Conference on a successful dental implantation procedure.
- **Zarb G and Schmitt A (1990)[19]** studied the clinical effectiveness of osseointegrated dental implants. Implants were placed following the surgical protocol described by Dr. P.I. Branemark. They observed that the two-stage surgical procedure of implant placement had successful osseointregrated rate of 89.05%. The authors appears to confirm and endorse Branemark's claim that osseointegrated implants are a predictably safe analogue for tooth roots, capable of supporting prosthesis in edentulous jaws.
- **Jaffin R and Berman C (1991)[20]** in clinical study spanning over 5years observed a failure rate of implant placement, following Branmark's protocol, of 35% in type 4 bone while only 3% of implants failed in type 1, 2, and 3 bone. The authors concluded that owing to high failure rate in type 4 bone, presurgical evaluation of type 4 bone could enhance the predictability of the treatment.
- **Brugnami et al (1996) and Dealemands et al (1997)[21]**observed autografts as superior to allografts due to the absence of immune reactions associated with the former. They advocated autografts as the best choice for osseoinductive purposes.

- **Venturelli A (1996)**[22] studied the impact of a modified surgical protocol for placing implants in the posterior maxilla. In an attempt to minimize the surgical trauma and heat generated, he used reduced one-stroke drilling technique with internally irrigated drills, reduced RPM and drilling time. All implants were checked radiologically for every 12 months. Only 1 of the 42 implants was lost at stage 2 surgery. The author concluded that considerable benefits may be obtained by modifying the standard protocol to maximize the results in poor density bone areas.
- **Schwartz A and Chaushu G (1998**)[23] evaluated the consequences of submerged implants placed into fresh extraction sites without incisions or primary closure. No barrier membranes were used and the sole grafting material was autogenous bone chips. Complete bony healing was noticed in all cases with high survival rates. Clinical osseointergration was achieved with minimal gingival recession and papilla preservation. They concluded that immediate implant placement can be successful for replacing a single tooth even without primary closure.
- **Esposito M et al (1998)**[24] reviewed the various biological factors associated with increased failure rates, based on literature. They suggested that radiographic examinations, showing less than 1.5 mm marginal bone loss during first year of function and less than 0.2 mm annually thereafter, along with implant mobility tests appeared to be the most reliable parameters in the assessment of success for osseointegrated implants. In addition, the failure rate in edentulous maxilla was almost three times higher when compared with the edentulous mandible. Authors concluded that jaw volume and bone quality as the major determinants for implant failures along with surgical trauma
- **Sennerby L and Roos J (1998)** [25]reviewed the current knowledge about the influence of surgical factors on implant failure. The reviewed data indicated that short implants placed in atrophic maxilla and poor quality bones were associated with high failure rates. They also observed that though bicortical fixation may improve implant stability in atrophic maxilla, the antral floor perforation increases the risk of infection. They concluded that the quality and quantity of bone has the greatest impact on implant success and hence stressed the need for further research to improve the success rates in severely resorbed maxilla.
- **Meredith N (1998)**[26]discussed the parameters necessary to monitor successful implant placement. They discussed various techniques for measuring implant stability

and osseointegration, such as cutting resistance, removal torque values, Periotest and Dental Fine Tester. They found that the RFA was easy to use in addition of being capable of eliciting quantitative information related to implant stability and stiffness and hence concluded that RFA has the potential application for predicting the outcome of implant as it yields valuable information of stability, both at placement and during function.

- **Mayfield L (1999**)[27] compared immediate (IIP), delayed and late submerged and transmucosal implants. They observed that the implant survival rate is similar with either an IIP or a delayed placement protocol. They concluded that IIP offers many advantages over delayed placement, these include improve healing without flap advancement and decreased treatment time, surgical procedures, cost and discomfort.
- **Martinez H et al (2000)[28]** proposed various protocols to achieve optimal implant stability in low density bone sites. They suggested the use of CT for qualitative and quantitative analysis of the residual bone and RFA for recording the primary and secondary implant stability. They advocated the use of Summer's osteotome technique and/or bicortical anchorage or tuberosity and ptyrego-maxillary implants with longer healing period for implants placed in type IV bone. They suggested that wider implants with sandblasted, hydroxyapatite, TPS, and acid-etched surface will increase the %BIC and hence the success rates of implants placed in compromised bone density sites.
- **Micheal et al (2002**)[29] used human mineralized cancellous bone as a graft material in an effort to preserve and create sufficient bone for implant placement after tooth extraction. Their result indicated that restoration of extraction sites using human mineralized bone has potential to preserve or recreate an extraction sites bone bulk in preparation for implant placement.
- **Hoextor (2002**)[30] observed that the advantages of autograph bone material is that it maintains bone structures such as minerals, collagen and viable osteoblasts and bone morphogenic proteins(BMPs), while the main disadvantage is the morbidity of a second surgical site.
- **Scott and Maurice (2002)[31]** in a study used a synthetic bio active restorable bone graft of low temperature hydroxyappetite material mixed with autogenous bone graft for implant placement. After 4 months they observed that, the underlying implants were covered with a thick layer of mature bone with the mature bone surrounding the

remaining crystals of the bioactive restorable particulates and hence improved osteointregation.

- **Morris H et al (2003)[32]** studied the influence of bone density on implant stability. Implants were placed into 4 blocks, selected to simulate the various bone densities. After 3, 6, 9, 12, 18, 24, 36, and 48 months they observed that the PTVs of implants in type 4 bone were significantly less negative than those of other bone densities, suggesting that the bone-implant complex does not improve with any appreciable amount and may, in fact, get slightly worsen during long term functional loading.

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- **Fugazzatto (2004)[34]** used a combination of osseous coagulum collected during preparation and freeze-dried bone allograft for immediate implant insertion and loading. The result was encouraging as after 6 months from surgery there was a clinically immobile implant and healthy surrounding soft tissue; no post operative gingival recession, no probing depth exceeding 3 mm; no bleeding on probing and no sensitivity to pressure.
- **Cornelini R et al (2004)[35]** evaluated the use of a porous bone mineral matrix xenograft as an adjunct to a biodegradable barrier membrane to support healing following the immediate placement of transmucosal implants into extraction socket. They observed unchanged radiographic bone level, compared to baseline, in both the groups. Moreover the soft tissue margin was located more coronal than the shoulder of the implants in the test group suggesting a higher aesthetic value, in terms of soft tissue support.

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- **Sullivan D et al (2004)[37]** compared two methods of enhancing implant primary stability in type IV bone 1) Standard Branemark System Implants inserted without using a surgical tap to prepare a threaded channel in the bone to enhance primary stability, and 2) Branemark MK IV implants inserted according to the manufacturer’s instruction. A statistically significant lower ITV and RFA values were observed in both the groups in type 4 bone. The authors hence concluded that the techniques used to maximize primary implant stability in type 4 bones were unable to achieve the desired results and success.
- **Buchter A et al (2005)[38]** compared the osseointegration and biomechanical behavior of implants placed by osteotome technique (group B) with the conventional implant

site preparation technique (group A) in an animal model. Histological analysis demonstrated fractured trabeculae in peri-implant bone in group B along with significantly lower implant stability. They concluded that there is a decrease in implant stability with osteotome technique mainly due to micro-fractures in peri-implant bone.

- **Miyamotto I et al (2005)**[39] evaluated role of regional bone structure on the dental implant stability at the time of surgery. CT scans were obtained to measure the cortical bone thickness of cortical bone at the sites of implant placement. The average ISQ value of the implants placed in mandible was higher than those placed in maxilla. They concluded that cortical bone thickness is extremely important for implants' stability and success.
- **Stavropoulos A et al (2006)**[40] evaluated the effect of osteotomes instead of conventional drilling in peri-implant bone density and/or osseointegration in implant site preparation.. All implants placed with osteotomes were lost, despite higher post-surgical ISQ values than the conventional group. None of the conventionally inserted implants were lost. They concluded that preparation of implant site by means of osteotomes had a deleterious effect on osseointegration
- **Shalabi M et al (2006)**[41] studied the effect of surgical technique on implant fixation in an in vitro study using femoral condyles of goats. The implant sites were prepared by three techniques: conventional, undersized, and osteotome technique. Peak insertion and removal torque were recorded and BIC was assessed by SEM and micro-CT. They recorded a significantly higher %BIC, ITVs and RTVs for implants inserted with the undersized preparation technique and hence higher success rate.
- **Beer A et al (2006)**[42] assessed the correlation between implant primary stability and the diameter of the implant bed. Implants were inserted in three groups based on implant bed diameter. They observed that the insertion torque was inversely proportional to the diameter of the implant bed. They concluded that higher torque values and implant stability can be achieved in poor density bone by under-preparing the insertion site diameter.
- **Alsaadi G et al (2007)**[43] evaluated the validity of subjective jaw bone quality assessment by radiographs and tactile sensation with objective parameters: the torque force needed to install implants, besides the primary stability of these implants measured either by ISQ or PTV, or both. The authors detected a significant

relationship between ISQ, PTV and cortical bone grades and between ISQ and trabecular bone grades. They concluded that subjective assessment of bone quality is related to PTV, ISQ and placement torque measurements at implant insertion.

- **Mesa F et al (2007)[44]** analyzed the variables associated with primary endosseous dental implant stability (DIS) in a 10-year retrospective study. Clinical variables, implant diameter, implant length, and Periotest value (PTVs) were analyzed in order to determine their influence on DIS. They observed that the site of implant insertion showed the strongest association with primary DIS failure, with implants in the posterior maxilla having highest risk. They also observed that shorter implants with <15 mm in length had a higher risk of failure than longer implants.
- **Hasan et al (2008)[45]** demonstrated a comparative evaluation of immediate dental implant with autogenous versus synthetic guided bone regeneration. Clinical and radiographic study showed that the autogenous bone graft appeared to be superior and the graft of choice because it maintained bone structure and activated the osteogenesis process.
- **Evans CJZ and Chen ST (2008)**[46] evaluated the esthetic outcomes of immediate implant placement. They observed that even when the clinician follows a correct IIP protocol, the resulting restoration may still present with an unacceptable esthetic outcome. They advocated for a stage approach in those patients with high esthetic expectations
- **Turkyilmaz I et al (2008)[47]** compared two surgical techniques for enhancing primary implant stability in the posterior maxilla. They noted a significantly higher mean maximum insertion torque and RFA values in the group where thinner drills were used. They also observed strong correlations between bone density and insertion torque, and implant stability values at implant placement. They concluded that using thinner drills for implant placement in posterior maxillary region may improve the primary implant stability and helps attaining higher success rates
- **Turkyilmaz I et al (2008)[48]** performed a biomechanical human cadaveric study to explore the effect of bone quality on initial intraosseous stability of implants, and to determine the correlations between bone quality and implant stability parameters. They observed that there were statistically significant correlations between bone density and ITV; bone density and ISQ values; and ITV and ISQ values. They

concluded that bone density has a prevailing effect on implant stability at placement and hence on implant's success.

- **Blanco J et al ((2008)**[49] compared peri-implant bone condensation following implant placement by the osteotome technique and standard drill technique, in the maxillary tuberosity of human cadavers. The histomorphometric evaluation revealed that the bone density of the entire peri-implant area was statistically greater with osteotome technique than the conventional drilling technique. This difference was greatest for the periapical zone. The authors concluded that peri-implant bone condensation following the osteotome technique is not homogenous through the entire peri-implant area and bone condensation is only significant in the fifth apical area.
- **Wang K et al (2006)[50]** investigated the influences of bi-cortical anchorage on primary implant stability by taking natural frequency (NF) as stability parameter. They observed that bi-cortical anchorage significantly increases both bucco-lingual and axial NF values of implants, and as the bicortical anchorage got deeper, the NF values got higher. Thus they concluded that bi-cortical anchorage can increase the bucco-lingual and axial primary stability of the implants.
- **Trisi P et al (2010)[52]** conducted an experimental study to evaluate the changes in micro-motion of implants with increasing insertion torque. Fresh bovine bone samples were divided into three groups: hard (H), normal (N), and soft (S). The implants were divided and placed according to five groups of peak insertion torque (20, 35, 45, 70, and 100 N/cm). They observed a statistically significant decrease in micro-movements of implants with increase in peak insertion torque. The authors observed that it was not possible to achieve more than 35N/cm of peak torque in soft type IV bone, thus making it the site of highest failure. They concluded that increasing the peak insertion torque reduces the implant micro-motion.
- **Roze J et al (2009)[53]** performed a human cadaveric study to demonstrate a possible correlation between bone micro-architecture and primary implant stability. Primary implant stability was recorded by RFA and bone structure was analyzed using micro CT. Bone histomorphometric evaluation revealed no correlation between ISQ values and structure of the trabecular bone, however, a significant correlation was observed between the ISQ values and cortical bone thickness. They concluded that a thick cortical bone is associated with a high implant stability quotient which is important for implant's success.

- **Huang H et al (2010)[54]** examined the correlations between bone structure and the primary implant stability indices: insertion torque value (ITV), Periotest value (PTV), and implant stability quotient (ISQ). They observed that the initial stability at the time of implant placement is influenced by both the cortical bone thickness and the elastic modulus of trabecular bone, and they concluded that the placement of an implant in areas with thin cortical bone and/or weak trabecular bone induces extreme bone strains and may increase the risk of implant failure.
- **Tabassum A et al (2010)[55]** assessed the effect of surgical technique and bone density on primary implant stability. Implants were inserted into bone equivalents of different densities by either a press-fit or by an undersized technique. Independent of the surgical technique used they observed a statistically significant increase in mean insertion & removed torque values with increase in bone density. The insertion & removed torque values were significantly higher in undersized osteotomy group. The authors concluded that bone densities play a significant role in implant primary stability and undersized osteotomy technique improves implant success rate.
- **Merheb J et al (2010)[56]** evaluated the relationship between primary implant stability and different parameters related to implant or bone properties. RFA was performed at implant placement, and RFA and PTV were recorded at the time of loading. The bone density and coronal cortical thickness at osteotomy sites were recorded using CT scans. They observed significant linear relation between RFA or PTV and HU values and cortical bone thickness, both at the time of insertion and loading. They concluded that the cortical bone thickness is a determining factor in implant primary stability and survival.
- **Shibly O et al (2010**)[57] evaluated the bone regeneration around implants in periodontally compromised patients treated by immediate implant with immediate loading. The results suggested that immediate tooth replacement along with IIP demonstrate bone gain and soft tissue outcomes similar to those seen in delayed loading. They also observed decreased marginal recession and bone loss around the implant. They concluded that if strict protocols are followed the results with IIP usually highly predictable.
- **Bilhan H. et al (2010)[58]** evaluated the role of under-dimensioned drilling and implant-related factors in implant primary stability. Implants with three different shapes and two different diameters were placed with two different surgical techniques

(conventional drilling and under-dimensioned drilling). The authors observed a significantly higher RFA and IT values in conical implants with wider diameter placed by under-dimensioned drilling surgical method, especially in cancellous bones.

- **Padmanabham. T.V and Gupta R K (2010)**[59] compared the crestal bone loss and implant stability between implants placed using conventional implant placement technique (group A) and Summer's osteotome technique (group B). They observed a significantly higher crestal bone loss in Group B. Group A demonstrated significantly higher implant stability than Group B, on the day of surgery. The authors concluded that the osteotome technique should be used only for the purpose it was introduced, that is, knife edged ridges, and it should not be considered a substitute for conventional procedures for implant placement.
- **Alghamdi H et al (2011)**[60] evaluated the survival rate of implants placed using undersized implant site preparation in areas with poor bone density. They observed that the test group where implants were placed by under-sizing the implant bed, by using 2.8-mm twisted drills for 4.1-mm diameter implants demonstrated higher mean insertion torque and RFA values than the control group. Thus they concluded that under-sizing the osteotomy site for implant placement is beneficial for enhancing the primary implant stability and improving survival rate in poor density bone like in posterior maxilla.
- **Trisi et al (2011)**[61] analyze the histologic and biomechanical phenomenon at the bone-implant interface with high torque (HT, 110 Ncm), achieved by undersized osteotomy technique, as compared to low torque (LT, 10 Ncm), achieved by conventional osteotomy technique, in an animal model. Significantly higher bone apposition, BV, RTV and BIC % were observed in implants from HT group. They concluded that higher ITV increases the primary and secondary stability of implants, especially in low density bone.
- **Marquezan M et al (2011)**[63] in a systemic review investigated the influence of bone mineral density on the primary stability of dental implants. They observed that the IT, PTV and ISQ values were higher in mandible than in maxilla. They also found a positive association between implant stability and bone density. They concluded that the higher bone mineral density of mandible is the rationale for its higher implant success rate.

- **Compose F et al (2012)**[64] evaluated the effect of drilling dimensions in insertion torque and early implant osseointegration, in an experimental study in dogs. Similar sized implants were placed into the three different sized osteotomies. They observed that the ITVs were inversely proportional to the drilling dimensions. However, they noted that despite increased ITVs, the secondary stability and BAFO values were not significantly different between all the groups, thus they concluded that although the undersized osteotomy preparation might increase primary stability, a greater amount of a necrotic 'die back' and interfacial remodelling will occur, potentially decreasing implant stability over time until secondary stability has been achieved..
- **Kut Kut A et al (2012)**[65] **e**valuated clinical and histologic outcome of using medical-grade calcium sulphate hemihydrates(MGCSH) mixed with platelet rich plasma(PRP) for extraction socket preservation graft. The test group received MGCSH mixed with PRP in extraction socket and the control group received collagen resorbable plug dressing material. They observed that a new vital bone percentage regenerated after 3 months was significantly higher in sockets grafted with MGCSH mixed with PRP compared to collagen resorbable plug. They concluded that MGCSH mixed with PRP showed rapid enhancement of bone healing compared to PRP free collagen resorbable graft..

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- **Fawad Javed et al (2013)**[67] reviewed the role of primary stability for successful osseointegration of dental implants. They observed that intraoperative surgical techniques, such as bone condensation, undersizing the osteotomy, improve the peri-implant bone density and increase the primary stability. The authors concluded that although many factors influence primary stability of implant, a poor bone quantity and quality were the main risk factors for implant failure due to its excessive bone resorption and impairment in the healing process.
- **Hsu J et al (2013)**[68] examined the relationship of three dimensional bone-to-implant contact (BIC), cortical bone height, and trabecular bone density, as measured by micro-CT, with primary implant stability in an immediate loading scenario. They observed that the 3D BIC ratio increased as the height of cortical bone and density of trabecular bone increased and a low 3D BIC ratio in type4 bone diminishes the primary implant stability.

- **Oliscovicz N et al (2013)**[69] analyzed the primary stability of dental implants inserted in different substrates using the pullout test and insertion torque. Implants were divided into 4 groups for insertion based on the stiffness of the substrates. The ITVs were recorded and the pullout test (N) was performed by an axial traction force. They observed that the ITVs and pullout force in stiffer material group was significantly higher, thus concluding that mandible being stiffer than maxilla has greater primary stability.
- **Coelho P et al (2013)**[70] evaluated the effect of different drilling dimensions, on insertion and removal torque in an experimental study on dogs. They observed that the insertion and removal torque values were inversely proportional to the drilling diameter. They concluded that different drilling dimensions resulted in variations in insertion torque values (primary stability) and stability maintenance over the first weeks of healing, with undersized drilling enhancing ITV and the primary stability of an implant.
- **Viswambaran M et al (2012)**[71] in a clinical study evaluated immediate implants placed with freezed-dried bone allograft and modified hydroxyapetite. Clinical and radiographic evaluation was done at base line, 3, 6, and 9 months. No statistically significant differences were observed for all clinical and radiographic parameters between the two groups. They concluded that both graft materials were equally effective
- **Jimbo R et al (2014)**[72] investigated the effects of undersized drilling and implant macrogeometry on bone healing around dental implants, in an experimental study on sheep. They observed that the undersized drilling implants presented significantly higher insertion torque. They observed that undersized drilling affects the biological establishment of bone formation around both implant macrogeometries, thus using undersized osteotomy in compromised bone will give better survival results
- **Hao Y et al (2014)**[73] assessed the bone quality of the dental implant site using CBCT and Simplant software, and established a quantitative range for each bone quality classification according to the classification proposed by Lekholm and Zarb. The authors found a statistically significant difference in the mean bone density of the implant sites between the regions of the jaws. They concluded that the anterior mandible has highest mean bone density and posterior maxilla has the lowest mean

bone density, they proposed a density scale that would help clinician to avoid placement of implants into the very poor quality bone where failure is more likely.

- **Galli S et al (2014)[74]** evaluated the efficacy of osteotomy dimension on osseointegration. 4.5mm diameter implants were divided and placed into 4 groups based on the final osteotomy diameters of 4.6mm (R), 4.1mm (L), 3.7mm (M), and 3.2mm (T) in the ileum of sheep. After 3 weeks, the RTV were statistically significant ordered, with higher torques correlating to tighter osteotomies. They concluded that higher primary stability of implants can be attained in poor density bone by placing then in tighter osteotomies.
- **Kyun Kim Y et al (2014)**[75] in a retrospective study compared the amount of bone resorption around implants between an autogenous tooth bone graft and a synthetic bone graft after a bone-added creastally approached sinus lift with simultaneous implant placements. After a year, they observed that the difference in bone height gain, between both groups was not significant. They concluded that autogenous tooth bone graft is a good alternative to synthetic bone graft in a bone-added sinus lift.
- **Mayer EG and Huwais S (2014)[76]** examined role of osseodensification in increasing the primary implant stability. Tests were conducted to measure primary stability in standard drilling (SD), extraction drilling (ED), and osseodensification (OD). Implants were inserted in porcine tibial plateau cancellous bone samples. Insertion and removal torques and stability as measured by RFA were significantly higher in OD group compared to SD or ED. They concluded that OD increases the primary stability and creates a densification crust around the preparation site.
- **Rola Muhammed Shadid et al (2014)[77]** carried out a study to review the influence of different surgical techniques including the undersized drilling, the osteotome, the piezosurgery, the flapless procedure, and the bone stimulation by low level laser therapy on the primary and/or secondary stability of dental implants. A search of PubMed, Cochrane Library, and grey literature was performed and they concluded that there is weak evidence suggesting that any of previously mentioned surgical techniques could influence the primary and/or secondary implant stability.
- **Degidi M et al (2015)[78]** performed an experimental study on fresh bovine bone to investigate the relation between implant site under-preparation and primary stability. Implants were inserted into 3 groups based on osteotomy bed size: group 1, standard sized; group 2, 10% undersized; and group 3, 25% undersized. Variable torque work

(VTW), maximum insertion torque (peak IT), and RFA values were recorded. The authors observed that the difference in VTW, peak IT and RFA values between the standard and undersized groups were statistically significant, but between the two undersized groups, no significant differences were observed. They concluded that in poor density bone, 10% undersized protocol is sufficient to improve implant primary stability.

- **Boustany C et al (2015)[79]** examined the effect of modified stepped osteotomy on the primary stability of dental implants in low-density bone, in a cadaver study. In modified stepped osteotomies, under-preparation of the apical portion of the osteotomy was done. They found a significant greater mean IT value in the modified step osteotomy group. But the difference in mean RFA value was not significant between the groups. They concluded that the modified stepped osteotomy provide greater implant stability and success rates than conventional osteotomy in soft bone like posterior maxilla.
- **Cappare P et al (2015)[80]** performed an investigation, in vivo, to study if any correlation existed between bone-to-implant contact and bone density. Histomorphometric study revealed a significant linear correlation between initial BIC and a) bone density at insertion site and b) torque/depth integral at placement. The authors concluded that initial BIC at insertion is correlated with primary stability and that topographical feature of the implant and surgical implant placement technique may modulate such correlation.
- **Li et al (2015) and Berardini et al (2016)[82]** in a review reported no significant difference in the crestal bone resorption and failure rate between implants inserted with either high or low insertion torque values. They also demonstrated the ability of OD drills to increase the %of BV and %of BIC for implants inserted into poor density bone compared to conventional osteotomies, which may help in enhancing osseointegration.
- **Trisi, et al (2016)[83]** evaluated the efficacy of the osseodensification technique to enhance bone density, ridge width, periimplant bone density and implant secondary stability. Biomechanical and histological examinations were performed after 2-months of healing. They observed that the increase of ridge width and bone volume percentage, RTVs, %BIC were significantly higher in the OD group. They also observed that wider implants could be inserted in narrow ridge without creating bone

dehiscence. The authors concluded that OD technique increases the primary implant stability, maintained the implant secondary stability and increases the %BV around implants inserted in low-density bone.

- **Lahens et al (2016)**[84] in an animal study investigated the effect of osseodensification on the initial primary stability and early osseointegration of endosteal implants in low density bone. The authors observed that in low density bone, endosteal implants presented higher insertion torque and %BIC when placed in osseodensification drilling sites, with no osseointegrated impairment compared to standard subtractive drilling method. They concluded that regardless of implant macrogeometry, the osseodensification technique improves the primary stability and BIC% by densifying the autologous bone debris acting as a compacted autograft.
- **Tsolaki I et al (2016)[85]** compared the condensing osteotome and conventional drilling techniques for primary implant stability in low density bone. They observed statistically significant higher IT and RFA data of implants placed in the osteotome group as compared to conventional drilling group. They also observed that implants of 13 mm length exhibited statistically significant IT and RFA values than the 10mm implants. The authors concluded that the condensing osteotome technique along with longer implants significantly increases the primary implant stability in areas of low bone densities.
- **Lopez et al (2017)[86]** in a clinical study used osseodensification for enhancement of spinal surgical hardware fixation to compare it with the regular surgical drilling (R). They found that OD group demonstrated statistically significant higher pullout strength, %BIC, and BAFO when compared with the R group, at 3 and 6 weeks. Histomorphological data demonstrated autologous bone chips in the OD group with greater frequency relative to the control, which acted as nucleating surfaces promoting new bone formation in the periimplant region, providing superior stability and greater bone density. The authors concluded that the osseointegration via OD yielded in a significantly better biomechanical and histological result when compared to the regular drilling method.
- **Raquel et al (2017)**[87]carried out a study to evaluate the primary and secondary stability of implants in the posterior maxilla. ISQ was measured 15, 30, 45, and 60 days after placement, to investigate the evolution to secondary stability. They observed a positive correlation between all variables (IT, ISQ at $t = 0$, $t = 60$), and

statistically higher IT and ISQ values were found for implants with satisfactory high primary stability. The author concluded that the evaluation of the primary and secondary implant stability may contribute to higher implant survival/success rates in poor density areas.

- **Mello C et al (2017)**[88]performed a systematic review and meta-analysis to compare the survival rate of the implants and the periimplant tissue changes associated with implants inserted in fresh extraction socket and those inserted in healed socket. They observed that the survival rate of delayed implants was significantly greater than immediate implants. For the marginal bone loss, implant stability quotient values and pocket probing depth there was no significant difference between the groups. They concluded that immediate implants placed in fresh sockets should be performed with quotient owing to the significantly lower survival rates than delayed implants.
- **Wang L. et al (2017)[89]** assessed the effects of condensation on peri-implant bone density and remodeling. They observed that condensation increased the interfacial bone density, as measured by a significant change in bone volume/total volume and trabecular spacing, but simultaneously damage the bone, which triggers an immediate and protracted period of bone resorption. They concluded that, while condensation did increase the apparent density of interfacial bone, this “densification” did not significantly improve the outcome
- **Tettamanti L et al (2017)[90]** reviewed the concept of OD. According to the authors, to achieve the necessary torque value, it is important to have good bone density at the implant site. The authors found that the clinical success of the technique depends upon many factors: bone quality & quantity, implant number & design, implant primary stability, occlusal loading & clinician’s surgical ability. They observed that the primary stability of the implants which in turn depends on the peri implant bone density plays the determining role in implant’s success & stated that the implant site under preparation & the bone condensing techniques as the methods of choice in compromised sites.
- **Chrcanovic B et al (2017)[91]** conducted a systematic review and meta-analysis to compare the survival rate of dental implants, postoperative infection, and marginal bone loss when implants were inserted in bone sites of different quantities and qualities. An electronic search was undertaken in January 2015 for randomized and nonrandomized human clinical trial. The authors observed that dental implants

inserted in bone quality 4 demonstrated highest failure rates. They concluded that poor bone quality and quantity are the main risk factors for implant failure, so thinner cortical bone combined with thicker trabecular bone are responsible for implant failure in posterior maxilla.

- **Gomes R et al (2017)**[92] evaluated the primary and secondary stability of implants placed in posterior maxilla. The ISQ was then measured periodically in implants with satisfactory primary stability (IT $\geq$ 45Ncm; ISQ $\geq$ 60) to record the evolution to secondary stability. A positive correlation was observed between all variables (IT, ISQ at t = 0, t = 60). Statistically higher IT and ISQ values were observed in implants with higher primary stability. The authors concluded that satisfactory higher primary implant stability in critical areas, such as the posterior maxilla, is pivotal for favorable outcome.
- **Paula G.F et al (2017)**[93] investigated the effect of osseodensification instrumentation on the primary stability and osseointegration in low-density bone. They observed that osseodensification counterclockwise-drilling (CCW) resulted in significantly higher insertion torque values, regardless of implant surface. Though BIC was not different as a function of time, the BAFO significantly increased at 6-weeks. They concluded that OD instrumentation improved the osseointegration of implants in low-density bone.
- **Merhab J et al (2018)**[94] investigated the relationship between implant stability and bone density derived from CT analysis. Implants were placed using digitally designed stereolithographical surgical guides. Implant stability was measured by means of RFA and damping capacity assessment (Periotest, PTV). Bone density was measured at different regions of interest (ROI) and cortex thickness was measured around each implant. They found that implant stability correlated significantly with bone density and cortex thickness. They concluded that implant stability can be predicted based on a preoperative analysis of bone characteristics
- **Pai U et al (2018)**[95] in a systematic review analyze if OD procedure had any advantages over conventional osteotomy on bone density and primary stability. An electronic database search revealed that the use of OD technique, using versah drills, resulted in undersized osteotomy compared to conventional drills. It also resulted in improved periimplant bone density and increase in %BV and also BIC, thereby improving implant stability. They concluded that OD is a specialized procedure for

osteotomy preparation that is inherently bone preserving and can improve implant survival rates in compromised sites, like posterior maxilla.

- **Gaspar J et al (2018)[96]** investigated the outcome of osseodensification technique for implant site preparation in maxilla. The authors found the success rate of osseointegration was 96.9%. All implants had insertion torque values ≥45 N cm. Greater bone expansion was observed at the coronal position compared to the apical. In the sinus lift group, the mean gain in bone height was 5.8mm. OD clearly helped to optimize the site for the implant placement by preserving bone bulk and predictable ridge expansion with enhanced primary stability and higher ITV. They also observed that crestal sinus lift by OD is a simple, safe and predictable way with reduced morbidity.
- **Neiva R et al (2018)[97]** studied the effects of osseodensification on the primary stability and healing of 2 different implant systems of different macrogeometries. The result showed that Densah system, in counter-clockwise rotation exhibits substantially higher values of insertion torque, BIC, BAFO and RFA values compared to the routine protocol. They also observed a higher amount of autogenous bone chips in the trabecular spaces and in intimate contact with the implant surfaces in the Densah drilling protocols. The authors concluded that the ossedensification provides a substantially improved osseointegration irrespective of implants' macrogeometries.
- **Gayathri S (2018)[98]** in a review article discussed the osseodensification procedure and its advantages over traditional drilling method. According to the author, OD is a unique; fast and efficient; bone preserving; biomechanical osteotomy preparation. Unlike conventional drilling procedures, OD does not sacrifice bone at osteotomy sites. OD also does not cause fracture of trabeculae that may result in a delayed bone growth like in the osteotome technique. The author suggested that the benefit of OD is the creation of a stronger expanded osteotomy for implant placement, through compaction and autografting the surrounding bone particularly in areas with low-density bone with significantly increased ITV, RTV, %BV and %BIC. Additionally, the author also suggested that the OD facilitates sinus autograft and expansion of narrow ridges allowing the placement of wider diameter implants without creating bone dehiscence thus concluding that OD in implant dentistry changed the paradigm of osteotomy preparation.

- **Kloss F et al (2018)**[99] Compared 3 dimensional alterations following the use of autogenous versus allogeneic onlay grafts for augmentation at single tooth defects. Alveolar bone width at specific implant sites were assessed using saggital and cross-sectional CBCT images. No statistically significant differences in graft remodeling rates and vertical and horizontal dimension change were observed between both the grafts. They concluded that although bone allografts demonstrates better compatibility, the allogenic bone grafts demonstrate additional advantages like unlimited supply, decrease operative trauma and blood loss, absence of donor site morbidity.
- **Alghamdi H (2018)**[100] explained various methods to improve osseointegration in low quality (Type 4) bone. He suggested that severe reduction of bone quality and quantity which is suggestive to be detrimental for bone-implant integration and the biomechanical characteristics of osteoporotic bone do not offer proper stability to implants. The authors studied various techniques of enhancing implant stability like modification of implant design, physicochemical surface modifications and drug-based implants modification, but none of the technique could yield the desired result in type 4 bone. He concluded that modified surgical techniques, like osteotom technique, undersized osteotomy preparation and OD stand-out among others in enhancing osseointegration and the success of implants in poor quality bone.
- **Baftijari D et al (2018**[101] analyzed the primary and secondary stability of dental implants placed in the maxilla using resonance frequency analysis. An ISQ value of ≥65 was recorded in 78.82% of total implants placed after 3 months of placement. The one year cumulative success rate of the inserted implants was 98.3%. The authors concluded that the ISQ value recorded by RFA is a reliable parameter for evaluating the success of implants, especially in suboptimal density bone.
- **Tanka K. et al (2018)**[102] evaluated the relationship between cortical bone thickness and implant stability at the time of surgery and secondary stability after osseointegration. They observed that the mean primary and secondary implant stability of the mandibular group was significantly higher than the maxillary group. They also observed a significant difference in the mean ISQ values for primary and secondary stability between both groups. They also noted a weak positive correlation between cortical bone thickness and implant stability for both primary and secondary

stability in all cases. They concluded that the ISQ may be affected by cortical bone thickness; as reflected in higher success rates in mandibular group.

- **Wu et al (2019)**[103] in a study compared the efficacy of the autogenous tooth bone and xenogenic bone grafted in immediate implant placement. The radiographic assessment revealed that the horizontal bone changes, marginal bone loss and complications, if any were almost same in both the groups. They concluded that the autogenous tooth bone made from compromised tooth can be an acceptable bone graft material.
- **Monje A. et al (2019)[104]** assessed the relationship between the primary and secondary implant stability. They found a strong statistically significant relationship between the primary and secondary implant stability in all the published literatures. They concluded that primary stability leads to more efficient achievement of secondary stability, but the achievement of high primary stability might be detrimental for bone level stability.
- **Kabi S et al (2020)**[105]evaluated the peri-implant hard and soft tissue changes following immediately placed implants with a jumping distance of 2mm with or without autogenous bone grafts. The alveolar bone loss was calculated using CBCT revealed that it was greater in the autogenous bone graft group, but other parameters were similar. They concluded that immediate implants placed with or without bone grafts had similar alveolar hard and soft tissue changes when the jumping distance was less than 2 mm.

Materials and Method

Study Design

A prospective, randomized, single center study was performed among patients with at least one or more missing teeth in posterior maxillary arch. Patients will be selected as per inclusion criteria, reporting to the out-patient department (OPD) of Oral and Maxillofacial Surgery, Babu Banarasi Das College of Dental Sciences, Lucknow.

Grouping of subjects

Total (n=14) patients were divided into two groups-

1. Test group (n=7 implants): Placement of dental implants into osteotomy done with Densah burs.
2. Control group (n=7 implants): Placement of dental implants into osteotomy done with Conventional drill.

Clearance was obtained from the Research Committee and Institutional Ethical Committee of Babu Banarasi Das College Of Dental Sciences.

Written informed consent was taken from patients.

Inclusion criteria

- ✓ Partially edentulous jaws with a unilateral or bilateral loss of teeth in the posterior maxilla(maxillary premolar and molar area)
- ✓ Patients with satisfactory oral hygiene status and no active periodontal disease.
- ✓ No intra oral soft tissue and hard tissue pathology.
- ✓ No systemic condition that contradict implant placement

Exclusion criteria

- ✓ Maxillary Sinus pathology.
- ✓ Heavy smokers (more than 20 cigarettes per day).
- ✓ Patients with systemic disorder that may affect normal healing.
- ✓ Psychiatric problems.
- ✓ History of radiation therapy to the head and neck neoplasm, or bone augmentation to implant site.

- ✓ Immunodeficiency pathology, bruxism, stress situation (socially and professionally), emotional instability, unrealistic aesthetic demands.

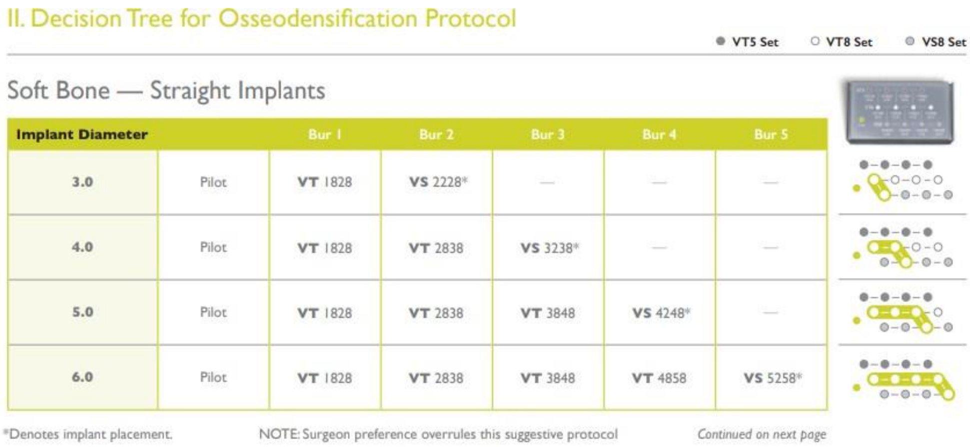
Materials Required-

- Mouth mirror and probe
- Metallic scale
- Periosteal elevator – Howarths
- Periosteal elevator - Molts
- Atraumatic Adson tissue holding forcep.
- Suture cutting scissors
- Needle holder
- Bard Parker handle – No. 3 and Blade-No.15
- Physiodispenser
- Implant hand piece
- Suture materials- 3-0 silk
- Disposable syringe
- Conventional implant placement drill kit
- Densah bur kit
- Resonance Frequency Analysis (RFA)
- Dental implants (Nobel Biocare and Adin Dental Ltd)
- Abutments
- Healing abutments (healing cap)

DENSAH BURS KIT

The Densah bur kit includes a total of 12 burs designed for non-subtractive osteotomy drilling. The burs have depth markings between 3-20 mm. The OD osteotomy begins with a tapered, multi-fluted bur drill or the pilot drill to create an osteotomy. The Densah burs that are used in a sequence, from narrow to wider diameter, to achieve the desired diameter of osteotomy. OD burs have atleast 4 tapered flutes with a negative rake angle. The drilling can be done in both clock-wise and anticlock-wise direction at speed of 800 to 1500 rpm with external irrigation. The burs are designed to create OD in smaller increments (by alternately using of VT5 andVT8) in a denser bone zone to allow gentle expansion of the osteotomy without any bony defect or dehiscence. In softer D4 and D3 bones, the final osteotomy diameter is recommended to be 0.5 to 0.7 mm smaller than the endosteal implant planned to be inserted. There are three types of Densah bars: VT5 bars with 4 diameters, 2 mm, 3 mm, 4 mm, 5 mm. VT8 burs with 4 different diameters, 2.3 mm, 3.3 mm, 4.3 mm, 5.3 mm. VS8 burs with diameters of 2.5 mm, 3.5 mm, 4.5 mm, 5.5 mm.

Protocol recommended by manufacturer



II. Decision Tree for Osseodensification Protocol

● VT5 Set ○ VT8 Set ◎ VS8 Set

Soft Bone — Straight Implants

Implant Diameter		Bur 1	Bur 2	Bur 3	Bur 4	Bur 5
3.0	Pilot	VT 1828	VS 2228*	—	—	—
4.0	Pilot	VT 1828	VT 2838	VS 3238*	—	—
5.0	Pilot	VT 1828	VT 2838	VT 3848	VS 4248*	—
6.0	Pilot	VT 1828	VT 2838	VT 3848	VT 4858	VS 5258*

*Denotes implant placement. NOTE: Surgeon preference overrules this suggestive protocol *Continued on next page*

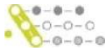
II. Decision Tree for Osseodensification Protocol

Sok Bone — Tapered Implanu

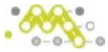
5.0, 5.2, 5.3	riloc	VT 1828	VT 2838	VT 3848*		
6.0, 6.2	Piloc	VT 1828	VT 2838	VT 3848	VT 4858*	

Hard Bone — Straight Jmplants

25 | **VT** 1828 | **VS** 2228*



5.0	R#x	vT NI8	WTu3&	VT18Z8	VT3&•s	VT3M8	vS44M	
&0	Rex	vT |0B	wT 1ea8	VT JWS	vTl0w8	Wr 4s55	Wr 't85g	YSSJS8•

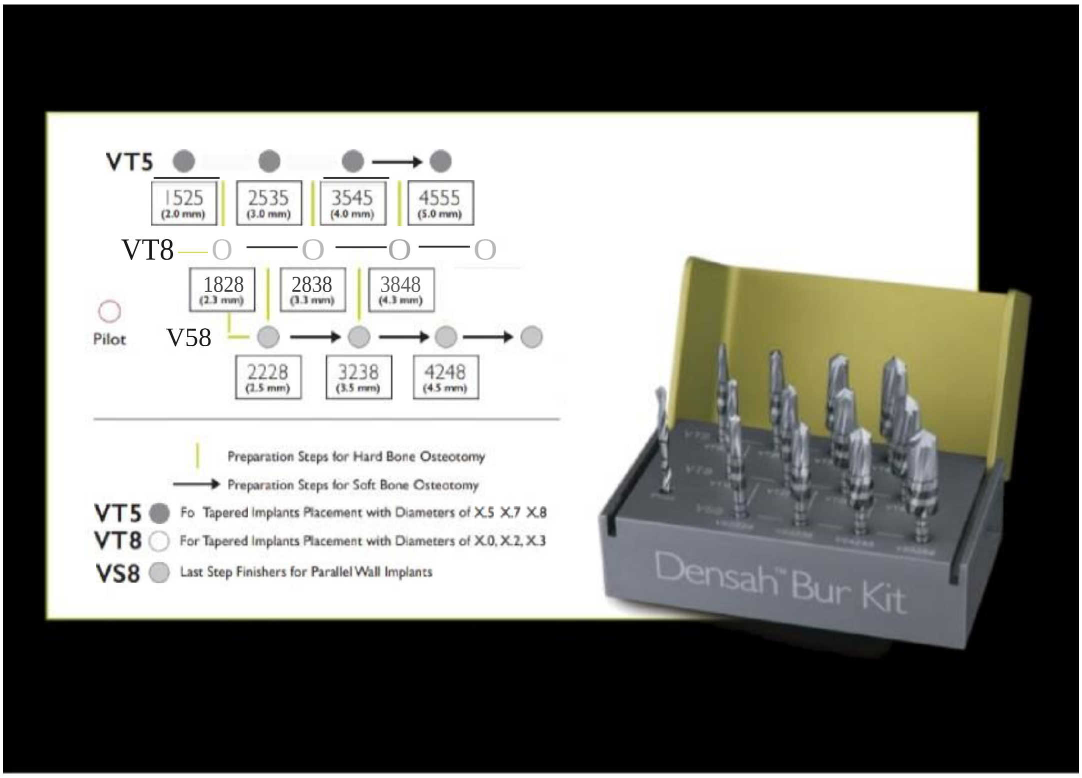


Denotes implant placement. MDTESurgeo gnsArenw owrruBs,hi,suggezGw pmorol

II. Decision Tree for Osseodensification Protocol

Hard Bone —Tapered lmplanu

4.5, 4.7, 4.8	Pilot	**VT** 1525	**VT** 2535	**VT** 2838	**VT** 3545*	—	—	
5.0, 5.2, 5.3	Pilot	**VT** 1828	**VT** 2535	**VT** 2838	**VT** 3545	**VT** 3848	**VS** 4248*	
5.5, 5.7, 5.8	Pilot	**VT** 1525	**VT** 2535	**VT** 2838	**VT** 3545	**VT** 3848	**VT** 4555*	
6.0, 6.2	Pilot	**VT** 1828	**VT** 2838	**VT** 3545	**VT** 3848	**VT** 4555	**VT** 4858	**VS** 5258*



IV. Densah " Bur l•tarkiiig

Densah " Burs are externally irrigated and designed to be used at drill speed» of 800- 1500 rpm.They' are marked with laser markings from 820 mm dept. Densah " Bws hae a tapered gaomety cataog number 1s a reflecoQc of thenr minor and maor dameter &mensJon.

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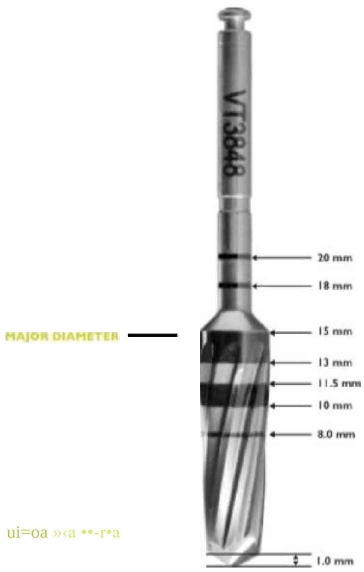
am‹

MOTE: Cutting and Densi$ing must oe done under constant water **irrigaoon. A pumping moclon is required to prevenc oyer heacing. 5ur$ical drills and burs should be replaced every I 2-20 osteotomies' or sooner when they are dulled, worn, or corroded.**

Drilling Depth

Neasure che drilling depth of chs Densah" Bur from che widesc parE of lts Eip to Ehe Indicador line. Regardless of the Densah" Bur diameter, the maximum additional tip death is 1.0 mm.

Densah™ Bur Laser Lines



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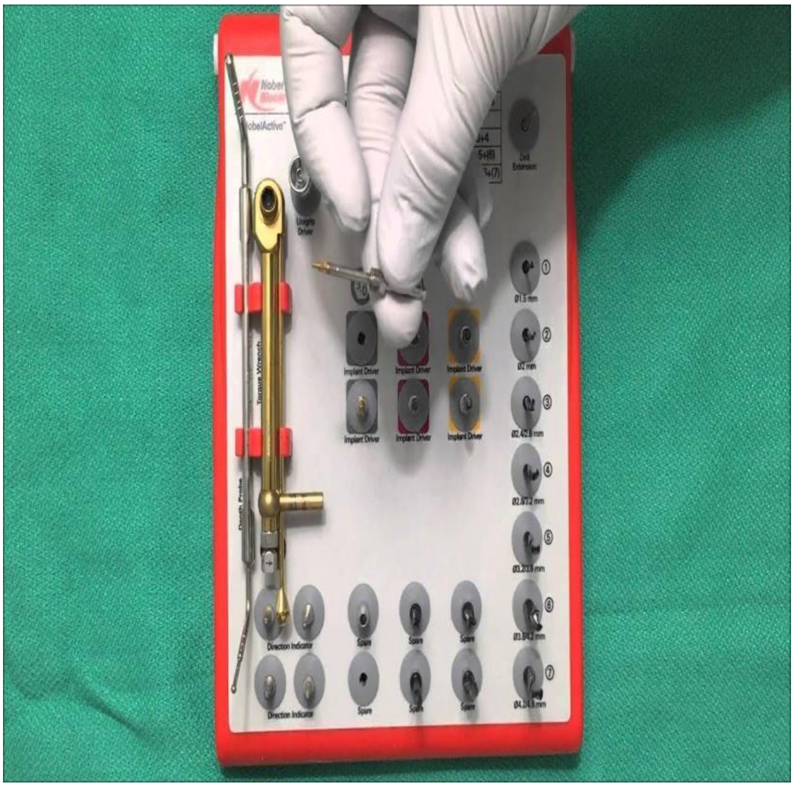
Conventional osteotomy drills



RFA

METHODOLOGY

Pre-surgical records:

1) Detailed medical history was taken, whether the patient was suffering from any major systemic disease (uncontrolled diabetes, hemophilia, hypertension, myocardial infarction etc.) and any past allergy due to any drug or food. Detailed dental history including previous restorative, periodontal, endodontic, reasons for loss of teeth or experience with orthodontic appliance and dental prosthesis were taken.
2) General examination, extra-oral examination, intraoral examinations were done and diagnostic records (panoramic radiograph, periapical radiograph, and diagnostic casts) were obtained before surgery. From the panoramic radiograph, the amount of clinical bone height was calculated using the formula proposed by **Alhassani and Alghamdi**.

$$\textbf{\textit{Clinical bone height}} = \frac{\textbf{\textit{Radiographic bone height}}}{\textbf{\textit{Magnification factor}}}$$

Where radiographic bone height is the measurement on the radiograph from the alveolar crest of the ridge to the sinus membrane and the magnification factor is a known number (that is, if a certain X-ray machine produces 30% magnification, the magnification factor will be 1.3, and if the magnification is 25%, the magnification factor will be 1.25).In our case magnification was 25%.

CBCT was used to accurately assess, in three dimensions (3D), the bone volume available for implant placement. CBCT data could be loaded in to specific navigation software (R2Gate®; MegaGen Implant, Gyeongbuk, South Korea), with the aim of performing a 3D reconstruction of the edentulous areas; it was therefore possible to correctly assess the volume of each implant site and the density of the cortical plates and cancellous bone, as well as the ridge angulations. The preoperative evaluation included stone casts & diagnostic wax-up.

Pre-surgical protocol:

Patients were prescribed Tab cefixime 200mg twice daily, two days prior to the surgery. Part preparation of patient was done extraorally with savlon followed by betadine solution and intraorally with betadine solution, and then patient was draped with sterile drape. Local anesthesia (2% Lignocaine hydrochloride with 1:80,000 adrenaline) was used to anesthetize the surgical site by suitable nerve block and regional infiltration.

Surgical procedure:

- Surgical access was achieved by making an incision through the gingival tissue down to alveolar bone or by tissue punch.
- After incision, hand instruments (Molts and Howarth's periosteal elevator) were utilized to elevate the tissues away from the bone, giving direct visual access to the surgical site. Typically, these flaps were elevated as full-thickness mucoperiosteal flap.
- Osteotomy was performed using drills in sequence from smaller to larger diameters in accordance with the diameter of implant to be placed at 800-1100 rpm in a clockwise direction.
- Before implant insertion, a periodontal probe was used to check for any bony fenestrations of the osteotomy.
- The implants were be inserted first with a hand piece at the recommended torque (about 40Ncm for both cortical and root form dental implant) and speed about 800 to 1000 rpm, final seating was done manually with a wrench.
- The final seating was confirmed when the implant bottomed out at the base of the osteotomy and will not show further apical movement.
- The fixture mount was removed and healing abutment was placed. Immediately postoperative radiographs was done to confirm complete seating of the abutments.
- For implants, where osteotomy was performed by OD, the procedure was similar as conventional drilling osteotomy technique. The pilot drill was used in clockwise direction and the other sequential drills were used in counter clockwise direction under copious irrigation at high speed (800-1500 rpm) in a pumping action. The pumping motion (in and out movement) creates a rate-dependent stress to produce a

rate-dependent strain and allows saline solution pumping to gently pressurize the bone walls. This combination facilitates increased bone plasticity and bone expansion Healing abutment was then placed and fitted to the implant. Flap closure was achieved using 3-0 silk sutures to protect the implant site.

- After the implants were placed, the primary stability was measured using Resonance Frequency Analysis (RFA) immediately to record and evaluate the primary stability. RFA was periodically performed at 3^{rd} and 6^{th} month, postoperatively.
- Patients were recalled for radiographic evaluations periodically (IOPARs/OPG) to record the crestal bone at day 1 and 3 and 6 months, to calculate and compare the crestal bone loss and CBCT was performed after 6 months of placement of implants to assess bone implant contact ratio.
- Patients will be prescribed tab-Cefexime 200mg twice daily for 5 days and tab-Diclofenac twice daily for 3 days. Instructions were be given to avoid rinsing, spitting, or touching the wound on the day of surgery, soft and cold diet for first 24 hours and chlorhexidine rinses – 3-4 times / day for two weeks. Patients were also being instructed to avoid smoking and alcohol beverages.
- Surgical access was achieved by making an incision through the gingival tissue down to alveolar bone. After incision, hand instruments (Molts and Howarth's periosteal elevator) were utilized to elevate the tissues away from the bone, giving direct visual access to the surgical site. Typically, these flaps were elevated as full-thickness mucoperiosteal flap. Osteotomies were performed using drills in sequence from smaller to larger diameters in accordance with the diameter of implant to be placed.

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ASSESSMENT PARAMETERS –

Clinical Evaluation:

1) Preoperative (in both groups)

a) Type of bone as assessed by CBCT

b) OPG/IOPAR

2) Immediately after implant placement (in both groups)

a) Stability of the implant with resonance frequency analysis (ISQ value)

b) Crestal bone height assessed by OPG/IOPAR

3) After 3 months postoperatively:

a) Stability of the implant with resonance frequency analysis (ISQ value)

b) Crestal bone height assessed by OPG/IOPAR

4) After 6 months postoperatively:

a) Stability of the implant with resonance frequency analysis (ISQ value)

b) Crestal bone height assessed by OPG/IOPAR

c) Bone-to-Implant contact (BIC) percentage as assessed by CBCT

Radiographic parameters assessed

Radiographic evaluation to assess Bone Implant Contact (BIC) ratio

- CBCTs were done at the follow-up of 3 months to calculate BIC ratio.
- i-CAT CBCT machine using i-CAT vision and anatomage software was used for the study.
- i-CAT vision software is the interactive measurement of all images for surgical implant planning and it also used for bone density measurement. The features are

basic 3D images with cross-sectional views and multiple customizable visual display modes available including axial, panoramic and cross-sectional views.

- The voxel size was 0.1 X 0.1 X 0.1 and 0.2 X 0.2 X 0.2 mm, respectively. The voltage (120volts) and current (30.89ma) were set as recommended by the manufacturer.
- The DICOM files of the axial images were saved to a portable hard disk.
- Cross-sectional and longitudinal 2-dimensional images of each dental implant were reconstructed.
- At first, the length of the implant covered by buccal bone was recorded using cross-sectional images. Also, the covered mesial, distal, and lingual/palatal lengths were measured in the same way.

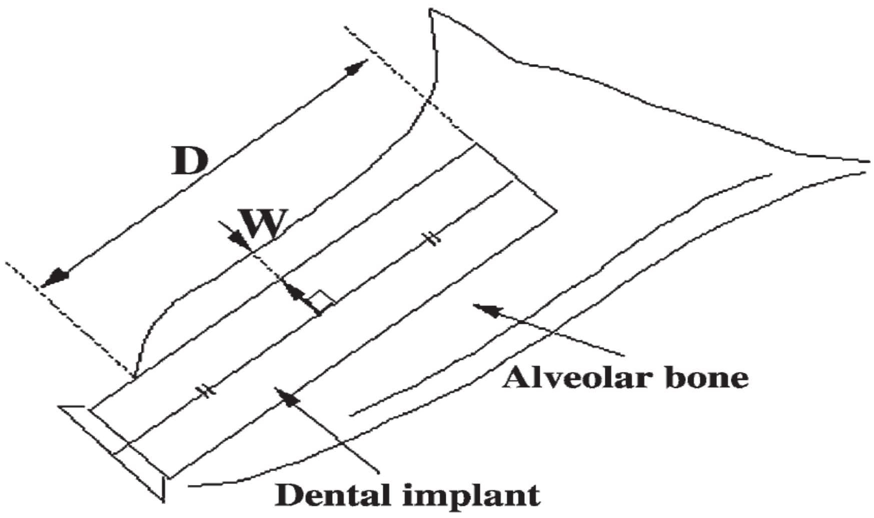


Fig. 2- Schematic *drawing of measurements of cone-beam computed tomography (CBCT) images*

The length of the dental implant covered by labial bone (D) was measured.

- The bone-to-implant contact (% BIC)[49] was calculated as:

$$\text{Bone implant contact ratio} = \frac{\text{Length of the implant covered by bone}}{\text{Actual length of the implant}} \times 100$$

- The mesial, distal, buccal, lingual/palatal values were measured.
- Bone implant contact ratio was compared at 6 months in both groups.

-

Black line denotes the bone covering the implant on labial side. Similarly, measurements will be taken on the mesial, distal and palatal side.

Radiographic Evaluation to assess crestal bone loss-

- IOPARs or OPGs were taken (whichever was available), at immediately after implant placement, and then again at 3rd and 6th month after implant placement to assess crestal bone loss.
- IOPARs were taken using paralleling cone technique using X-MIND AC machine (Maximum voltage and maximum current- 70 kV, 8 mA, Exposure time- 0.08-3.2 s).

- OPGs were done using PLANMECA PROLINE with DIMAX 3 machine (Magnification- 1.2, Exposure time- 2.5-18 s, maximum voltage and maximum current- 80 kV, 12 mA).
- A horizontal line drawn tangential to the coronal border of the implant, and was marked as reference point for radiological evaluation.
- Measurements from this line to the most coronal point of the crestal bone, on the proximal surfaces around the implant, were done to evaluate the mesial and distal vertical crestal height of the residual alveolar bone.
- The method described by **Yoo et al**[50] was used. The length (mm) of the implant was measured on the radiograph. Next the distance between the observed crestal bone and the implant abutment interface was measured at both the mesial and distal surfaces. The actual implant length was known on manufacturing standards. To adjust the measurements for magnification error, the following equation was used to determine the correct crestal bone levels:

$$\text{Corrected crestal bone level} = \text{Measured crestal bone level} \times \frac{\text{Actual implant length}}{\text{Measured implant length}}$$

Dental Implant Stability Evaluation:

Resonance Frequency Analysis (RFA) assessment was done immediately after implant placement, and then after 3 and 6 months after implant placement. RFA records the implant micro-movements as implant stability quotient (ISQ) value based on the resonance frequency by use of magnetic smart pegs that have to be attached to the implant after implant insertion by hand tightening with a torque of 5-10 Nm.. The ISQ is presented as a value from 1 (lowest stability) to 100 (highest stability). ISQ values was recorded twice at each time (first perpendicularly and then parallel to the alveolar ridge) and the average mean of two would was registered for later evaluation. The ISQ was recorded by an Osstell instrument with a commercially available transducer adapted to the implants. The ISQ values were further recorded after 3 and 6months.

Statistical Analysis

The data was recorded in a preformed case/sheet, according to the parameters mentioned and were tabulated and statistical analysis was carried out using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical Analysis Software.

Blood investigations -

BT, CT, Hb%, ESR, TLC, DLC, HbsAg, Blood sugar, HIV, S.Urea, S.Creatinine,

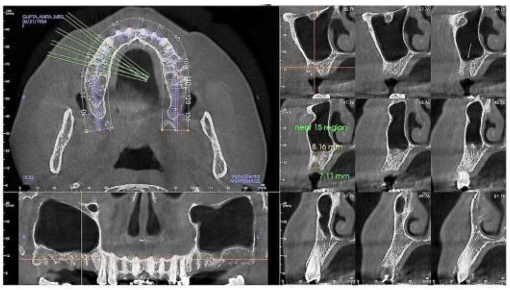
Radiographic investigations - CBCT, OPG, IOPAR

ARMAMENTARIUM FOR OSTEOTOMY

OD OSTEOTOMY
PRE OPERATIVE PHOTOGRAPS

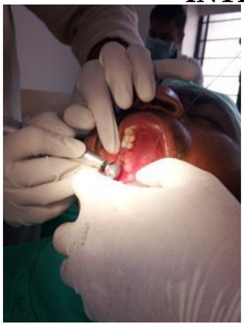
MISSING 16,17

OPG



CBCT

INTRA OPERATIVE PHOTOGHRAPS



OSTEOTOMY

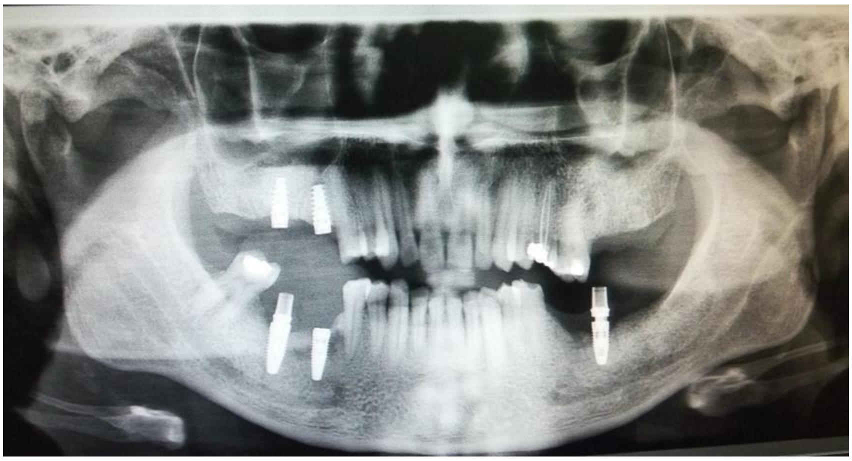
RFA MEASUREMENT

PREPERATION

IMPLANT INSERTION

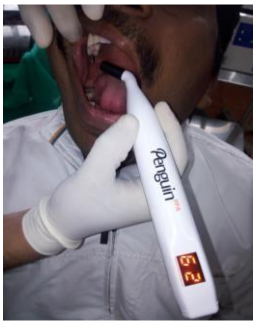
PLACEMENT OF IMPLANT

<u>IMMEDIATE OPERATIVE RADIOGRAPH</u>



3rd MONTH POST OPERATIVE

ISQ VALUE



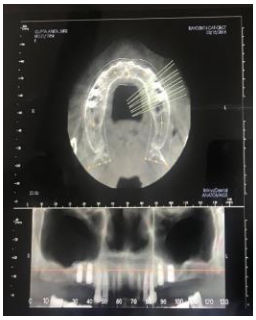
ISQ VALUE

OP
G

6th MONTH POST OPERATIVE

OPG

RVG

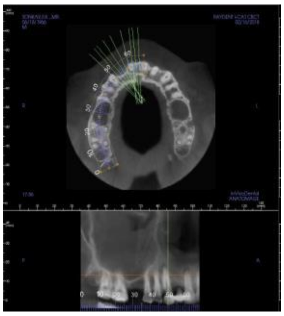


CBCT

CONVENTIONAL OSTEOTOMY
PRE OP PHOTOGRAPS

MISSING 16

OP



CBC

INTRA OPERATIVE

OSTEOTOMY PREPERATION

IMPLANT INSERTION

PLACEMENT OF IMPLANT

POST-OPERATIVE PHOTOGRAPH

1st WEEK POST OPERATIVE

CLINICAL VIEW OF SOFT TISSUE

RVG

3rd MONTH POST OPERATIVE

CLINICAL VIEW OF SOFT TISSUE

RV

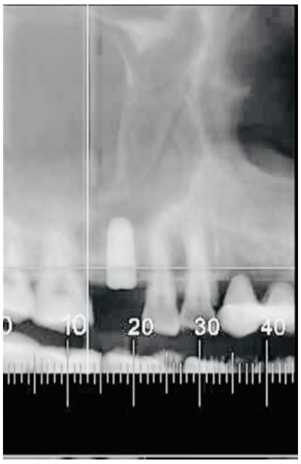
6th MONTH POST OPERATIVE

CLINICAL VIEW OF SOFT TISSUE

RV
G

6 MONTH POST OPERATIVE

RF



CBC
T

RESULT AND OBSERVATION

Results

Table 1: Groupwise comparison of mean RFA, Overall crestal bone height and Crestal bone height on mesial side and distal side immediate post operative

Preoperative/immediate post operative	gps	N	Mean	Std. Deviation	Std. Error Mean	P value
RFA	Group I-Coventional drills	7	52.714	1.1127	.4206	.0001*
	Group II-Densah burs	7	60.714	1.1127	.4206	
Crestal bone height on mesial side	Group I-Coventional drills	7	10.971	.4231	.1599	.319 NS
	Group II-Densah burs	7	11.200	.4000	.1512	
Crestal bone height on distal side	Group I-Coventional drills	7	10.800	.5033	.1902	.0.260 NS
	Group II-Densah burs	7	11.086	.3934	.1487	
Overall crestal bone height	Group I-Coventional drills	7	10.8857	.46252	.17482	.286NS
	Group II-Densah burs	7	11.1429	.39626	.14977	

Independent t test, Statistical significance set at p<0.05, NS- not statistical significant difference, *- statistically significant difference

Figure 1: Groupwise comparison of mean RFA, Overall crestal bone height and Crestal bone height on mesial side and distal side immediate post operative

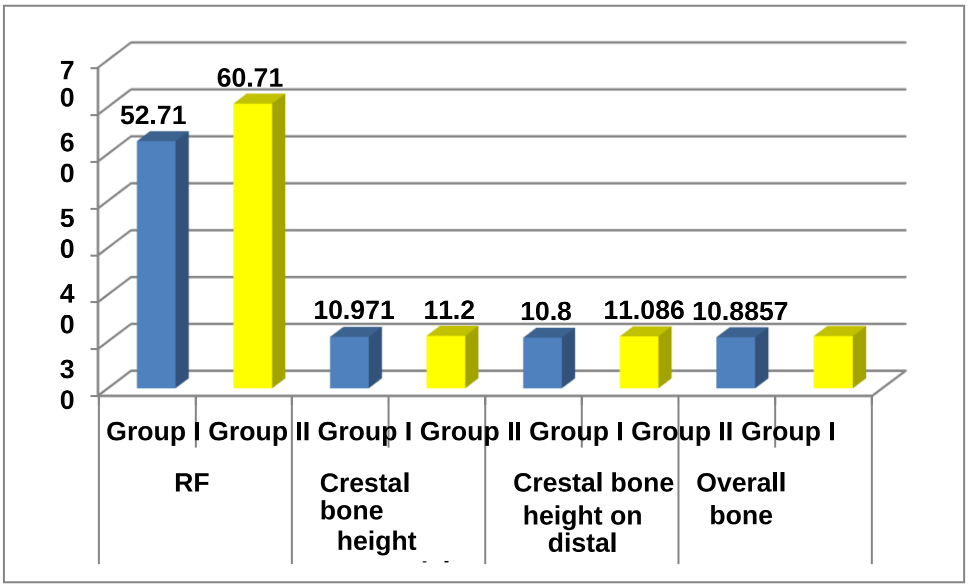


Table 1 showed Groupwise comparison of mean RFA, Overall crestal bone height and Crestal bone height on mesial side and distal side immediate postoperatively. When this comparison was made using Independent t test, only RFA was found to be statistically significant i.e primary stability was found to be more among subjects where implants were placed using Densah burs as $p<0.05$. No statistically significant difference was seen in overall crestal bone height, bone height on distal side or bone height on mesial side when compared bw two study groups as $p>0.05$.

Table 2: Groupwise comparison of mean RFA, Overall crestal bone height and Crestal bone height on mesial side and distal side at 3 months

At 3 months	gps	N	Mean	Std. Deviation	Std. Error Mean	P value
RFA	Group I-Coventional drills	7	60.286	1.3801	.5216	.0001*
	Group II-Densah burs	7	67.857	1.4639	.5533	
Crestal bone height on mesial side	Group I-Coventional drills	7	10.1000	.40415	.15275	.315 NS
	Group II-Densah burs	7	10.3286	.41115	.15540	
Crestal bone height on distal side	Group I-Coventional drills	7	9.9857	.41404	.15649	.407 NS
	Group II-Densah burs	7	10.1714	.39461	.14915	
Overall crestal bone height	Group I-Coventional drills	7	10.0429	.40869	.15447	.357 NS
	Group II-Densah burs	7	10.2500	.40000	.15119	

Independent t test, Statistical significance set at $p<0.05$, NS- not statistical significant difference, *- statistically significant difference

Figure 2: Groupwise comparison of mean RFA, Overall crestal bone height and Crestal bone height on mesial side and distal side at 3 months

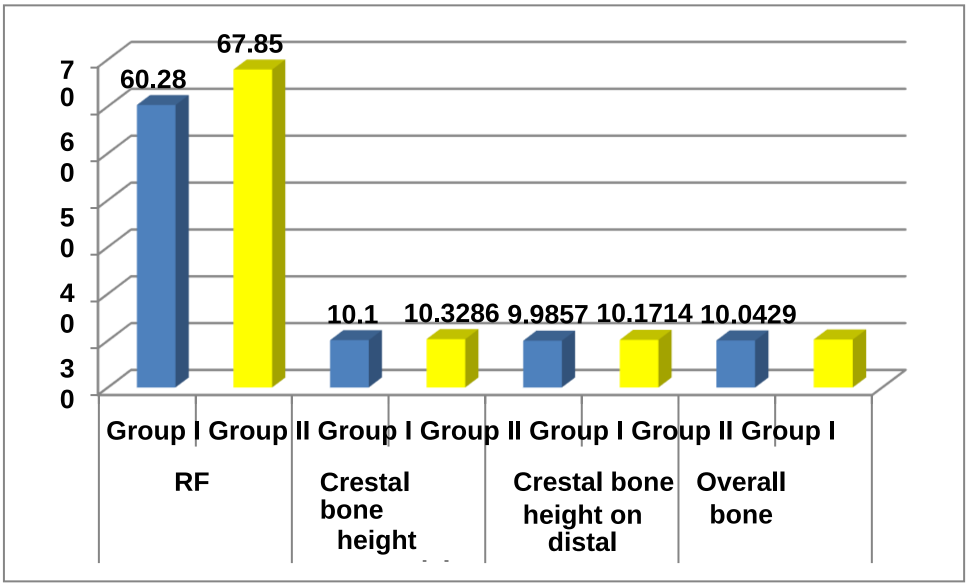


Table 2 showed Group wise comparison of mean RFA, Overall crestal bone height and Crestal bone height on mesial side and distal side at 3 months. When this comparison was made using Independent t test, only RFA was found to be statistically significant i.e primary stability was found to be more among subjects where implants were placed using Densah burs as p<0.05.. No statistically significant difference was seen in overall crestal bone height, bone height on distal side or bone height on mesial side when compared bw two study groups as p>0.05.

Table 3: Group-wise comparison of mean RFA, Overall crestal bone height and Crestal bone height on mesial side and distal side at 6 months

At 6 months	gps	N	Mean	Std. Deviation	Std. Error Mean	P value
RFA	Group I-Coventional drills	7	63.571	1.2724	.4809	.0001*
	Group II-Densah burs	7	73.714	.7559	.2857	
Crestal bone height on mesial side	Group I-Coventional drills	7	9.929	.3988	.1507	0.416 NS
	Group II-Densah burs	7	10.114	.4259	.1610	
Crestal bone height on distal side	Group I-Coventional drills	7	9.786	.4259	.1610	0.457 NS
	Group II-Densah burs	7	9.957	.4077	.1541	
Overall crestal bone height	Group I-Coventional drills	7	9.8571	.41072	.15524	0.434 NS
	Group II-Densah burs	7	10.0357	.41404	.15649	

Independent t test, Statistical significance set at $p<0.05$, NS- not statistical significant difference, *- statistically significant difference

Table 3 showed Groupwise comparison of mean RFA, Overall crestal bone height and Crestal bone height on mesial side and distal side at 6 months. When this comparison was made using Independent t test, only RFA was found to be statistically significant primary stability was found to be more among subjects where implants were placed using Densah burs as p<0.05.. No statistically significant difference was seen in overall crestal bone height, bone height on distal side or bone height on mesial side when compared bw two study groups as p>0.05.

Figure 3: Groupwise comparison of mean RFA, Overall crestal bone height and Crestal bone height on mesial side and distal side at 6 months

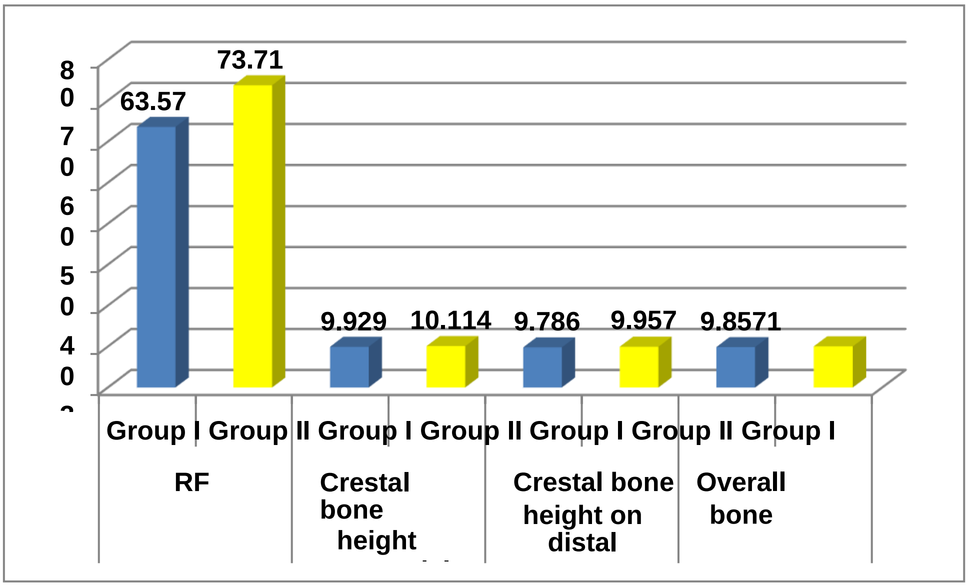


Table 4: Groupwise comparison of mean BIC% at 6 months

	Groups	N	Mean	Std. Deviation	Std. Error Mean	P value
BIC at 6thmonth	Group I-Coventional drills	7	62.143	2.2678	.8571	<0.0001*
	Group II-Densah burs	7	76.000	1.2910	.4880	

Independent t test, Statistical significance set at p<0.05, NS- not statistical significant difference, *- statistically significant difference

Table 4 showed Groupwise comparison of mean BIC% at 6 months. Statistically significant differences were found in mean BIC % bw two groups when compared using Independent t test as p<0.05.

Figure 4: Groupwise comparison of mean BIC% at 6 months

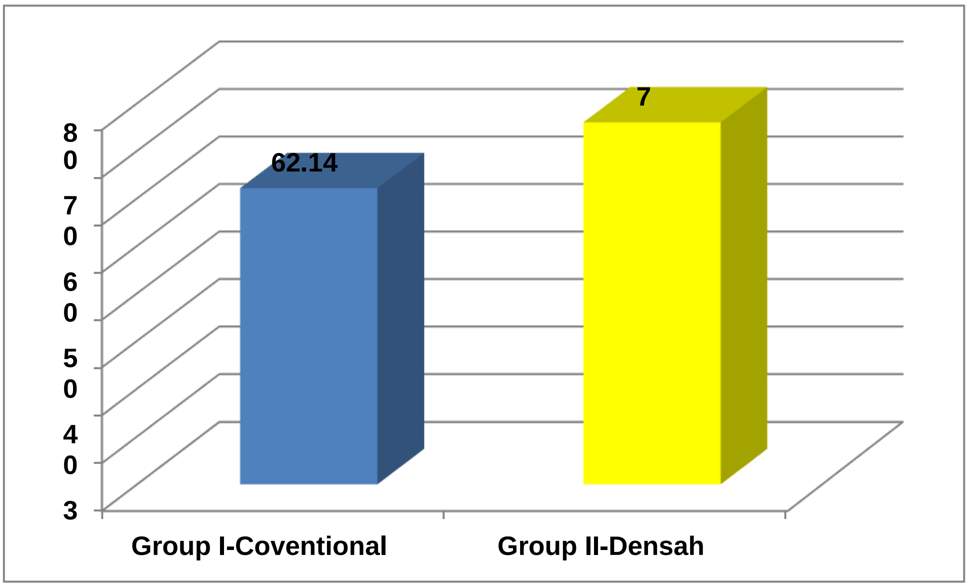


Table5: Intragroup comparison of RFA from baseline to 6 months

RFA		Paired Differences					t	df	P value
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Group I	Baseline to 3 months	7.5714	1.3973	.5281	6.2792	8.8637	14.337	6	.0001*
	3 months to 6 months	3.2857	1.3801	.5216	2.0093	4.5621	6.299	6	.001*
	Baseline to 6 months	10.8571	.6901	.2608	10.2189	11.4953	41.627	6	.0001*
Group II	Baseline to 3 months	7.1429	1.3452	.5084	5.8988	8.3869	14.049	6	.0001*
	3 months to 6 months	5.8571	1.8645	.7047	4.1328	7.5815	8.312	6	.0001*
	Baseline to 6 months	13.0000	1.0000	.3780	12.0752	13.9248	34.395	6	.0001*

Paired t test, Statistical significance set at p<0.05, NS- not statistical significant difference, *- statistically significant difference

Figure5: Intragroup comparison of RFA from baseline to 6 months

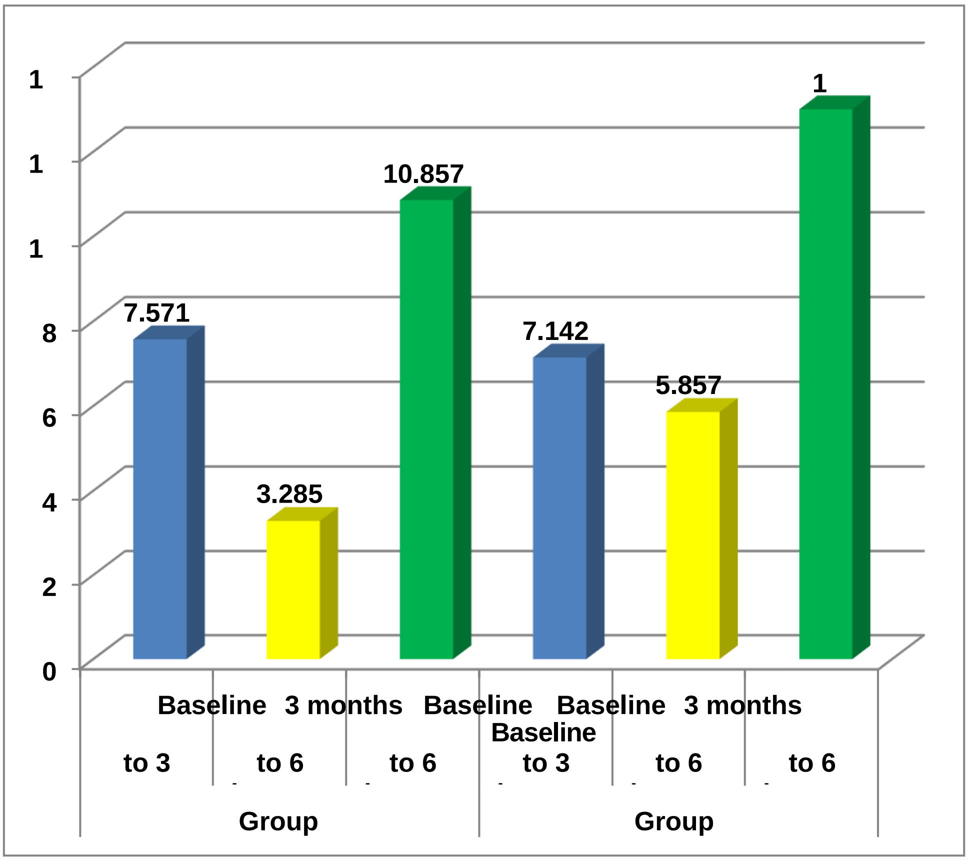


Table 5 showed Intragroup comparison of RFA from baseline to 6 months. When intragroup comparison of mean RFA was made for both the groups using paired t test, significant differences were found in mean RFA from baseline to 3 months, 3 months to 6 months and from baseline to 6 months as p<0.05 for both study groups at all time intervals.

Table 6: Intragroup comparison of crestal bone height loss on mesial side from baseline to 6 months

Crestal bone height loss on mesial side		Paired Differences					t	df	Sig. (2tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Group I	Baseline to 3 months	.87143	.11127	.04206	.97434	.76852	20.721	6	.0001*
	3 months to 6 months	.17143	.07559	.02857	.24134	.10152	6.000	6	.0001*
	Baseline to 6 months	1.0429	.1718	.0649	1.2018	.8839	16.058	6	.0001
Group II	Baseline to 3 months	.87143	.17995	.06801	1.03785	.70501	12.813	6	.0001*
	3 months to 6 months	.21429	.03780	.01429	.24924	.17933	15.000	6	.0001*
	Baseline to 6 months	1.0857	.1864	.0705	1.2581	.9133	15.407	6	.0001*

Paired t test, Statistical significance set at p<0.05, NS not statistical significant difference, * statistically significant difference

Figure 6: Intragroup comparison of crestal bone height loss on mesial side from baseline to 6 months

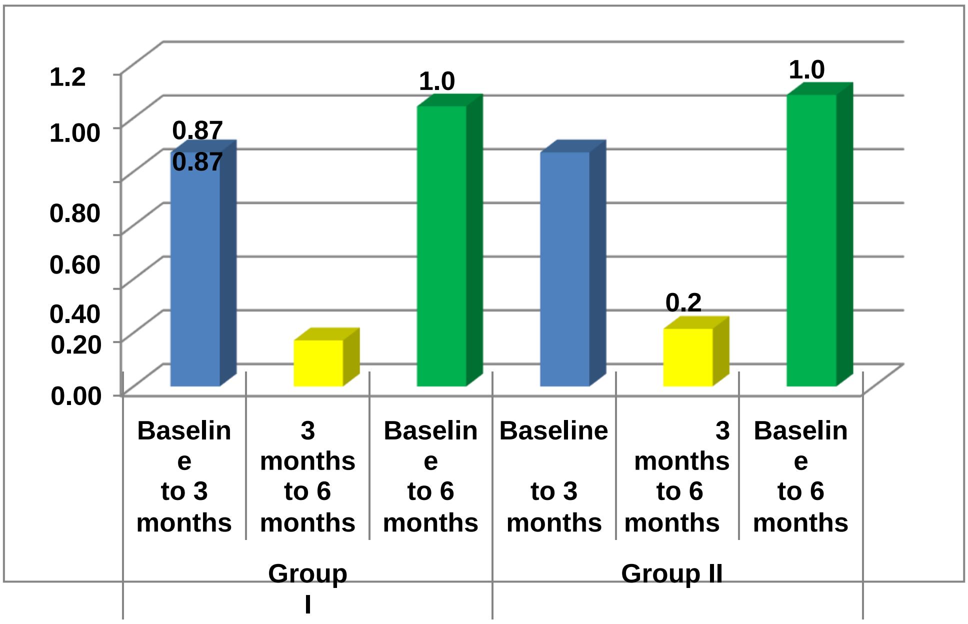


Table 6 showed Intragroup comparison of crestal height on mesial side from baseline to 6 months, baseline to 3 months and from 3 months to 6 months When intragroup comparison of mean crestal height on mesial side in group I and group II was made using paired t test, significant differences were observed from baseline to 3 months, baseline to 6 months and from 3 months to 6 months also as p<0.05 in both the groups at all the study intervals.

Table7: Intragroup comparison of crestal bone height loss on distal side from baseline to 6 months

CRESTAL BONE HEIGHT on distal side		Paired Differences					t	df	Sig. (2tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Group I	Baseline to 3 months	.81429	.13452	.05084	.93869	.68988	16.016	6	.0001*
	3 months to 6 months	.20000	.08165	.03086	.27551	.12449	6.481	6	0001*
	Baseline to 6 months	1.0143	.1864	.0705	1.1867	.8419	14.393	6	0001*
Group II	Baseline to 3 months	.91429	.15736	.05948	1.05982	.76875	15.372	6	0001*
	3 months to 6 months	.21429	.03780	.01429	.24924	.17933	15.000	6	0001*
	Baseline to 6 months	1.1286	.1604	.0606	1.2769	.9803	18.620	6	0001*

Paired t test, Statistical significance set at $p<0.05$, NS not statistical significant difference, * statistically significant difference

Figure7: Intragroup comparison of crestal bone height loss on distal side from baseline to 6 months

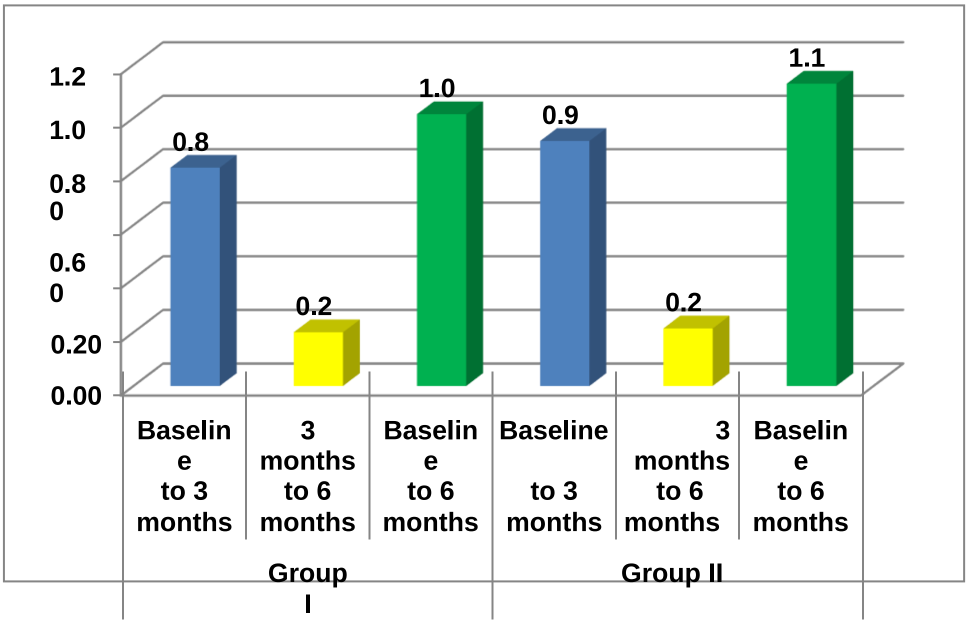


Table 7 showed Intragroup comparison of crestal height on distal side from baseline to 6 months, baseline to 3 months and from 3 months to 6 months When intragroup comparison of mean crestal height on distal side in group I and group II was made using paired t test, significant differences were observed from baseline to 3 months, baseline to 6 months and from 3 months to 6 months also as $p<0.05$ in both the groups at all the study intervals.

Table8: Comparison of intergroup mean difference of RFA from baseline to 3 months and baseline to 6 months

RFA	Groups	N	Mean	Std. Deviation	Std. Error Mean	P VALUE
From baseline to 3 months	Group I	7	7.5714	1.39728	.52812	0.570 NS
	Group II	7	7.1429	1.34519	.50843	
From baseline to 6 months	Group I	7	10.8571	.69007	.26082	0.001*
	Group II	7	13.0000	1.00000	.37796	

Paired t test, Statistical significance set at p<0.05, NS not statistical significant difference, * statistically significant difference

Figure8: Comparison of intergroup mean difference of RFA from baseline to 3 months and baseline to 6 months

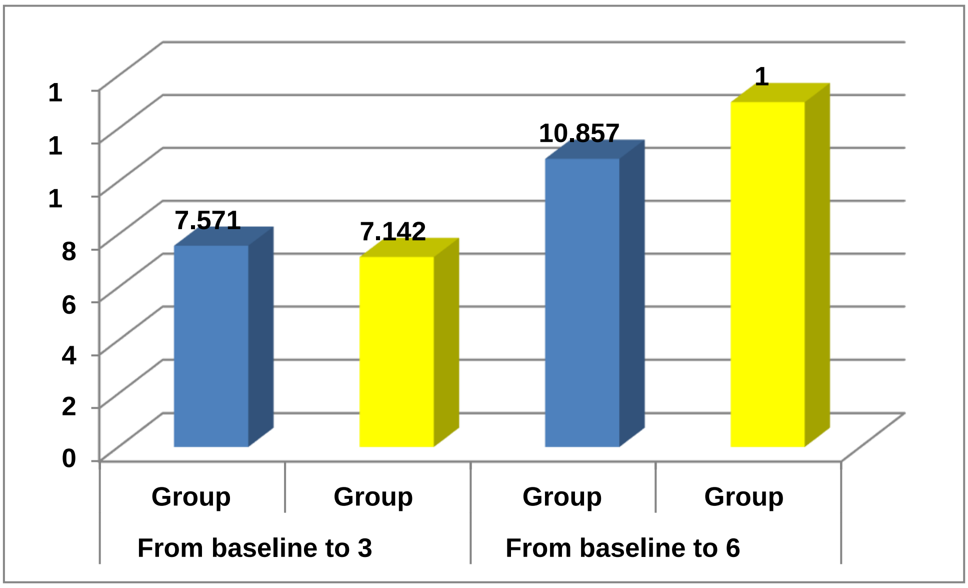


Table 8 showed Comparison of intergroup mean difference of RFA from baseline to 3 months and baseline to 6 months. No significant changes were found in mean difference in RFA from baseline to 3 months but significance differences were observed from baseline to 6 months.

Table9: Comparison of intergroup mean bone loss of overall crestal bone height and crestal bone height on mesial side and distal side from baseline to 3 months and baseline to 6 months

Crestal bone height	gps	N	Mean	Std. Deviation	Std. Error Mean	P value
On mesial side from baseline to 3 months	Group I	7	.8714	.11127	.04206	1.000 NS
	Group II	7	.8714	.17995	.06801	
On mesial side from baseline to 6 months	Group I	7	1.0429	.17182	.06494	0.663 NS
	Group II	7	1.0857	.18645	.07047	
On distal side from baseline	Group I	7	.8143	.13452	.05084	0.225 NS
	Gro	7	.9143	.15736	.05948	

to 3 months	Group II					
On distal side from baseline to 6 months	Group I	7	1.0143	.18645	.07047	0.242 NS
	Group II	7	1.1286	.16036	.06061	
Overall baseline to 3 months	Group I	7	.8429	.11701	.04422	0.516 NS
	Group II	7	.8929	.15924	.06019	
Overall from baseline to 6 months	Group I	7	1.0286	.17286	.06534	0.401 NS
	Group II	7	1.1071	.16439	.06213	

Independent t test, Statistical significance set at $p<0.05$, NS not statistical significant difference, * statistically significant difference

Figure9: Comparison of intergroup mean bone loss of overall crestal bone height and crestal bone height on mesial side and distal side from baseline to 3 months and baseline to 6 months

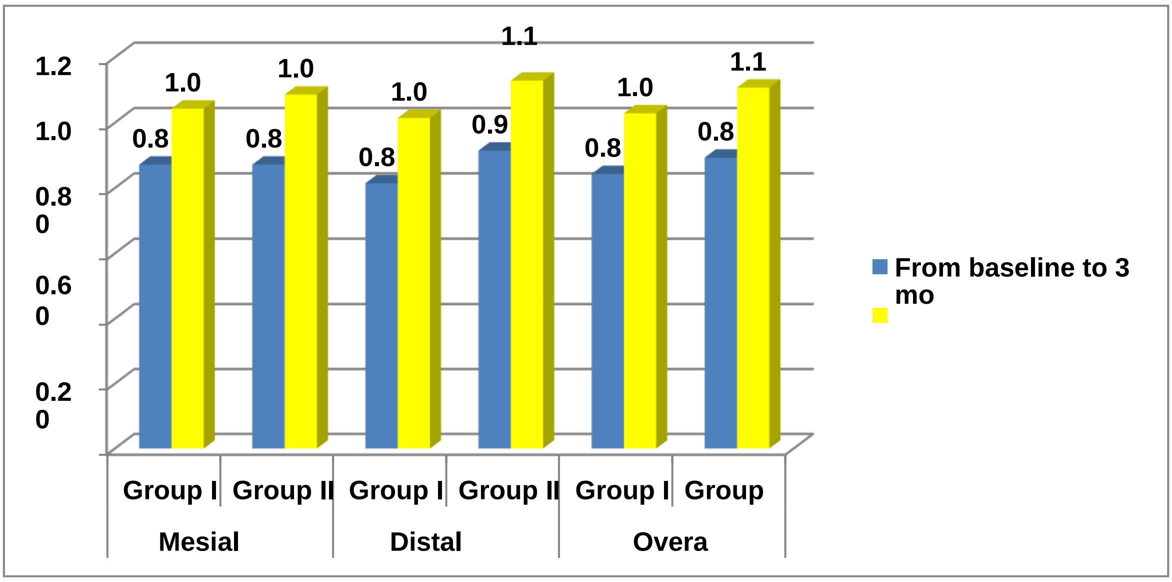


Table 9 showed Comparison of intergroup mean difference of overall crestal bone height and crestal bone height on mesial side and distal side from baseline to 3 months and baseline to 6 months. No significant differences were observed in Overall crestal bone height and crestal bone height on mesial side and distal side from baseline to 3 or 6 months.

Discussion

The concept of "osseointegration" was introduced by Dr. Per-Ingvar Branemark in 1969 [108-110] It refers to the process that takes place between the living bone and the surface of implant. Although the direct bone to implant surface connection without intervening connective tissue was described way back in 1939 by Strock, it was Branemark, who scientifically explained the philosophy that the absence of connective tissues at the bone implant interface is the key to clinical success in dental implantology, for the first time.[108] He defined osseointegration as "Direct structural and functional connection between the ordered, living bone and the surface of load carrying implant". It was an exemplary milestone in the field of dental rehabilitation. Loss of teeth not only reduces the functional efficacy of jaws, but also detrimentally affects the aesthetics leading to severe emotional and psychological peril. Implant therapy has become a reliable, safe and highly predictable treatment option for the replacement of missing teeth.[108-110] However, it's not completely glitch free and as more dentists and patients choose the implant option; more complications began to surface.

Although the process of osseointegration has been proven to be predictable and highly successful by evidence based data, the process itself is relatively complex and is influenced by various factors. This complex process of constant formation and adaptation to function and repair is due to osteoblastic and osteoclastic activities of the peri-implant bone, also known as coupling.[111-113]

Lekholm U, Zarb GA[114] explains the classification system of bone as follows: Based on its radiographic appearance and the resistance at drilling, bone quality has been classified into four categories:

Type 1 bone: entire bone is composed of homogenous compact bone.

Type 2 bone: a core of dense trabecular bone surrounded by a thick layer of compact bone

Type 3 bone: a core of dense trabecular bone surrounded by a thin layer of cortical bone

Type 4 bone: a thin layer of cortical bone surrounding a core of low density trabecular bone of poor strength.

Misch[115] classified bone density types into 4 classes based on the trabecular and cortical parts of these bone macroscopically.

Class D I: dense cortical bone

Class D II: porous cortical bone

Class D III: coarse trabecular bone

Class D IV: fine trabecular bone

Class D V: immature non-mineralized bone

To preserve a persistent and sufficient level of bone remodeling, there should be appropriate local functional stimulation as well as crucial levels of calcium metabolism hormones: thyroid hormone, calcitonin, and vitamin D within the system. Occlusal force stimulus and general health management are both important for perfect bone remodeling at the fixture sites.[116]

The two basic theories regarding the bone-implant interface and retention of an endosteal implants in function.

1. Fibro-osseous integration supported by **Linkow (1970), James (1975), and Weiss (1986)**[117]
2. Osseointegration supported by **Branemark (1985)**[118]

Stages of Osseointegration:

In bone defects, principal fractures and in osseointegration the healing follows a common, biologically determined program that is subdivided in to 3 stages:

1. Incorporation by woven bone formation.

2. Adaptation of bone mass to load

3. Adaptation of bone structure to load.

The alveolar process is a tooth-dependent tissue, so tooth extraction inevitably results in significant resorption and atrophy,[119-120] leading to significant three dimensional changes of the alveolar bone, particularly in the first 6 months.[121,122] This not only prevent the placement of endosseous implant in a favorable prosthetic position but also hinder appropriate fabrication of pontic when conventional fixed prostheses are considered.[123]Along with this natural process of socket healing, several pathologic conditions can locally contribute to damage the integrity of one or more walls of the postextractive alveolus.[124]

In the literature, the primary stability has been demonstrated as a necessary condition to obtain the osseointegration of the dental implant.[125,126,127]

This feature is conditioned by several factors related to the surgical technique, bone quantity and density, macro and microgeometry of the dental implant [128-132]

According to the Misch classification (1988), compromised quality bone, such as D4 bone type, could influence the obtaining of primary stability during the implant positioning.[8]Several techniques had been proposed to increase primary stability in vivo in maxillary posterior region such as: under-preparation drilling protocols, manual condensation osteotomy, piezoelectric devices.[132,133,134,135]

However successful dental rehabilitation in posterior maxilla could present problems due to disuse atrophy that occurs after extraction of the teeth because of the lack of stimuli [136]and sinus pneumatisation. [137,138] The bone quality in the maxilla is less favorable than in the mandible and is generally classified as type III or type IV.[139]Inadequate quantity and low quality of bone is a challenge in achieving adequate primary stability, which is important for successful osseointegration.[131--133] It has been reported that primary stability decreased in poor bone density sites.[132-134] Primary stability results from mechanical engagement between the implant surface and the peri-implant bone of the implant bed. Secondary stability is the progressive increase in stability achieved through bone neo-formation and remodeling in contact with the implant surface during the healing period.[136-138] In addition, it is not possible to place dental implants with an adequate length in some clinical situations, primarily due to the lack of sufficient bone and pneumatisation of the maxillary sinus.[139,142]Thus, an augmentation procedure is often indicated in this area. Maxillary sinus lift is one of the most common surgical techniques.[143-145] it has been considered a safe treatment modality with a low complication rate.[146] Several systematic reviews of the literature showed high overall implant survival rates well beyond 90% for sinus floor evaluation.[147] The aim of sinus lift procedure is to compensate this bone loss by adding bone volume in the maxillary sinus, which will allow the installation of dental implants of sufficient size to enhance the primary stability,[148] as main risk factor for implant failure is the primary stability of the implant.[149] Bone density and especially cortical thickness are important factors in achieving adequate primary stability.[150] Secondary stability is the biologic stability provided achieved through bone regeneration and remodelling.[150,151,152] Both parameters are interrelated positively, which would ensure a successful osseointegration.[150-153]Osseointegration is the result of initial mechanical stability complemented by biological stability; the sum of these two parameters will give the value of the final stability.[152-154]Several techniques have been advocated in the literature for increasing local bone volume like lateral sinus lifting, GBR and onlay block graft. The problem with these procedures include longer treatment period, increased morbidity, and an additional surgical site with increased cost to the patient.[154,155,156]

The bone density evaluation through preoperative tomography planning could be useful for the qualitative and quantitative diagnostic of the native alveolar ridges according to the Hounsfield scale [157]. These values, in conjunction with RFA values and insertion torque measurements can provide the surgeon with an objective assessment of bone quality and may be especially useful where a low density bone is suspected. The introduction of the newer techniques and materials adopted has allowed more surgeons and patients to use this type of therapy, making possible the placement of implant elements in very hard situations where only a few years ago the professional would have chosen a different therapeutic choice.[158] One of the main principles for successful therapy is the achievement of suitable primary stability during the implant placement[159] in respect to the biology of the host1[160] and factors depending on the invasiveness of the operation; the more the preparation of the implant site will be performed in an conservative way by avoiding the overheating, and so the necrosis of the site, the more we will be able to respect tissues of the host by eliminating complications of hard and soft tissues (bleeding, swelling, local infection, invasion of the noble structures adjacent to the surgery, implant early loss, inadequate healing of hard and soft tissues involved during the operation, presence and/or formation of pus immediately after the operation, pain, alteration of the sensitivity of the area) [160,161] Among the mentioned factors, we chose to focus on the primary stability because this is an indicator of the predictability of healthy that the implant will keep by the time and therefore the success of the therapy [162] There are several techniques have been developed to increase the primary stability; some of those include the use of condensers of bone tissue and osteotomes, specific tools to improve the bone quantity used as anchorage for the implant.[163] Despite having success by these techniques as supported by the scientific community, they have considerable complications and sometimes they appear to be difficult to perform[164] The OD technique of n introduced by Huwais in 2015 allows us to increase the bone tissue density surrounding the preparation implant site during the surgery with adequate drills designed working in opposite direction, with low-speed irrigation (by avoiding the overheating of the tissue, and so its necrosis)[165] A comparison about the quantity and quality of the autologous bone maintained by the preparation with osseodensification than the Summers osteotomes, has reported a BIC higher than 19.4% with the use of the technique with drills Versah (Densah, MI, USA) [166]

In conventional osteotomy bone is removed to enlarge the osteotomy site,[167,168] since it removes autologous bone from the insertion site of the dental implant. In contrast the technique for the osseodensification compacts the bony particles and re-models while healing in favor of the implanted graft[169-170]. The OD drills have at least four tapered flutes with a negative rake angle. The drilling is done by both CW and CCW and is performed at high speeds (800-1400 rpm). The counterclockwise drilling direction is utilized in bone with low density, while the clockwise drilling direction is better for higher density bone.[171] In our study we found that the CCW direction for drilling osteotomy with speed of 800-1400 rpm, as indicated by the aforementioned protocols set by Huwais, since we placed the implants in low-density posterior maxilla.

It has been proved by many analyzed studies confirms the OD for what concerns the maintaining of the quality and quantity of autologous bone, which will influence the result of the implant surgery in a notable way [172] because it ensures the primary stability of the implant placed . [165]Several alveolar preparation techniques have been described to increase the interface of the implant with surrounding bone [173] in order to improve the primary stability and the osseointegration outcomes. The mechanical friction between implant–bone is responsible for primary stability, decreasing the degree of dental fixure micro-movements, which is one of the main causes of implant loss [174-180] In the literature, an insertion torque value should never increase in excess of 35 Ncm and is considered a fundamental clinical condition of optimal primary stability and the long-term predictability of dental implant rehabilitation, that could be clinically affected by compromised jaws anatomies, such as the D 4 areas in posterior maxilla[176,177].

After the surgery, we may assess the primary stability of the placed implants, a value that indicates the contact of the implant surface with the surrounding bone [178]; after this, the secondary stability will follow, which is reached after the processes of remodeling and healing of the bone [179] usually, the achievement of good primary stability will be followed by correct secondary stability[180]. In this way, the dynamic functional response of the bone tissue is determined by the bone-to-implant contact percentage (BIC), which is constantly improves in remodeling and healing processes under the functional loading[180]. In order to measure the implant stability, we may use the implant stability quotient (ISQ), a unit of measurement, which allows us to assess the degree of micro-movement and thus the degree of integration of the placed implants[179] the clinical range of the ISQ is ranged between 55 and 80, and if the value is higher than 65, it is commonly accepted as a favorable situation for implant stability; on the contrary, values under 45 are considered as insufficient implant stability

The ISQ has no relation with the micromovements suffered by the implants,[155] representing another factor to consider from the beginning of the post-operation step because if it is higher than 50–100 µ, it may influence negatively on the implant stability [148]. Moreover, the insertion torque (IT) represents one of the most common clinical predictors for dental implant primary stability[175] This value is correlated to the mechanical frictional relationships between the implant fixture and the surrounding bone during the device positioning. The short coming of IT is its non-repeatability of this measurement during the operative practice.

Maxillary sinus floor elevation through crestal approach is a fairly common procedure for implant rehabilitation of posterior maxilla with successful outcome in means of grafting technique and long-term implant survival rate.[46] Primary stability has traditionally been assessed by the practitioner by manual verification (Merheb et al. 2010). In researches, however, two methods, based on implant vibration produced by two electronic appliances (Osstell – Integration Diagnostics, Sweden – and the Periotest – Medizintechnik Gulden, Germany) are now being preferred. Osstell gives the implant stability quotient (ISQ) through resonance frequency analysis on a scale from 1 to100. The higher the ISQ value represent the higher stability. The Periotest produces percussion of the implant and also provides a stability number on a scale ranging from -8 to +50. The lower the Periotest value (PTV), the higher is the stability. These methods are noninvasive and repeatable (Cehreli et al. 2009), thus allow the practitioner to follow the establishment of secondary stability. RFA is a conservative non-invasive method for assessing primary stability, and is used extensively in clinical practice is the measurement of insertion torque (IT) in Ncm during the fixture placement (Pagliani et al. 2010). This method, however, allows a single measurement of primary stability. It cannot be used for evaluating second implant stability.

Resonance frequency Analysis is a noninvasive diagnostic method that measures implant stability and bone density at various time points using vibration and structural principle analysis[36].

Frequency between 3.52 KHz and 8.54 KHz are formed from the magnetic field and is converted into ISQ values. It has a magnetic peg which is fixed to the implant fixture or abutment by a screw below. The magnetic resonance frequency emitted from the probe, activates the magnetic peg. The activated peg starts to vibrate, and the magnet induces electric volt into the probe coil and the electric volt is sampled by the magnetic RFA.

After the osteotomy preparation and implant placement, prior to the placement of cover screw the smart peg (respective for the implant system) is placed onto the implant with the help of the smart peg mount. The mount is removed after securing the smart peg in the implant. The RFA instrument is activated and the probe tip is placed maintaining a 1–3 mm distance from the smart peg, at an angle of 90°, and 3-3.2 mm away the soft tissues, otherwise the recorded value may be affected. The values are expressed as numbers between the range of 1 and 100 in ISQ.

It has been recorded that ISQ is affected by diameter and surface of implant, form, bone contact ratio, implant site, implant system, surgical procedure, and bone quality and bone height.

Histomorphologic studies report that the RFA value has a high correlation with the bone implant contact. On the contrary, many clinical studies recorded that there is no correlation between the bone density of implant placement site and ISQ value. Thus the RFA signifies the bone anchorage of implants but the relation of RFA and bone structure is still not clear. Such diverse results showed, RFA value decreases during the first 2 weeks after implant placement, and this change can be related to early bone healing such as biological change and marginal alveolar bone resorption. Bone remodeling decreases the mechanical bony contact and in the early stage after implant placement, the formation of bony callus and increasing lamellar bone in the cortical bone causes major changes in bone density. Thus, during healing process, primary stability and %BIC decreases and secondary stability and %BIC increases. Furthermore, the three-dimensional implant-bone contact is displayed two-dimensionally in the histological sample and BIC has possibility of inaccuracy to signify bone-implant contact.The relationship of bone structure and RFA is not fully understood. Since primary stability is influenced by bone volume or nature and density of bone trabeculae structure, as well as cortical bone thickness and density, the effect of bone quality on implant stability, cannot be explained by bone.

Application

1) Helps in making loading decisions: The prosthetic phase can be planned when an ISQ of 70 or more has been reached. However, high primary stability does not always mean the secondary stability of the fixture will also be the same or even more since bone remodeling is variable. Similarly a lower initial dental implant stability does not indicate implant failure since following the waiting period of osseointegration there is an increase in bone implant contact. Hence, an ISQ of more than 70 achieved over the waiting period of osseointegration would be more valuable.

2) Warns of impeding failure: An ISQ of 55 or an ISQ which is gradually declining over the waiting period suggests of an impending failure and warns to take up necessary measures[44].

Lai C. H. et al in 2009[181]had ISQ values over 66 at first measurement, indicating that osteotome procedure provided good primary stability, which is most important basis for implant success.

Marco T et al in 2016[182] had a mean ISQ value 65.5 at implant placement and it increased to 74.1 at the 6 month examination

This present study was conducted to assess the use of densah bur as a drilling technique in comparison to the use of standard drilling in implant placement. This was a randomized controlled clinical trial conducted on 14 patients to evaluate available %BIC, crestal bone height loss and implant stability after implant placement in healed posterior maxillary alveolar ridge.

All patients were recalled 2 days after the operation, then weekly for one month, then monthly until the prosthetic phase (6 month postoperative). Radiographic evaluation involved cone beam CT radiographs taken for every patient preoperatively and 6 months postoperatively to evaluate %BIC. OPG/RVG was done immediately after implant placement, then at 3months and 6 months postoperatively, respectively to evaluate the crestal bone loss. While implant stability quotient was obtained by taking osstell readings using osstel device immediately after implant insertion, at 3 months and 6 months postoperative, to follow the maturity of the primary stability into secondary stability.

In our study when the intragroup comparison of the ISQ values was made from baseline to 6 months for both the groups using paired t-test, significant differences ($p<0.05$) were found in the mean ISQ values from baseline to3months: 3 months to 6 months and from baseline to 6 months for both the study groups at all time intervals. All implants in both groups had ISQ values ranging from 52 to 71 for group A and from 51 to 82 for group B indicating fair primary stability which is very important for success of dental implant. [164,165] The basic characteristics such as available bone height and width were found similar i.e. did not differ significantly ($p>0.05$) between the two groups. The clinical mobility was absent in both the groups intra-operatively ($p=1.0$) which shows no significant difference ($p>0.05$) in both the groups. Intra-operative clinical mobility may be present due to lack of primary stability. To maximize initial stability, it has been recommended that the recipient bed should be prepared in a slightly smaller size than the implant diameter; at the same time, the use of a fixture with specific microscopical features may be helpful. In our present study, a strict surgical protocol has been followed: in soft bone (typesIV) and implants were placed in underprepared osteotomies. In addition, insertion, and it may be particularly useful in areas of poor bone quality. The OD osteotomy by Densah burs compacts the bone particles in an outward fashion as it expand the osteotomy, thus providing the increased primary stability that is necessary to achieve a higher success rate. The current literature has conclusively demonstrated a strong correlation with bone density and jaw as well as location: it is well-known that the quality of bone is poorer in the posterior maxilla, in the context of achieving primary implant stability[175].

Turkyilmaz et al. found a positive strong correlation between bone density (calculated with computed tomography) and ISQ values, he reported that high ISQ values recorded (70.5±6) resulted from the higher quality of bone in the anterior mandible, the surgical technique with no pre-tapping, and the roughened-surface implants used.[154-156]A significant difference of implant stability observed within each group when comparing implant stability after 3 months to initial stability. Then ISQ values showed slight increase for both groups when measured after 3 months of implant insertion. This change in stability matched the pattern of stability with implants placed in routine procedure without sinus lifting procedure. The variation in ISQ values is reflective of the biologic changes at the bone implant interface. This finding is similar to the results of Alfadda, S.A (2014) [180]and Kim, J.M., Kim, S.J., Han, I., Shin, S.W. and Ryu, J.J., (2009). [174]The results from our study concluded that there is no statistically significant difference between the control and test groups from baseline to 3 months, but difference was significant from baseline to 6 months. The mean ISQ value of the Densah group was found to be significantly higher than the convensional group in the immediate postoperative period. The result suggests that osseodensification osteotomy was able to achieve a superior primary stability than the convensional technique. The significant raise of the ISQ values for the Densah group from the baseline to 3 months and from 3 months to 6 months holds the hypothesis valid that autocompaction of the peri-implant density results in a more successful osseointegration. Padmanabham et al (2010) in a comparison of the crestal bone loss and implant stability between implants placed using conventional implant placement technique and Summer;s osteotome technique observed a longer period of attaining sufficient stability in the osteome group. This was because of the longer healing period that was required following the trabecular fracture at the osteotomy site by the osteotome. [155]

The bone compaction technique through the OD drilling increased the insertion torque, bone-to-implant contact, and accordingly resulted in greater primary stability compared to conventional drilling. They proposed that the osseodensification technique conserves bone by compaction of cancellous bone due to viscoelastic and plastic deformation, and compaction autografting of bone particles along the length and at the apex of the osteotomy which meet the results from our study. Shayesteh at al. 2011 observed that though the primary stability among the patients where osteotome technique was used was higher, the difference was not significant after 3 months. In addition the osteotome group patients have more crestal bone loss than conventional group. The crestal bone loss in our study was not significant between the groups at 3 months and 6 months. However the intragroup bone loss was significant in both the groups at all study intervals.

The bone implant contact ratio was significantly higher among the patients in the Densah group (76 vs 62.143) than the control group after 6 months. Higher %BIC helps to achieve better stability which is the most important factor that determines a successful osseointegration.[124]

The overall patient satisfaction was high in both study groups and patients were satisfied regarding function, and the treatment procedure.
In our knowledge there has been no direct comparison between the Densah bur osteotomy technique and conventional osteotomy technique. We have made an attempt to compare the two techniques based on the parameters of ISQ, %BIC, and crestal bone loss. The results of our study gives valuable inputs to increase the success rate of implant placement at compromised sites without the longer waiting period and increased morbidity.

CONCLUSION

Based on the observations, statistical analysis, and evidence based discussion, the following conclusion has been drawn;

1) The osseodensification drilling protocol produces a positive influence in enhancing the primary stability in suboptimal density bone compared to the conventional osteotomy technique.

2) The enhanced primary stability of dental implant produces a favorable and faster healing as a result of more BIC resulting in successful osseointegration of the implant placed with OD technique.

3) The higher BIC after 6 months in OD group indicates higher final implant stability due to increased peri-implant density produced by autografting process of the bone tissues to the walls of the osteotomy.

4) No significant changes were recorded between for crestal bone loss between both the groups, although the crestal bone lossigher is in first 3 months .

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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 IIIrd Institutional Ethics Sub - Committee

IEC Code: 24 **BBDCODS/05/2016**

Title of the Project: Cortical Vs Root form dental implant: A Clinical & Radiographic Study

Principal Investigator: Dr. Ashutosh Tiwari **Department:** Oral & Maxillofacial Surgery

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

Type of Submission: New, MDS Project Protocol

Dear Dr. Ashutosh Tiwari

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 03rd May, 2016.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Narendra Kumar Gupta Member	Prof., Department of Prosthodontics, BBDCODS, Lucknow
3.	Dr. Smita Govila Member	Reader, Department of Conservative Dentistry, BBDCODS, Lucknow
4.	Dr. Subhash Singh	Reader, Department of Pedodontics, BBDCODS, Lucknow

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.
The proposal was reviewed, 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 26/05/16

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

(Dr. Lakshmi Bala)
Member-Secretary
IEC

(Dr. Vivek Govila)
Principal
BBDCODS

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

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

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **Cortical V/S Root form dental implant: A Clinical and Radiographic Study** submitted by **Dr. Ashutosh Tiwari** Post graduate student from the Department of **Oral and Maxillofacial Surgery** as part of MDS Curriculum for the academic year **2015-2018** with the Accompanying proforma was reviewed by the institutional research committee present on **5th March 2016** 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. (Dr).Vivek Govila

Dean

Chairperson Institutional Research Committee

Consent Form (English)

Title of the Study

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 [ ] Not Applicable [ ]**
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

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Babu Banarasi Das College of Dental Sciences

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Patient Information Document (PID)

1. **Study title**

   Cortical Vs. Root form dental implant: A clinical and Radiographic study.

2. **Invitation paragraph**

   You are being invited to take part in a research study, it therefore is 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. It is up to you to decide whether or not to take part.

3. **What is the purpose of the study?**

   The purpose of study is to compare the efficacy of cortical vs. root form dental for the Rehabilitation of edentulous area

4. **Why have you been chosen?**

   You have been chosen for this study as fulfilling the required criteria for the diseased condition.

5. **Why would you take part?**

   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.

6. **What will happen to you if you take part?**

   My study will last for 3 years and you will be involved in my study for 3 months, an attempt is made to compare the efficacy of cortical & root form dental Implants .The study includes each cortical and root form dental implants. Using a standardized implant placement protocol, the stability of different implants will be assessed at intervals of immediately after placement, 7 days, 1 month & 3 months. The clinical performance of the implants will be evaluated by two experienced oral & maxillofacial surgeons.

7. What would you have to do?

You do not have to change your regular lifestyles for the investigation of the study.

8. What is the procedure that is being tested?

The purpose of this study is to compare the efficacy of cortical & root form dental Implants.

9. What are the interventions for the study?

There are no such interventions, risk and adverse effects related to the study. There is clinical benefit to the volunteer as he/she will receive implant with crowns.

10. What are the side effects of taking part?

There are no side effects on patients of this study.

11. What are the possible disadvantages and risks of taking part?

Some disadvantages which may happen such as implant mobility, perimplantitis etc.

12. What are the possible benefits of taking part?

We wish that you will get benefits after taking part in our study. Your participation in the study may help others, because this participation will help us determine if the study procedure is efficacious.

13. What if new information becomes available?

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 weather 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.

14. What happens when the research study stops?

If the study stops/finishes before the stipulated time, this will be explained to you.

15. What if something goes wrong?

If any severe adverse event occurs, or something goes wrong during the study, the complaints will be handled by reporting to the institution (s), and IEC.

16. Shall i take part in this study be kept confidential?

Yes it will be kept confidential.

17. What will happen to the results of the research study?

The result of the study will be published in the indexed journal. Your identity will be kept confidential in case of any report/publications.

18. Who is organizing the research?

This research study is organized by the candidate and Department of Oral & Maxillofacial Surgery.

19. Will the results of the study be made available after study is over?

Yes, only the data obtained will be published.

20. Who has reviewed the study?

The study has been reviewed and approved by the Head of the Department and the IEC of the institution.

Contact for further information

Dr. Ashutosh Tiwari
Department of Oral and Maxillofacial Surgery
dr.ashutosh1988@gmail.com
BBDCODS, Lucknow.

Dr. Laxmi Bala
Secretary Ethics committee
bbdcods_iec@gmail.com

Name of principle investigator……………………………………….

Signature of principle investigator …………………………….

Date………………………………………...

URKUND

Urkund Analysis Result

Analysed Document: Dr. Hrishijit Saikia-converted.pdf (D110196735)
Submitted: 7/6/2021 11:47:00 AM
Submitted By: hemantmehra121@bbdu.ac.in
Significance: 9 %

Sources included in the report:

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