# EVALUATION OF CRESTAL BONE LEVEL WITH NARROW DIAMETER PLATFORM SWITCHED IMPLANTS IN MANDIBULAR POSTERIOR EDENTULOUS REGION

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**In**

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**By**

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Dedicated To

My Mother

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# LIST OF ABBREVIATIONS

| | |
|---|---|
| ACD | Apico Coronal Distance |
| BLW | Bucco Lingual Width |
| BIC | Bone Implant Contact |
| BT | Bleeding Time |
| BVD | Bone Volume Density |
| CBC | Complete Blood Count |
| CBH | Crestal Bone Height |
| CBHM | Crestal Bone Height Mesial |
| CBHD | Crestal Bone Height Distal |
| CI | Confidence Interval |
| CT | Clotting Time |
| GIC | Glass Ionomer Cement |
| IAJ | Implant Abutment Junction |
| IOPAR | Intra Oral Peri Apical Radiograph |

| | |
|---|---|
| ISQ | Implant Stability Quotient |
| MMBL | Mean Marginal Bone Level |
| NDI | Narrow Diameter Implant |
| NI | Narrow Implant |
| OCBH | Overall Crestal Bone Height |
| OPG | Orthopantomogram |
| PDL | Periodontal Ligament |
| PTV | Periotest Value |
| RFA | Radio Frequency Analysis |
| RPM | Rotation Per Minute |
| SLA | Sandblasted Large grit and Acid etched |
| UNC | University of North Carolina |
| XCP | Extension Cone Paralleling |

# ABSTRACT

## ABSTRACT

The goal of dentistry is to provide a patient with good mastication, esthetics and phonation. An ideal implant improves the masticatory function as well as it stimulates the bone and maintains the gingival contour. The most important criteria for the success of dental implants, is to provide them with appropriate bone housing. Hence narrow bone ridges could be rehabilitated with narrow diameter implants instead of opting for bone augmentation. Use of a small diameter implant may increase the stress on bone around the implant neck which may lead to loss of crestal bone support. In such condition, a platform switch design may mitigate these stress concentrations and aid in crestal bone preservation around implants. The study was conducted with the aim of evaluation of crestal bone level with narrow diameter platform switched implants in mandibular posterior edentulous region. A total of 20 implants were placed and the implant stability was assessed with RFA and the crestal bone level was evaluated with the help of intraoral periapical radiographs with grid at implant placement time, at 6 months and at 1 year. The ISQ of patients increased at 1 year of follow up but was found to be not significant ($p=0.003$). The crestal bone level in platform switched narrow diameter implants decreased significantly ($p<0.001$) from the placement time to 6 months and 1 year, but was well within the range for the criteria for successful implants. Hence, it can be inferred that platform switched narrow diameter implants are viable options in narrow ridges in posterior edentulous areas.

# INTRODUCTION

Loss of tooth is a pervasive problem that affects millions of people world-wide. It often presents the biggest technical challenge for a clinician and results in reduction of masticatory efficiency. Failure to replace missing teeth leads to various deleterious consequences which include alveolar bone resorption, supra-eruption, drifting of teeth, decrease in vertical dimension, loss of intercuspation, increase in anterior overbite, extrusion and flaring of anterior teeth. Occlusal disharmonies created by the altered tooth position traumatize the supporting tissue of the periodontium and aggravate the destruction caused by the inflammation.[1] The replacement of missing teeth can be achieved in multiple ways e.g. removable dentures which are the least esthetic option for an edentulous region or tooth retained restorations which can damage the adjacent abutment teeth. Endosseous dental implants are a viable alternative to removable or fixed prosthetic restorations as they overcome the above said drawbacks. Furthermore research has validated the success of osseointegrated implants, over the past many decades.[2]

According to Glossary of Periodontal Terms, dental implant is defined as "An alloplastic material or device that is surgically placed into the oral tissue beneath the mucosal or periosteal layer or within the bone for functional, therapeutic, or esthetic purposes".[3]

Irrespective of the surgical protocol followed for implant placement the main aim of a dentist is to achieve successful osseointegration, minimal crestal bone loss and achievement of primary and secondary implant stability as these are the most important prerequisite for successful outcome of implants and have also been included in the success criteria proposed by Albrektsson.[4]

Restoration of the posterior edentulous region by means of implants require sufficient quantity & quality of residual bone, especially the crestal bone. Adequate crestal bone level is considered as an important clinical determinant for the success of implants.[5]

In alveolar ridges less than 6mm width, various augmentation surgeries, such as ridge splitting, ridge expansion, lateral augmentation & horizontal distraction osteogenesis are advocated[6,7]; which cause increased trauma, economic burden, increased surgical and healing time as well as increase morbidity. To overcome these, narrow diameter implants were introduced. However, crestal bone loss is one adversity which is bound to occur and needs to be minimized to achieve adequate implant stability. And it is here, the concept of platform switching proves to be beneficial in preventing peri-implant bone loss. In this, an under-sized or narrower diameter abutment is used in relation to the given diameter implant collar to limit the peri-implant bone resorption[8]. The connection shifts the perimeter of the implant–abutment junction inward toward the central axis of the implant. This shift in the direction of forces acts by shifting the inflammatory cell infiltrate inward and away from the adjacent crestal bone, thereby reducing marginal bone loss[9]. Hence, platform switching is useful in cases with narrow alveolar ridges where least amount of bone loss is desired.

Implant stability is a measure of the clinical immobility of an implant. Various diagnostic techniques have been proposed to evaluate implant stability e.g. standardized radiographs, percussion test, cutting torque resistance analysis, reverse torque test, and periotest[10,11]. However these techniques lack resolution, have poor sensitivity, can be destructive and are also technique sensitive.[10] To overcome these limitations a novel technique was developed by Dr. Neil F Meredith in 1996 to assess implant stability called RFA. This has been widely accepted as an appropriate method for the assessment of the implant stability and the strength of implant- bone interface.[12]

In our study, we will evaluate the implant stability using RFA and amount of crestal bone loss with the help of IOPAR with grid while using platform switched narrow implants in mandibular posterior edentulous ridges of less than 6mm width.

After the literature search only one article could be found with narrow diameter platform switched implants. So this study was taken up to further assess the outcome and support the existing literature.

# AIM AND OBJECTIVES

**AIM:** In Vivo evaluation of Crestal bone level with narrow diameter platform switched implants in mandibular posterior edentulous region

**OBJECTIVES:**

- To assess the implant stability in platform switched narrow diameter implants at placement time, after 6 months, and after one year.
- To evaluate crestal bone level changes in platform switched narrow diameter implants at placement time, after 6 months, and after one year.

# REVIEW OF LITERATURE

## Implant Success

**Alberktsson T et al (1986)**[4] proposed that the following criteria are supported as valid for determining the clinical success of endosseous dental implants:

1. The individual unattached implant is immobile when tested clinically.
2. No evidence of peri-implant radiolucency is present as assessed on an undistorted radiograph.
3. The mean vertical bone loss is less than 0.2 mm annually after the first year of service.
4. The individual implant performance is characterized by an absence of persistent and/or irreversible signs and symptoms such as pain, infections, neuropathies, paresthesia, or violation of the mandibular canal.
5. By these criteria, success rate of 85% at the end of a 5-year observation period and 80% at the end of a 10-year period are minimum levels for success.

**Bauman GR et al (1992)**[13] reviewed investigations concerning the clinical parameters of dental implants during the maintenance phase of therapy. Clinical parameters that were discussed included mobility, gingival alterations, tissue movement, probing and attachment level measurements, bleeding upon probing, occlusion, and microbial monitoring. This study examined the role of implant radiology surrounding radiographic interpretation, interval and technique.

**Henry PJ (1999)**[14] addressed some of the background issues pertinent to the long-term success, survival, safety and effectiveness of these devices. The requirements for clinical acceptance of implants are controlled initially by regulatory bodies. However, the dentist eventually must make a decision on what type of implant should be used in clinical practice. While short to medium term data have been accumulated on the success rates of several implant systems, it is

apparent that long-term data comparing and contrasting the various advantages and disadvantages of different systems do not exist. Also, the adequate criteria applicable to the collective clinical experience need to be defined. Expanding areas of application are dependent on continuous improvements in implant hardware, surgical protocol development and rationalized osteo-promotive and site installation augmentation technology.

**Tehemar SH (1999)[15]** concluded that atraumatic preparation of the recipient site was of utmost importance for the implant survival during conventional loading of dental implants.

**Position Paper (2000)[2]** This research paper, 'Dental Implants in Periodontal Therapy', has validated the success of osstoeintegrated implants as a viable alternative to fixed or removable prosthetic restorations. It was prepared by Research, Science and Therapy Committee of American Academy of Periodontology and is intended to inform the dental professionals regarding the utility of endosseous dental implants in the treatment of full and partial edentulism.

**Cagna et al (2003)[16]** conducted a literature review on the concept of bicortical stabilization and suggested that bicortical engagement without peri-implant defects reduces maximum stress in the superior cortical plate, which may not be clinically significant when considering the increased surgical risks necessary to achieve bicortical implant placement.

**Narrow Ridges**

**Anitua E et al (2010)**[17] conducted a study with the aim to assess retrospectively the survival of narrow-diameter implants (2.5 and 3 mm in diameter) in patients with insufficient bone ridge thickness for placement of standard-diameter implants. Fifty-one patients with 89 inserted narrow-diameter implants (2.5 and 3.0 mm) were included; and treated between June 2004 and December 2005. The observation period for all included implants was at least 3 years after implant loading. Outcome measures were implant survival, complications and marginal bone level changes evaluated on panoramic radiographs. Twenty-four months after implant insertion, mean bone loss was 1.26 mm (SD 0.51). This study concluded that narrow-diameter implants can be successfully used to treat narrow bone ridges upto 3 years after loading.

**Jung-Seok Lee et al (2012)**[18] The objectives of this study were to analyze retrospectively the long-term survival and success rates of Narrow implants (NIs) placed with various implant systems, and the association with biological and technical complications. In total, 338 patients (men = 45.6%, women = 54.4%) who received 541 NIs (3.5 mm in diameter) for fixed prostheses were enrolled in this retrospective study. The mean marginal bone level (MMBL) change was calculated. The annual MMBL change was 0.07 ± 0.20 mm. The 12-year cumulative survival (success) rates of NIs were 98.1% (91.8%) and 98.5% (93.8%) for the implant- and subject-based analysis, respectively. During the observation period up to 12 years (mean 4.9 years), six implants were lost in the maxilla, whereas three implants were lost in the mandible. Technical complications were more frequent than biological complications. Infection was the most common underlying cause of biological complications and the most frequent technical complication was decementation. In conclusion, the findings of this study suggested that NIs could be used safely for narrow alveolar ridges or narrow mesiodistal spaces on the basis of their high survival rate.

**Ahmad Y. Imam et al (2014)[19]** Limited available alveolar ridge bone and space deficiencies are some of the challenging scenarios that have led many dental implant manufacturers to develop narrow-diameter implants of various designs. Clinicians may have concerns about the durability and function of the narrow-diameter implants. The purpose of this study was to explore and compare the ultimate failure resistance of the smallest diameter of the 2-stage type implant provided by 5 commonly used dental implant systems. Thirty implants, Astra Osseo Speed 3.0 mm and 3.5 mm, Straumann Bone Level 3.3 mm, Zimmer Tapered Screw-Vent 3.7 mm, Full Osseotite Certain 3.25 mm, and Nobel Speedy Replace 3.5 mm, 5 of each type, were tested in this study. With regard to implant diameter and ultimate failure strength, Osseotite Certain 3.25 mm was considered to be more advantageous in comparison with the other implants tested.

**M. Saad et al (2016)[7]** According to this study, implant rehabilitations in the posterior jaw are influenced by many factors such as condition of remaining teeth, force factors related to the patient, quality of bone, hygiene maintenance, limited bone height, type and extent of edentulism, and the nature of the opposing arch. The gold standard is to place a regular diameter implant (>3.7 mm) or a wide one to replace every missing molar. Unfortunately, due to horizontal bone resorption, this option is not possible without lateral bone augmentation. In this situation, narrow diameter implant (NDI < 3.5mm) could be the alternative to lateral bone augmentation procedures. This paper presents a clinical study where NDIs were used for the replacement of missing molars. They were followed up to 11 years. NDI could be used to replace missing molar in case of moderate horizontal bone resorption if strict guidelines are respected. Yet, future controlled prospective clinical trials are required to admit their use as scientific evidence.

**Pommer B et al (2016)[20]** This study discussed the trends in techniques to avoid bone augmentation surgery, which included application of short implants,

narrow-diameter implants and guided surgery. It was concluded that narrow diameter implants, short implants (most frequent in partial edentulism) and guided implant surgery (most frequent in complete edentulism) represented uprising and promising surgical approaches to avoid patient morbidity associated with bone graft surgery.

## Platform Switching

**Atieh MA et al (2010)[21]** carried out a review and meta-analysis on platform switching for marginal bone preservation around dental implants to show that platform switching may preserve inter-implant bone height and soft tissue levels. The degree of marginal bone resorption is inversely related to the extent of the implant-abutment mismatch.

**Krishna Prasad et al (2011)[9]** reviewed literature dealing with the platform switching concept. This included preservation of the crestal bone, the mechanism by which it contributes to maintenance of marginal bone, its clinical applications, advantages and disadvantages, in order to assess its survival rates. He concluded that platform switching helps preserve crestal bone around the implants and this concept should be followed when clinical situations in implant placement permit.

**Canullo L et al (2011)[22]** conducted a study to evaluate the influence of platform switching on the biomechanical aspects of the implant-abutment system. It concluded that the platform switching configuration led to not only to a relative decrease in stress levels compared to narrow and wide standard configurations, but also to a notable stress field shift from bone towards the implant system, potentially resulting in lower crestal bone overloading.

**Moergel M et al (2015)[23]** conducted a prospective study for radiographic evaluation of conical tapered platform-switched implants in the posterior mandible showing 1year postoperative results. This study assessed bone level

changes around implants with internal conical connection and platform-switching abutments. A total of 71.7% of all implants presented bone preservation or gain. No implant was lost at 1 year and the success rate was 100%.

**Pozzi A et al (2016)[24]** conducted a study to report upto 2 year outcomes of the immediately loaded novel variable-thread tapered implant with an internal conical connection and built in platform shifting. This study demonstrated good treatment outcomes with regard to implant and prosthetic survival rate and soft tissue conditions, in both post extraction and healed sites.

**Rocha S et al (2016)[25]** conducted a randomized prospective study of sixty-three patients with a total of 135 implants to evaluate crestal bone levels between implants restored with single crowns with platform-matched or platform-switched abutments after 3 years. The author concluded that after 3 years, platform-switching restorations showed a significant effect in the preservation of marginal bone levels compared to platform-matching restorations.

**In-Hee Woo et al (2016)[6]** conducted a retrospective study to show results from platform-switched narrow-diameter implants in the posterior edentulous region, which were followed up for more than 1 year after functional loading. A total of ninety-eight narrow implants were placed into 66 patients. After healing, fixed implant-supported prostheses were delivered to the patients, and Periotest and radiographic examinations were performed. After the first year of loading, the implant outcome was again evaluated clinically and radiographically using the Periotest analysis. Crestal bone loss and Periotest values (PTVs) were used to evaluate the effect of surgery, prosthesis, implant, and a host-related factor. Implants were followed over 1 to 4 years of loading. Their survival rate was 100%. Bone loss after functional loading was 0.14 ± 0.39 mm. The stability value from the Periotest was −3.29 ± 0.50. Within the limitations of this study, judicious use of platform-switched narrow implants with a conical connection

must be considered an alternative for wide-diameter implants to restore a posterior edentulous region.

## Radio Frequency Analysis

**Meredith N et al (1996)[26]** stated that implant stability can be evaluated by applying RFA and architectural engineering. RFA involves resonating sine wave with a certain frequency width, continuously from high to low or from low to high. So, RFA can reveal the effective length of implant out of bone and also the stiffness of bone-implant interface.

**Araceli Boronat López et al (2006)[27]** analyzed 133 implants using resonance frequency analysis. Measurements were made in 133 implants (62 in the upper jaw and 71 in the mandible) of resonance frequency and insertion force to determine implant stability on the day of surgery, with an evaluation of its relationship to different variables. The stability quotient of the implants on the day of surgery was 62.1, with an insertion force of 35.7 N. The insertion force was proportional to the resonance frequency, with an increasing stability quotient with growing insertion force. The stability quotient was greater in the larger diameter implants, shorter implants, in mandibular placement and in areas of more compact bone. They concluded that stability quotient on the day of implant placement is greater in higher bone density areas.

**Lachmann S et al (2006)[28]** compared reliability of both Osstell and Periotest in an *in vitro* study. The experiment was executed on eight implants in which the stability was measured in three different variation without withdrawing the transducer, after withdrawing transducer and manual torqueing, and after withdrawing transducer and mechanic torqueing with a 10 N control torque rotary unit. The final result reflected that Osstell system was more precise with a 95% confidence interval.

**H. Schliephake et al (2006)[29]** test the hypothesis that measurements of implant stability using resonance frequency analysis (RFA) correlate with histomorphometric data of bone anchorage in dog's jaw. At the time of implant placement, torque required for bone tapping was registered as a measure of bone density and immediately after placement implant stability was assessed using RFA. Peri-implant bone regeneration was assessed histomorphometrically by measuring bone-implant contact (BIC) and the volume density of the newly formed peri-implant bone (BVD). RFA values at the time of implant placement did not correlate with the torque required to tap the bone for implant placement. After 1 and 3 months, RFA values were significantly increased compared with baseline values. BIC and BVD, however, had increased significantly during this interval. There was no correlation between bone-implant contact and RFA values or between peri-implant bone density and RFA values. Thus, the hypothesis could not be verified. It is concluded that the validity of the individual measurement of implant stability using RFA should be considered with caution.

**Par Olav Ostman et al (2006)[30]** evaluated primary stability by resonance frequency analysis measurements of implants placed according to a surgical protocol that aimed for high primary stability and also aimed to correlate RFA measurements with factor related to the surgical technique, the patient and implants design. Results showed higher ISQ value in men compared with women in mandible compared with maxillae, in posterior region compared with anterior site and for wider platform implants in comparison with regular/narrow platform implants. There was correlation between bone quality and primary stability with lower ISQ value obtained for implants placed in softer bone, lower implant stability was seen with increased implant length. Jaw type and gender has independent effect on primary stability.

**Wei-Jen Chang et al (2007)[31]** calibrated and tested the performance of the newly designed dental implant stability detector on in vitro and in vivo models respectively. The RF values of the test implants detected using their new device

and a commercially available analogous device (Osstell) were compared. Further, implant stability status was also detected clinically using our device at 2, 4, 8, and 12 weeks after surgery.

A high correlation was demonstrated between the values measured with the two devices. In conclusion, these results indicated that our new device might be useful in a clinical setting for evaluating the healing status of a placed implant

**Pilar Valderrama et al (2007)[32]** conducted a study "**Evaluation of Two Different Resonance Frequency Devices to Detect Implant Stability: A Clinical Trial**" the goal of this clinical trial was to evaluate the ability of the magnetic RFA device to detect changes in stability during early healing following implant placement and to determine whether the implant stability quotient (ISQ) values obtained correlated with those made with the electronic device. RFA assessments were performed using electronic and magnetic based devices on 34 non-submerged titanium dental implants in 17 patients. Each patient received two implants in the posterior maxilla or mandible. Implant stability was measured at placement and weekly until week 6, when implants received provisional crowns and at 12 weeks, when definitive crowns were cemented. During each visit measurements were taken three times and averaged to obtain a single representative ISQ for each device. They found that at placements both devices indicated a pattern of decreased mean stability from 1 to 3 weeks post-placement, small fluctuations in mean ISQ from 3 to 6 weeks and significantly increased mean stability from 6 to 12 weeks. For the complete set of implant measures across all weeks, the paired electronic and magnetic ISQ values correlated significantly ($r=-0.52$; $P<0.001$). They concluded that this study demonstrates that changes in implant stability measured with the newer magnetic device correlate well with those found with the electronic device. Both devices confirmed the initial decreases in implant stability that occur following placement and identified an increase in stability during the first 6 weeks of functional loading.

**Masahiko Yamaguchi et al (2008)[33]** conducted a study titled **"Resonance frequency analysis of long-term implant success in the posterior partially edentulous mandible"** This study evaluated the long-term stability of end osseous implants according to an ISQ scale of 1 to 100, as estimated by RFA in the posterior partially edentulous mandible. A 2-stage procedure was used to place 328 Branemark implants in the edentulous mandibular molar region (second premolar to second molar) of 113 patients (49 men and 64 women). Patients were followed at regular intervals postoperatively, and ISQ scores were evaluated by RFA every year for 10 years. They found that implant success rate was 100%. ISQ scores did not significantly differ in the pattern of stability changes among different bone quantities and qualities during long-term follow-up. There was no significant difference in implant stability among the mandibular sides, the sites, and the sexes. They concluded that long-term stability of Branemark implants was excellent in the posterior partially edentulous mandible.

**Jurgen Zix et al (2008)[34]** evaluated the reliability of Osstell and Periotest systems on 213 Straumann tissue level implants. They revealed that the Periotest measurements manifested range of atypical or extreme measures that did not appear in Osstell measurements. Their final conclusion reflected that Osstell device is more precise

**K. Akea et al (2010)[35]** They used Torque-fitting and resonance frequency analyses (RFA) to assess primary implant anchorage and stability. The torque-fitting and RFA of implants placed in conventional surgical sockets and sockets with controlled coronal bone defects was compared. The possible relation between torque-fitting and RFA was explored. Ø3.3 mm_12 mm implants were placed in 16 sockets finalized with Ø2.8 mm surgical pilot drills in the right iliac crests of two fresh cadavers (control). In the test group, implants were placed into sockets prepared by Ø2.8 mm drill followed by Ø 4.2 mm twist drills to a

depth of 6 mm to create circumferential controlled coronal bone defects (50% bone loss).

Primary implant stability was assessed using insertion torque values (ITV) followed by RFA. Mean ITV and RFA measurements for test groups (7.83 ± 0.91 N cm and 40.88 ± 3.57) were significantly lower than controls (14.80 ± 1 N cm and 66.31 ± 0.9) ($P<0.05$). Reductions of ITV and RFA measurements in relation to bone defect were 47% and 38%. The existence of controlled bone defects eliminating contact coronally leads to decrease in torque-fitting and primary stability of implants. No relationship was observed between torque fitting and RFA.

**Al-Jetaily et al (2011)**[36] investigated the sensitivity and reliability of the Osstell systems comparing to Periotest system. They indicated that ISQ values and PTVs showed a significant difference between a direct contact and soft interface Another remarkable discrepancy was recognized in different horizontally exposed fixture groups, which were strongly correlated with PTVs and with ISQ values on the day of surgery.

**Mariano Herrero Climent et al (2012)**[37] conducted in vivo study to assess reliability, repeatability and reproducibility in the Osstell Mentor system using statistical methods. ISQ readings were made in 85 implants placed in 23 patients. 6 measurements were on each implant by means of two different Smart Pegs (types I and II): that is, three consecutive measurements with each transducer. Results showed that RFA system contributed by Osstell Mentor renders almost perfect reproducibility and repeatability, as proven by statistical analysis.

**Mehran Shokri et al (2013)**[38] The aim of this workwas to measure the stability of dental implants prior to loading the implants, using a resonance frequency analysis (RFA) by Osstell mentor device. Ten healthy and non-smoker patients over 40 years of age with at least six months of complete or partial edentulous

mouth received screw-type dental implants by a 1-stage procedure.RFA measurements were obtained at surgery and 1, 2, 3, 4,5, 7, and 11 weeks after the implant surgery. They found that among fifteen implants, the lowest mean stability measurement was for the 4th week after surgery in all bone types. At placement, the mean ISQ obtained with the magnetic device was 77.2 with 95% confidence interval (CI) = 2.49, and then it decreased until the 4th week to 72.13 (95% CI = 2.88), and at the last measurement, the mean implant stability significantly (P value <0.05) increased and recorded higher values to 75.6 (95%CI=1.88), at the 11th week. They concluded that loading might be disadvantageous before 4$^{th}$ week of implant placement.

**Ahmet Umut Guler et al (2013)**[39] done an in-vivo study to determine implant stability as ISQ values, at implant placement and healing periods. 208 Straumann implants were evaluated for the ISQ values during the healing period using Osstell mentor. ISQ value ranges showed a significant increase during the healing period. Only the posterior maxilla showed lowest ISQ value at the time of placement. The second measurement was significantly higher in men compared with women. Test concluded that repeated ISQ measurements of the implant have some diagnostic benefit.

**Bertl MH et al (2013)**[40] conducted in vivo study to determine the inter and intra observer variability of RFA stability measurements of palatal implants and to evaluate influence of age, sex, time after implant insertion and measurement direction on variability. Three Observers conducted RFA measurements of palatal implants in 16 patients. Measurements were taken in antero-posterior and latero-lateral directions and were repeated after 1 hour. Data showed a small inter-observer variation with intra observer variations its largest component Time after implantation showed strong influence on the inter-observer variation.

**Alberto Monje et al (2014)**[41] Tested the sensitivity of the RFA for detecting early implant failure. In vivo, 20 implants out of the 3786 implants placed which

failed over the 6 years period were evaluated for the ISQ values at the time of implant placement and prior to loading which lead to failure. The study showed that ISQ values are not reliable in predicting early implant failure. In addition, the real cut-off ISQ value to differentiate between success and early implant failures remains to be determined.

**R. Jaramillo et al (2014)**[42] conducted a study to compare the reliability of Osstell Mentor and Osstell ISQ for implant stability measurement. They recorded the primary stability of 58 implants with both devices. At last, they stated both devices showed almost precise reproducibility and repeatability with no significant differences at confidence level of 95%.

**Farshad Bajoghli et al (2015)**[43] done a brief review on contemporary methods and equipment used for implant stability assessment. Aim of this review article was to screen the advantage and disadvantages of using resonance frequency analysis, periotest analysis and insertion torque values namely, for Implant Stability Assessments. They concluded that it is somehow difficult to suggest the most precise and accurate equipment for implant stability assessment as the literature show controversial results. Overall, it seems that Osstell system (especially Osstell Mentor) provides more accuracy and convince due to its recent updates and developments.

**Rajiv K. Gupta et al (2016)**[44] reviewed "Resonance Frequency Analysis" his aim was to analyse critically the current available literature in the field of RFA, and to also discuss based on scientific evidence, the prognostic value of RFA to detect implants at risk of failure. Initial stability at the placement and development of osseointegration are two major issues for implant survival. Implant stability is a mechanical phenomenon which is related to the local bone quality and quantity, type of implant, and placement technique used. The application of a simple clinically applicable, non-invasive test to assess implant stability and osseointegration is considered highly desirable. Resonance

frequency analysis (RFA) is one of such technique which is most frequently used now days. A search was made using the PubMed database to find all the literature published on "Resonance frequency analysis for implant stability" till date. Articles discussed in vivo or in vitro studies comparing RFA with other methods of implant stability measurement and articles discussing its reliability were thoroughly reviewed and discussed. A limited number of clinical reports were found. Various studies have demonstrated the feasibility and predictability of the technique. However, most of these articles are based on retrospective data or uncontrolled cases. Randomized prospective, parallel-armed longitudinal human trials are based on short-term results and long-term follow-ups are still scarce in this field. Nonetheless, from available literature, they concluded that RFA technique evaluates implant stability as a function of stiffness of the implant bone interface and were influenced by factors such as bone type, exposed implant height above the alveolar crest.

Resonance frequency analysis could serve as a non-invasive diagnostic tool for detecting the implant stability of dental implants during the healing stages and in subsequent routine follow up care after treatment. Future studies, preferably randomized, prospective longitudinal studies are certainly needed to establish threshold ranges for implant stability and for implants at risk for losing stability for different implant system.

**Jaisika Rajpal et al (2016)**[45] conducted a study named "Assessment of hard and soft tissue changes around Implants: A clinic-radiographic in vivo study". The aim of the present study was to evaluate the hard and soft tissue changes around two-stage implant both radiographically and clinically to assess the success the implants. Seven patients with 10 dental implants were examined clinically for 6 months after prosthodontic treatment. Plaque index and health indices of soft tissue including pocket depth, mobility, bleeding index, calculus and gingival index were measured.

Marginal crestal bone loss and peri-implant radiolucency were checked radiographically. The criteria, both subjective and objective, were used to evaluate the success of the implant process. The necessary statistical analysis was performed for radiographic and clinical evaluation methods. They found that the values of all clinical criteria under study had no significant changes from baseline to 6 months. The vertical crestal bone loss on the mesial and distal side was within the normal range of bone loss given by Branemark. There was no mobility and no peri-implant radiolucency around any of the implants. They demonstrated that in a group of patients with no periodontal disease, the survival rate of two-stage, countersunk submerged implants in the edentulous sites is 100% during the follow-up period of 6 months.

# MATERIAL AND METHODS

The current study was carried out to evaluate and compare alterations in crestal bone level and implant stability in platform switched narrow diameter implants in posterior mandibular region. The study was conducted in the Department of Periodontology, Babu Banarasi Das College Of Dental Sciences, Lucknow after obtaining an appropriate clearance from the Institutional Ethics Committee. (Annexure II). A total of 20 implants were placed in posterior mandibular edentulous sites.

**Eligibility Criteria:**

**Inclusion criteria:**

- Age 25-65 years
- Posterior partially edentulous region
- Mandibular alveolar ridge width less than 6mm
- Systemically healthy patients
- Periodontally healthy patients
- Adequate patient compliance

**Exclusion criteria:**

- Systemically compromised and immune compromised patients
- Patients with psychiatric disorders
- Patients with bone disorders
- Pregnant or lactating women
- Alcoholic, drug abusers and smokers
- History of consumption of drugs affecting bone metabolism
- Known allergy/hypersensitivity to any product to be used in the study.

## MATERIAL:

## (PLATE I, II & III )

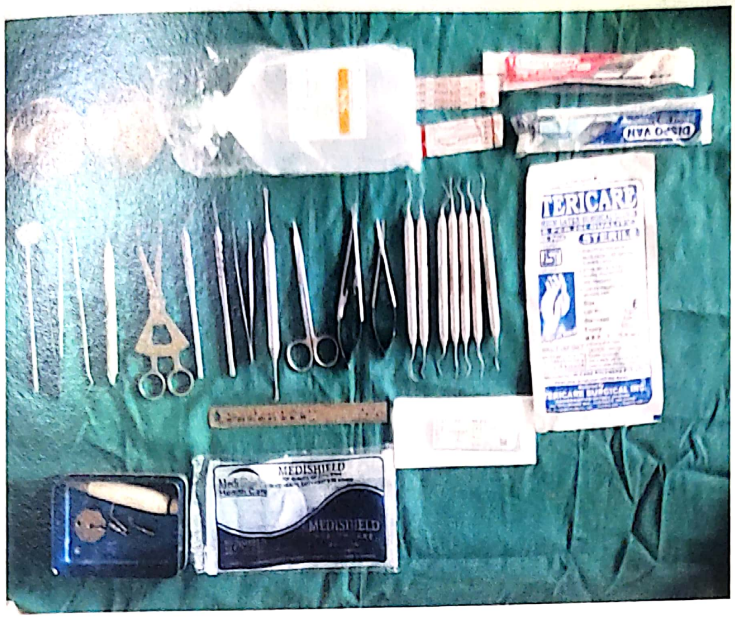
### Armamentarium for Diagnosis and Pre-clinical Assessment:

- Mouth mirror
- UNC Periodontal probe
- Tweezers
- Metallic scale
- Hard tissue caliper (GDC Marketing, India)
- Digital OPG
- Diagnostic casts

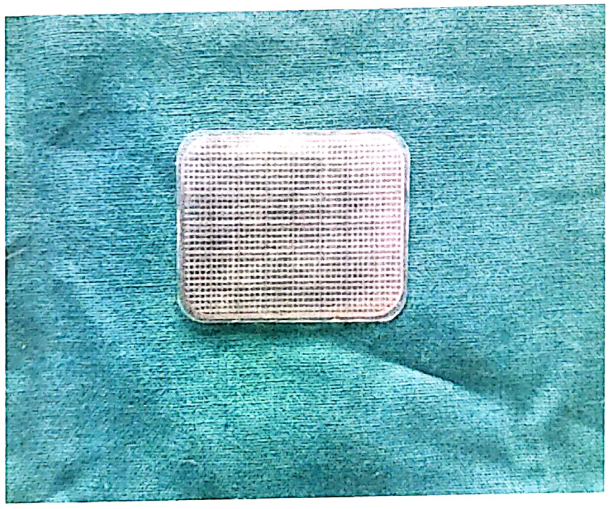
### Armamentarium for surgery:

- Local anesthesia (Xylocaine® 2% with Adrenaline)
- Syringe 3ml
- Saline
- Bard Parker Handle
- Blade (no.11,12,15)
- Periosteal elevator
- Tissue holding forceps
- Castroviejo scissors
- Castroviejo needle holder
- Suture material (4-0 Ethicon)
- Suture cutting scissors
- Implant system

  Superline Implant (3.6mm) from Dentium was used in this study. It is a platform switched, double threaded tapered implant with SLA surface having conical hex connection. The implant kit used was UXIF Surgical kit (Full) from Dentium consisting of surgical drills, counter sink, paralleling pin, hex driver, drill extender, depth guage and ratchet. Hand piece attached to W&H physiodispenser with external irrigation was used.

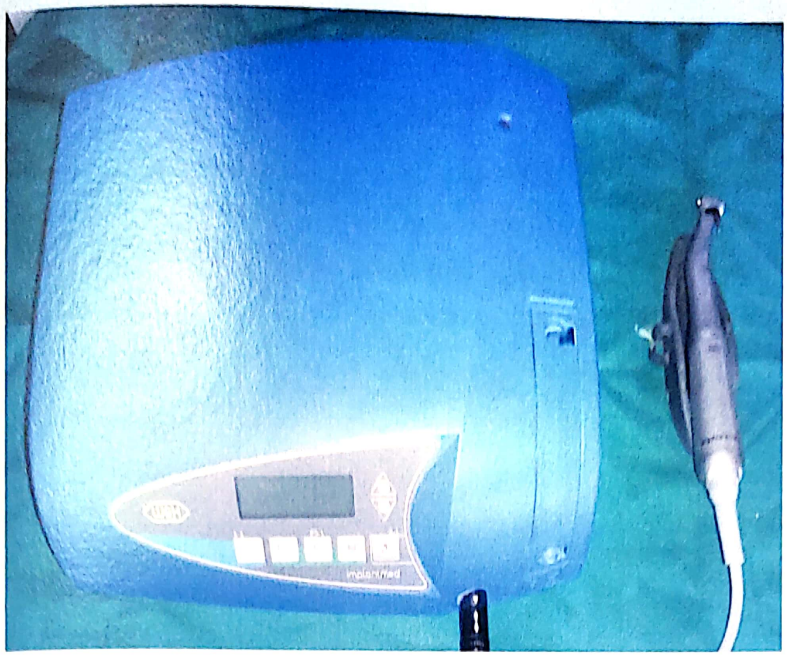



Armamentarium for Diagnosis & Surgery

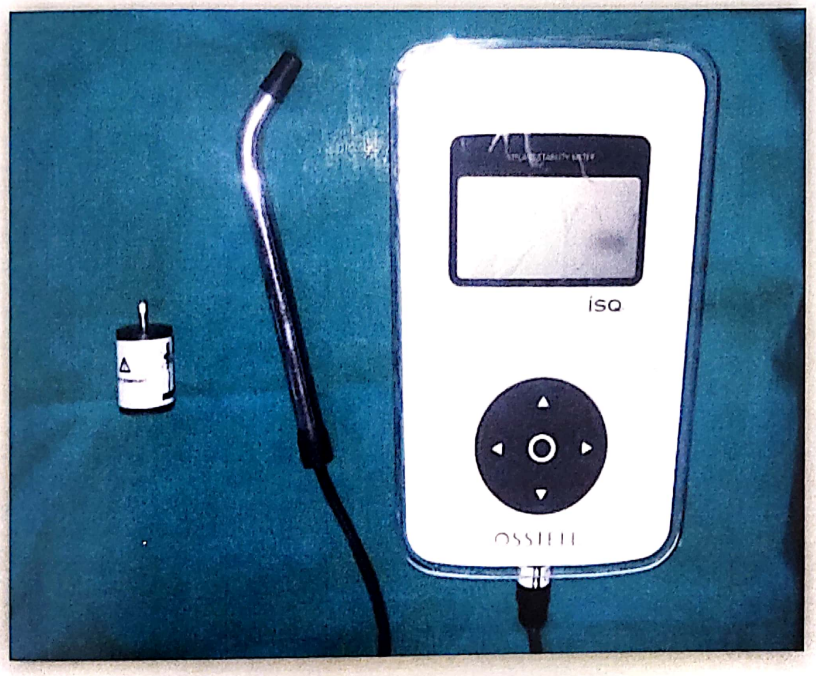


Grid

Plate -I



Physiodispenser




Osstell ISQ (RFA) with Smart Peg

Plate-II


**Implant kit and Implant Fixture**

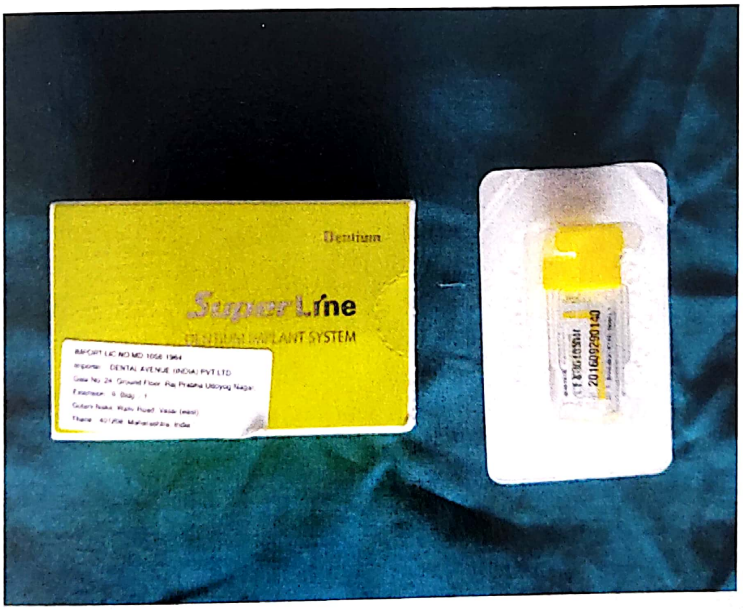



**Plate - III**

- Radio Frequency Analyser

Resonance frequency analysis applies a bending load, which mimics the clinical load and provides information about the strength of the implant–bone junction. In the current study the most recent version of resonance frequency analysis i.e. the 4th generation RFA (Osstell ISQ TM; Ostell AB) was employed which stimulates a transducer (SmartPeg™) that has been attached to the implant, by emitting magnetic pulses. The SmartPeg has a small magnet attached to its top (Osstell ISQ TM; Ostell AB) and this causes the SmartPeg to resonate with certain frequencies (5 to 15 kHz) depending on the stability of the implant. The resonance is picked up by the Osstell ISQ meter and displayed on the digital screen of the machine in ISQ units.

Following is the clinical translation of ISQ Values

| ISQ | Clinical Translation |
|---|---|
| < 60 | Low Stability |
| 60 to 69 | Medium Stability |
| >70 | High Stability |

- Grid :

Dental size X-ray Mesh Gauge from Dentech Corporation

**METHODOLOGY:**

**Study Design**

A prospective study was designed and the patients were selected considering which included a thorough medical and dental history, current general and oral health status & inclusion and exclusion criteria. A case record sheet was formulated for all cases. Patients were provided with a consent form with a written explanation regarding the nature of treatment and the potential risks involved.

**Pre-operative Implant Site Assessment**

IOPAR with grid was taken at this stage to evaluate the edentulous site. The parallel cone technique with an XCP (DentsplyRinn's XCP film holding system) device was used. Apico-coronal distance from the mandibular canal till the alveolar crest was measured.

Hard tissue calliper (GDC Marketing, India) was used for bone mapping to measure the bucco-lingual width of the alveolar ridge.

**Surgical Protocol Followed**

Patients underwent routine blood examination like CBC, BT, CT and blood sugar prior to surgery. All surgical procedures were performed under local anesthesia and strict aseptic conditions. The unit, instrument tray, patient, operating clinician and assistants were covered with sterile drapes. The surgical armamentarium including the implant kit was autoclaved. All the patients were given Alprazolam 0.25mg for anxiety

All the implants were placed in the posterior mandibular region. Delayed loading protocol was followed i.e. loading was done after 3 months which is the time recommended for osseointegration of implants placed in mandible.

**Surgical Procedure**
**(PLATE IV-VI)**

Local anesthesia was administered by inferior alveolar and long buccal nerve block technique with lignocaine (2%) and adrenaline (1:80,000).

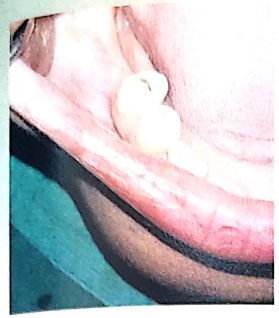
After achieving profound anesthesia, a full thickness mucoperiosteal flap was elevated with a mid crestal incision. The bucco-lingual and mesio-distal implant position was determined with the help of a pre-fabricated surgical stent. Following sequence was used for implant bed preparation, under copious irrigation with 0.9% Nacl solution and light pressure:

1. Drilling with a first guide drill XLD 22 29 (2.2mm) at a speed of 1000 rpm, to the appropriate insertion depth of the selected implant.
2. Depth gauge was placed against the wall of the osteotomy to check depth of drilling.
3. Osteotomy with sequential second guide drill XLD 26 29 (2.6mm) at a speed of 1000 rpm, to the appropriate bone depth.
4. Osteotomy with final drill XFD 34 35 (2.9mm) at a speed of 1000 rpm, to the appropriate bone depth.
5. Drilling with countersink XCS 36 29 SW (3.6mm) at a speed of 1000 rpm, up to the top or bottom line depending upon the bone quality.
6. Insertion of the dental implant with help of a hand-piece adapter XID 27 H with torque 35-40 N cm at 20 rpm.
7. SmartPeg was attached to the implant and the measurement probe was held close to the top of the SmartPeg without touching it. A total of 6 readings were taken, two in bucco-lingual direction (perpendicular to the jaw-line), two in mesio-distal (along the jaw-line) and two in apical direction. The highest of the six readings was considered. Results were displayed on the instrument as the Implant Stability Quotient (ISQ),
8. Cover screw was then placed with the help of the hex driver XHD 26 T.

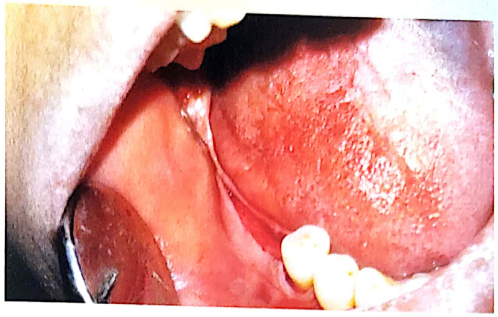
The primary closure of the wound was achieved by stabilization of the flap with simple interrupted suture with 4-0 ethicon suture.

IOPAR with grid was taken to assess the crestal bone height along the mesial and distal aspect of implant.

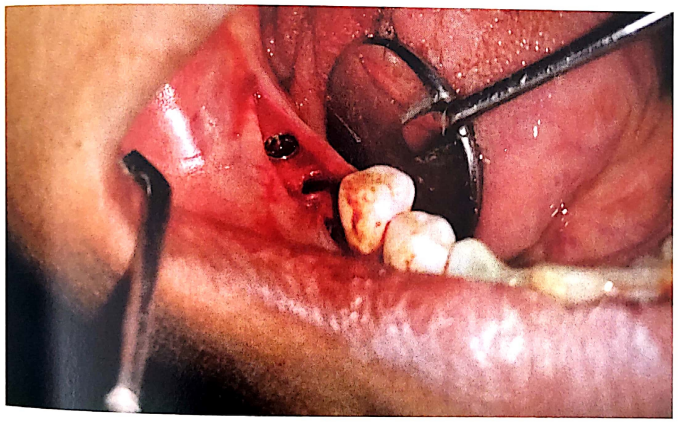
## Surgical Procedure



Missing 46, 47

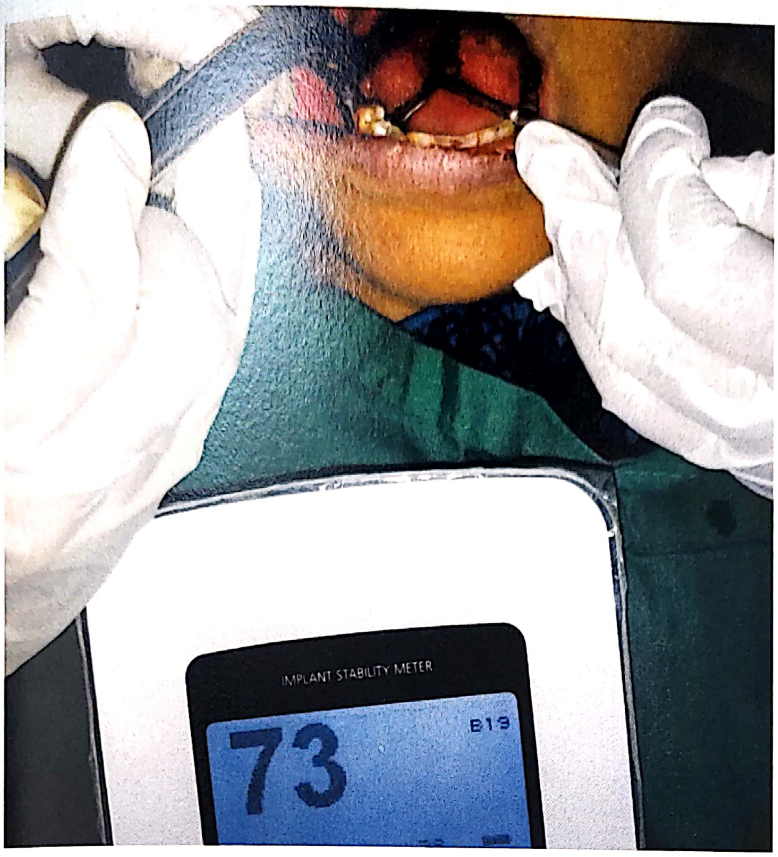


Flap Reflaction

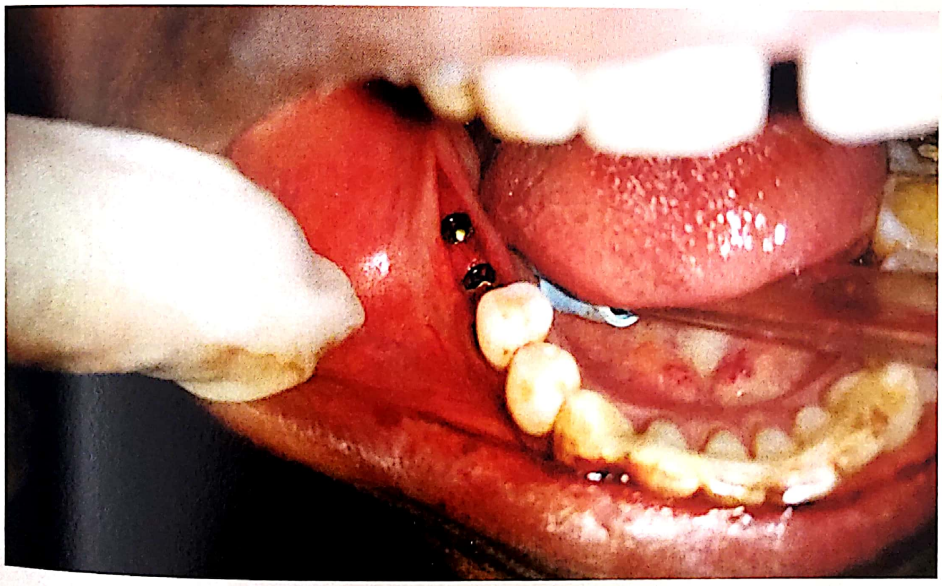


Implant placed

Plate- IV

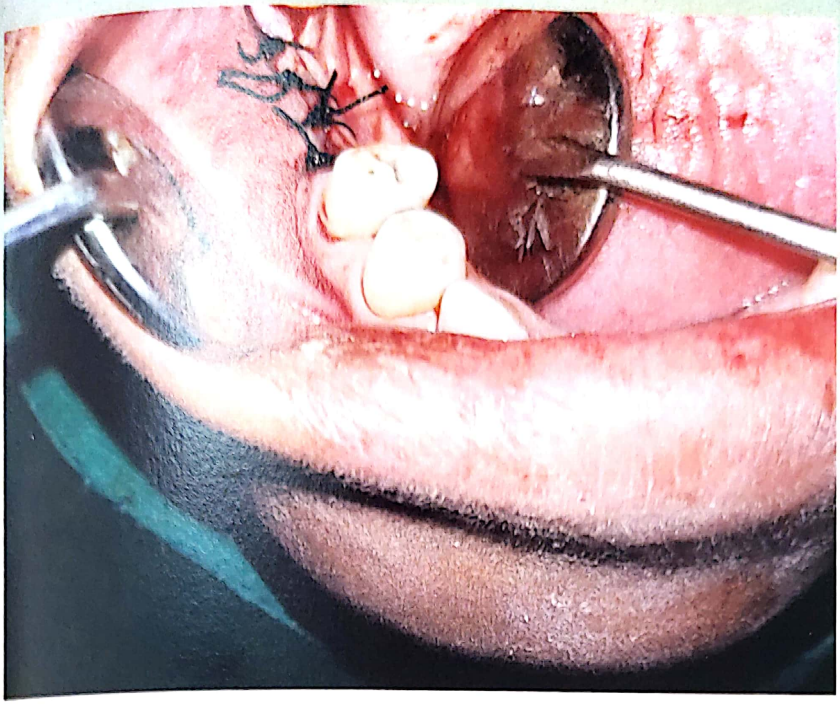



**ISQ Reading on Digital Display**

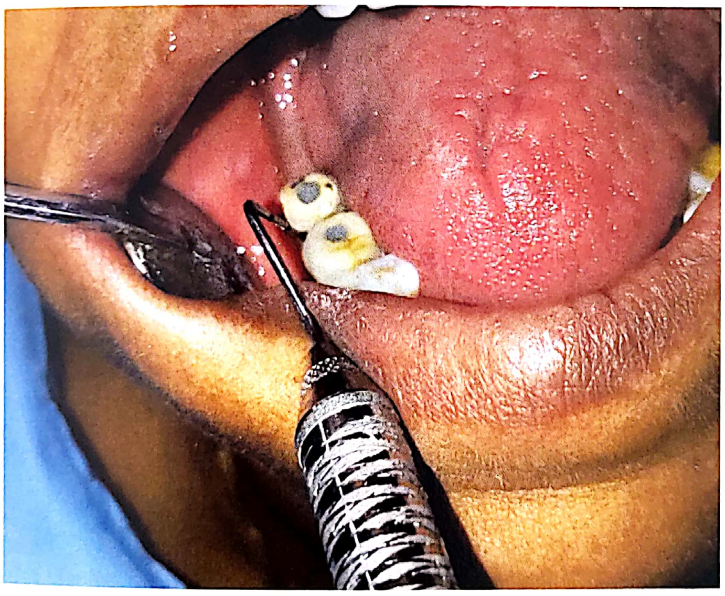


**Cover Screw Placed**

**Plate - V**



Flap closure with Suture



Rehabilitation with Screw Retained Prosthesis

Plate -VI

Antimicrobial prophylaxis (amoxicillin 500 mg) was given one hour before surgery and continued twice daily for 7 days. Post surgical analgesics (Paracetamol 500 mg + Aceclofenac 100 mg) were prescribed twice daily for one week and oral hygiene instructions were given. Chlorhexidine mouthwash 0.2% also prescribed twice daily. Suture was removed one week after the implant surgery.

**Prosthetic Phase**

After 3 months of implant placement, the patients were subjected to a **second stage surgical procedure**. A mid crestal incision was given and healing abutment was mounted on to the implant in order to condition the peri-implant soft tissues for 7-10 days.

Impression was made using elastomeric impression material, placing an impression coping in place and cast was poured with implant analog.

Screw retained final prosthesis was delivered with the help of hex driver and the remaining portion of screw retained prosthesis was then restored with GIC.

Patient was recalled for checkup.

**Follow ups at 6$^{th}$ month and at 1 year**

**Implant stability assessment**

Restoration was removed and prosthesis was unscrewed with hex driver. Implant stability was assessed with RFA. The prosthesis was again screwed back onto the implant and restored.

**Radiographic evaluation**

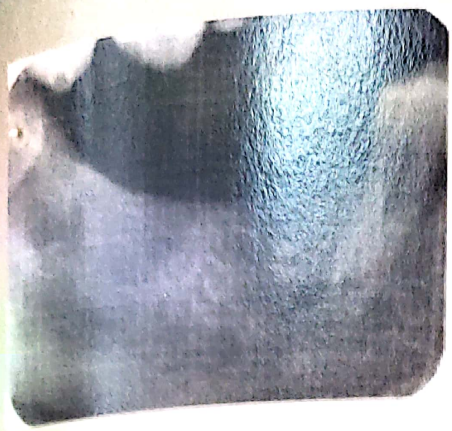
**(PLATE VII)**

IOPAR with grid were taken. Crestal bone height was measured from the level of implant shoulder at mesial as well as distal aspect. Data was calculated according to the mathematical formula. (Annexure)

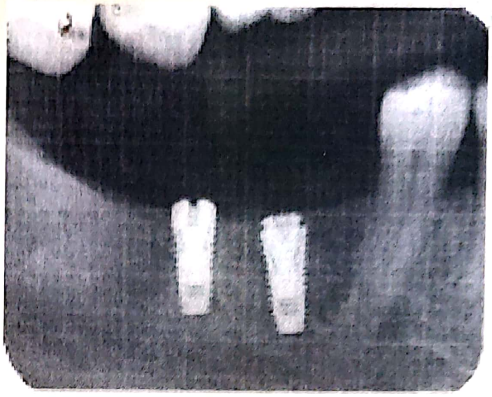
**Statistical analysis**

Data were summarised as Mean ± SE (standard error of the mean). Three dependent groups (periods) were compared by repeated measures one factor analysis of variance (ANOVA) and the significance of mean difference between the groups was done by Newman-Keuls post hoc test after ascertaining normality by Shapiro-Wilk's test and homogeneity of variance between groups by Levene's test. A two-tailed ($\alpha$=2) $p<0.05$ was considered statistically significant. Analysis was performed on SPSS software (Windows version 17.0).

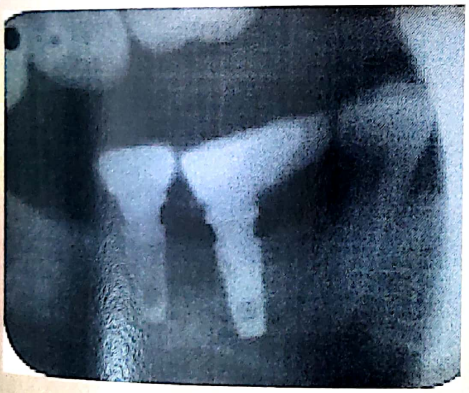
# RADIOGRAPHIC COMPARISION



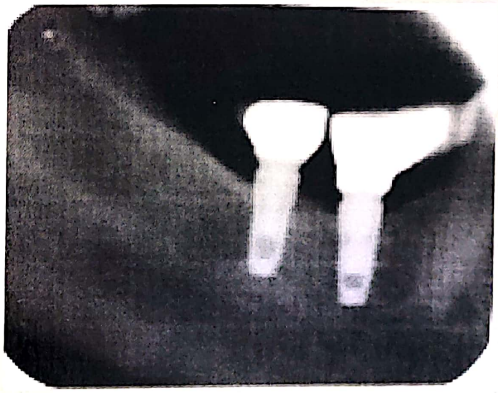
PRE -OP



BASELINE



AT 6 MONTHS



AT 1 YEAR

Plate -VII

# RESULTS AND OBSERVATIONS

## Results and Observations

The present study deals with evaluation of crestal bone level with narrow diameter platform switched implants in mandibular posterior edentulous region. Total 20 patients were selected and evaluated. The outcome measures of the study were Implant Stability Quotient (ISQ) and Crestal Bone Height (CBH) at Mesial (CBHM) and Distal (CBHD) aspect. The outcome measures were assessed at baseline (at placement time) and post treatment (at 6 months and at 1 year). The crestal bone height was measured in millimeter (mm). The objective of the study was to compare outcome measures over the periods.

### Demographic characteristics

The demographic characteristics (age, sex, tooth region, bucco-lingual width and apico-coronal distance) of patients at presentation was recorded. The age of patients ranged from 19 to 58 yrs with mean (± SE) 34.65 ± 3.19 yrs and median 30 yrs. Further, among patients, 12 (60.0%) were females and 8 (40.0%) were males, thus the study population was female predominance with 1 to 1.5 male to female ratio.

Moreover, the bucco-lingual width and apico-coronal distance of patients ranged from 5 to 6 mm and 10 to 17 mm respectively with mean (± SE) 5.49 ± 0.07 mm and 13.55 ± 0.54 mm respectively and median 6 mm and 14 mm respectively.

### Outcome measures

### Implant Stability Quotient

The baseline and post treatment (at 6 month and at 1 year) ISQ of patients is summarized in Table 1 and also shown in Fig. 1. The ISQ of patients at time of placement is ranged from 53 to 97 with mean (± SE) 72.30 ± 2.07 and median 74

whereas at 6 month, it ranged from 59 to 90 with mean (± SE) 70.70 ± 1.67 and median 70 and at 1 year, it ranged from 65 to 94 with mean (± SE) 76.15 ± 1.52 and median 75.

After 6 months, mean ISQ of patients decreased slightly whereas increased comparatively at 1 year as compared to baseline. The mean ISQ was highest at 1 year and minimum at 6 months. (Table 1 and Fig. 1)

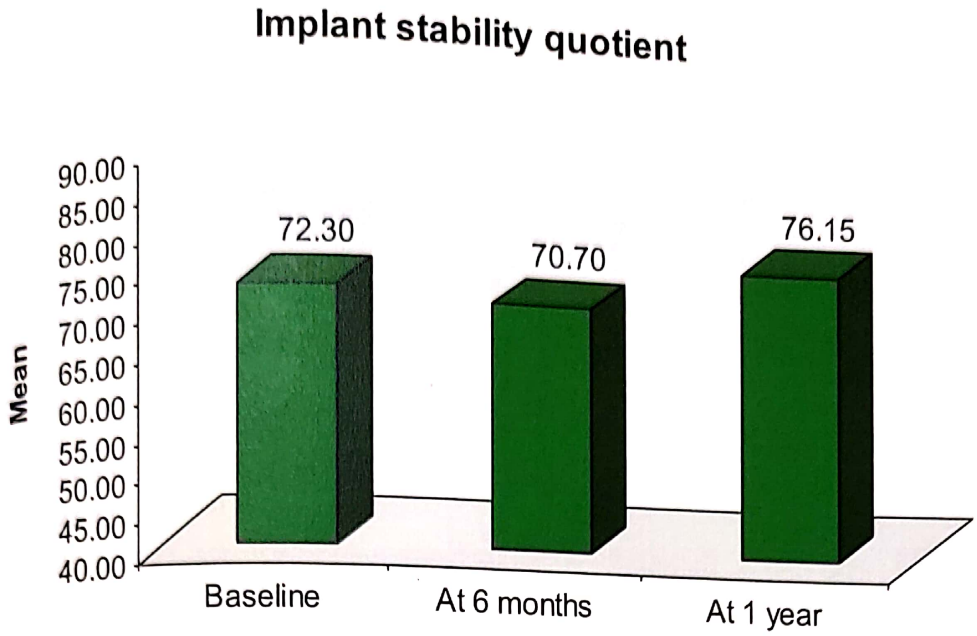
Comparing the mean ISQ at three time intervals, ANOVA showed significantly different ISQ. ($F=10.45$, $p<0.001$) (Table 1).

Further, comparing the difference in mean ISQ at three time intervals, Newman-Keuls test showed significantly different and higher ISQ at 1 year as compared to both at placement (72.30 ± 2.07 vs. 76.15 ± 1.52, mean difference=3.85 ± 1.45, $p=0.003$) and at 6 months (70.70 ± 1.67 vs. 76.15 ± 1.52, mean difference=5.45 ± 0.76, $p<0.001$). It did reduce from baseline to 6 month (72.30 ± 2.07 vs. 70.70 ± 1.67, mean difference=1.60 ± 1.35, $p=0.200$) but was found to be statistically non significant (Table 2 and Fig. 2-3).

**Table 1: ISQ at different time intervals**

| Period | Mean ± SE (n=20) | F value | p value |
|---|---|---|---|
| At baseline | 72.30 ± 2.07 | 10.45 | <0.001 |
| At 6 months | 70.70 ± 1.67 | | |
| At 1 year | 76.15 ± 1.52 | | |

**ISQ:** implant stability quotient. **n:** no. of patients (n=20). ISQ at three time intervals were summarised as Mean ± SE and compared by repeated measures ANOVA.

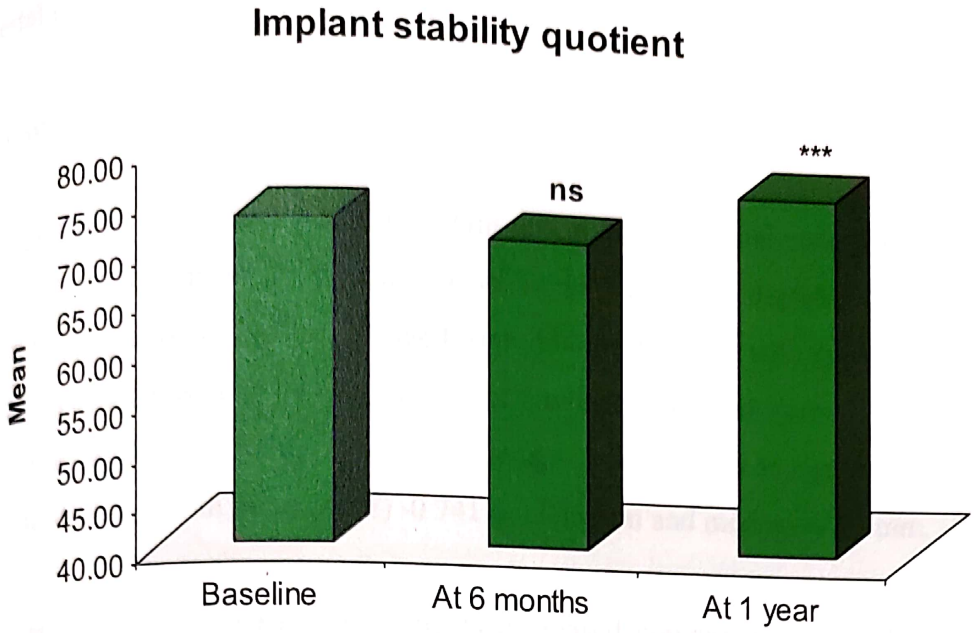



**Graph 1. Mean ISQ at different time intervals**

**Table 2: Comparison of difference in mean ISQ by Newman-Keuls test**

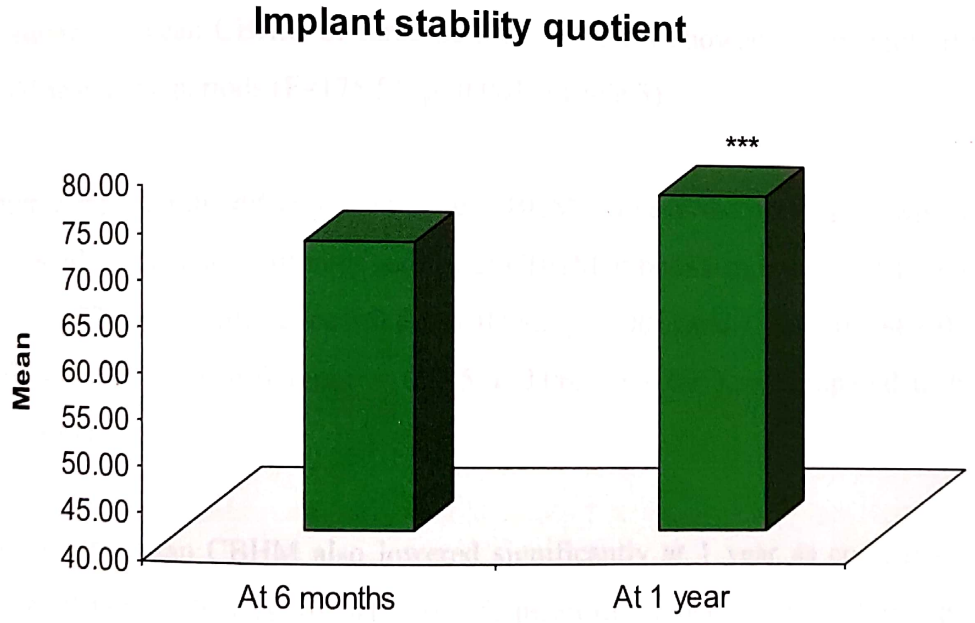
| Comparison | Mean difference | p value |
|---|---|---|
| Baseline vs. 6 month | 1.60 ± 1.35 | 0.200 |
| Baseline vs. 1 year | 3.85 ± 1.45 | 0.003 |
| 6 months vs. 1 year | 5.45 ± 0.76 | <0.001 |

Mean difference between periods is summarised as Mean ± SE and compared by ANOVA followed by Newman-Keuls test.




$^{ns}p>0.05$ or $^{***}p<0.001$- as compared to baseline

**Graph 2. Comparisons of difference in mean ISQ at different time intervals**




$^{***}p<0.001$- as compared to after 6 month

**Graph 3. Comparisons of difference in mean ISQ at 6 months and at 1 year**

## Crestal Bone Height

### I. Mesial

The baseline and post treatment (at 6 months and at 1 year) crestal bone height at mesial site (CBHM) of implants is summarised in Table 3 and also depicted in Fig. 4. The CBHM of implants at baseline is ranged from 0.00 to 0.91 mm with mean (± SE) 0.154 ± 0.071 mm and median 0.00 mm whereas at 6 months it ranged from -0.90 to 0.55 mm with mean (± SE) -0.349 ± 0.070 mm and median -0.39 mm and at 1 year it ranged from -1.26 to -0.09 mm with mean (± SE) -0.741 ± 0.055 mm and median -0.73 mm.

After treatment, mean CBHM of patients decreased comparatively and linearly with time. The mean CBHM was highest at baseline followed by at 6 months and then at 1 year, the least (at baseline > at 6 months > at 1 year) (Table 3 and Fig. 4).

Comparing the mean CBHM of three periods, ANOVA showed significantly different CBHM among the periods ($F=175.51$, $p<0.001$) (Table 3).

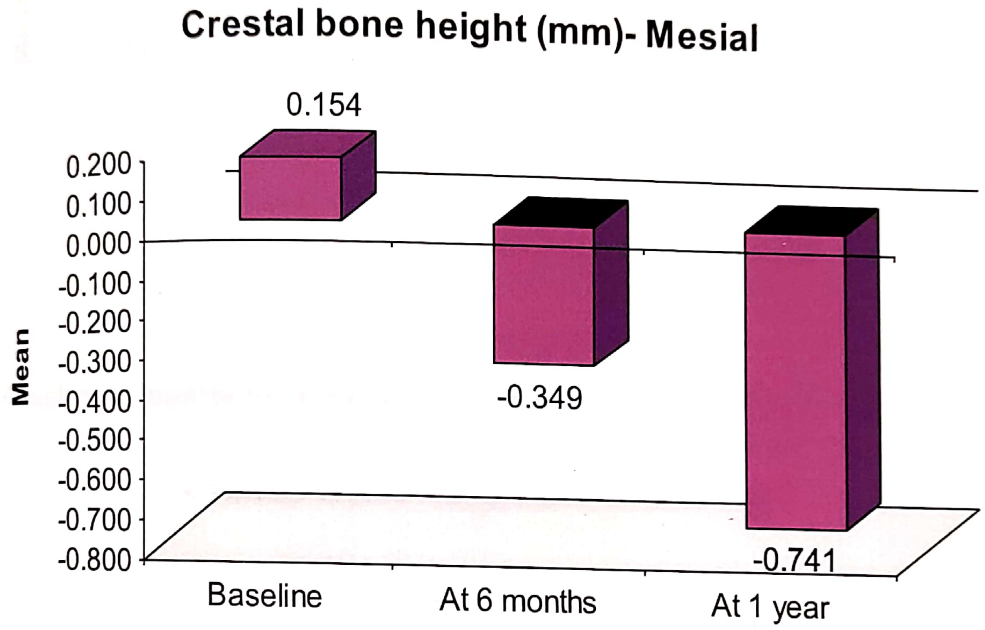
Further, comparing the difference in mean CBHM between the periods, Newman-Keuls test showed significantly different and lower CBHM at both 6 months (0.154 ± 0.071 vs. -0.349 ± 0.070, mean difference = 0.503 ± 0.042, $p<0.001$) and 1 year (0.154 ± 0.071 vs. -0.741 ± 0.055, mean difference = 0.895 ± 0.063, $p<0.001$) as compared to baseline (Table 4 and Fig. 5).

Moreover, the mean CBHM also lowered significantly at 1 year as compared to at 6 months (-0.349 ± 0.070 vs. -0.741 ± 0.055, mean difference=0.392 ± 0.033, $p<0.001$) (Table 4 and Fig. 6).

**Table 3: CBHM (mm) of patients at different time intervals**

| Period | Mean ± SE (n=20) | F value | p value |
|---|---|---|---|
| At baseline | 0.154 ± 0.071 | 175.51 | <0.001 |
| At 6 months | -0.349 ± 0.070 | | |
| At 1 year | -0.741 ± 0.055 | | |

**CBHM:** crestal bone height at mesial. **n:** no. of patients (n=20). CBHM of three periods were summarised as Mean ± SE and compared by repeated measures ANOVA.

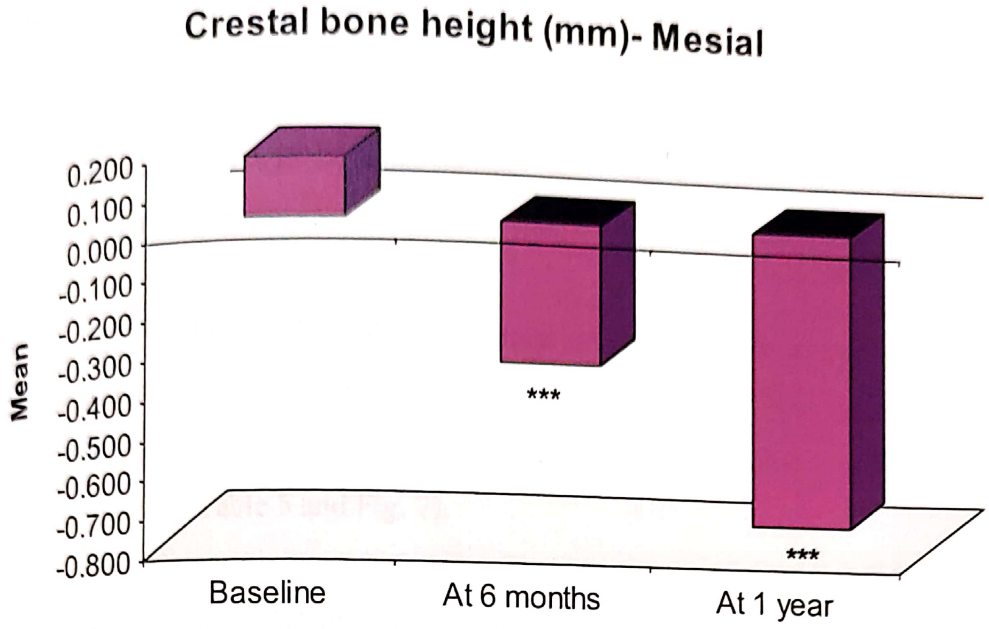



**Graph 4. Mean CBHM of patients at different time intervals**

**Table 4: Comparison of difference in mean CBHM by Newman-Keuls test**

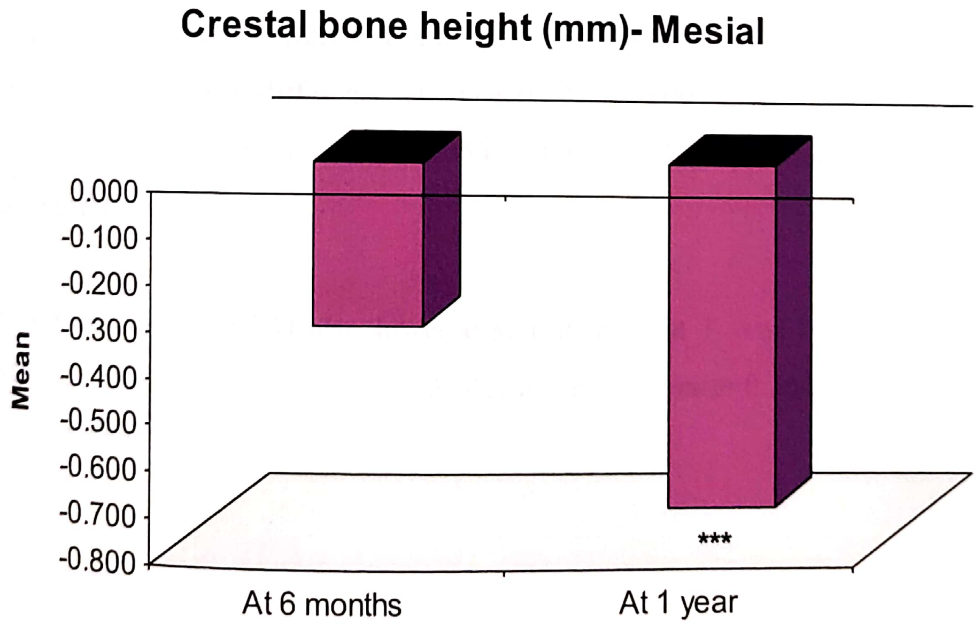
| Comparison | Mean difference | p value |
|---|---|---|
| Baseline vs. 6 months | 0.503 ± 0.042 | <0.001 |
| Baseline vs. 1 year | 0.895 ± 0.063 | <0.001 |
| 6 months vs. 1 year | 0.392 ± 0.033 | <0.001 |

Mean difference between periods is summarised as Mean ± SE and compared by ANOVA followed by Newman-Keuls test.




***p<0.001- as compared to baseline

**Graph 5. Comparisons of difference in mean CBHM at different time intervals**




***p<0.001- as compared to after 6 month

**Graph 6. Comparisons of difference in mean CBHM at 6 months and at 1 year**

II. Distal

The baseline and post (at 6 months and at 1 year) crestal bone height at distal site (CBHD) of implants is summarised in Table 5 and also shown in Fig. 7. The CBHD of implants at baseline is ranged from 0.00 to 0.91 mm with mean (± SE) 0.122 ± 0.058 mm and median 0.00 mm whereas at 6 months it ranged from -0.72 to 0.45 mm with mean (± SE) -0.368 ± 0.058 mm and median -0.45 mm and at 1 year it ranged from -0.91 to -0.18 mm with mean (± SE) -0.731 ± 0.042 mm and median -0.82 mm.

With time, the CBHD also showed similar trend as of CBHM, decreased comparatively and linearly with time but the decrease was less than CBHM. The mean CBHD was highest at baseline followed by at 6 months and at 1 year, the least (at baseline > at 6 months > at 1 year) (Table 5 and Fig. 7).

Comparing the mean CBHD of three periods, ANOVA showed significantly different CBHD among the periods ($F=214.52$, $p<0.001$) (Table 5).

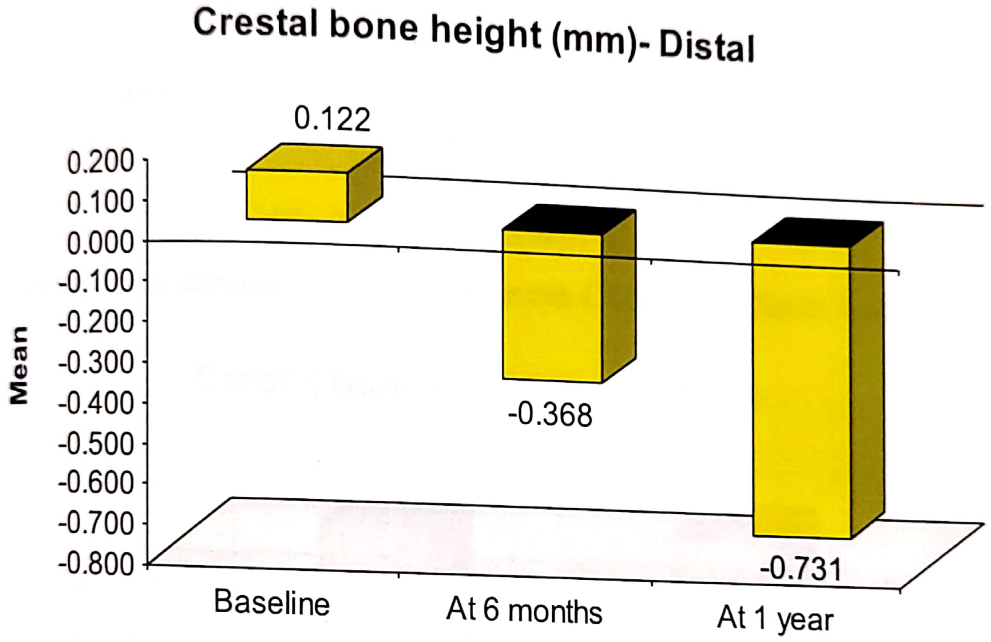
Further, comparing the difference in mean CBHD between the periods, Newman-Keuls test showed significantly different and lower CBHD at both at 6 months (0.122 ± 0.058 vs. -0.368 ± 0.058, mean difference=0.490 ± 0.028, $p<0.001$) and 1 year (0.122 ± 0.058 vs. -0.731 ± 0.042, mean difference=0.853 ± 0.053, $p<0.001$) as compared to baseline (Table 6 and Fig. 8).

Moreover, the mean CBHD also lowered significantly at 1 year as compared to at 6 months (-0.368 ± 0.058 vs. -0.731 ± 0.042, mean difference=0.364 ± 0.039, $p<0.001$) (Table 6 and Fig. 9).

Table 5: CBHD (mm) of patients at different time intervals

| Period | Mean ± SE (n=20) | F value | p value |
|---|---|---|---|
| At baseline | 0.122 ± 0.058 | 214.52 | <0.001 |
| At 6 months | -0.368 ± 0.058 | | |
| At 1 year | -0.731 ± 0.042 | | |

**CBHD:** crestal bone height at distal. **n:** no. of patients (n=20). CBHD of three periods were summarised as Mean ± SE and compared by repeated measures ANOVA.

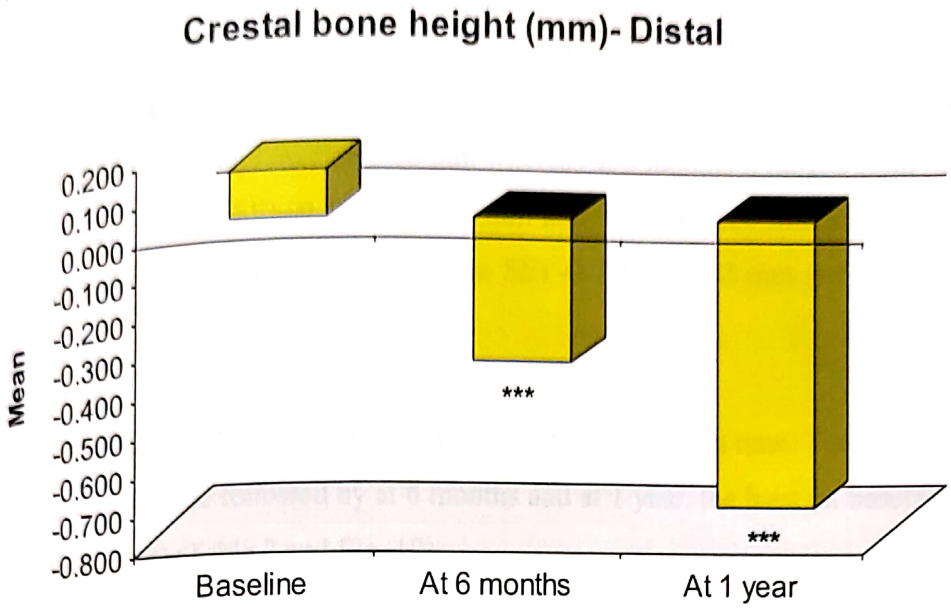



**Graph 7. Mean CBHD of patients at different time intervals.**

Table 6: Comparison of difference in mean CBHD by Newman-Keuls test

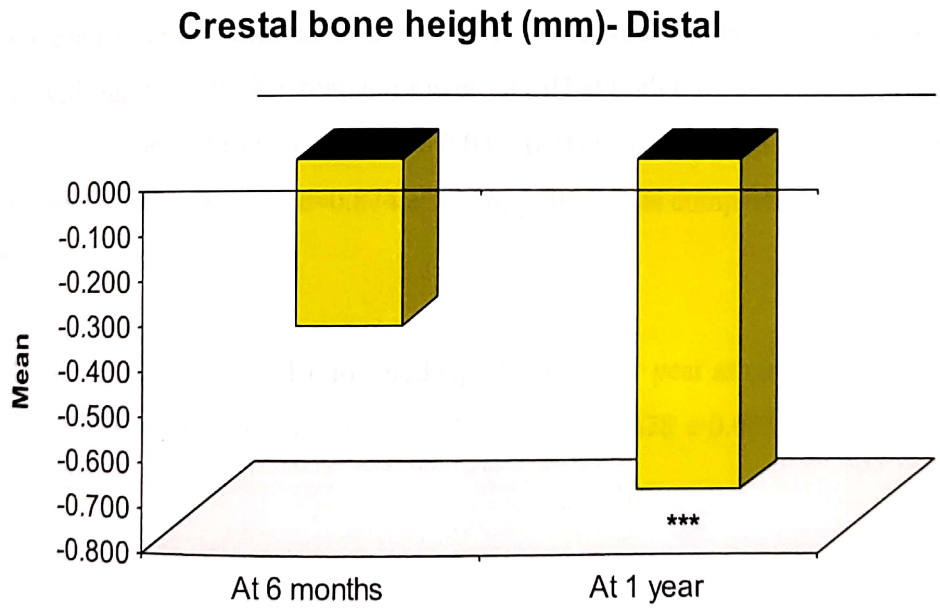
| Comparison | Mean difference | p value |
|---|---|---|
| Baseline vs. 6 months | 0.490 ± 0.028 | <0.001 |
| Baseline vs. 1 year | 0.853 ± 0.053 | <0.001 |
| 6 months vs. 1 year | 0.364 ± 0.039 | <0.001 |

Mean difference between periods is summarised as Mean ± SE and compared by ANOVA followed by Newman-Keuls test.




***p<0.001- as compared to baseline

**Graph 8. Comparisons of difference in mean CBHD at different time intervals.**




***p<0.001- as compared to after 6 month

**Graph 9. Comparisons of difference in mean CBHD at 6 months and at 1 year**

**III. Overall**

The baseline and post (at 6 months and at 1 year) overall (average of mesial and distal) crestal bone height (OCBH) of implants is summarized in Table 7 and also shown in Fig. 10. The OCBH of patients at baseline is ranged from 0.00 to 0.91 mm with mean (± SE) 0.138 ± 0.063 mm and median 0.00 mm whereas at 6 months it ranged from -0.81 to 0.50 mm with mean (± SE) -0.358 ± 0.061 mm and median -0.38 mm and at 1 year it ranged from -1.08 to -0.14 mm with mean (± SE) -0.736 ± 0.045 mm and median -0.75 mm.

The mean OCBH also decreased comparatively and linearly with time. The mean OCBH was highest at baseline followed by at 6 months and at 1 year, the least (at baseline> at 6 months > at 1 year) (Table 7 and Fig. 10).

Comparing the mean OCBH of three periods, ANOVA showed significantly different OCBH among the periods ($F=217.48$, $p<0.001$) (Table 7).

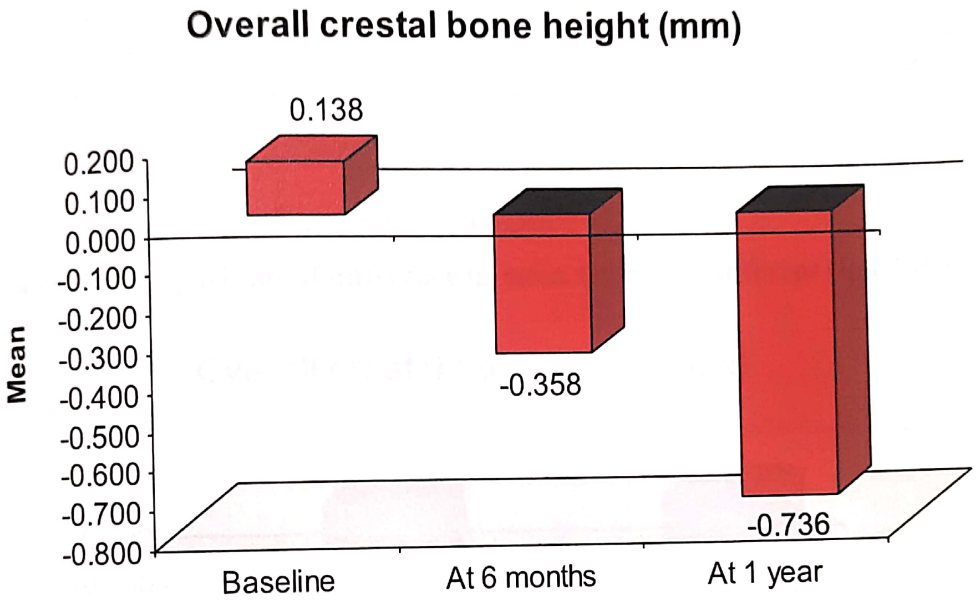
Further, comparing the difference in mean OCBH between the periods, Newman-Keuls test showed significantly different and lower OCBH at both 6 months (0.138 ± 0.063 vs. -0.358 ± 0.061, mean difference=0.496 ± 0.033, $p<0.001$) and 1 year (0.138 ± 0.063 vs. -0.736 ± 0.045, mean difference=0.874 ± 0.056, $p<0.001$) as compared to baseline (Table 8 and Fig. 11).

Moreover, the mean OCBH also lowered significantly at 1 year as compared to 6 months (-0.358 ± 0.061 vs. -0.736 ± 0.045, mean difference = 0.378 ± 0.033, $p<0.001$) (Table 8 and Fig. 12).

**Table 7: OCBH (mm) of patients at different time intervals**

| Period | Mean ± SE (n=20) | F value | p value |
|---|---|---|---|
| At baseline | 0.138 ± 0.063 | 217.48 | <0.001 |
| At 6 months | -0.358 ± 0.061 | | |
| At 1 year | -0.736 ± 0.045 | | |

**OCBH:** overall crestal bone height. **n:** no. of patients (n=20). OCBH of three periods were summarised as Mean ± SE and compared by repeated measures ANOVA.

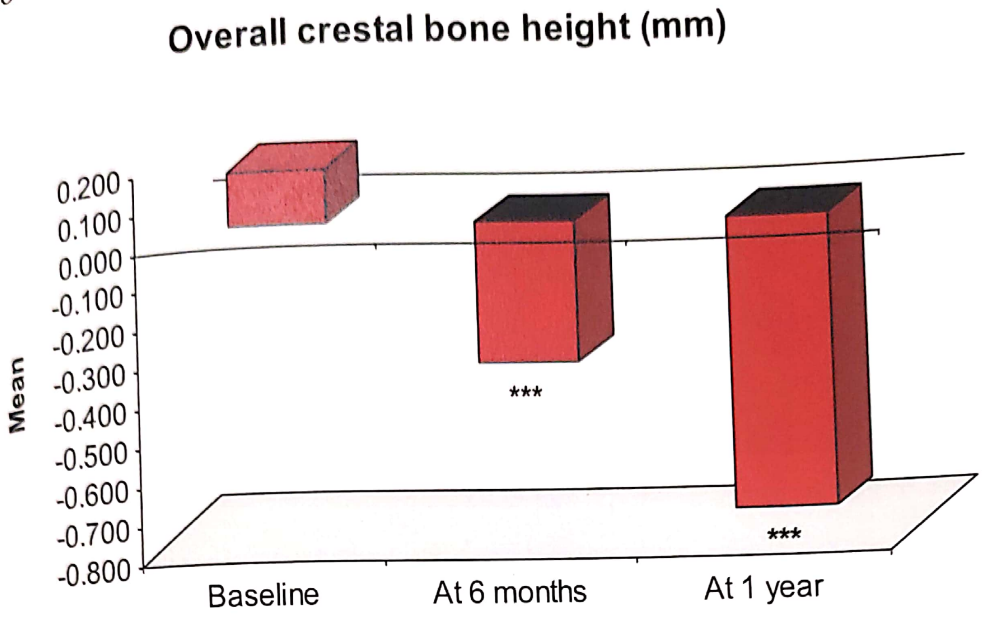



**Graph 10. Mean OCBH of patients at different time intervals.**

**Table 8: Comparison of difference in mean OCBH by Newman-Keuls test**

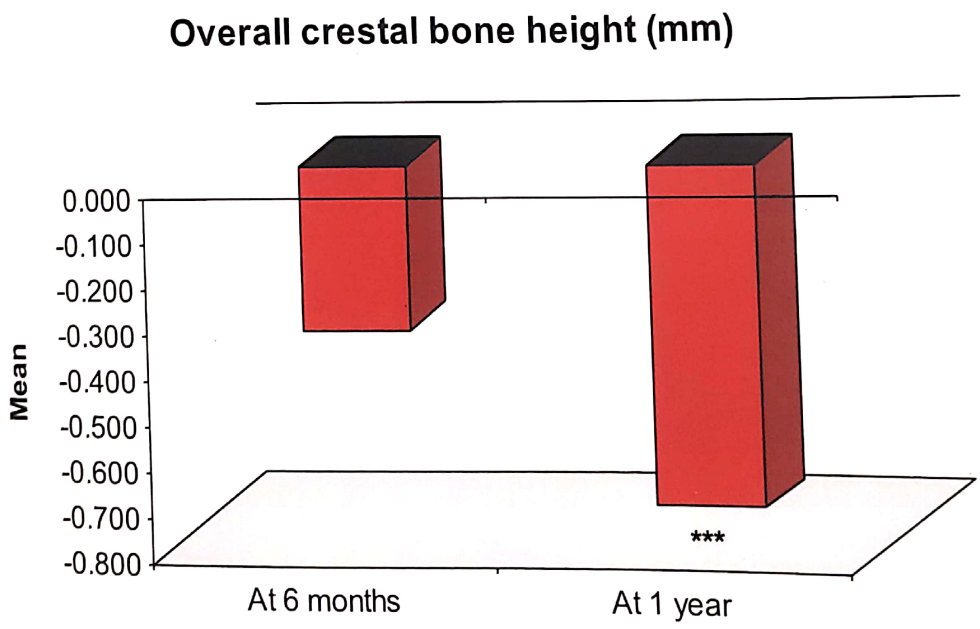
| Comparison | Mean difference | p value |
|---|---|---|
| Baseline vs. 6 months | 0.496 ± 0.033 | <0.001 |
| Baseline vs. 1 year | 0.874 ± 0.056 | <0.001 |
| 6 months vs. 1 year | 0.378 ± 0.033 | <0.001 |

*Mean difference between periods is summarised as Mean ± SE and compared by ANOVA followed by Newman-Keuls test.*




***p<0.001- as compared to baseline

**Graph 11. Comparisons of difference in mean OCBH at different time intervals.**




***p<0.001- as compared to after 6 months

**Graph 12. Comparisons of difference in mean OCBH at 6 months and at 1 year.**

# DISCUSSION

Patients with edentulism, either partial or complete, found a boon in dentistry since implants came into existence. Earlier, acrylic dentures as well as metal or porcelain fused metal bridges majorly solved the problem. But there were drawbacks, and that is when, the concept of dental implants revolutionized the treatment plan. Here also, a set of parameters had to be followed and ridge deficiencies would lead to failures. Bone augmentation procedures are often necessary to enlarge the bone width and facilitate regular or wide implant positioning. Additional surgeries to augment the bone, leads to morbidity and economic burden. When wide implants are installed in narrow ridges, many clinicians must use bone graft around the fenestrated implant surfaces. However, it is postulated that peri-implant grafted bone will be resorbed if the grafted bone does not have an optimal osteogenesis period[6]. Hence, in reduced ridge width region, narrow diameter implants could be safely placed with adequate bicortical stabilization and decreased chances of fenestration. In the anterior region, these implants are highly successful, but in posterior molar areas, high masticatory forces may pose a risk to their stability. Fatigue fracture of the narrow implant body from mechanical weakening has been reported[6]. The occlusal load on prosthetics of narrow implant causes crestal bone loss around implants which leads to failure and generation of high stresses at implant-bone interface[46].

Bahiram et al did a review and found that conventional implant abutment systems are generally flush with implant shoulder which results into micro crack between implant and abutment due to stress exceeding yield strength leading to failure of system. This problem is overcome in platform switching with use of mismatch diameter of abutment[46].

The success of implants can be assessed by implant stability quotient and crestal bone loss. In this study the observations are discussed as follows:

## Implant Stability Quotient

In this prospective study, the implant stability was measured through RFA at the time of placement of implant (baseline), at 6 months and at one year respectively and subsequent ISQ values were recorded. The mean ISQ value at baseline was found to be 72.30 ± 2.07 predicting good implant stability. At 6 months time, the values comparatively decreased to 70.70 ± 1.67 but increased to 76.15 ± 1.52 at one year duration.

There was a decrease in ISQ values from baseline to 6 months but was not significant (p value = 0.200). There was an increase in ISQ from baseline to 1 year and this was also not significant (p value = 0.003). There was a significant increase in ISQ values from 6 months to 1 year (p value<0.001). All these findings indicate that the implant was stable throughout our study.

Implant stability, which is an indirect indication of osseointegration, is achieved at two different stages: primary and secondary stability.

Primary stability occurs at the time of implant placement and is believed to be related to the level of primary bone contact and mostly comes from mechanical engagement with the cortical bone, while Secondary stability is the result of the formation of woven bone, followed by its maturation into lamellar bone which may be reflected in terms of increased ISQ values. It dictates the time of functional loading[10].

Various factors influence implant stability[10]

Factors Affecting Primary Stability

1) Bone quantity and quality

2) Surgical technique, including the skill of the surgeon

3) Implant (e.g., geometry, length, diameter, surface characteristics)

Factors Affecting Secondary Stability

1) Primary stability

2) Bone remodeling

3) Implant surface conditions

The RFA can assess implant stability which is a function of strength of implant-bone interface. It may provide a possibility to individualize implant treatment with regard to healing periods, detecting failing implants, type of prosthetic construction, and if one- or two-staged procedures should be followed[47,48,49,50]. It can also establish prognostic criteria for long-term implant success[10].

A delayed loading protocol was followed and all the implants were loaded after 3 months from their placement into the mandible. This was done because early loading could result in fibrous encapsulation of the implant and lack of osseointegration. Also the overheated bone tissue, which undergoes necrosis from the osteotomy preparation, is rapidly remodeled and during that period, the strength of the bone to implant contact is compromised, which explains the decrease in the mean ISQ value at 6 months. Lastly, 3- to 6-month healing period is essentially required in order to remodel bone adjacent to the bone implant interface. Conventional loading protocol has also been supported by Szmukler-Moncler et al. 2002 who gave the above possible biological events that could account for the required healing time which was clinically established as 3 months for mandible and 6 months for maxilla[51].

Our study is in accordance with studies done by Masahiko Yamaguchi et al 2008[33], Mehran Shokri et al 2013[38] and various other researchers who have demonstrated an increase in implant stability over time[52,53,54,55,56,57,58,59].

There are different methods and equipments available and many are being discovered to predict implant stability at the time of placement and after that at different time periods. Some methods are Surgeon's perception, Insertion torque, seating torque, percussion testing, reverse torque testing, radiographs, periotest, resonance frequency analysis. Several studies have been conducted to check their authenticity and usefulness. Among them some are based on clinical criteria like clinician perception as in insertion torque test, reverse torque test, percussion test, push out/pull out test, histomorphic data which needs experience of clinician and utilizes more objective and quantifiable criteria, and are invasive as well, therefore can be used for experimental studies only. So far, only radiographic analysis, periotest and RFA are the non invasive methods available. Periotest and RFA both are among the most useful non invasive methods to predict implant stability although there is indirect evaluation of implant stability and osseointegration. Periotest originally used for measurement of natural tooth mobility. Major difference between implants and teeth is the presence of PDL fibres in natural condition, which put great impact on reliability of periotest. It is not capable of evaluating the mesiodistal stability. Moreover, reproducibility of results derived from periotest measurements have been subject to a number of factors such as vertical position of the measuring point on the abutment, angulation of the handpiece and horizontal distance of the handpiece from the abutment. PTV of an osseointegrated implant falls in a relatively narrow zone (-5 to +5) within a wide scale (-8 to +50). Other studies have indicated that the PTVs of clinically osseointegrated implants fall within an even narrower zone (-4 to -2 or -4 to +2). Therefore, the measured PTV may be falsely interpreted as having a small standard deviation and therefore having a good accuracy. PTV cannot be used to identify a "borderline implant" or "implant in the process of osseointegration" which may or may not continue to a successful osseointegration. On the other hand, measurement of implant stability, with the use of RFA method is supposed to reduce these observer-dependent errors because of the fact that a transducer is screwed on to the implant and measurements are completely automated. The torque used during the fixation of the transducer to the implant has been shown not to alter the results of RFA measurements and the results obtained from this type of measurement were highly reproducible. A comparison between the torque technique and the RFA

method, emphasized another advantage of the later technique. According to an animal study on rabbits, the removal torque method is supposed to measure the strength of the bone implant interface in terms of shear, whereas the RFA is considered to measure the stability during bending. So on the basis of different studies, RFA is supposed to be superior among all the available implant stability measures[10,60].

## Crestal Bone Height

The peri-implant bone level has been used as one of the criteria to assess the success of dental implants. Traditionally, a radiographic marginal bone loss of 1.5 mm during the first year followed by a radiographic marginal bone loss of +0.2 mm during each succeeding year is an important parameter for the assessment of implant success[21]. At the time of implant placement (baseline), the crestal bone level was assessed radiographically at mesial and distal aspect. At 6 months, the bone levels reduced significantly from +0.154 ± 0.071 mm to -0.349 ± 0.070 mm, which further reduced to -0.741 ± 0.555 at 1 year in the mesial aspect. In the distal aspect, it reduced from +0.122 ± 0.058 mm to -0.368 ± 0.058 mm at 6 months and to further to -0.731 ± 0.042 mm at 1 year respectively.

The comparative reduction in the bone level at the said time intervals was highly significant (p value<0.001). But the amount of total bone loss occurring after 1 year duration of the platform switched narrow diameter implant placement was found to be 0.874 ± 0.056 mm which provides for an improved scenario when compared with the marginal bone loss of 1.5 mm in regular implants[21].

The platform switching effect was accidentally established in the 1980s. Later on various studies were carried out and long term follow ups around these implants showed higher level of bone preservation and proper stress distribution and esthetic outcome. Correct location of the soft tissues in dental implant restorations depends on the

preservation of bone crestal height. Consequently, hard tissues are the principal determinant of aesthetic outcome[21].

The biomechanical theory proposed that connecting the implant to a smaller-diameter abutment may limit bone resorption by shifting the stress-concentration zone away from the crestal bone–implant interface and directing the forces of occlusal loading along the axis of the implant. One theory assumed that shifting the implant-abutment connection may medialize the location of the biologic width and minimize the marginal bone resorption. The physical repositioning of the IAJ away from the external outer edge of the implant and neighboring bone may limit bone resorption by containing the inflammatory cell infiltrate within the angle formed at the interface away from the adjacent crestal bone[21].

In a prospective study[61], 41 pairs of platform-switched implants were placed at <3mm of inter implant distance. The radiographic evaluation showed that a platform-switched implant design can reduce the vertical and horizontal components of bone loss and may be used in atrophic sites. Maeda et al[62] carried out 3D finite element analysis and concluded platform switching has the biomechanical advantage of shifting the stress concentration away from implant-bone interface, but also has the disadvantage of increased forces in abutment and abutment screw. This concentration of forces along the implant axis, transmitted through the retention screw, increases the possibility of abutment fracture, and may lead to restoration failure.

Vigolo P[63] in 2009 placed 182 single 5mm diameter implants in 144 patients in which 85 implants were restored with matching wide diameter prosthetic components (group A) and 97 implants were restored with platform switched prosthetic components (group B). A significant difference in marginal bone levels was found between group A and group B implants after 1 year. He found mean marginal bone resorption was 0.9mm for group A implants and 0.6mm for group B implants.

Hst JT et al[64] carried bone strain and interfacial sliding analyses of platform switched implants and his results showed 10% decrease in all prosthetic loading forces transmitted to bone implant interface. It is presumed that narrow fixtures were generally used in the narrow ridges because patients with a narrow bone width may have a weaker occlusal force than patients with normal- or wide-width bones.

Bone loss in two-stage implant supported restorations is estimated to be 1.5 - 2mm below the implant-abutment junction. However, in the studies on platform switching involving a follow-up period of 4-169 months, the reported bone loss varies between 0.05 - 1.4 mm[65]. Canullo et al[22] assessed the marginal bone level around 80 implants which were randomly assigned into four groups based on the discrepancy between the diameters of the abutment and the implant platform. The findings suggested that the extent of the inward shifting was inversely proportional to the amount of marginal bone loss. In other words, more inward shifting leads to decreased marginal bone loss. Cappiello et al[66]. evaluated the marginal bone levels of 73 implants with an extended platform of 4.8 mm and 55 implants with a matched platform of 4.0 mm. One implant failed in the control group. After 1 year of function, the radiographic examination showed that the marginal bone loss around the platform-switched implants ranged between 0.6 and 1.2 mm (mean: 0.95 – 0.32 mm), whereas the marginal bone loss around the control implants ranged between 1.3 and 2.1mm (mean: 1.67 – 0.37mm). The difference between the two groups was considered to be statistically significant.

Crespi et al[67] placed 30 platform-switched and 34 platform-matched immediate implants. A radiographic marginal bone resorption of 0.73 – 0.52 mm and 0.78 – 0.49 mm were reported in the platform switched and platform-matched groups, respectively. No statistically significant difference was shown between the two groups. In the authors' view, the use of an atraumatic surgical protocol might have preserved the peri-implant bone levels and minimized the difference between the two groups. Enkling et al[68] performed a split-mouth trial of 50 platform-switched and matched implants placed in the posterior mandible and followed up for 12 months. The radiographic examination

included the measurement of the vertical and horizontal extents of marginal bone loss. The differences in both dimensions were not statistically significant.

Although this study has provided a positive insight into the utility of platform switched narrow diameter implants in posterior mandibular edentulous areas having reduced bucco-lingual dimension, a few limitations have been encountered. The sample size was relatively smaller, and the duration of follow up shorter. More number of studies with larger sample size and long term follow up are needed to establish the benefits of platform switching in narrow diameter implants.

# CONCLUSION

Within the limitations of the study, the conclusion is as follows:

- Implant stability of the platform switched narrow diameter implants remained the same throughout the follow up.
- The crestal bone level in platform switched narrow diameter implants decreased significantly ($p<0.001$) from the placement time ($0.138 \pm 0.063$) to 6 months ($-0.358 \pm 0.061$) and 1 year ($-0.736 \pm 0.045$) respectively, but was well within the range for the criteria for successful implants according to Alberktsson et al.
- On comparison with regular diameter implants the narrow diameter implants showed the same level of crestal bone loss throughout the follow up period.

Hence platform switched narrow diameter implants can be considered as viable options in narrow ridges in posterior edentulous areas. However, more long term studies are needed to consolidate the above said fact.

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# APPENDICES

ANNEXURE I

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

## INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **Evaluation of Crestal Bone Level with Narrow Diameter Platform Switched Implants in Mandibular Posterior Edentulous Region** submitted by **Dr. Swati Srivastava** Post graduate student from the Department of **Periodontics** as part of MDS Curriculum for the academic year 2016-2019 with the Accompanying proforma was reviewed by the institutional research committee present on 7th and 8th December 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**
Principal

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

Chairperson Institutional Research Committee

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

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

**Communication of the Decision of the V[th] Institutional Ethics Sub-Committee**

**IEC Code: 02**

**BBDCODS/03/2017**

**Title of the Project:** Evaluation of Crestal Bone level with narrow diameter platform switched Implants in Mandibular Posterior Edentulous region.

**Principal Investigator:** Dr. Swati Srivastava **Department:** Periodontology

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

**Type of Submission:** New, MDS Project Protocol

Dear Dr. Swati Srivastava

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 02[nd] March, 2017.

| | | |
|---|---|---|
| 1. | Dr. Lakshmi Bala<br>Member Secretary | Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow |
| 2. | Dr. Neerja Singh<br>Member | Prof. & Head, Department of Pedodontics, BBDCODS, Lucknow |
| 3. | Dr. Rana Pratap Maurya<br>Member | Reader, Department of Orthodontics, BBDCODS, Lucknow |
| 4. | Dr. Manu Narayan<br>Member | Reader, Department of Public Health Dentistry, 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
01/05/2017
Member-Secretary
Institutional Ethic Committee
College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

**(Dr. Lakshmi Bala)**
Member-Secretary
IEC

**(Dr. Parik Govila)**
Principal
BBDCODS

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

## ANNEXURE III

# CONSENT FORM

Title of the study.....

Study Number.....

Subject's Full Name.....

Date of Birth/Age.....

Address of the Subject.....

Phone No. and email address.....

Qualification.....

Occupation: Student/Self employed/Service/Housewife/Other

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 the free will without any duress and that I am free to withdraw at any time, without given 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 trail. 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 any data or results that arise from this study provided such a use is only for scientific purpose(s).

5. I agree to participate in the above study for the future research

Yes [ ] No [ ] Not Applicable [ ]

6. I have been explained about the study, and have fully understood them. I have also read and understand the participant/volunteer's information document given to me

Signature/Thumb impression of the subject/Legally acceptable Representative.....

Signatory's Name.....Date.....

Signature of Investigator's Name.....

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

Signature of the witness.....

Name of witness.....Date.....

Received a signed copy of the duly filled consent form

Signature/Thump Impression of the subject/Legally acceptable representative.....Date.....

## सहमति पत्र

अध्ययन शीर्षक _____

अध्ययन संख्या _____

प्रतिभागी के पूर्ण नाम _____

जन्म तिथि / आयु _____

पता _____

1. मेरी पुष्टि है कि मैने अध्ययन हेतु सूचना पत्र दिनांक _____ को पढ व समझ लिया तथा मुझे प्रश्न पुछने या मुझे अध्ययन अन्वेषक ने सभी तथ्यों को समझा दिया है तथा मुझे प्रश्न पुछने के समान अवसर प्रदान किए गये।

2. मै यहाँ समझ लिया कि अध्ययन में मेरी भागीदारी पूर्णतः स्वैच्छिक है और मै किसी भी समय किसी भी कारण के बिना , मेरे इलाज या कानूनी अधिकारो को प्रभावित किए बिना , अध्ययन में भाग न लेने के लिए स्वतंत्र हुँ ।

3. मै यह समझ लिया है कि अध्ययन के प्रायोजक , प्रायोजक की तरफ से काम करने वाले लोग, आचार समिति और नियामक अधिकारियों को मेरे स्वास्थ्य रिकार्ड को वर्तमान अध्ययन या आगे के अध्ययन के सन्दर्भ देखने के लिए मेरी अनुमति की जरूरत नही है, चाहे मैने इस अध्ययन से नाम वापस ले लिया है। हॉलाकि मै यह समझता हुँ कि मेरी पहचान को किसी भी तीसरे पक्ष या प्रकाशित माध्यम में नही दी जायेगी।

4. मै इससे सहमत हूँ कि कोई भी डेटा या परिणाम जो इस अध्ययन से प्राप्त होता है उसका वैज्ञानिक उद्देश्य (ओं) के उपयोग के लिए मेरी तरफ से कोई प्रतिबंध नही है।

5. भविष्य के अनुसंधान के लिए भंडारित नमूना (ऊतक/रक्त) पर अध्ययन के लिए अपनी सहमति देता हुँ। हॉ [ ] नही [ ] अनउपयुक्त [ ]

6. मै परीक्षण की अनुमति देता हुँ। मुझे इसके द्वारा यदि कोई परेशानी होती है, के बारे में जानकारी दे दी गई है।

मैने रोगी जानकारी सूचना पत्र को पढ तथा समझ लिया है।

प्रतिभागी / कानूनी तौर पर स्वीकार्य प्रतिनिधि का हस्ताक्षर ( या अंगूठे का निशान _____ दिनांक _____

हस्ताक्षरकर्ता का नाम _____ अन्वेषक के

हस्ताक्षर _____ दिनांक _____

अध्ययन अन्वेषक का नाम _____

गवाह के हस्ताक्षर _____ दिनांक _____ गवाह के

नाम _____ मैनें हस्ताक्षर युक्त

सूचना तथा सहमति पत्र प्राप्त किया।

प्रतिभागी कानूनी तौर पर प्रतिनिधि का हस्ताक्षर/ अंगूठे का निशान _____ दिनांक _____

## ANNEXURE IV

**Babu Banarasi Das College of Dental Sciences**

**(A constituent institution of Babu Banarasi Das University)**

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

### Participant Information Document (PID)

**1. Study title**

EVALUATION OF CRESTAL BONE LEVEL WITH NARROW DIAMETER PLATFORM SWITCHED IMPLANTS IN MANDIBULAR POSTERIOR EDENTULOUS REGION.

**2. Invitation paragraph**

You are being invited to take part in a research study, therefore it 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. Whether or not you wish to take part is your decision.

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

The purpose of this study is to evaluate the changes in crestal bone level around implant and implant stability after placing platform switched narrow diameter implants.

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

You have been chosen for this study as you are fulfilling the required criteria for this study.

**5. Do I have to 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 me if I take part?**

Implant will be placed at the edentulous area.

**7. What do I 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?**

Platform switched narrow diameter implant would be placed in the narrow edentulous ridge. Then crestal bone level and implant stability would be assessed at placement time, at 6 months and at 1 year.

**9. What are the interventions for the study?**

Implant placement in partially edentulous patient.

**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?**

There is no risk or disadvantages of taking part in this study.

**12. What are the possible benefits of taking part?**

This study will evaluate the changes in crestal bone level and implant stability. Positive results will help in establishing the utility of platform switched narrow diameter implants.

**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 whether you want to continue in the study. If you decide to withdraw, your researcher will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

**14. What happens when the research study stops?**

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

**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 Institutional ethical community.

**16. Will my taking part in this study be kept confidential?**

Yes, it will be kept confidential.

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

This study will evaluate the changes in crestal bone level and implant stability. Positive results will help in establishing the utility of platform switched narrow diameter implants.

**18. Who is organizing the research?**

This research study is organized by the academic institution (BBDCODS).

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

Yes.

**20. Who has reviewed the study?**

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

Signature of PI.....

Name.....

Date .....

**Babu Banarasi Das College of Dental Sciences**
**(A constituent institution of Babu Banarasi Das University)**
**BBD City, Faizabad road, Lucknow – 227105 (INDIA)**

## प्रतिभागी जानकारी दस्तावेज़ (पीआईडी)

**1. अध्ययन का शीर्षक**

नीचे के जबड़े के पिछले दंत रहित क्षेत्र में संकीर्ण व्यास के, मंच में बदलाव वाले implant प्रत्यारोपण उपरान्त crestal हड्डी के स्तर का मूल्यांकन

**2. निमंत्रण अनुच्छेद**

आप एक शोध अध्ययन में भाग लेने के लिए आमंत्रित किये जा रहे हैं, इसलिए आप का जानना महत्वपूर्ण हैं कि ये अध्ययन क्यों किया जा रहा है और इसकी क्या प्रक्रिया हैं कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने के लिए समय लें। किसी भी स्पष्टीकरण या अधिक जानकारी के लिए पूछें। चाहे आप भाग लें या न लें यह आपका निर्णय है।

**3. अध्ययन का उद्देष्य क्या है?**

अध्ययन का उद्देश्य नीचे के जबड़े के पिछले दंत रहित क्षेत्र में संकीर्ण व्यास के, मंच में बदलाव वाले implant प्रत्यारोपण उपरान्त implant के स्थायित्व एवं crestal हड्डी के स्तर का मूल्यांकन करना है।

**4. मैं क्यों इस अध्ययन के लिए चुना गया ?**

आप इस अध्ययन के लिए चुने गये है क्योंकि आप आवश्यक मानदण्डों को पूरा कर रहे हैं।

**5. क्या मुझे भाग लेना है?**

अनुसंधान के क्षेत्र में आपकी भागीदारी पूरी तरह स्वैच्छिक है। यदि आप भाग लेते हैं तो आपको इस जानकारी को रखने के लिए पत्र दिया जाएगा और एक सहमति पत्र पर हस्ताक्षर करने के लिए कहा जाएगा। अध्ययन के दौरान आप किसी भी समय बिना कारण बताए निष्कासित होने के लिए स्वतंत्र हैं।

**6. अगर मैं इस अध्ययन में भाग लेता हूं तो मुझे का क्या होगा?**

Implant दंत रहित क्षेत्र में प्रत्यारोपित किया जाएगा ।

**7. मुझे क्या करने की जरूरत है?**

आपको अध्ययन की जॉच के लिए अपनी नियमित जीवन शैली बदलने की जरूरत नहीं है।

**8. किस प्रक्रिया का परीक्षण किया जा रहा है?**

नीचे के जबड़े के पिछले दंत रहित क्षेत्र में संकीर्ण व्यास का, मंच में बदलाव वाला implant प्रत्यारोपित किया जाएगा । तत्पश्चात implant के स्थायित्व एवं crestal हड्डी के स्तर का मूल्यांकन किया जाएगा । यह मूल्यांकन implant प्रत्यारोपण के समय, छः महीने एवं एक वर्ष के उपरान्त किया जाएगा ।

**9. इस अध्ययन के लिए कौन हस्तक्षेप कर रहे है?**

नीचे के जबड़े के पिछले दंत रहित क्षेत्र में implant प्रत्यारोपण

**10. भाग लेने के दुष्प्रभाव क्या हैं?**

इस अध्ययन का मरीजों पर कोई दुष्प्रभाव नहीं है।

**11. संभावित नुकसान और भाग लेने का जोखिम क्या हैं?**

इस अध्ययन में मरीजों पर कोई सम्भव नुकसान/जोखिम नहीं हैं।

**12. भाग लेने के संभावित लाभ क्या है?**

इस अध्ययन में implant के स्थायित्व एवं crestal हड्डी के स्तर का मूल्यांकन किया जाएगा । सकारात्मक परिणाम संकीर्ण व्यास के, मंच में बदलाव वाले implant की उपयोगिता सत्यापित करेंगे ।

**13. अगर कोई नई जानकारी उपलब्ध हो जाती है?**

यदि शोध के दौरान कोई नई जानकारी उपलब्ध हो जाती है तो आपको सूचित किया जायेगा और आप इस पर चर्चा करने के लिए स्वतंत्र हैं। यदि आप शोध से निष्कासित होने का निर्णय लेते हैं तो शोधकर्ता आपके निष्कासन की व्यवस्था कर देगें। यदि आप भाग लेते हैं तो आपको एक अद्यतन सहमति पत्र पर हस्ताक्षर करने के लिए कहा जायेगा।

**14. जब शोध अध्ययन बंद हो जाता है क्या होता है?**

जब अध्ययन निर्धारित समय से पहले बंद हो जाता है/खत्म हो जाता है। इसका कारण मरीज/स्वयंसेवक को समझाया जायेगा।

**15. जब कुछ गलत हो जाता है?**

कोई गम्भीर प्रतिकूल घटना होती है, या कुछ और अध्ययन के दौरान गलत हो जाता है, शिकायतों को संस्था(एस), और आईईसी में रिपोर्टिंग करके नियंत्रित किया जाएगा एवं खर्च का भार मुख्य अन्वेषक द्वारा वहन किया जाएगा ।

**16. क्या मेरी सहभागिता को गोपनीय रखा जाएगा?**

हाँ, आपकी सहभागिता गोपनीय रखी जायेगी ।

**17. शोध अध्ययन के परिणामों का क्या होगा?**

इस अध्ययन में पूर्व निर्धारित समय पर implant के स्थायित्व एवं crestal हड्डी के स्तर का मूल्यांकन किया जाएगा । सकारात्मक परिणाम संकीर्ण व्यास के, मंच में बदलाव वाले implant की उपयोगिता सत्यापित करेंगे ।

**18. इस शोध का आयोजन कौन कर रहा है?**

इस शोध का आयोजन अकादमिक संस्थान (बी०बी०डी०को०ड०स०) द्वारा किया जा रहा है।

**19. अध्ययन खत्म होने के बाद क्या परिणामों को उपलब्ध कराया जायेगा?**

हाँ ।

**20. किसने अध्ययन की समीक्षा की है?**

अध्ययन की समीक्षा विभाग के प्रमुख और संस्था के आईईसी० द्वारा अनुमोदित किया गया है।

# ANNEXURE V

# CASE HISTORY PROFORMA

## EVALUATION OF CRESTAL BONE LEVEL WITH NARROW DIAMETER PLATFORM SWITCHED IMPLANTS IN MANDIBULAR POSTERIOR EDENTULOUS REGION

DEPARTMENT OF PERIODONTOLOGY
BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

OPD NO: Date:

Name: Age:

Sex: Contact No:

Occupation:

Address:

Chief Complaint:

History of present illness:

Medical History:

Drug History and Allergy:

Past Dental History:

Family History:

Personal History:

(i) Oral Hygiene Habits:

(ii)Abusive Habits

**EXTRA ORAL EXAMINATION:**

**INTRAORAL EXAMINATION:**

Teeth Present:

Missing:

Dental Caries:

Attrition, Abrasion, Erosion:

Mobility:

**SOFT TISSUE EXAMINATION:**

**Gingival & Periodontal Status:**

Color-

Contour-

Consistency-

Surface texture-

Recession-

Bleeding on probing-

Pocket-

**Diagnosis:**

**Prognosis**

**Treatment Plan:**

**CLINICAL PARAMETER**

Buccolingual width : .....mm

Apico-coronal distance : .....mm

**Radiological Assessment:**

**Crestal Bone Level (mm)**

| | Mesial | Distal |
|---|---|---|
| At baseline (after implant placement) | | |
| At 6 months | | |
| At 1 year | | |

**Implant Stability**

| **At Baseline** | **At 6 months** | **At 1 year** |
|---|---|---|
| | | |

SIGNATURE OF STUDENT

SIGNATURE OF GUIDE

## ANNEXURE- VI

### Formula used for the analysis

**Arithmetic Mean**

The most widely used measure of central tendency is arithmetic mean, usually referred to simply as the mean, calculated as

$$\bar{X} = \frac{\sum_{i=1}^{n} X_i}{n}$$

**Standard deviation and standard error**

The standard deviation (SD) is the positive square root of the variance, and calculated as

$$SD = \sqrt{\frac{\sum X_i^2 - \frac{(\sum X_i)^2}{n}}{n-1}}$$

and SE (standard error of the mean) is calculated as

$$SE = \frac{SD}{\sqrt{n}}$$

Where, n= no. of observations

**Minimum and Maximum**

Minimum and maximum are the minimum and maximum values respectively in the measure data and range may be dented as below

Range = Min to Max

and also evaluated by subtracting minimum value from maximum value as below

Range = Maximum value-Minimum value

**Median**

The median is generally defined as the middle measurement in an ordered set of data. That is, there are just as many observations larger than the median as there are smaller. The median (M) of a sample of data may be found by first arranging the measurements in order of magnitude (preferably ascending). For even and odd number of measurements, the median is evaluated as

$M= [(n+1)/2]^{th}$ observation- odd number

$M= [n(n+1)/2]^{th}$ observation – even number

**Analysis of Variance**

Analysis of variance (ANOVA) is used when we compare more than two groups simultaneously. The purpose of one-way ANOVA is to find out whether data from several groups have a common mean. That is, to determine whether the groups are actually different in the measured characteristic. One way ANOVA is a simple special case of the linear model. For more than two independent groups, simple parametric ANOVA is used when variables under consideration follows Continuous exercise group distribution and groups variances are homogeneous otherwise non parametric alternative Kruskal-Wallis (H) ANOVA by ranks is used. The one way ANOVA form of the model is

$Y_{ij} = \alpha_{.j} + \varepsilon_{ij}$

Where;

- $Y_{ij}$ is a matrix of observations in which each column represents a different group.
- $\alpha_{.j}$ is a matrix whose columns are the group means (the "dot j" notation means that $\alpha$ applies to all rows of the $j^{th}$ column i.e. the value $\alpha_{ij}$ is the same for all i).
- $\varepsilon_{ij}$ is a matrix of random disturbances.

The model posits that the columns of Y are a constant plus a random disturbance. We want to know if the constants are all the same.

**Newman-Keuls multiple comparison Test**

After performing ANOVA, Newman-Keuls post hoc test is generally used to calculate differences between group means as

where,

$$q = \frac{\bar{X}_1 - \bar{X}_2}{SE}$$

$$SE = \sqrt{\frac{S^2}{2}\left(\frac{1}{n_1} + \frac{1}{n_2}\right)}$$

$S^2$ is the error mean square from the analysis of variance and $n_1$ and $n_2$ are number of data in group 1 and 2 respectively.

**Statistical significance**

Level of significance "p" is the probability signifies level of significance. The mentioned p in the text indicates the following:

| | |
|---|---|
| $p > 0.05$ | Not significant (ns) |
| $p < 0.05$ | Just significant (*) |
| $p < 0.01$ | Moderate significant (**) |
| $p < 0.001$ | Highly significant (***) |

MASTER CHART

| Sr no | BAW (mm) | ACD (mm) | Implant Stability Quotient | | | Crestal Bone Height (mm) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Mesial | | | Distal | | | Overall (Mesial & Distal) | | |
| | | | At baseline | At 6 month | At 1 year | At baseline | At 6 month | At 1 year | At baseline | At 6 month | At 1 year | At baseline | At 6 month | At 1 year |
| 1 | 5.5 | 11 | 73 | 70 | 75 | +0.90 | 0.00 | -0.72 | +0.70 | 0.00 | -0.90 | +0.80 | 0.00 | -0.81 |
| 2 | 5.5 | 10 | 53 | 67 | 73 | 0.00 | -0.90 | -1.26 | 0.00 | -0.72 | -0.90 | 0.00 | -0.81 | -1.08 |
| 3 | 5.8 | 16 | 97 | 90 | 94 | 0.00 | -0.32 | -0.54 | 0.00 | -0.46 | -0.60 | 0.00 | -0.39 | -0.57 |
| 4 | 5.7 | 15 | 73 | 78 | 77 | 0.00 | -0.42 | -0.72 | +0.20 | -0.18 | -0.56 | +0.10 | -0.30 | -0.64 |
| 5 | 5.3 | 13 | 68 | 62 | 65 | +0.45 | 0.00 | -0.72 | 0.00 | -0.54 | -0.81 | +0.23 | -0.27 | -0.77 |
| 6 | 5.3 | 13 | 74 | 66 | 70 | 0.00 | -0.55 | -0.91 | 0.00 | -0.45 | -0.82 | 0.00 | -0.50 | -0.87 |
| 7 | 5.9 | 10 | 68 | 65 | 72 | +0.09 | -0.36 | -0.73 | +0.18 | -0.27 | -0.55 | +0.14 | -0.32 | -0.64 |
| 8 | 5.9 | 10 | 69 | 62 | 75 | 0.00 | -0.45 | -0.82 | 0.00 | -0.36 | -0.64 | 0.00 | -0.41 | -0.73 |
| 9 | 5.6 | 16 | 75 | 76 | 80 | 0.00 | -0.27 | -0.64 | 0.00 | -0.36 | -0.82 | 0.00 | -0.32 | -0.73 |
| 10 | 5 | 11 | 68 | 65 | 71 | 0.00 | -0.64 | -1.09 | 0.00 | -0.55 | -0.91 | 0.00 | -0.60 | -1.00 |
| 11 | 5.1 | 13 | 59 | 70 | 76 | +0.91 | +0.55 | -0.09 | +0.91 | +0.45 | -0.18 | +0.91 | +0.50 | -0.14 |
| 12 | 5.1 | 12 | 75 | 73 | 78 | 0.00 | -0.36 | -0.64 | 0.00 | -0.27 | -0.55 | 0.00 | -0.32 | -0.60 |
| 13 | 5.5 | 14 | 64 | 68 | 72 | 0.00 | -0.45 | -0.73 | 0.00 | -0.55 | -0.82 | 0.00 | -0.50 | -0.78 |
| 14 | 5.8 | 16 | 76 | 70 | 78 | 0.00 | -0.73 | -1.09 | 0.00 | -0.64 | -0.91 | 0.00 | -0.69 | -1.00 |
| 15 | 5.7 | 16 | 80 | 77 | 85 | 0.00 | -0.55 | -0.82 | 0.00 | -0.45 | -0.91 | 0.00 | -0.50 | -0.87 |
| 16 | 5.4 | 17 | 74 | 71 | 83 | 0.00 | -0.36 | -0.64 | 0.00 | -0.27 | -0.55 | 0.00 | -0.32 | -0.60 |
| 17 | 5.5 | 14 | 78 | 73 | 75 | 0.00 | -0.45 | -0.73 | 0.00 | -0.55 | -0.82 | 0.00 | -0.50 | -0.78 |
| 18 | 5 | 12 | 63 | 59 | 68 | +0.73 | 0.00 | -0.55 | +0.45 | -0.18 | -0.73 | +0.59 | -0.09 | -0.64 |
| 19 | 5.2 | 15 | 77 | 69 | 71 | 0.00 | -0.27 | -0.55 | 0.00 | -0.45 | -0.73 | 0.00 | -0.36 | -0.64 |
| 20 | 5.9 | 17 | 82 | 83 | 85 | 0.00 | -0.45 | -0.82 | 0.00 | -0.55 | -0.91 | 0.00 | -0.50 | -0.87 |