# COMPARISION OF SOFT AND HARD TISSUE PARAMETERS IN CONVENTIONAL VERSUS FLAPLESS IMPLANT SURGERY: A CLINICO-RADIOGRAPHIC STUDY

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**Submitted to**

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***In the partial fulfilment of the requirements for the degree***

**Of**

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**In**

**PERIODONTOLOGY**

**By**

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**LUCKNOW**

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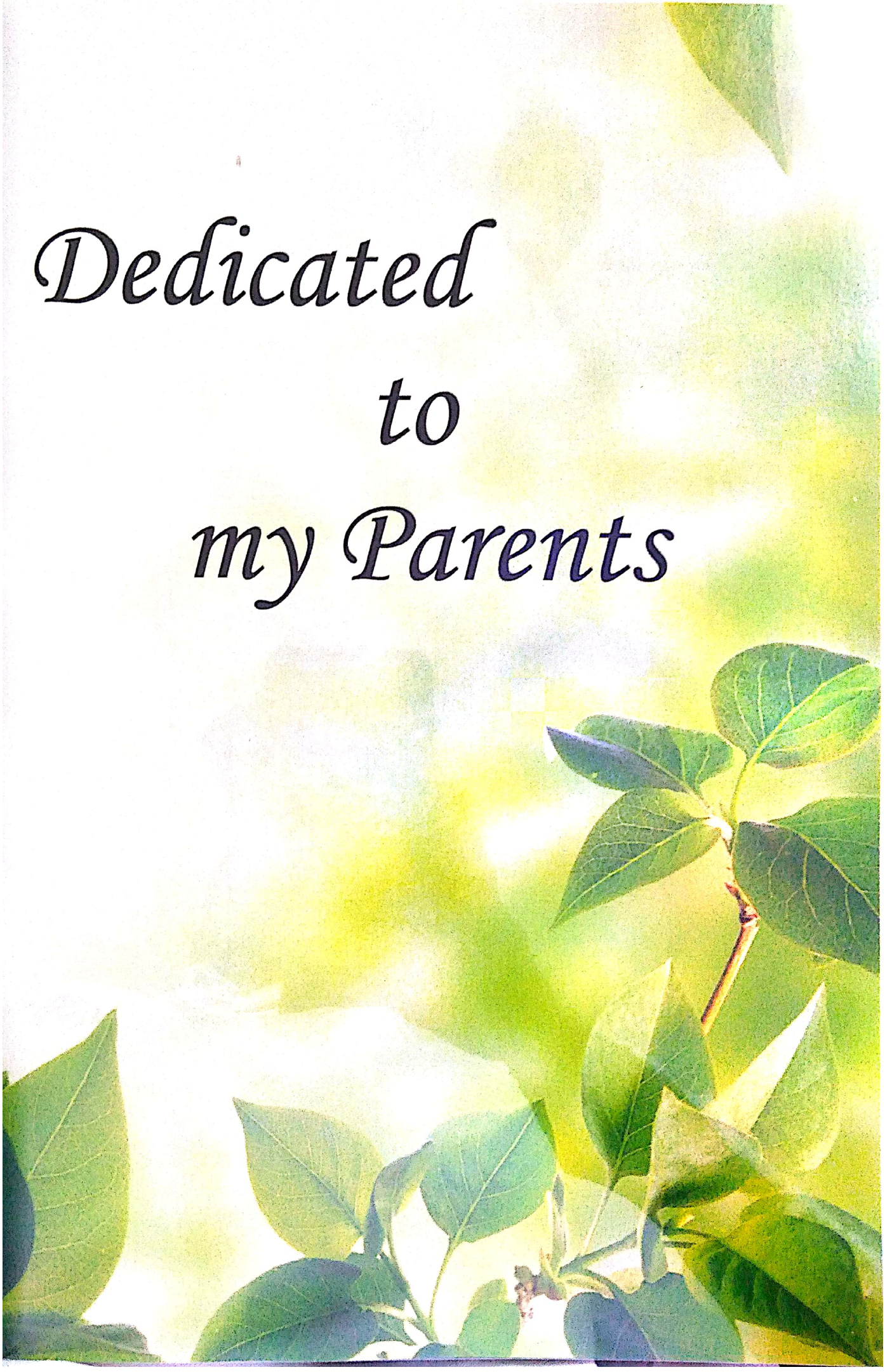

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***Dr. Sumaiya***

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| | |
|---|---|
| BIC | Bone Implant Contact |
| BOP | Bleeding On Probing |
| BVD | Bone Volume Density |
| CBCT | Cone Beam Computed Tomography |
| CBL | Crestal Bone Loss |
| CT | Computed Tomography |
| DBL | Distal Bone Level |
| DL | Delayed Loading |
| 3D-CR | 3-Dimensional Computed Radiography |
| FT | Flapped Technique |
| FL | Flapless |
| GI | Gingival Index |
| GDC | General Dental Council |
| HA | Hydroxyapatite |
| HU | Hounsfield Unit |

| | |
|---|---|
| IES-R | Impact Of Event Scale- Revised |
| IL | Immediate Loading |
| IO | Intra Oral |
| ISQ | Implant Stability Quotient |
| MBI | Modified Bleeding Index |
| MBL | Mesial Bone Level |
| mPI | Modified Plaque Index |
| ML | Marginal Levels Of Soft Tissue |
| MMP | Matrix Metalloproteinase |
| Nacl | Sodium Chloride |
| PDs | Probing Depth |
| p.*gingivalis* | Porphyromonas *Gingivalis* |
| PPD | Probing Pocket Depth |
| PPI | Pappillay Index |
| s-DAI | Short Version Of The Dental Anxiety Inventory |
| SLA | Sandblasted And Acid-Etched |

| | |
|---|---|
| t. *forsythia* | tannetella *Forsythia* |
| UNC | University of North Carolina |
| VAS | Visual Analog Scale |
| WKM | Width of Keratinized Mucosa |
| XCP | Extension Cone Parelleling |

# ABSTRACT

# ABSTRACT

In the late 1970s, Brånemark established the use of extensive surgical flaps to better visualize the surgical field during implant surgery. Following this protocol, flap was reflected to expose the underlying bone. The implants were then placed and the flaps repositioned with sutures. However, flap elevation is always associated with some degree of morbidity and discomfort, and requires suturing to close the surgical wound. There are situations where flap elevation may not be necessary since the amount of bone is sufficient and the risk of complications is minimal. Under these circumstances, flapless implant placement may be indicated.

Hence, this study has been undertaken to compare the outcome of esthetic & clinico-radiographic parameters when comparing conventional and flapless implant surgery.

20 patients were randomly divided into conventional and flapless group (10 each). CBL & ISQ was assessed at baseline and 9 months, PPI was observed at 6 and 9 months.

Crestal bone loss was observed in both the group however, flapless group showed lesser CBL as compared to conventional group which was statistically significant with p value <0.001. ISQ value was slightly higher at 9 months than that obtained at baseline in both the group. This increase was statistically non significant for both the group. PPI index showed papilla fill in both the groups from 6 months to 9 months. However papilla regeneration is higher in flapless group than conventional group which was statistically significant with p value < 0.02.

In this clinical study implants placed with flapless surgery showed equal clinical success, as those placed with conventional flap surgery. It seems that flapless surgery in healed bone with delayed loading offers a good alternative to conventional surgery

# INTRODUCTION

The goal of modern dentistry is to restore the patient to normal contour, function, comfort, esthetics, speech, and health, whether by removing caries from a tooth or replacing several teeth. To accomplish this goal oral implantology has emerged as successful replacement option regardless of the atrophy, disease, or injury of the stomatognathic system.[1]

When placing dental implants, a flap is usually elevated for better accessibility. Flap elevation ensures that some anatomical landmarks (e.g. foramina, lingual undercuts) are clearly identified and protected. When the amount of available bone is limited, flap elevation will facilitate implant placement by optimizing implant positioning and minimizing the risk of bone fenestrations. However, flaps are associated with some degree of morbidity and discomfort, and require suturing. There are situations where flap elevation may not be necessary since the amount of bone is sufficient and the risk of complications is minimal.[2]

Under these circumstances, flapless implant placement may be indicated. Guided surgery using customized surgical templates derived from computerized tomography (CT) scans can help clinicians minimize the risk of perforation and incorrect implant alignment.[3]

Retrospective and prospective studies have shown that it is possible to place dental implants successfully without raising a flap, even when loading the implants immediately reducing patients discomfort, treatment time and costs, if the risks of implant failures are not increased.[3]

Flapless or minimally invasive surgery offers clinicians the possibility of placing implants in less time, without extensive flaps, and with perceived less bleeding and postoperative discomfort for the patient. [4]

Traditional implant placement protocol involves exposure of the alveolar ridge using a full thickness mucoperiosteal flap.[5] Reflection of the mucoperiosteal flap compromises

the vascular supply of bone, which may lead to crestal bone loss (CBL) and long-term esthetic complications.[6-8]

An explanation of this may be derived from the fact that using a flapless approach during implant placement preserves the periosteal vascular supply to bone, thereby minimizing the possibility of future CBL. However, controversial results have also been reported in an study by Froum et al.[9] and De Bruyn et al.[10] CBL around implants placed in healed sites using flapped and flapless surgery were comparable.[5]

Vander Zee reported postsurgical tissue loss following flap reflection in the two-stage procedure of implant placement, implying that flap surgery for implant placement may negatively influence implant aesthetic outcomes especially in the maxillary anterior region.[8] William *et al.* suggested that implants placed without flap reflection remain stable and exhibit clinically relevant osseointegration similar to implants placed with flapped procedures.[4]

With the rapid advancement of dental implant therapeutics, the current trend is more geared toward enhancing esthetics and patient comfort and satisfaction. Papilla preservation and predictable soft tissue margins around dental implants are major esthetic concerns, particularly for patients who have a high smile line. There has been a report of postsurgical tissue loss from flap reflection, implying that flap surgery for implant placement may negatively influence implant esthetic outcomes.[11]

A clinical study related the presence or absence of the papilla between two teeth to the contact point between the teeth. When the distance was 5mm or less, the papilla completely filled this space almost 100% of the time. When the distance was 6mm, the interdental space filled about 55% of the time; and at 7mm, the interdental space was completely filled about 25% of the time.[12]

Conflicting reports are available in literature regarding the outcomes of esthetic and clinico- radiographic parameters when comparing conventional and flapless implant

surgery. Hence this study has been undertaken to compare the outcome of esthetic & clinico-radiographic parameters when comparing conventional and flapless implant surgery.

# AIM AND OBJECTIVES

**AIM:**

- The aim of the study is to evaluate the changes in crestal bone loss, implant stability and soft tissue profile around implant when comparing conventional and flapless implant surgery.

**OBJECTIVES:**

- To assess the crestal bone loss around implants at baseline (at the time of implant placement) and at 9 months.

- To assess implant stability at baseline (at the time of implant placement) and at 9 months.

- To assess the health and soft tissue profile of the peri-implant tissues, at 6 months and after 9 months.

# REVIEW OF LITERATURE

**Adell R et al. (1981)**[13] reviewed a long term 15 year study of osseointegrated implant in the treatment of 410 edentulous jaws of 371 consecutive patients. 130 jaws were provided with 895 fixtures, among them 81% of the maxillary and 91% of the mandibular fixture remained stable. During healing and the first year after connection of the bridge, the mean value for marginal bone loss was 1.5mm. Thereafter only 0.1 mm was lost annually.

**Zarb GA et al. (1990)**[14] conducted longitudinal prospective study on 46 edentulous patients who had undergone traditional denture optimization therapy without success were treated using Branemark technique. 274 implants were placed in 49 dental arches. 4 to 9 years after insertion of the implants, 244 or 89.05% remained osseointegrated. Of the 262 implants in place more than 5 years, 232 or 88.55% were still integrated. The implant success criteria developed in this clinical study endorsed the predictably favorable outcome of the Branemark technique.

**Laney WR et al.(1994)**[15] conducted a prospective multicenter study of single-tooth restorations supported by Brånemark implants for 3 years. After 1 year of function, 97.2% of the implants survived in 88 patients, and between the 1- and 3-year follow-up, 100% survived in 82 patients, giving a 3-year cumulative success rate of 97.2%. Marginal bone resorption remained at a low level—less than 0.1 mm annually during the second and third years.

**Lekholm U et al.(1999)**[16] conducted a long term prospective multicentre study based on survival of Branemark implant in partially edentulous jaws in 127 patients. 461 implants were placed. In 125 patients, 163 fixed partial prostheses were attached to the implants; a majority of the prostheses (83%) were located in posterior regions. At the end of the 10-year period, 73% of the implants could be traced either as failed or in function, providing cumulative implant survival rates of 90.2% and 93.7% for the maxilla and mandible, respectively. Marginal bone resorption at the implants was low and mucosal health was good. No severe complications apart from the above-mentioned implant and prosthetic failures were reported. Hence the Brånemark Implant System

demonstrated a safe and predictable method for restoring partially edentulous patients by the 10-year follow-up investigation.

**Spray JR et al (2000)**[17] evaluated the changes in vertical dimensions of facial bone between implant insertion and uncovering and compared these changes to facial bone thickness for more than 3000 HA coated and non HA coated root form dental implants. The distance from the top of the implants to the crest of the facial bone was measured using periodontal probes. Implants were uncovered between 3 to 4 months in the mandible and 6 to 8 months in the maxilla after insertion. the result demonstrated significantly higher amounts of facial bone loss which was associated with implants that failed to integrate. As the bone thickness approached 1.8 to 2 mm, bone loss decreased significantly and some evidence of bone gain was seen.

**Schropp L et al. (2003)**[18] assessed the bone formation in the alveolus and the contour changes of the alveolar process following tooth extraction. The tissue changes after removal of a premolar or molar in 46 patients were evaluated in a 12-month period by means of measurements on study casts, linear radiographic analyses, and subtraction radiography. The results demonstrated that major changes of an extraction site occurred during 1 year after tooth extraction.

**Van Assche N et al. (2007)**[19] evaluated computer-based three-dimensional (3D) planning, using re-formatted cone-beam images, for oral implant placement in partially edentulous jaws. 4 formalin-fixed cadaver jaws were imaged with CBCT(CT). Data were used to produce an accurate implant planning with a transfer to surgery by means of stereolithographic drill guides. Pre-operative cone-beam CT images were subsequently matched with post-operative ones to calculate the deviation between planned and installed implants. Placed implants (length: 10–15 mm) showed an average angular deviation of 21 as compared with the planning, while the mean linear deviation was 1.1 mm at the hex and 2 mm at the tip and hence they concluded that Cone-beam images could be used for implant planning.

**Corpas LDS et al. (2010)**[20] compared the outcome of intra-oral radiograph and CBCT analyses to the histological standard. 80 implants were placed in 10 mini pigs to assess matching between different image modalities and histologic imaging by using Spearman's correlation. A Significant correlation between bone defect depth on IO and histological slices as well as on CBCT images and histological slices were found.. For bone density assessment, significant but weaker correlations were found for intra-oral radiography vs. histology. Significant marginal bone-level changes observed after 3 months of healing using intra-oral radiography. Therefore a correlation between radiographic bone defect depth to the histological observations of the peri-implant bone observed. however, CBCT was not found to be reliable for bone density measures, but might hold potential with regard to the structural analysis of the trabecular bone.

**Linkevicius APT et al. (2013)**[21] evaluated the influence of mucosal tissue thickening on crestal bone stability around bone-level implants. 97 bone-level implants in 97 patients based on vertical gingival thickness, patients assigned into test T1 (thin, 2 mm or less), test T2 (thin thickened with allogenic membrane) and control C groups (thick, more than 2 mm). Radiographic examination were performed after implant placement,2 months after healing, after prosthetic restoration and after 1-year follow-up. Statistically significant difference were obtained between T1/T2, and T1/C both mesially and distally. After 1-year significant difference were obtained between T1/T2 and T1/C. Thus concluded as significantly less bone loss occurs around bone-level implants placed in naturally thick mucosal tissues, in comparison with thin biotype.

**Ritter L et al. (2014)**[22] assessed the accuracy of 3D cone beam CT (CBCT) and intra-oral radiography (CR) in visualizing peri-implant bone compared with histology. 26 titanium dental implants were placed in dog jaws with chronic type vestibular defects. After healing period of 2 and 8 weeks animals were sacrificed. CBCT scans and CR of the specimen were recorded. By the two modalities they were measured twice by two observers and compared with histomorphometry regarding bone levels and thickness around implants as well as length and diameter of implants and they concluded that 3D CR and CBCT perform similar in assessing MBL and DBL, but, within its limits, the

CBCT can assess oral and buccal bone. Metallic artefacts limit the visualization quality of bone around implants and therefore when information about osseous perforation of implants is needed, CBCT may still provide clinically valuable information.

**Atsuta I et al. (2016)**[23] reviewed a study on the biology and soft tissue sealing around dental implants and teeth which is dependent on both osseointegration around the implant body and the establishment of a soft tissue barrier that determines the longevity and functionality of dental implants, health and stability of the peri- implant mucosa also affects the esthetics of the implant.

**Surgical Approaches**

**Conventional Implant Surgery**

**Casino AJ et al. (1991)**[24] conducted a study in the Dental Implant Clinical Research Group comprising 30 Department of Veterans Affairs medical centers and two dental schools initiated a long-term clinical study to investigate the clinical performance of Implants, the study database related to incision type, implant success rates, and response of crestal bone up to the time of surgical uncovering. The crestal incision was used for 1,705 implants (381 patients) and the remote incision for 593 implants (141 patients) and demonstrated that there was no statistically significant difference was found in implant integration or the response of crestal bone.

**Scharf DR et al. (1993)**[25] compared a retrospective analysis on the effect of crestal versus mucobuccal incision on the success rate of implant osseointegration at stage 2 surgery. A total of 386 implants were placed in 92 patients; 265 implants were placed in 60 patients using a mucobuccal fold incision, with a success rate of 98.8%, and 121 implants were placed in 32 patients using a crestal incision, with a success rate of 98.3%. and they demonstrated that there was no difference in the implant success rates when implants were placed with a mid-crestal incision. However, they concluded that it was far more advantageous to use a mid-crestal incision since the swelling and the postoperative pain were greatly minimized.

**Al-Ansari BH et al. (1998)**[26] investigated a clinical report on 20 maxillary and mandibular implants placed in seven adult male patients. The sites for implant placement were prepared according to an alternative surgical technique without raising a surgical flap. Patients were recalled periodically for 2 years to evaluate healing and clinical integration of implants. The results showed normal clinical healing at the first week of reexamination in all implant sites; periodontal probing of less than 2 mm circumferentially around all healing caps at 3 months and later at subsequent recall periods; no radiolucency observed in the peri-implant zone; no sign of clinical mobility during recall examination; and no persistent or irreversible sign or symptoms of pain, infection, or necrosis.

**Roman GG (2001)**[7] evaluated the influence of flap Design on Peri-implant Interproximal Crestal Bone Loss around Single-tooth Implants. The prospective study investigated interproximal crestal bone loss occurring after placement of single-tooth implants using 2 different flap designs: a widely mobilized flap design that included papillae, and a limited flap design that protected papillae. The interproximal crestal bone loss was of practical importance and statistically significantly less following the use of a limited flap design versus the widely mobilized flap procedure.

**Shahindi. P et al. (2008)**[27] compared the efficacy of a new uncovering technique with that of the conventional uncovering technique for papilla generation. Implants of the test group were uncovered by the new technique and implants of the other group were uncovered by the conventional technique (simple mid-crestal incision). Based on this study, it appears that over the course of 6 months, the new surgical approach for uncovering leads to a more favorable soft tissue response.

**Jensen OT et al. (2009)**[28] compared the marginal stability using 3 different flap approaches for alveolar split expansion for dental implants. 40 patients treated with 65 alveolar split expansion procedures during a 2-year period and were statistically analyzed for buccal bone augmentation presence and implant restorability after 1 year of healing . Facial bone loss of 2 mm or more was seen in 11 sites, 10 of which were full

flap reflections and 1 wan osteoperiosteal flap site. Implant osseointegration was 92.5% for the osteoperiosteal flaps, 93.3% for the partial-thickness flaps, and 94.4% for the full-thickness flaps. The 3 flap approaches to alveolar widening by crest splitting with implant placement had a sustained increased alveolar width after 1 year. However, most full flap alveolar split cases had facial bone loss and gingival recession. The osteoperiosteal flaps and partial-thickness flaps showed stable buccal bone patterns.

**Lindeboom JA et al (2010)[29]** compared patient outcome variables using flapless and flapped implant surgical techniques. 16 consecutive patients with edentulous maxillas were included in the study. Patients were randomly allocated to either implant placement with a flapless or surgery with a conventional flap procedure. 96 implants were successfully placed. All implants were placed as two phase implants and the after-implant placement dentures were adapted. No differences could be shown between conditions on dental anxiety (s-DAI), emotional impact (IES-R), anxiety, procedure duration or technical difficulty, although the flapless group did score consistently higher. The flap procedure group reported less impact on quality of life and included more patients who reported feeling no pain at all during placement hence concluded that patient outcome variables in the flapless implant group had to endure more than patients in the flap group.

**Flapless Implant Surgery**

**Campelo LD et al. (2002)[6]** investigated a 10-year retrospective analysis. 359 edentulous or partially edentulous patients received 770 implants to support either fixed partial dentures or removable overdentures and implants placed without the use of soft tissue flaps. Criteria for failure were used: (1) mobility or pain at any time following treatment, (2) removal as a result of pain, or (3) demonstrated bone loss after the 1$^{st}$ year of more than 0.5 mm a year for 2 or more consecutive years . Result showed the success rate for implants placed by means of the flapless technique was 74.1% implants placed in 1990 and 100% for implants placed in 2000. The failures occurred 37.83%

between placement and loading, 16.21% in the year after placement, and 45.94% after the first year.

**Becker W et al. (2005)**[30] evaluated implant placement using a minimally invasive one-stage flapless technique up to 2 years. 57 patients with 79 implants were placed. A small, sharp-tipped guiding drill was used to create a precise, minimally invasive initial penetration through the mucosa and into bone. The parameters recorded were total surgical time, implant survival, bone quality and quantity, implant position by tooth type, depth from mucosal margin to bone crest, implant length, probing depth, inflammation, and crestal bone changes. After 2 year, the cumulative success rate was 98.7%, indicating the loss of 1 implant. The study demonstrated that flapless surgery using a minimally invasive technique is a predictable procedure with lessened surgical time; minimal changes in crestal bone levels, probing depth, and inflammation; perceived minimized bleeding; and lessened postoperative discomfort.

**Oh T et al.(2006)**[11] assessed the effect of flapless implant surgery on soft tissue profile. 24 patients were randomly assigned into two groups IL or DL. Clinical measurements including the PPI , ML, PDs, mBI, mPI, and the WKM were performed at baseline at 2, 4, and 6 months. Mean PPI in the IL group significantly increased from 2 months, and the significance remained up to 6 months whereas in the DL group, no significant changes were found from baseline to 6 months in mean PPI. Thus the result demonstrated that creeping attachment might occur within 2 months after IL and suggests the flapless implant surgery provides esthetic soft tissue results in single-tooth implants either immediately or delayed loaded.

**Becker W et al. (2009)**[31] conducted a multicentre study for an average of 3 years and 8 months. Thirty-seven patients with 52 implants returned for a follow-up examination. The cumulative survival rate at the 3- to 4-year follow-up examination remains at 98.7%, reflecting the loss of one implant. The mean probing depth at abutment connection was 2.2 mm, as reported in the initial study (examination 2 at; 2 years postplacement); it was 2.4 mm at the 3- to 4-year second follow-up examination. This

change was not clinically or statistically significant. Bleeding score changes also were not significant between the two intervals. The average crestal bone level was -0.7mm at examination 2 and -0.8mm at examination 3 and hence concluded as minimally invasive flapless surgery offers patients the possibility of high implant predictability with clinically insignificant crestal bone loss for up to 4 years.

**Nadine Brodala (2009)**[32] reviewed literature with regard to the efficacy and effectiveness of flapless surgery. The results indicated high implant survival. 6 studies reported mean radiographic alveolar bone loss ranging from 0.7 to 2.6 mm after 1 year of implant placement. Intraoperative complications were reported in 4 studies, and these included perforation of the buccal or lingual bony plate. Overall, the incidence of intraoperative complications was 3.8% of reported surgical procedures.therefore,flapless surgery placement, demonstrating both efficacy and clinical effectiveness. However, these data are derived from short-term studies with a mean interval of 19 months, and a successful outcome with this technique is dependent on advanced imaging, clinical training, and surgical judgment.

**Jeong SM et al.(2009)**[33] described a flapless implant surgery method using a mini-incision and compares the effects of soft tissue punch and mini-incision surgery on both the amount of osseointegration and the bone height around the implants using a canine mandible model on 6 mongrel dogs. After 3-months of healing period, two implants were placed on each side of the mandible using either soft tissue punch or mini-incision procedures. After an additional 3-month healing period, a second stage surgery and transmucosal abutment attachment was performed for mini-incision implant cases. Average bone height was 9.6± 0.4 mm in the soft tissue punch group and 9.8 ± 0.3 mm in the mini-incision group. Average osseointegration was 70.4± 6.3% in the soft tissue punch group and 71.2 ±7.1% in the mini-incision group.No significant differences were noted between the two groups in vertical alveolar ridge height or bone/ implant contact.

**Lee DH et al. (2010)**[34] examined the effects of soft tissue punch size on the healing of peri-implant tissue in a canine mandible model on 6 mongrel dogs. 3 fixtures were

placed on each side of the mandible using 3-mm, 4-mm, or 5-mm soft tissue punches. After subsequent healing periods of 3 weeks and 3 months, the peri-implant mucosa was evaluated using clinical, radiologic, and histometric parameters, which included GI, BOP, PPD, marginal bone loss, and vertical dimension measurements of the peri-implant tissues. Result showed significant differences between the 3-mm, 4-mm, and 5-mm tissue punch groups for the length of the junctional epithelium, probing depth, and marginal bone loss at both 3 weeks and 3 months after implant placement. When the mucosa was punched with a 3-mm tissue punch, the length of the junctional epithelium was shorter, the probing depth was shallower, and less crestal bone loss occurred than when using a tissue punch with a diameter ≥4 mm. Hence soft tissue punch plays an important role in achieving optimal healing.

**Jeong SM et al. (2011)**[35] Evaluated soft tissue conditions and marginal bone changes around dental implants 1 year after flapless implant surgery. 432 implants were placed in 241 patients by using a flapless 1-stage procedure. Peri-implant soft tissue conditions and radiographic marginal bone changes were evaluated 1 year after surgery. 100% success rate were recorded. The mean probing depth was 2.1 mm and the average bleeding on probing index was 0.1 The average gingival index score was 0.1 and the mean marginal bone loss was 0.3 mm .Ten implants exhibited bone loss >1.0 mm, whereas 125 implants experienced no bone. Thus the study demonstrated that flapless implant surgery is advantageous for preserving crestal bone and mucosal health surrounding dental implants.

**Resonance Frequency Analysis**

**Turkyilmaz (2006)**[36] compared between an insertion torque and resonance frequency in the assessment of torque capacity and primary stability of Branemark system implants. 30 edentulous patients were treated with 60 implants using a one-stage technique. The insertion torque values of all implants were recorded with the Osseocare equipment. Immediately after implant placement, each implant was connected to the transducer of an Osstell machine to measure the primary implant stability. The average insertion torque and resonance frequency values were 41.5 ± 5.8 and 74.1 ± 3.8 for 30 implants.

The correlation between insertion torque and resonance frequency values indicated a statistical significance. The difference between mean insertion torque values for female and male patients was statistically. The results of this study showed a strong correlation between the primary stability and insertion torque values of Branemark System implants at the time of implant placement.

**Schliephake H et al. (2006)**[37] correlated the measurements of implant stability using RFA with histomorphometric data of bone anchorage. 10 female foxhounds received 80 implants in their mandibles. 3 months after removal of all premolar teeth. 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. RFA measurements were repeated at the time of implant retrieval after 1 month and 3 months. Peri-implant bone regeneration was assessed histomorphometrically by measuring 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 nor between peri-implant bone density and RFA values.

**Becker W et al. (2006)**[38] conducted a study on 5 Hound Labrador mongrel dogs using flapless or conventional one-stage surgery in contralateral jaw quadrants. ISQ was recorded using RFA. Measurements were repeated following a 3-month healing interval. Implants and surrounding tissues were retrieved and processed for histologic analysis. The implants were stable upon insertion and demonstrated increased stability at 3 months without significant differences between surgical protocols. The histologic evaluation showed high bone-implant without evidence of gingival tissue or foreign body inclusions, ISQ values depended on the amount of torque delivered. Immediately post-insertion, for every 1-unit increase in torque value, the ISQ increased by 0.3. Three months postoperatively, for every one-unit increase in torque the ISQ value decreased 0.2. Hence the results suggested that implants placed without flap reflection remain

stable and exhibit clinically relevant osseointegration similar to when implants are placed with flapped procedures. Greater torque at implant placement resulted in less implant stability at 3 months.

**Oates TW et al. (2007)**[39] examined the changes in stability for implants with a chemically modified SLA surface and to compare their outcomes to those of control implants. 31 patients received 2 implants with the same physical properties but with surfaces that were chemically different. The control implants had a standard SLA surface, while the test implants had a chemically modified surface. RFA was assessed weekly over the first 6 weeks following implant placement. All implants proved clinically successful, allowing for restoration. A shift in implant stability from decreasing stability to increasing stability occurred after 2 weeks for the test implants and after 4 weeks for the control implants. The findings from this pilot study provide clinical support for the potential for chemical modification of the SLA surface to alter biologic events during the osseointegration process and demonstrate levels of short-term clinical success similar to those observed for implants with an SLA surface.

**Seong WJ et al. (2008)**[40] determined whether initial implant stability varies with anatomical regions of the jawbone. 4 pairs of edentulous maxillae and mandibles were retrieved from fresh human cadavers. 6 implants per pair were placed in different anatomical regions. Immediately after implant placement, initial implant stability was measured with a custom-made resonance frequency analyzer, a commercial resonance frequency analysis device (Osstell), and a mechanical tapping device (Periotest). All implant surgeries and initial stability measurements were performed within 72 hours of death to simulate a clinical setting. Mandibular implants had significantly higher initial stability than maxillary implants. Posterior maxillary implants were least stable. Stability was less bucco-lingually than mesio-distally. The measurements from 3 stability measuring devices were strongly associated with each other. Hence initial implant stability varied among anatomical regions of jawbone. Rank of Periotest value and implant stability quotient (Osstell) had the highest correlation.

**Lopez AB et al. (2008)**[41] Conducted a study to measure the implant stability quotient (ISQ) values during the osseointegration period, and determined the factors that affect implant stability implant. RFA was performed in 24 patients with a total 64 implants. Direct measurement of implant stability on the day of implant placement consecutively once a week for 8 weeks and at week 10 was performed. The mean ISQ of all measured implants was 62.6. The lowest mean stability measurement was at 4 weeks for all bone type. Thus in relation to location within the dental arch, statistical analysis showed higher ISQ values for anterior implants than posterior fixtures

**Kim JM et al. (2009)**[42] determined the change in stability of single-stage, three different design of implant systems in humans utilizing RFA for early healing period (24 weeks), without loading. In 25 patients a total of 45 implants, three different design of implant systems (group A,C,R) were placed in the posterior maxilla or mandible. The specific transducer for each implant system was used. ISQ reading were obtained for each implant at the time of surgery, 3, 6, 8, 10, 12, 24 weeks postoperatively. All the implant groups A, C and R, the change patterns of ISQ over time differed by bone type. Implant stability increased greatly between week 0 and week six and showed slow increase between week six and six months (plateau effect).

**Al-Jetaily S et al. (2010)**[43] Investigated the sensitivity and reliability of the Osstell systems RFA compared to the Periotest system in implant bone simulated conditions. 3 conditions were simulated: (1) the direct fixture-bone contact and fibrous tissue fixture contact, (2) The different levels of horizontal bone loss (3) The hardening implant–bone interface . 49 dental implant fixtures were placed in the center of acrylic cubes. The stability of these fixtures was measured using Osstell and Periotest systems. The mean Periotest value and Osstell measurements showed a significant difference between the direct contact and soft interface. A strong correlation was found between the Osstell readings and the change in the stiffness of the autopolymerizing resin fixture interface group Thus both Osstell and Periotest systems proved to be sensitive in measuring dental implant stability in hard and in soft interfaces. Osstell also proved to be sensitive in detecting changes in the fixture interface stiffness.

**Atieh MA et al. (2012)**[44] reviewed a systematic and meta analysis that determine the prognostic accuracy of RFA in predicting implant failure following immediate loading protocols. The sensitivity, specificity, and accuracy of RFA in the selected studies were evaluated using a random effects model. 15 studies with 2,236 immediately loaded implants were identified. The sensitivity of RFA in predicting failure of immediately loaded implants were suggesting a poor predictive and discriminative ability and concluded that RFA measurement at the time of implant placement is not sufficiently accurate to determine implant stability and osseointegration during immediate loading protocols.

**Kokovic V et al. (2013)**[45] determined the influence of implant surface modification and implant length on primary implant stability using RFA. 27 patients with bilateral mandible were treated with 162 dental self-tapping implants (72 implants with SLA with 8 and 10 mm length, respectively; 90 implants with chemically modified SLA surface and a length of 8 mm). ISQ values were determined and were compared in between the implant types. Statistically significant differences were noted between mean ISQ value of SLA and mod SLA implants (76.92 vs. 80.80). Also significantly lower mean ISQ values have been recorded for 8 mm length implants compared to 10 mm length implants in the SLA group (74.15 vs. 79.57). hence all ISQ values indicate the high primary stability for tapper implants inserted in the posterior part of the mandible. Self-tapping implant design provides sufficient initial stability even for implants with nonstandard length.

**Vlahovi Z et al. (2013)**[46] compared a study on flap and flapless surgical techniques for implant placement through radiographic and radiofrequency analyses. After 9 weeks of extraction implants were placed on 5 domestic pigs, right side with FT, and left side with FL. Peri-implant bone resorption in the first 4 weeks in both techniques were negligible. After 3 months, mean value of peri-implant bone resorption of the implants placed using flap tehnique was 1.86 mm, and of those placed using flapless tehnique was 1.13 mm. In the first and second week there was an expected decrease in ISQ values, but it was less expressed in the dental implants placed using the flapless technique. In

the third week the ISQ values increased by using both techniques, but the increase in flapless implant placement was higher (7.4 ISQ) than in flap implant placement (1.5 ISQ). After 3 months implant stability using flap technique were higher than the primary stability for 7.1 ISQ, and in the implants placed using flapless technique were higher comparing to the primary stability for 10.1 ISQ units. Hence, concluded that the flapless technique in surgical implants placement, leads to better results.

**Climent MH et al. (2013)**[47] assessed a cross- sectional clinical study on implant stability by measuring implant oscillation frequency on the bone. Implants stability were measured by means of Osstell ISQ on 85 implants in 23 patients. 6 measurements were completed on each implant by means of two different SmartPegs (types I and II); i.e. 3 consecutive measurements with each transducer. Average ISQ was 72.40, 72.22 and 72.79, and 72.06, 72.59 and 72.82 in the first, second, and third measurements with SmartPegs I and II, respectively. Equal values or differences below three ISQ points were observed in 52.9% and 62.4% of the cases with SmartPegs I and II, respectively. The intraclass correlation coefficient was 0.97 for both SmartPegs, and repeatability and reproducibility also reached 0.97 for both Smart Pegs. Thus the RFA system Osstell ISQ presents almost perfect repeatability and reproducibility after intraclass correlation coefficient analysis.

**Monje A et al. (2014)**[48] evaluated a retrospective a study to test the sensitivity of the RFA for detecting early implant failure. A total of 20 implants placed in pristine bone were found to have failed before loading. The implant stability quotient (ISQ) values were extracted from the 20 implants at baseline (immediate) and 4 months after placement (delayed).Immediate ISQ values were significantly related to failure. Furthermore, the results of the second regression showed a significant relationship between ISQ at delayed measurement and implant failure. For immediate ISQ, it seems that the 73.7% correct classifications were obtained at the cost of an incorrect classification of 55% of the implant failures. However, for the delayed ISQ, 86.2% correct classifications were obtained at the cost of assuming that all implants will

survive. Thus the study showed that ISQ values are not reliable in predicting early implant failure.

**Sachdeva A et al. (2018)**[49] conducted a study to measure the stability and crestal bone level changes of indigenously developed implants in fresh extraction sockets. 40 implants were placed immediately in fresh extraction sockets in 27 patient. Impant stability was measured at the time of placement of implant at 3, 6, and 12 months postoperatively, and radiographic crestal bone changes were evaluated using digital radiograph at 0, 6, and 12 months. The distance between the first visible bone- implant contact and implant shoulder was measured, and crestal bone loss was calculated. The mean RFA values obtained were 48.08 ISQ at the time of placement and reached 66.32 ISQ after a follow- up period of 12 months. The mean radiographic bone loss was 0.67 mm at the end of 12 months. Hence concluded that Immediate placed implants can attain adequate level of primary stability. These stability levels improve with time, reaching similar values irrespective of the initial stability. About 50% of mean crestal bone loss occurred during the first 6 months after implant placement suggesting several factors other than occlusal load affecting bone levels around implants.

**Comparision of Flapless and Flapped Techniques**

**Fortin T et al. (2006)**[50] compared the pain experienced after implant placement with 2 different surgical procedures i.e flapless surgical procedure using an image guide system based on template and open flap procedure. 60 patients referred for implant placement. 30 patients referred for 80 implant placement and treated with flapless procedure. Other 30 patient were referred for the placement of 72 implants with a conventional procedure. A questionnaire using a VAS to assess the pain experienced and to indicate the number of analgesic tablets taken every postoperatively day from the day of the surgery to 6 days after surgery. Result showed a significant difference in pain measurements, with higher scores on the VAS with the open flap surgery.

**Ozan O et al. (2007)**[51] Evaluated a study to compare the survival rates of early loaded implants placed using flapless and flapped surgical techniques and to determine the bone

density in the implant recipient sites using CT. 12 patients were selected randomly with. CT machine was used for pre-operative evaluation of the jaw bone. All implants were placed using CT guided surgical stents. The early loading protocols included 2 months of healing in the mandible and 3 months of healing in the maxilla. 59 implants placed, one was lost in the conventional flapped group within the first month of healing, meaning overall implant survival rate of 98.3% average 9 months later. The highest average bone density value (801±239 HU) was found in the anterior mandible, followed by 673±449 HU for the posterior maxilla, 669±346 HU for the anterior maxilla and 538±271 HU for the posterior mandible. The results of this study show that the early loading of implants placed utilizing flapless surgical technique with CT-guided surgical stents may be possible.

**Jeong SM et al. (2007)**[52] examined the effect of flapless implant surgery on crestal bone loss and osseointegration in a canine mandible model. On 6 mongrel dogs after 3 months of healing, 2 implants in each side were placed by either flap or flapless procedures. After a healing period of 8 weeks, microcomputerized tomography at the implantation site was performed. Osseointegration was calculated as percentage of implant surface in contact with bone. Additionally, bone height was measured in the peri-implant bone. Mean osseointegration was greater at flapless sites (70.4%) than at sites with flaps (59.5%) The mean peri-implant bone height was greater at flapless sites (10.1 mm) than at sites with flaps 9mm.

**Paulo M et al. (2008)**[53] conducted a prospective cohort study on the rehabilitation of partial edentulism with immediate function implants placed in predominantly soft bone with flap and flapless surgical techniques. 72 implants placed in 41 patients rehabilitated from partial edentulism, followed for 1 year. Clinical examinations and radiographic assessment of the marginal bone level at 6 months and 1 year were evaluated. Implant success, evaluated using implant success criteria: clinical stability implants fulfilled purported function without any discomfort to the patient; no suppuration or infection present; no radiolucent areas around the implants at time of evaluation; and no aesthetic complaints from the patient. The overall cumulative

survival rate at 1 year was 98.6% for the implants placed with the flap surgical technique, and 96.9% for thr implants placed with the flapless surgical technique. The overall average marginal bone resorption was with 1.4mm and 2.0mm for the flap and flapless surgical technique study groups, respectively. Thus, the flapless technique revealed more marginal bone resorption compared with the flap technique. Extra care should be taken in the flapless approach with respect to the inclusion criteria and difficulty of the surgery.

**Job S et al. (2008)**[54] evaluated the changes in crestal bone height around implants placed with flapless surgery and with-flap surgery. 10 implants were placed in six patients – five using flapless and 5 using with-flap techniques. Single-piece root-form implants and a one-stage approach with immediate nonfunctional loading protocol were used. On mesial side, the mean change from months 0–1, months 1–3, and months 0–3 for flapless method was significantly lower than with-flap method [0.01–0.06 mm for flapless and 0.13–0.40 mm for with-flap. On the distal side, the mean change from months 0–1, months 1–3, and months 0–3 for flapless method was significantly lower than with-flap method 0.02–0.05 mm for flapless and 0.09–0.30 mm for with-flap. During the three-month period, reduction of crestal bone height around the implants placed with flapless surgery (0.06 mm) was not statistically significant, while the reduction of crestal bone height around the implants placed using with-flap surgery (0.4 mm) was statistically significant. Thus flapless approach showed lesser crestal bone height reduction, which was statistically significant.

**Cannizzaro G et al. (2008)**[3] compared the efficacy of immediate functionally loaded implants placed with a flapless procedure versus implants placed after flap elevation and conventional load-free healing in partially edentulous patients. In their study 40 patient were randomly divided into two groups: 20 to the flapless immediately loaded group & 20 to the conventional group .52 implants were placed in the flapless group & 56 in the conventionally loaded group. In the flapless group, 1 flap had to be raised to control the direction of the bur & 1 implant did not reach the planned primary stability and was treated as belonging to conventional group. After 3 years no dropouts or failure

occurred. There was no statistically significance difference for complications; however, patients in the conventional group had significantly more postoperative edema and pain and consumed more analgesics than those in the flapless group. Osstell values were significantly higher at baseline in the flapless group (P=.033). When comparing baseline data with years 1,2 and 3 within each group, mean Osstell values of the flapless group did not increase, whereas there were statistically significant increase in the Periotest values.

**Bruyn HD et al. (2009)**[10] Compared single implants installed with a flap (F) or flapless (FL) surgery with respect to survival and marginal bone preservation after at least 3 years. 53 TiUnite™ Brånemark implants, installed in 49 patients were examined. 25 F and 28 FL were delayed loaded; bone level from the abutment-implant level was measured on intraoral radiographs. Radiographs were available at baseline and after 1 and 3 years of function. The overall survival rate was 100% and the overall mean bone loss after an average of 38 months was 1.35 mm .Both F and FL showed increasing bone loss during the first year with a higher bone loss for FL than for F sites. Afterward, no further bone loss occurred and both groups were statistically equal . On individual implant level, nearly 80% in both F and FL were considered a success showing bone loss between 1.5 and 1.9 mm.

**You TM et al. (2009)**[55] compared the morphogenesis of the peri-implant mucosa between flap and flapless implant surgeries by using a canine mandible model. On 6 mongrel dogs, after 3 months of healing, 2 implants were placed in each side by either the flap or the flapless procedure. 3 months after implant insertion, the peri-implant mucosa was evaluated by using clinical, radiologic, and histometric parameters, which included the GI, BOP, PPD, marginal bone loss, and the vertical dimension of the peri-implant tissues. The height of the mucosa, length of the junctional epithelium, gingival index, bleeding on probing, probing depth, and marginal bone loss were all significantly greater in the dogs that had the flap procedure than in those that had the flapless procedure. Result indicated that gingival inflammation, the height of junctional

epithelium, and bone loss around nonsubmerged implants can be reduced when implants are placed without flap elevation.

**Caneva M et al. (2010)**[56] compared the remodeling of the alveolar process at implants installed immediately into extraction sockets by applying a flap or a flapless surgical approach in a dog model. Mandibular premolars of six Labrador dogs. In one side of the mandible, a full thickness mucoperiosteal flap was elevated (control site), while contra-laterally, the mucosa was gently dislocated, but not elevated (test site) to disclose the alveolar crest. After 4 months of healing, histomorphometric analysis was performed. After 4 months of healing, all implants were integrated. Both at the test and at the control sites, bone resorption occurred with similar outcomes. The buccal bony crest resorption was 1.7 and 1.5mm at the control and the test sites, respectively. Flapless implant placement into extraction sockets did not result in the prevention of alveolar bone resorption and did not affect the dimensional changes of the alveolar process following tooth extraction when compared with the usual placement of implants raising mucoperiosteal flaps.

**Jeong SM et al. (2011)**[57] compared dental implant stabilization patterns between flap and flapless implant surgeries over the first 8 weeks after implant placement. 6 mongrel dogs, After 3 months of healing, 2 implants were placed in each side of the mandible using either a flap or flapless procedure. The implant stability quotient (ISQ) was obtained from Osstell Mentor was measured at the time of implantation and weekly over the first 8 weeks after implant placement. Implants stabilized more quickly without flap elevation than with flap elevation. For flapless implants, an increase in stability occurred after 2 weeks without a period of decreasing stability. However, for flap implants, a shift in implant stability from decreasing stability to increasing stability occurred after 2 weeks.

**Froum SJ et al.(2011)**[9] compared the survival of a one-piece anodically oxidized surface implant when placed with a flapless or flap protocol. Bone loss measurements on radiographs and changes in clinical probing depths 1 year post-definitive restoration

placement were recorded and compared. Fifty-two of 60 patients (implants) remained in the study at the 1-year follow-up. At the time of final evaluation, no implant was lost in either group. At the time of placement of the definitive restoration, there was a mean mesial and distal bone gain in both groups. There were no significant changes in bone levels between placement of the definitive restoration and those recorded 12 months later, and no significant differences in bone levels between the flap or flapless group at 6 or 12 months were noted. No significant differences were seen either in pocket depth or change in pocket depth at 6 and 12 months in the flapless and flap groups. It was therefore concluded that one-piece anodically oxidized surface implants, 1 year post-definitive restoration insertion, had high survival rates (100%) and stable marginal bone and probing depth levels whether a flapless or flap protocol was used for implant insertion.

**Cannizzaro G et al. (2011)**[2] evaluated the efficacy of flapless versus open flap implant placement in partially edentulous patients. 40 patients with two separate edentulous areas characterised by residual bone at least 5 mm thick and 10 mm in height had these sites randomised following a split-mouth design to receive at least one implant to each side after flap elevation or not. Implants were first placed in one site, and after 2 weeks in the other site freehand. Implants inserted with a torque >48 Ncm were immediately loaded with full occluding acrylic temporary restorations. Definitive single cemented crowns or screw-retained metal ceramic fixed dental prostheses were delivered after 2 months. Outcome measures were prosthesis and implant failures, complications, postoperative swelling and pain, consumption of analgesics, patient preference, surgical time, marginal bone level changes, and implant stability quotient (ISQ) values. There were no statistically significant differences for prosthetic and implant failures, complications, ISQ values and marginal bone levels between groups. However, flapless implant placement required significantly less operation time (17 minutes less, saving almost two-thirds of the time for implant placement), induced less postoperative pain, swelling, analgesic consumption and was preferred by patients. Mean ISQ values of both groups significantly decreased over time. Implants can be successfully placed flapless and loaded immediately, reducing treatment time and patient discomfort.

**Al-Juboori MJ et al. (2012)**[58] Compared flapless and conventional flap and the effect on crestal bone resorption during a 12 week healing period. 22 implants were placed by FL and FT in 9 patients with split mouth design; each patient received two implants, except for two patients who received four implants. A periapical radiograph was taken at implant placement, as well as 6- and 12-week intervals. Crestal bone level was compared between Flapless and Flap during these intervals and compared between intervals for each group. There was a significant difference between the bone level at implant placement and at the 6-week interval for both the Flapless and Flapped group. Hence concluded upon the study of 9 patients with 22 implants, there were no significant difference obtained in crestal bone resorption between FL and FT during a 3 month healing period.

**Tsoukaki M et al. (2012)**[59] compared a study on the placement of flapped vs. flapless dental implants utilizing clinical, radiographic, microbiological, and immunological parameters. 20 patients received 30 dental implants following a one-stage protocol. Follow-up examinations were carried out after 1, 2, 6, and 12 weeks. Peri-implant sulcus depth were significantly greater in flapped implants at both 6 and 12 postsurgical weeks. Flapped implants showed crestal bone loss whereas no bone resorption was detected around flapless implants. MMP-8 values were higher to a statistically significant level in the control group at 1 and 6 weeks after placement. In the test group, the presence of P.gingivalis was significantly higher at the 2nd postoperative week whereas the counts of T. forsythia were significantly elevated at the 1$^{st}$, 2nd and 12$^{th}$ postoperative weeks, possibly indicating an earlier formation and maturation of the peri-implant sulcus. Patients reported more pain after flapped implant placement.

**Vohra F et al. (2015)**[5] reviewed to compare the crestal bone loss (CBL) around dental implants placed in healed sites using flapped and flapless surgical techniques. The test group comprised implants placed using flapless surgery, and the control group, implants placed after reflection of a full-thickness mucoperiosteal flap. 10 clinical studies were included. In five studies, CBL around implants was comparable between the test and control groups. In four studies, implants in the test group showed significantly less CBL

compared with the control group. In one study, CBL was significantly higher in the test group than the control group.hence concuded CBL around dental implants placed in healed sites using flapped and flapless techniques is comparable.

**Salas EJ et al. (2018)[60]** compared the immediate postoperative period of participants rehabilitated with dental implants placed with a conventional technique or with a minimally invasive technique, without a mucoperiosteal flap elevation (flapless). Clinical parameters including oral hygiene, mouth opening, inflammation surgical time and analgesic consumption, as well as subjective parameters of pain and degree of satisfaction with the procedure, were evaluated. 48 implants were placed in 30 participants .Oral hygiene index, maximum interincisal opening, pain and analgesic consumption values had a significant difference between groups favoring the flapless technique at 24 h and 7 days but at the 15 days' follow-up the differences were only significant for oral hygiene and pain. Average on the degree of satisfaction was of 2.6. Participants operated for implant placement with flapless surgical technique gone through less postoperative discomfort.

# MATERIALS AND METHOD

The subjects for the study were selected from the Out Patient Department of Periodontology, Babu Banarasi Das College of Dental Sciences, BBDU, Lucknow. A total of 20 two-piece implants were placed in 11 partially edentulous subjects (5 males and 6 females; age ranging between 25-65 years). Of these, 10 implants were placed following flapless while the other 10 implants were placed following conventional and a written informed consent was obtained on the prescribed format. A strict inclusion and exclusion criteria was followed for the recruitment of the subjects:

**Inclusion criteria**

- Age range 25-65 yrs.
- Periodontally healthy patients.
- Proper oral hygiene.
- Adequate patient compliance.
- Adequate patient's availability to meet the follow-up schedule.
- Missing molar or premolar tooth in the maxilla or mandible with at least 1 year of gap after extraction.
- No contraindication to periodontal surgery.

**Exclusion criteria**

- Systemically compromised and immuno-compromised patients.
- Pregnant or lactating women.
- Alcoholic, drug abusers and smokers.
- Subjects with parafunctional habits.
- History of consumption of drugs affecting bone metabolism.
- Insufficient availability of bone.
- Any limiting vital structure at the proposed site of implant placement.

- Insufficient inter-arch distance.
- History of radiation therapy in the head and neck region.
- Known allergy/hypersensitivity to any product to be used in the study.
- History of any ridge augmentation procedure.

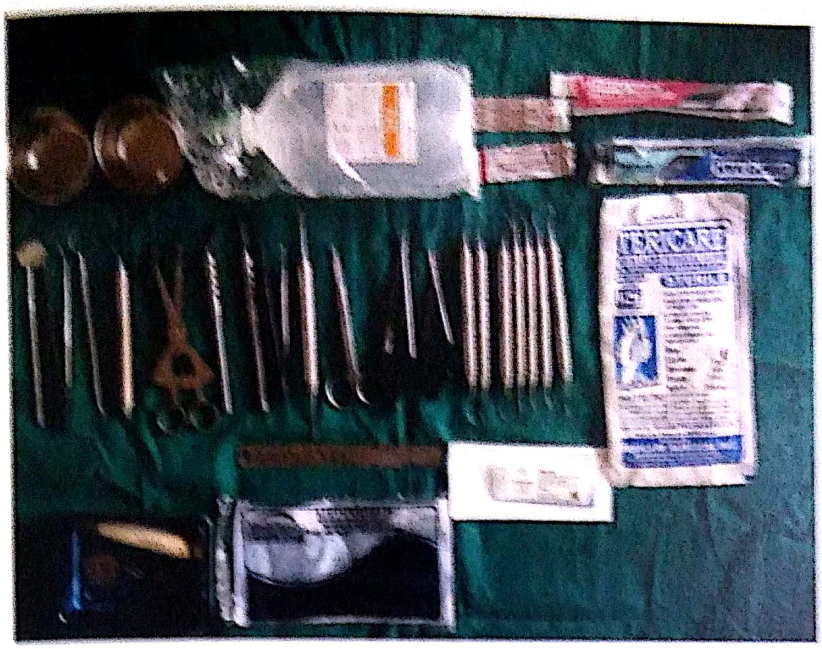
**MATERIALS:** (Plate I, II, III)

**Armamentarium for Diagnosis and Pre-clinical Assessment**

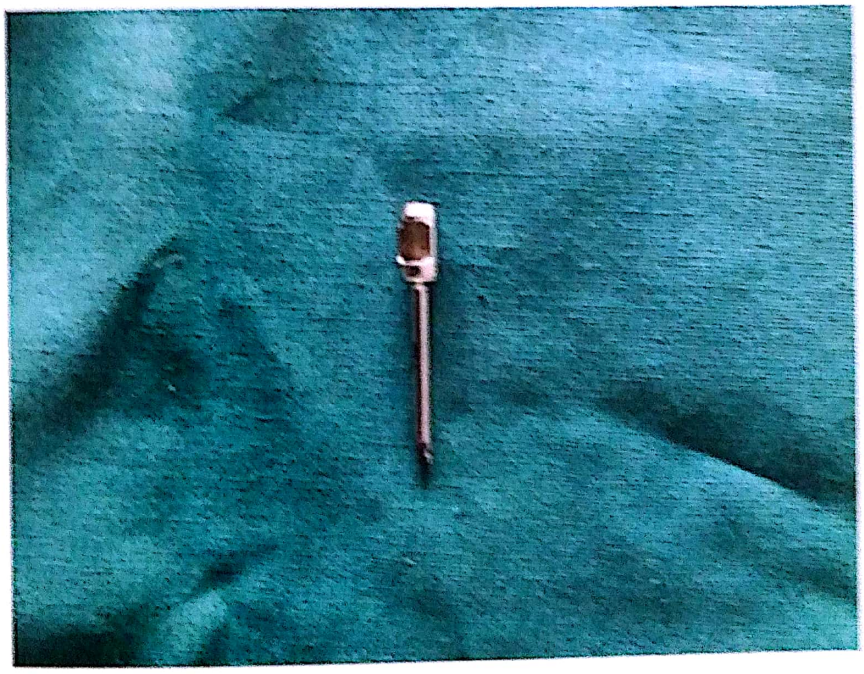
- Mouth mirror
- UNC Periodontal probe
- Tweezers
- Metallic scale
- Hard tissue caliper (GDC Marketing, India)
- Diagnostic casts
- Resonance frequency Analysis (RFA)
- Cone beam computed tomography (CBCT)

**Armamentarium for surgery**

- Local anesthesia (Xylocaine® 2% with Adrenaline)
- Syringe 3ml
- Saline
- Bard Parker Handle
- Blade (no.15,12)
- Periosteal elevator
- Tissue holding forceps
- Castroviejo scissors
- Castroviejo Needle holder
- Suture material (3-0 Silk)
- Suture cutting scissors
- Tissue punch (Plate- I)



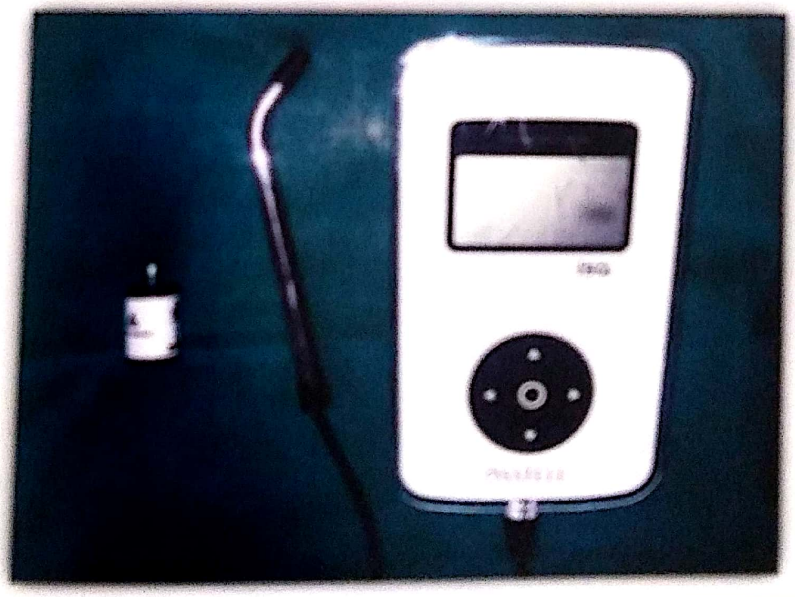
Armamentarium for Diagnosis & Surgery



Tissue Punch

Plate -I

Physiodispenser



Osstell ISQ (RFA) with Smart Peg

Plate-II


**Implant kit and Implant Fixture**

**Plate - III**

- Physiodispenser (Plate –II)
- Implant kit (Plate- III)
- Implants fixture (Plate-III)

## METHODOLOGY:

### STUDY -DESIGN

A randomized prospective study was designed to evaluate the clinical and radiological parameters in flapless and conventional delayed loading group in single tooth implant placement. Each individual were assigned as one subject with ≥ one implant sites.

The single tooth implant sites were randomly selected in either the upper or lower jaw, irrespective of posterior region. The selected patients were categorized into two groups based on flapless delayed loading and conventional delayed loading (with flap reflection).

**Conventional implant**

In Group A, 10 single tooth implants were placed after giving mid-crestal incision with conventional flap procedure, the implants were then inserted. The soft-tissue flaps were approximated around the implants and sutured with interrupted sutures. And in second stage surgery healing abutment and delayed loading after 3-4 months were performed. ( Plate IV,V,VI,VII)

**Flapless Implant Surgery**

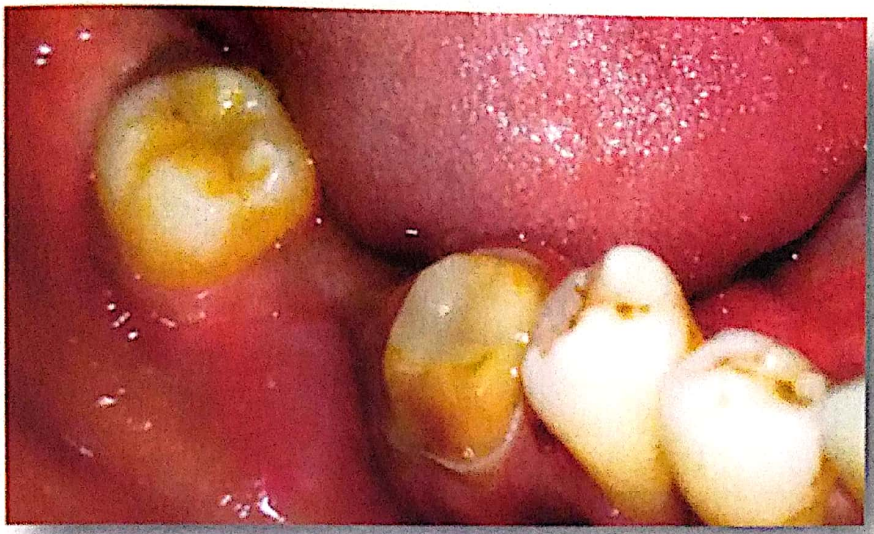
In Group B, 10 single tooth implant placed by using tissue punch flap, Implants were then inserted. In second stage surgery healing abutment and delayed loading after 3-4 months were performed. (Plate VIII, IX, X, XI)

**Pre-Operative Implant Site Assessment:**

Periapical radiograph were taken at this stage before the placement of the implant, to evaluate the implant site. The parallel cone technique with an XCP (Dentsply Rinn's XCP film holding system) device was used. Cone beam computed tomography (i-cat vision software) was used after implant placement and at 9 months.

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

# Conventional Implant



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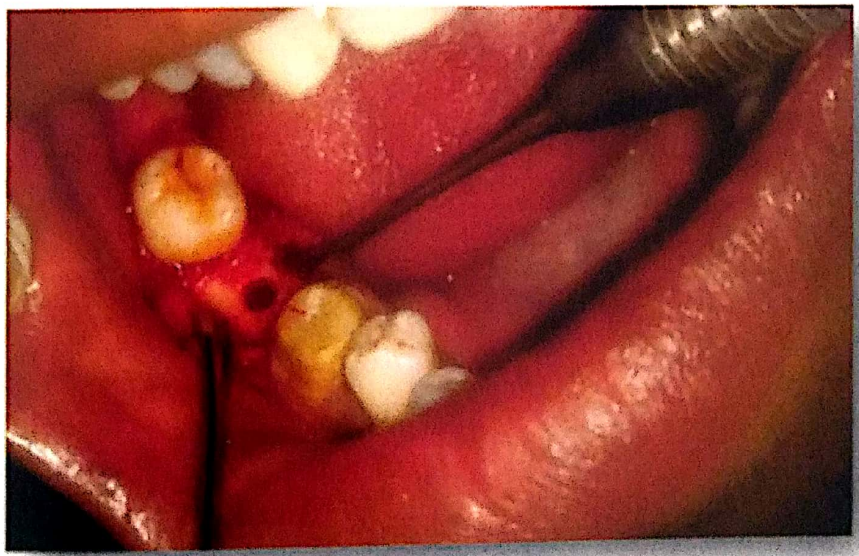
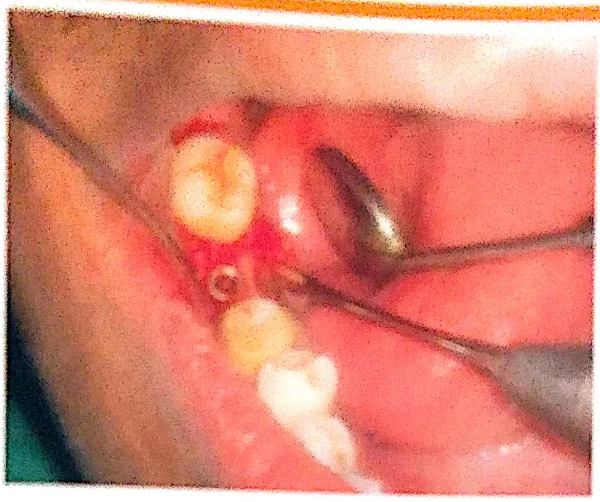
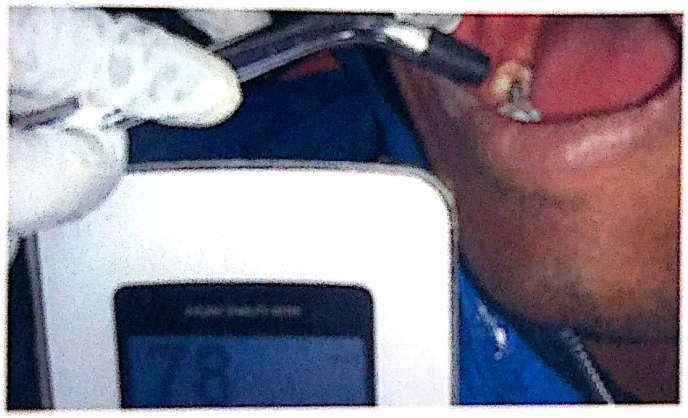


Sequential Drilling

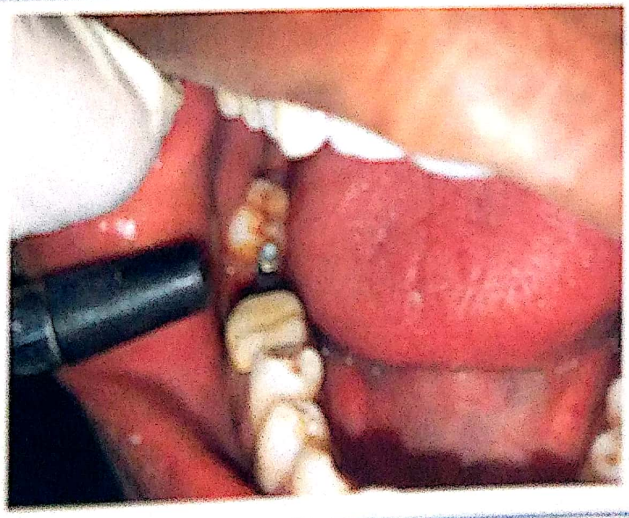
Plate- IV



Implant Placed at Crestal Level

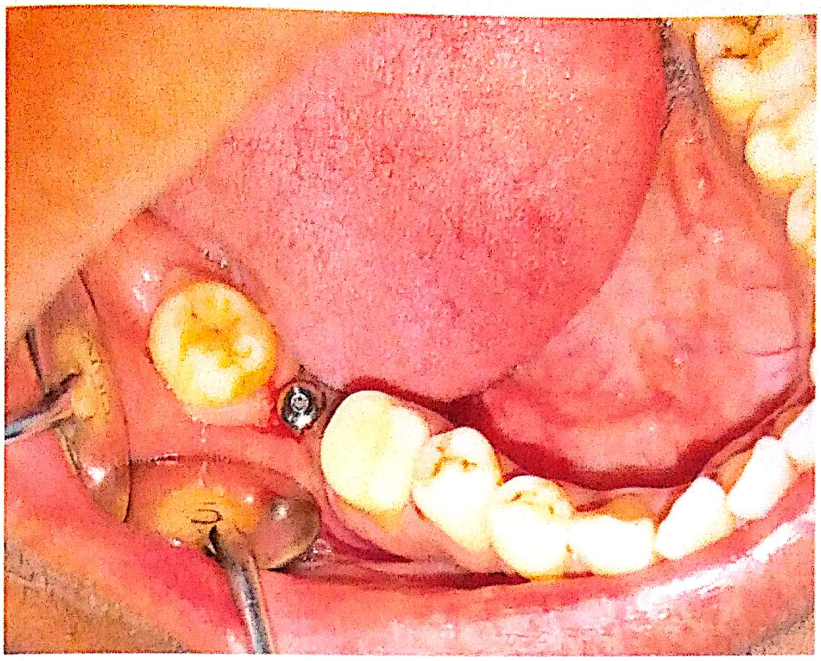


ISQ Reading on Digital Display

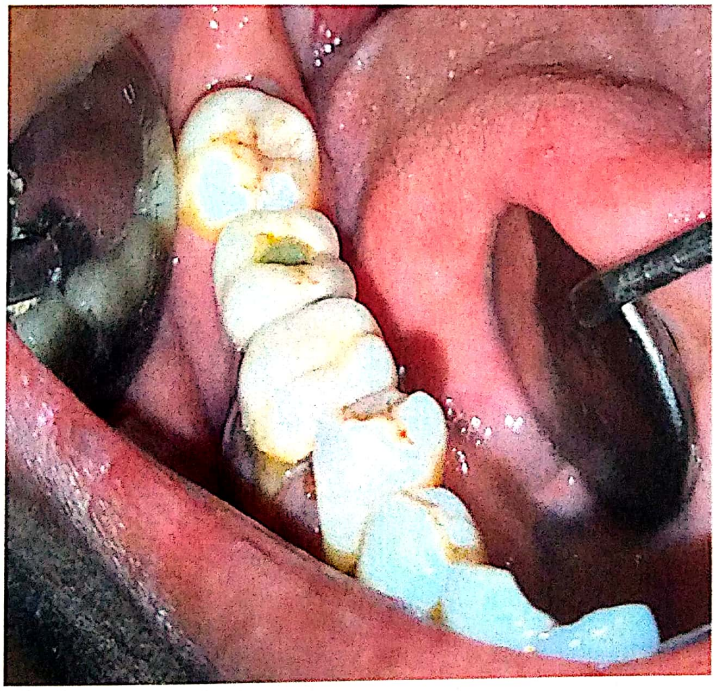


Smart Peg attached to Implant

Plate - V



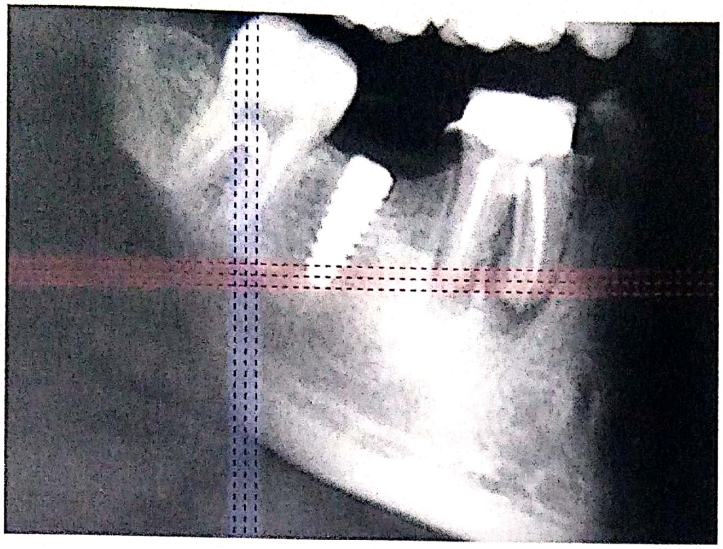
Cover Screw Replaced With Healing Abutment



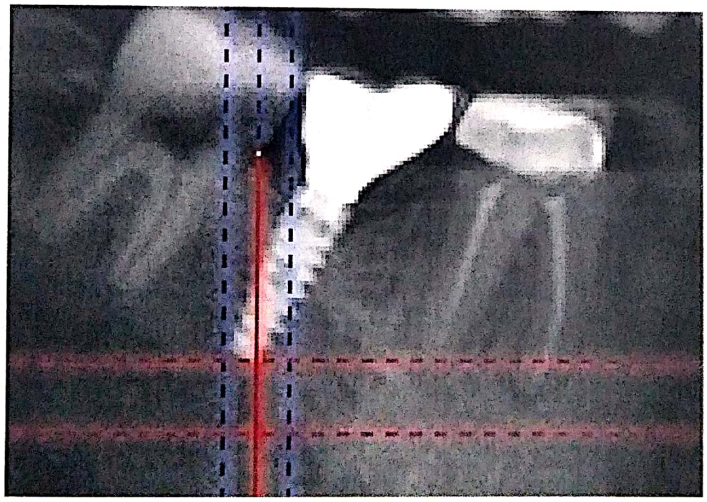
Rehabilitation with Screw Retained Prosthesis

Plate -VI

# CBCT



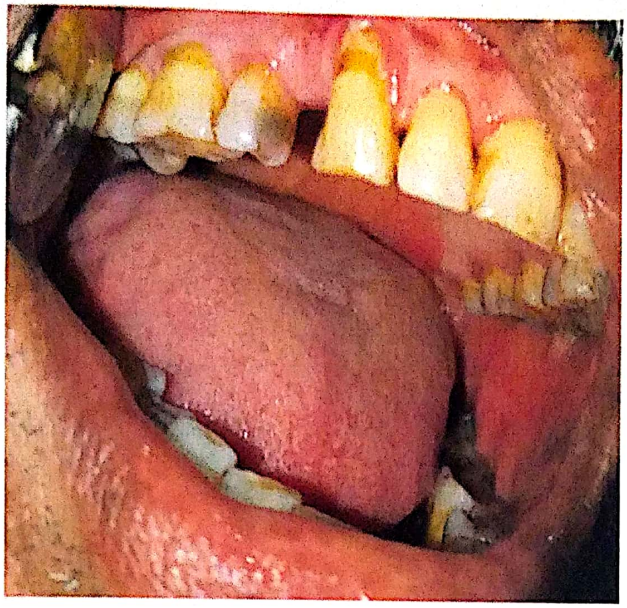
At Baseline (After implant Placement)



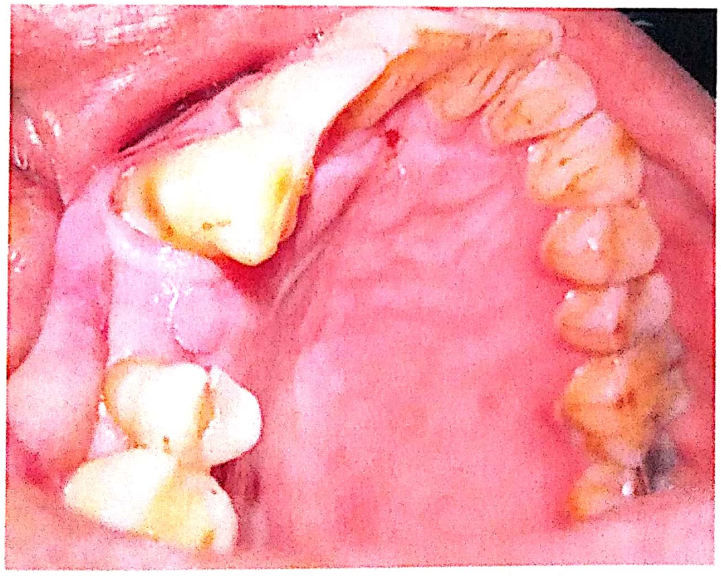
After 9 months of Implant Placement

Plate -VII

# Flapless Surgery

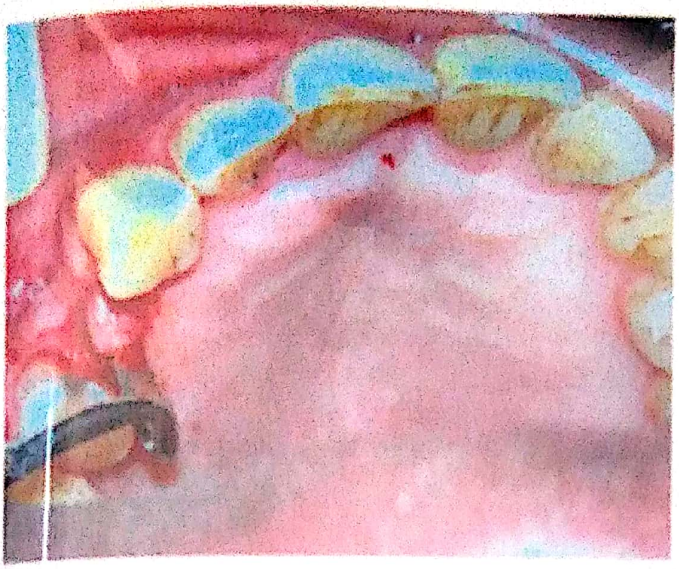


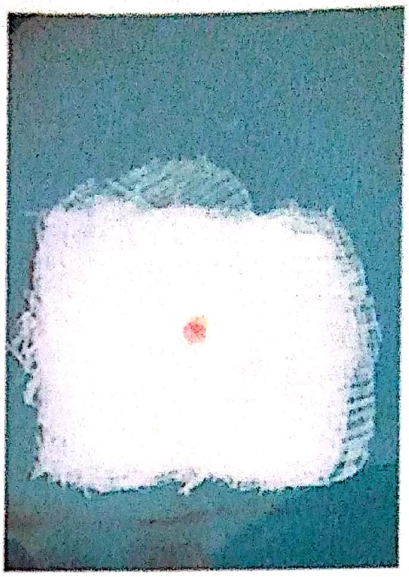
Missing 14



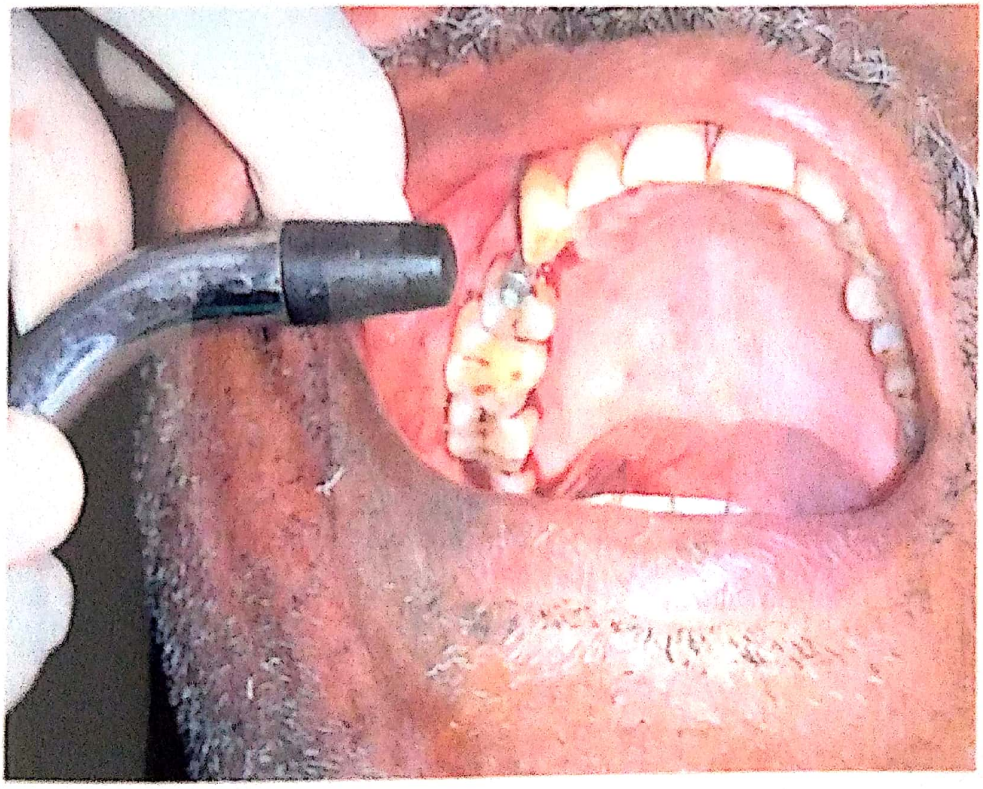
Marked With Tissue Punch

Plate -VIII



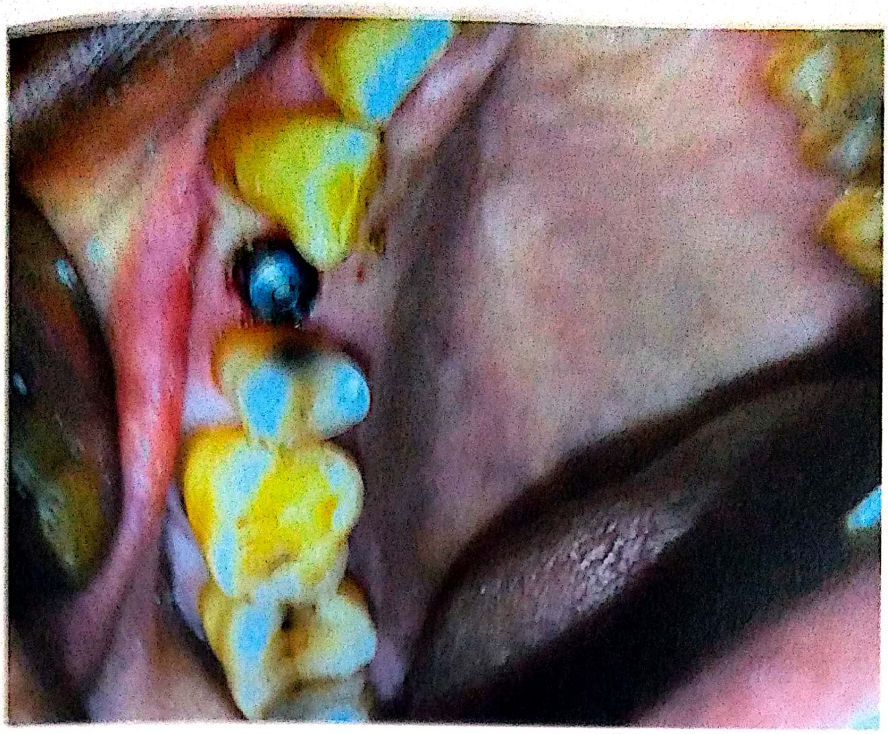


**Removal of Tissue for the Osteotomy Site**

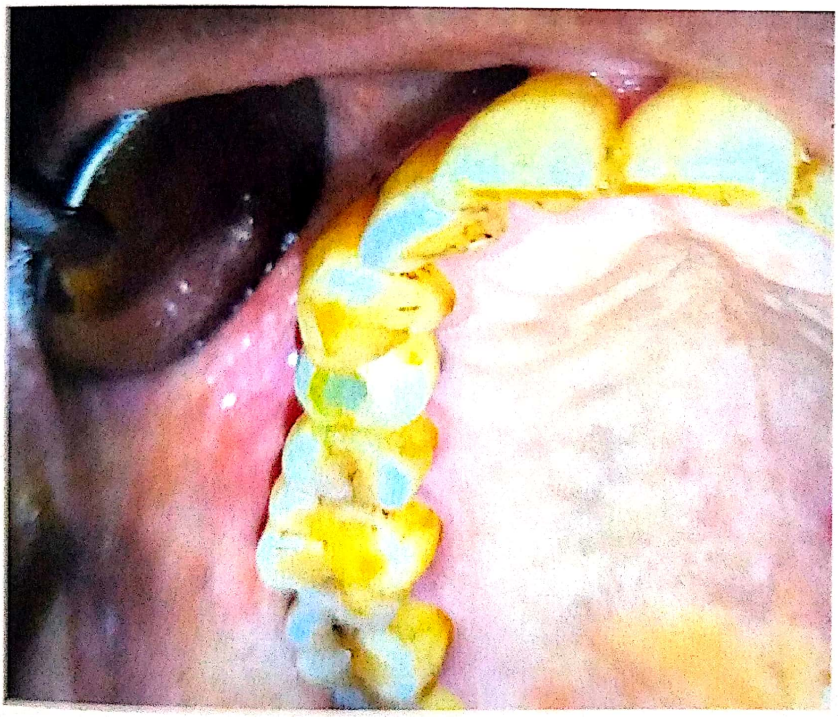


**Measuring Implant Stability Using RFA**

Plate -IX



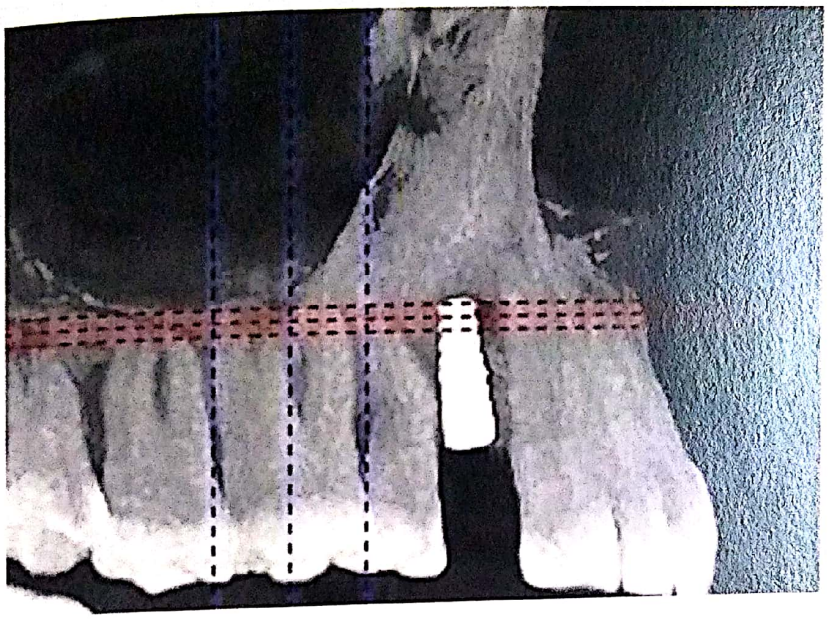
Healing Abutment Placed



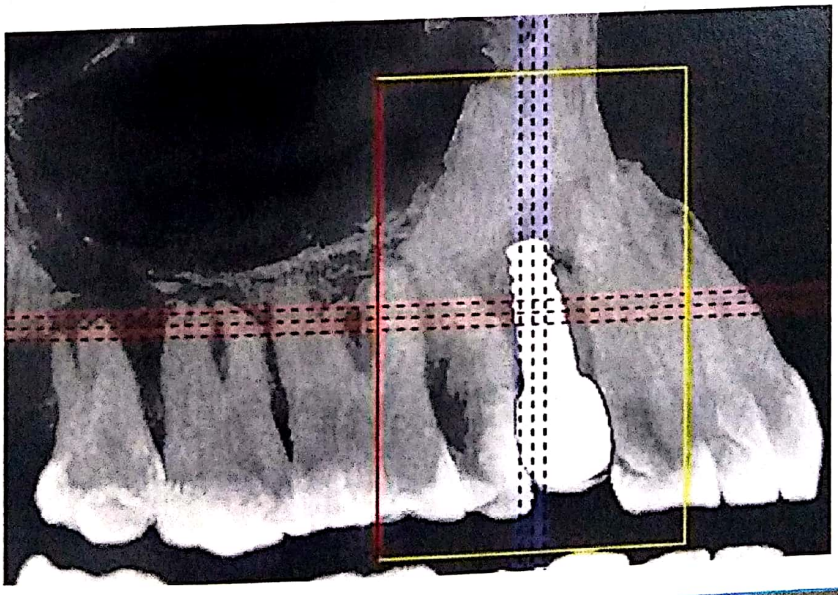
Rehabilitation with Screw Retained Prosthesis

Plate -X

# CBCT



At Baseline (After implant Placement)



After 9 months of Implant Placement

Plate -XI

**Surgical Protocol Followed**

All surgical procedures were performed under local anesthesia and strict aseptic conditions. The unit, instrument tray, patient, operating assistants were covered with sterile drapes. The surgical armamentarium including the implant kit was autoclaved. All the implants were placed at the crestal level in the posterior mandibular and maxilla region. Delayed loading protocol was followed i.e. loading was done in second stage surgery.

**Surgical Procedure**

All the 20 patients were surgically prepared with routine blood investigation and radiographic assessment. Local anesthesia was induced by infiltration with lignocaine (2%) and adrenaline (1:80,000) for both the groups.

In conventional delayed loading group after achieving profound anesthesia, the mucoperiosteal flap was elevated with a mid crestal incision. The bucco-lingual and mesio-distal implant position was partially determined by the morphology of alveolus. Following sequence was used for implant bed preparation, under copious irrigation with 0.9% Nacl solution and the light pressure:

1. Drilling with a pilot drill (2.0mm) at a speed of 1200 rpm, to the appropriate insertion depth of the selected implant.
2. Osteotomy with sequential drill 2.5 (02.5mm) at a speed of 1200 rpm, to the appropriate initial depth.
3. Osteotomy with sequential drill 2.8 (02.8mm) at a speed of 1200 rpm, to the appropriate intial depth.
4. Osteotomy with sequential drill 3.2 (03.2mm) at a speed of 1200 rpm,to the appropriate initial depth.
5. Manual tapping of the thread ( tap 03.3mm)
6. Insertion of the dental implant with help of a torque rachet with minimum torque essential for up to 35-40 Ncm.
7. Cover screw was then placed in such a way corresponding to the level of the adjacent bone, leaving the implant submerged.

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

In flapless delayed loading group, proper bone sounding, bone mapping and measurement of bone width and length and radiographic evaluations done before implant placement to avoid perforation, if the amount of bone is limited surgeon will work blindly and bone perforations may occur.

Soft tissue preparation of the implant site was done using a motor driven 3.5 mm wide circular tissue punch and 3-4mm tissue removed from the crestal area for then achieving center point for pilot drill. The implant bed was prepared following the same sequence used for the conventional implant surgery. The cover screw was then placed corresponding to the level of the adjacent bone.

Antimicrobial prophylaxis (amoxicillin 500 mg) was given one hour before surgery and continued thrice daily for 7 days. Post surgical analgesics (Paracetamol 500 mg + Acceclofenac 100 mg) were prescribed thrice daily for one week and oral hygiene instructions were given. Chlorhexidine mouthwash 0.2% also prescribed for twice daily. In conventional group suture was removed one week after the implant surgery. After 6 months of implant placement, the patients were subjected to a second stage surgical procedure in both the group. Healing abutments were mounted on to the implants in order to condition the peri-implant soft tissues for 7-10 days. This healing abutment connection was done by a simple midcrestal incision.

**Clinical parameters**

Assessment of soft tissue at the implant site was performed after crown cementation at 6th and 9$^{th}$ month by a single examiner. At the follow up visits, the following parameter was assessed.

- Papilla index (Jemt T 1997)

Hard tissue assessment at the site of implant were performed at baseline (after the implant placement), and at 9 months. The following parameters were assessed

- Crestal bone loss
- Implant stability

**Evaluation method**

**Papilla index[4] : The Jemt index 1997 [61]** (Score 0 to 4) was used to assess the size of the interproximal gingival papillae adjacent to single implant restoration. Measurement were made from the reference line connecting the highest gingival curvatures of implant crown restoration and adjacent tooth on buccal side.

Score 0: No papilla was present

Score 1: Less than half the height of papilla

Score 2: Half the height of the papilla

Score 3: Complete fill

Score 4: Hyperplastic / Overfill

**IMPLANT STABILITY:**

It was measured in implant stability quotient ISQ units using fourth generation Resonance Frequency Analyser Osstell ISQ®. (Plate II) Mobile implants were considered as being lost and were removed.

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 at each recall visit; 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), which is scaled from 1 to 100 (The higher the number, the greater the stability).

Following is the clinical translation of ISQ Values:-

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

## RADIOGRAPHIC EXAMINATION

Cone beam computed tomography were taken at baseline and after 9 months to assess the 3 dimensional changes in crestal bone loss around an implant. The crestal bone loss was measured in millimeter (mm) from a fixed reference point on the implant i.e. implant shoulder to the most coronal position of crestal bone contacting the implant on its mesial and distal aspect.

**Measurements:**

The Marginal bone height of each fixture was measured mesially and distally by using fixture threads as an internal dimensional reference.

**Mesial**: Distance from the first thread (coronal) on the implant fixture to the most coronal point on the mesial alveolar bone crest.

**Distal:** Distance from the first thread (coronal) on the implant fixture to the most coronal point on the mesial alveolar bone crest.

**Prosthetic protocol**

After 6 months second stage surgery was carried out and after 7-10 days of gingival collar placement. 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 then tightened and the remaining portion of screw retained prosthesis was then restored with composite. Final prosthesis was also kept in centric contact with no excursive contacts. Patient appointment was rendered for check up.

## STATISTICAL ANALYSIS

Data were summarised as Mean ± SE (standard error of the mean). Pre and post group were compared by paired t test. Pre to post change (post-pre) in outcome measures of two independent groups were compared by independent Student's t test. Discrete (categorical) groups were compared by chi-square ($\chi^2$) test. A two-tailed ($\alpha$=2) $p<0.05$ was considered statistically significant. Analyses were performed on SPSS software (Windows version 17.0).

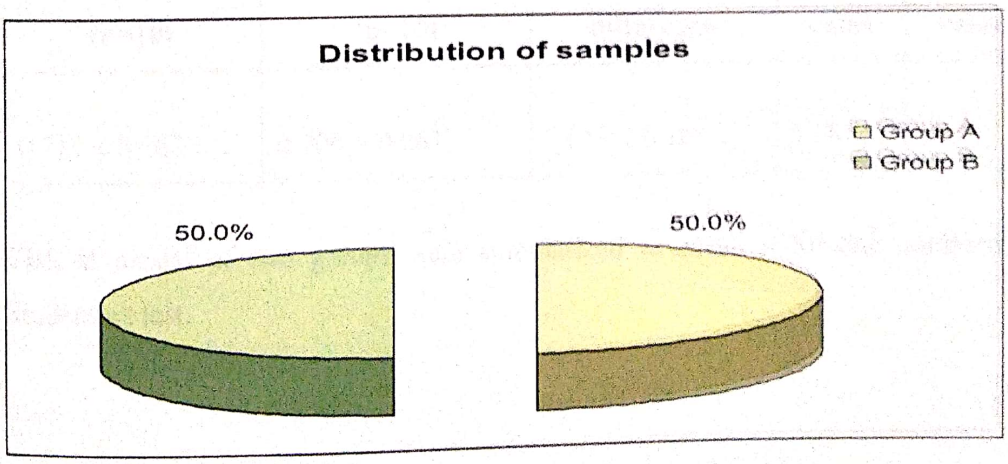
# RESULTS AND OBSERVATIONS

## RESULTS AND OBSERVATIONS

The present clinico-radiographic study compares soft and hard tissue parameters in flapless versus conventional implant surgery. Total 20 sites (samples) were selected and randomized equally into two groups and treated with conventional implant surgery (*Group A, n=10*) or flapless implant surgery (*Group B, n=10*) (Table 1 and Fig. 1). The outcome measures of the study were hard tissue i.e. Crestal Bone Loss (CBL), soft tissue i.e. Papillary Index (PPI) and International Stability Quotient (ISQ). The CBL and ISQ were assessed at pre treatment i.e. at the time of placement of implant (or at the time of implant) and 9 month post treatment whereas PPI were assessed at 6 and 9 month post treatment. The CBL were measured in millimetre (mm). The objective of the study was to compare the outcome measures between the two groups.

**Table 1: Group allocation and distribution of samples**

| Treatment/Intervention | Group | No of samples (n=20) (%) |
|---|---|---|
| Conventional implant surgery | Group A | 10 (50.0) |
| Flapless implant surgery | Group B | 10 (50.0) |




**Graph 1: Distribution of samples in two groups.**

## OUTCOME MEASURES

### CRESTAL BONE LOSS (CBL)

In both groups, the pre treatment CBL at both mesial and distal site of implant was 0.00 mm and thus not comparable (due to 0 mean and 0 variance) and hence excluded from the analysis.

**1. Mesial**

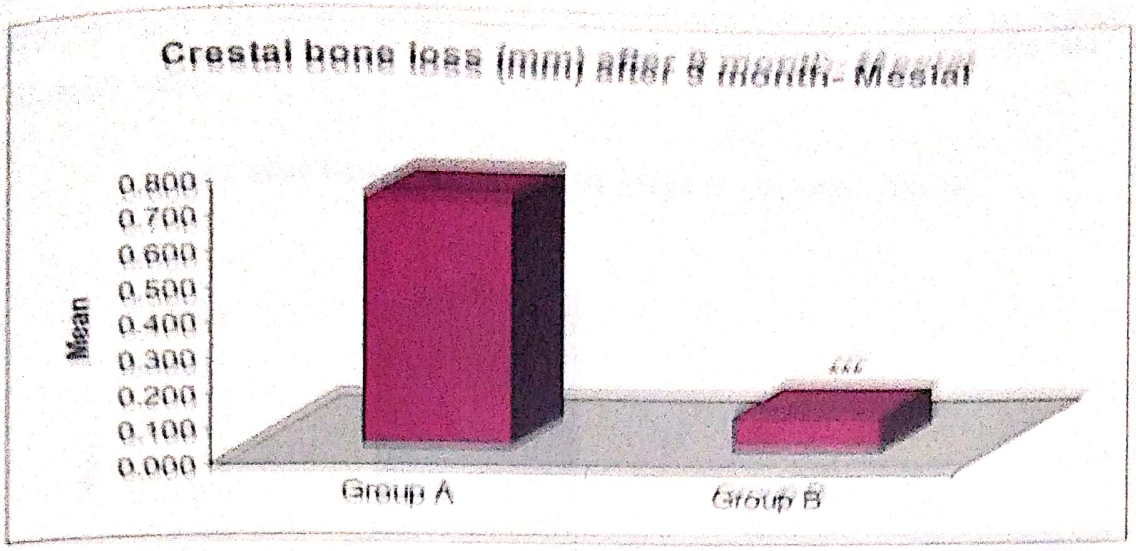
The 9 month post CBL at mesial site of two groups is summarized in Table 3 and also shown in Fig. 4. The CBL at mesial site in Group A ranged from 0.40 to 1.10 mm with mean (± SE) 0.712 ± 0.082 mm and median 0.66 mm whereas in Group B, it ranged from 0.00 to 0.50 mm with mean (± SE) 0.100 ± 0.067 mm and median 0.00 mm. After 9 month, mean CBL at mesial site lowered comparatively in Group B than Group A.

Comparing the 9 month post mean CBL at mesial site of two groups, Student's t test showed significantly different and lower (86.0%) CBL at mesial in Group B as compared to Group A (0.712 ± 0.082 vs. 0.100 ± 0.067, difference=0.612 ± 0.106, 95% CI=0.39 to 0.84, t=5.78, p<0.001) (Table 3 and Fig. 4).

**Table 2: CBL at mesial (Mean ± SE) of two groups after 9 month**

| Group A (n=10) | Group B (n=10) | Mean difference | t value | p value |
|---|---|---|---|---|
| 0.712 ± 0.082 | 0.100 ± 0.067 | 0.612 ± 0.106 | 5.78 | <0.001 |

CBL at mesial of two groups were summarized as Mean ± SE and compared by Student's t test.




***p<0.001- as compared to Group A

**Graph 2: Comparison of mean CBL at mesial of two groups after 9 month.**

**II. Distal**

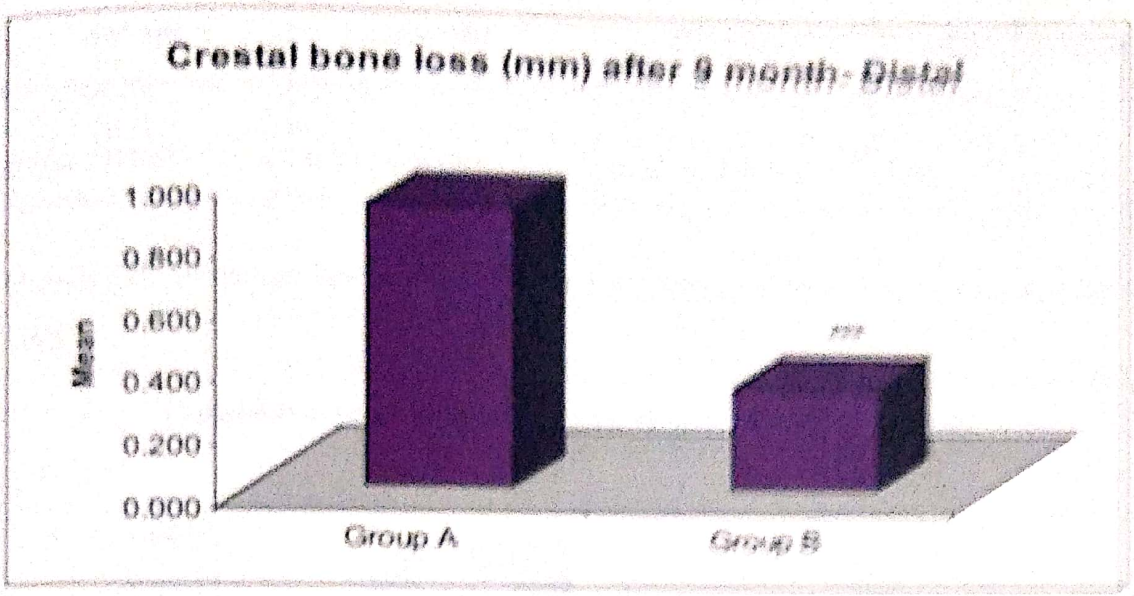
The 9 month post CBL at distal site of two groups is summarized in Table 4 and also shown in Fig. 5. The CBL at distal site in Group A ranged from 0.60 to 1.13 mm with mean (± SE) 0.903 ± 0.059 mm and median 0.80 mm whereas in Group B, it ranged from 0.00 to 0.80 mm with mean (± SE) 0.330 ± 0.094 mm and median 0.50 mm. After 9 month, mean CBL at distal lowered comparatively in Group B than Group A.

Comparing the 9 month post mean CBL at distal of two groups, Student's t test showed significantly different and lower (63.5%) CBL at distal site in Group B as compared to Group A (0.903 ± 0.059 vs. 0.330 ± 0.094, difference=0.573 ± 0.111, 95% CI=0.34 to 0.81, t=5.15, p<0.001) (Table 4 and Fig. 5).

**Table 3: CBL at distal site (Mean ± SE) of two groups after 9 month**

| Group A (n=10) | Group B (n=10) | Mean difference | t value | p value |
|---|---|---|---|---|
| 0.903 ± 0.059 | 0.330 ± 0.094 | 0.573 ± 0.111 | 5.15 | <0.001 |

CBL at distal site of two groups were summarized as Mean ± SE and compared by Student's t test.




***p<0.001- as compared to Group A

**Graph 3: Comparison of mean CBL at distal site of two groups after 9 month.**

### III. Overall

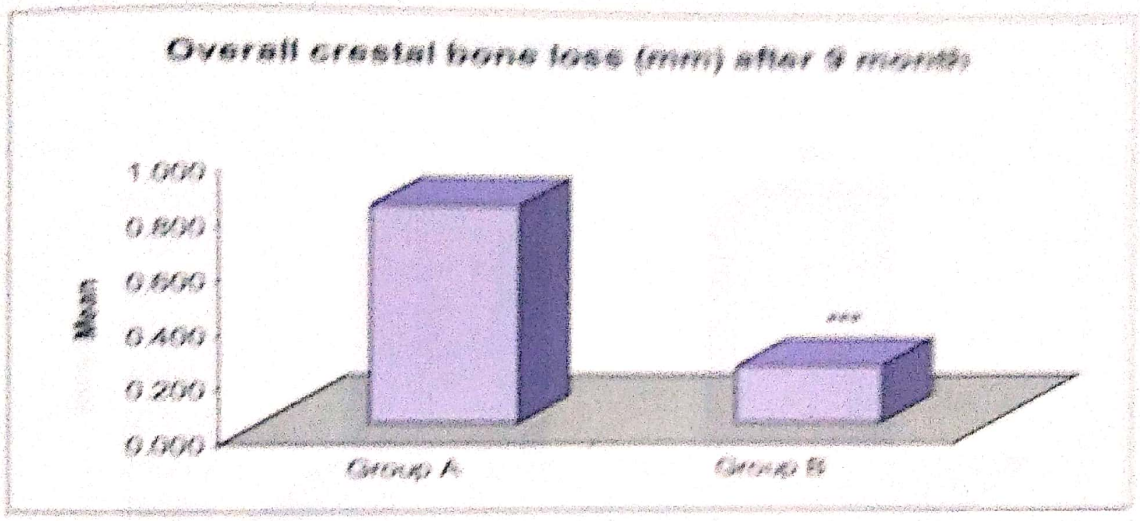
The 9 month post overall or total (average of mesial and distal) CBL of two groups is summarized in Table 5 and also shown in Fig. 6. The overall CBL in Group A ranged from 0.50 to 0.95 mm with mean (± SE) 0.808 ± 0.049 mm and median 0.85 mm whereas in Group B, it ranged from 0.00 to 0.65 mm with mean (± SE) 0.215 ± 0.061 mm and median 0.25 mm. After 9 month, overall mean CBL lowered comparatively in Group B than Group A.

Comparing the 9 month post overall mean CBL of two groups, Student's t test showed significantly different and lower (73.4%) overall CBL in Group B as compared to Group A (0.808 ± 0.049 vs. 0.215 ± 0.061, difference=0.593 ± 0.078, 95% CI=0.43 to 0.76, t=7.59, p<0.001) (Table 5 and Fig. 6).

**Table 4: Overall CBL (Mean ± SE) of two groups after 9 month**

| Group A (n=10) | Group B (n=10) | Mean difference | t value | p value |
|---|---|---|---|---|
| 0.808 ± 0.049 | 0.217 ± 0.063 | 0.591 ± 0.078 | 7.59 | <0.001 |

Overall CBL of two groups were summarized as Mean ± SE and compared by Student's t test.




***p<0.001- as compared to Group A

**Graph 4: Comparison of overall mean CBL of two groups after 9 month.**

## B. IMPLANT STABILITY QUOTIENT (ISQ)

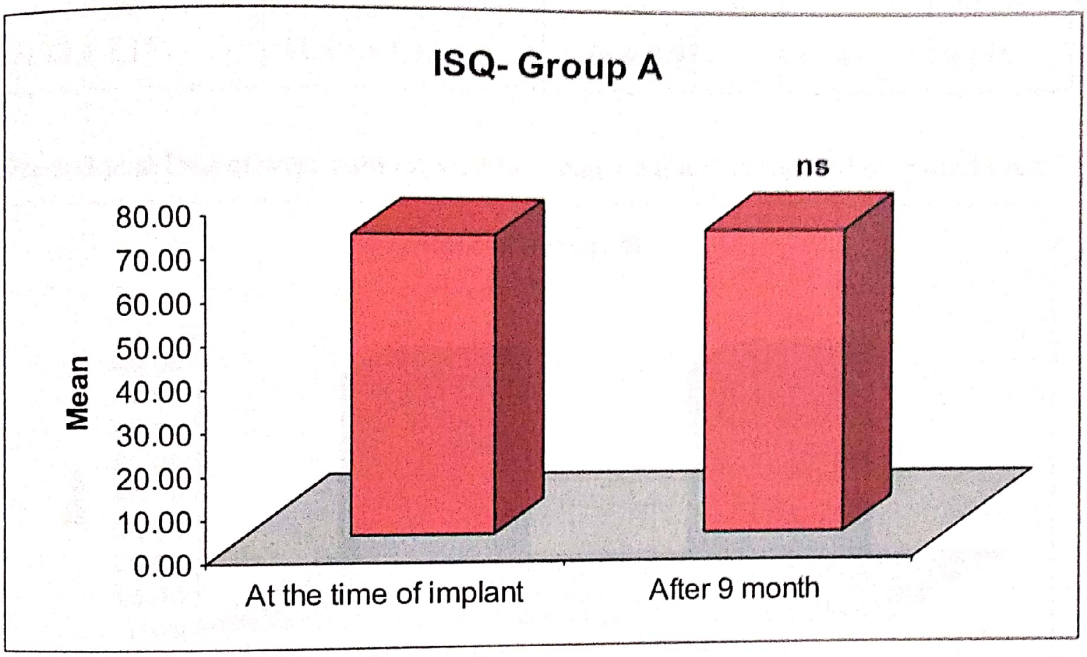
### 1. Group A

The pre (at the time of implant) and post (after 9 month) ISQ of Group A is summarized in Table 6 and also depicted in Fig. 7. The ISQ at the time of implant ranged from 53 to 76 with mean (± SE) 69.80 ± 2.18 and median 73 whereas after 9 month it ranged from 62 to 79 with mean (± SE) 71.40 ± 1.81 and median 72. The mean ISQ increased slightly at post as compared to pre. Comparing the pre and post ISQ, paired t test showed similar ISQ between the two periods (69.80 ± 2.18 vs. 71.40 ± 1.81, difference=1.60 ± 1.63, 95% CI=-2.10 to 5.30, t=0.98, p=0.353) though it increased 2.2% at post as compared to pre (Table 6 and Fig. 7).

**Table 5: Pre and post ISQ (Mean ± SE) of Group A**

| At the time of implant (n=10) | After 9 month (n=10) | Mean change (Post-Pre) | t value | p value |
|---|---|---|---|---|
| 69.80 ± 2.18 | 71.40 ± 1.81 | 1.60 ± 1.63 | 0.98 | 0.353 |

Pre and post ISQ were summarized as Mean ± SE and compared by paired t test.




$^{ns}p>0.05$- as compared to At the time of implant

**Graph 5: Pre and post mean ISQ of Group A.**

**II. Group B**

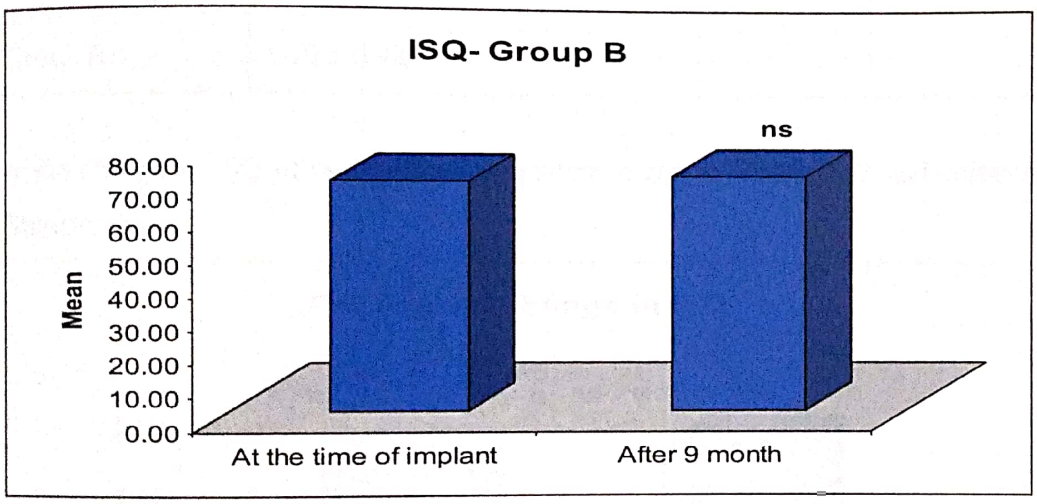
The pre (at the time of implant) and post (after 9 month) ISQ of Group B is summarized in Table 7 and also depicted in Fig. 8. The ISQ at the time of implant ranged from 65 to 76 with mean (± SE) 69.70 ± 1.15 and median 69 whereas after 9 month it ranged from 68 to 79 with mean (± SE) 71.40 ± 1.11 and median 71. The mean ISQ increased slightly at post as compared to pre. Comparing the pre and post ISQ, paired t test showed similar ISQ between the two periods (69.70 ± 1.15 vs. 71.40 ± 1.11,

difference=1.70 ± 0.98, 95% CI=0.51 to 3.91, t=1.74, p=0.116) though it increased 2.4% at post as compared to pre (Table 7 and Fig. 8)

**Table 6: Pre and post ISQ (Mean ± SE) of Group B**

| At the time of implant (n=10) | After 9 month (n=10) | Mean change (Post-Pre) | t value | P value |
|---|---|---|---|---|
| 69.70 ± 1.15 | 71.40 ± 1.11 | 1.70 ± 0.98 | 1.74 | 0.116 |

Pre and post ISQ of were summarized as Mean ± SE and compared by paired t test.




$^{ns}$p>0.05- as compared to At the time of implant

**Graph 6: Pre and post mean ISQ of Group B.**

**III. Group A vs. Group B**

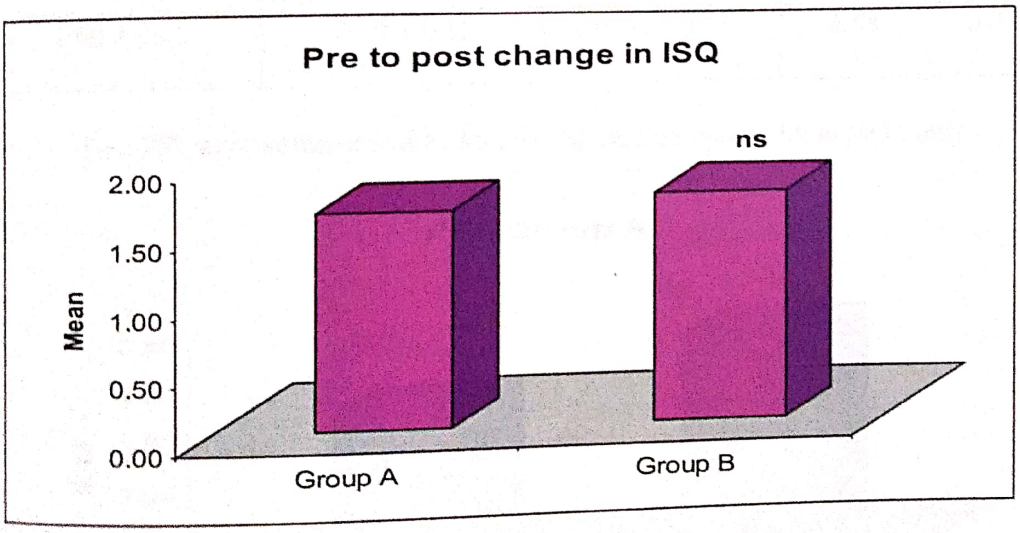
The pre to post mean change in ISQ (i.e. mean difference at the time of implant and after 9 month) of two groups were further summarized in Table 8 and also shown in Fig. 9. In Group A, the pre to post change in ISQ ranged from -6 to 11 with mean (± SE) 1.60 ± 1.63 and median 1 whereas in Group B, it ranged from -6 to 5 with mean (± SE) 1.70 ± 0.98 and median 2. The pre to post mean change in ISQ of Group B was slightly

higher than Group A. Comparing the pre to post mean change in ISQ of two groups, Student's t test showed similar change in ISQ between the two groups (1.60 ± 1.63 vs. 1.70 ± 0.98, difference=0.10 ± 1.91, 95% CI=-3.90 to 4.10, t=0.05, p=0.959) though it was 5.9% higher in Group B as compared to Group A (Table 8 and Fig. 9).

**Table 7: Pre to post mean change in ISQ (Mean ± SE) of two groups**

| Group | Mean change (Post-Pre) | t value | p value |
|---|---|---|---|
| Group A | 1.60 ± 1.63 | 0.05 | 0.959 |
| Group B | 1.70 ± 0.98 | | |

Mean change in ISQ of two groups were summarized as Mean ± SE and compared by Student's t test.




nsp>0.05- as compared to Group A

**Graph 7: Pre to post mean change in ISQ of two groups.**

## C. PAPPILARY INDEX (PPI)

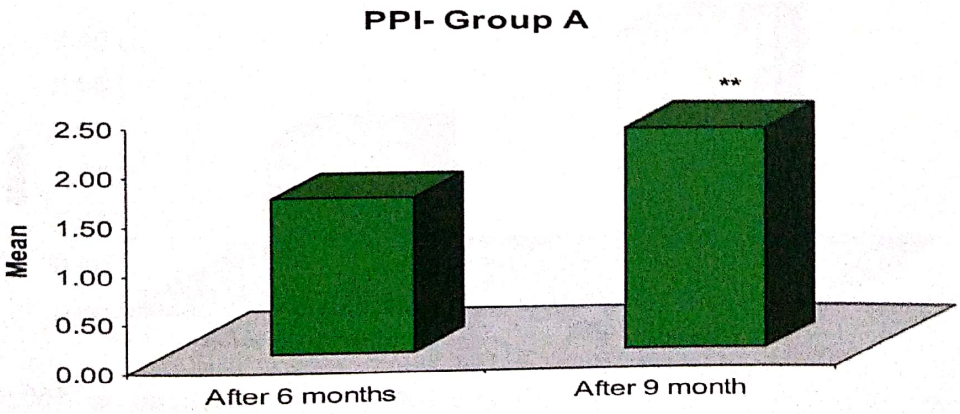
### I. Group A

The post (after 6 and 9 month) PPI of Group A is summarised in Table 9 and also shown in Fig. 10. The PPI after 6 month ranged from 1 to 3 with mean (± SE) 1.60 ± 0.22 and median 2 whereas after 9 month it ranged from 2 to 3 with mean (± SE) 2.30 ± 0.15 and median 2. The mean PPI increased comparatively at 9 month as compared to 6 month. Comparing the post PPI of two periods, paired t test showed significant increase (30.4%) in PPI at 9 month as compared to 6 month (1.60 ± 0.22 vs. 2.30 ± 0.15, difference=0.70 ± 0.15, 95% CI=0.35 to 1.05, t=4.58, p=0.001) (Table 9 and Fig. 10).

**Table 8: Post PPI (Mean ± SE) of Group A**

| After 6 month (n=10) | After 9 month (n=10) | Mean change (9 month-6 month) | t value | p value |
|---|---|---|---|---|
| 1.60 ± 0.22 | 2.30 ± 0.15 | 0.70 ± 0.15 | 4.58 | 0.001 |

Post PPI were summarised as Mean ± SE and compared by paired t test.




**p<0.01- as compared to After 6 month

**Graph 8: Pre and post mean PPI of Group A.**

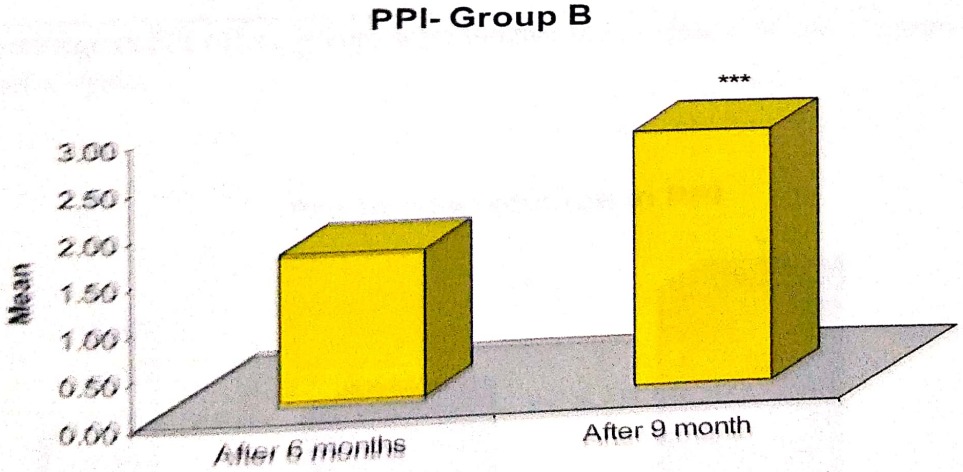
**II. Group B**

The post (after 6 and 9 month) PPI of Group B is summarised in Table 10 and also depicted in Fig. 11. The PPI after 6 month ranged from 1 to 2 with mean (± SE) 1.60 ± 0.16 and median 2 whereas after 9 month it ranged from 2 to 3 with mean (± SE) 2.80 ± 0.13 and median 3. The mean PPI increased comparatively at 9 month as compared to 6 month. Comparing the post PPI of two periods, paired t test showed significant increase (42.9%) in PPI after 9 month as compared to after 6 month (1.60 ± 0.16 vs. 2.80 ± 0.13, difference=1.20 ± 0.13, 95% CI=0.90 to 1.50, t=9.00, p<0.001) (Table 10 and Fig. 11).

**Table 9: Post PPI (Mean ± SE) of Group B**

| After 6 month (n=10) | After 9 month (n=10) | Mean change (9 month-6 month) | t value | p value |
|---|---|---|---|---|
| 1.60 ± 0.16 | 2.80 ± 0.13 | 1.20 ± 0.13 | 9.00 | <0.001 |

Post PPI were summarised as Mean ± SE and compared by paired t test.




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

*Graph 9: Pre and post mean PPI of Group B.*

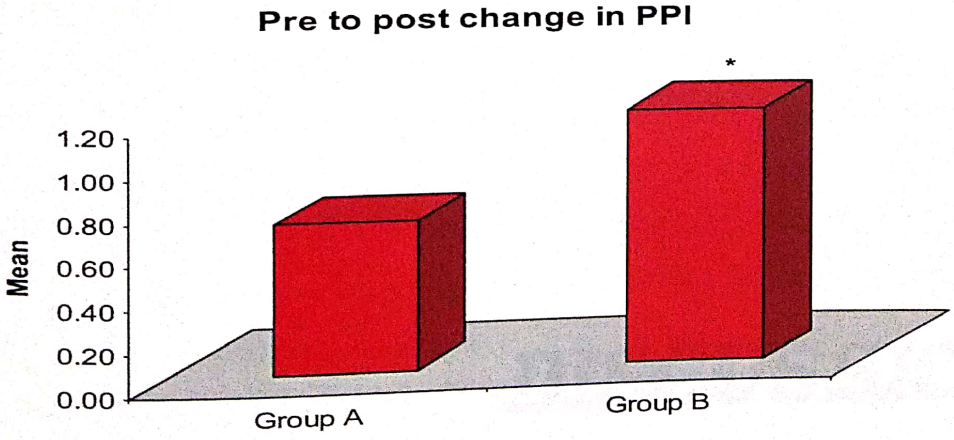
### III. Group A vs. Group B

The post mean change/increase in PPI (i.e. mean difference after 6 month and after 9 month) of two groups were further summarised in Table 11 and also depicted in Fig. 12. In Group A, the change in PPI ranged from 0 to 1 with mean (± SE) 0.70 ± 0.15 and median 0 whereas in Group B, it ranged from 1 to 2 with mean (± SE) 1.20 ± 0.13 and median 1. The mean change in PPI of Group B was comparatively higher than Group A. Comparing the mean change/increase in PPI of two groups, Student's t test showed significantly different and higher change/increase (41.7%) in PPI of Group B as compared to Group A (0.70 ± 0.15 vs. 1.20 ± 0.13, difference=0.50 ± 0.20, 95% CI=0.07 to 0.93, t=2.47, p=0.024) (Table 11 and Fig. 12).

**Table 10: Post mean change in PPI (Mean ± SE) of two groups**

| Group | Mean change (9 month-6month) | t value | P value |
|---|---|---|---|
| Group A | 0.70 ± 0.15 | 2.47 | 0.024 |
| Group B | 1.20 ± 0.13 | | |

Mean change in PPI of two groups were summarised as Mean ± SE and compared by Student's t test.




*p<0.05- as compared to Group A

**Graph 10: Pre to post mean change in PPI of two groups.**

# DISCUSSION

The aim of todays dentistry is to return back the oral health of patient effectively. Implants are promising for hopeless teeth. The single tooth implant survival rates have progressively improved.[62] The outcome of these implants can be assesed on the basis of aesthetics, soft and hard tissue changes, patient satisfaction and complications. With advancement in implant dentistry, more progressive treatment strategies have developed either in placement or loading of the implants.

According to Degidi M et al.(2008) clinician and patient dependent factors may play an important role in the aesthetic outcome of the single tooth implants.[63] Clinician dependent factors were included proper three dimensional implant positions and angulation, as well as appropriate contour of the provisional restoration, as well as patient dependent factors were included bone level, hard and soft tissue relationship, bone thickness, and soft tissue biotype.

Once the tooth is lost replicating the papilla at the original level is a challenge. Similarly, prevention of any type of crestal bone loss is a requisite. Implants are conventionally placed after flap reflection to visualize the bone sufficiently in order to avoid perforation of critical anatomical structures. The other method can be a flapless entry for implants minimizing the surgical flap for soft tissue healing and patient comfort.

Despite the long standing and successful use of conventional flap approach for the surgical placement of dental implants, this technique had been associated with several disadvantages. Acc. to Oh TJ (2006), Fortin T (2006),Hunt BW (1996) Chief disadvantage among these is a loss of alveolar crest bone due to decreased supraperiosteal blood supply because of raising the tissue flap during the surgical procedure.[11,50,64] Additional concerns include postoperative blood loss and hemorrhage, esthetically displeasing soft tissue.

To overcome these disadvantages flapless implant surgery was introduced. Flapless implant surgery is thought to be a procedure with many limitations, including the inability to save the keratinized mucosa because a tissue punch removes some of this tissue; a lack of proper depth of osteotomy assessment as it is difficult to see lines on the drill at the bone crest; an inability to assess the location of the implant because there is no direct visualization of the bone; and an inability to correct peri-implant defects as

they are not exposed during surgery. As a result, guidelines on the flapless procedure were that it should be used only when the bone has abundant width and when the soft tissue has sufficient amounts of keratinized mucosa. Following the above mentioned guidelines the flapless technique can be used.[6, 64]

Acc. to Hassan AF et al.(2016) advantages of flapless over flapped technique is that it require less time for placement of implant. This may be due to:

- It does not requires flap to be elevated (which reduces time of incision, flap elevation as well as reflection during the whole course of surgery)
- There was no need for suturing in flapless surgical procedure.
- The flapless procedure was less invasive than the flapped one so there was less trauma to the soft and hard tissue and that was leading to less bleeding in the surgical field that resulted rationally in faster and more comfortable work (less time required for blood suction and dryness of the surgical field).[65]

The crestal incisions, including the papilla, allowes a complete overview of the edentulous alveolar ridge furthermore, primary wound closure can also be achieved.[66] It becomes difficult to achieve primary closure of the peri-implant gingival wound margin when a tissue-punch flapless is used to expose the alveolar bone. Implants can be placed 2-3 mm below the gingival margin to achieve the crown emergence profile, but when the implants is placed by flapless technique in thin gingival tissue, this rule cannot be achieved unless the implants has been deeply seated.

Many authors found that the bulk amount of bone loss was between fixture insertion and prosthesis connection (the healing period). It is interesting, therefore, to start examination of the crestal bone loss at fixture insertion.[26, 67, 68, 69]

Present study was conducted to evaluate the clinico-radiographic study on soft and hard tissue parameters in conventional versus flapless implant surgery and to compare the outcome measures between the two groups

## CRESTAL BONE LOSS (CBL):-

### PROXIMAL ASPECTS

Crestal bone loss measurements at implants placement showed no significant difference between the two flaps groups which was 0.00 mm and thus not comparable (due to 0 mean and 0 variance). This means that the implants in the flapless and flap groups had been placed at the same level to the crestal bone.

The result of the present study showed CBL at mesial site of two groups summarized in table 3; The CBL in group A ranged from 0.40- 1.10mm, whereas in group B ranged from 0.00- 0.50mm and showed significantly different and lesser CBL in group B as compared to group A ,9 months post implant placement.

Similarly, On the distal site of two groups summarized in table 4; CBL in group A ranged from 0.60-1.13mm, whereas in group B, it ranged from 0.00-0.80 mm and showed significantly different and lesser CBL in group B as compared to group A nine months post implant placement.

In a similar study evaluated by Job S et al (2008) on mesial side, the mean change for flapless method was significantly lower than with flap method. On the distal site, the mean change for flapless method was significantly lower than with flap method. [54]

Similar study assessed by Gupta R et al. (2017) showed that on both proximal sides, the mean change from 0 months, 6 weeks, 12 weeks and 6 months for flapless method was significantly lower than with traditional flap method (+0,07 against +0.26 mm on mesial side and +0.15 against +0.33mm on distal side at 6 months).[70]

Wadhwan B et al. (2015) observed bone loss in flapless technique with non significant reduction in initial 9 months ($P > 0.05$) on both proximal aspects while significant reduction was observed ($P < 0.05$) from 9 to 15 months. On the other hand, statistically significant reduction of CBH was observed at different time intervals on both proximal aspects of implants placed "open flap technique ($P<0.05$). i.e. both techniques showed that the mean difference of crestal bone levels at different time intervals around both the proximal aspects of implants placed with flapless technique was significantly lower than open flap technique.[71]

Comparing the 9 month overall CBL in the study, group A ranged from 0.50-0.95 mm, whereas in group B ranged from 0.00-0.65 mm .Hence it can be inferred that CBL was significantly less with p value <0.001 in group B when compared to group A at 9 months of implant placement.

Roman GG (2001) and few other researchers reported similar study in which decrease interproximal crestal bone height (in the range of 0.5 to 1.59 mm) after a full thickness periosteal flap has been observed.[7, 72-75] Based on the results of this investigation, the use of a limited flap design is recommended to minimize interproximal crestal bone loss.

The present results also meet the success criteria for implant treatment proposed, in the consensus report of the 1st European Workshop on Periodontology: According to Albrektsson's success criteria the average marginal bone loss should be <1.5 mm during the first year of functional use of an implant. The marginal bone loss is reported to range from 0.4 to 1.2 mm 1 year after flap implant surgery.[76-81]

Similar result was assessed by Jeong et al (2011) of mean bone loss 0.3-1 mm in 1 year after flapless implant surgery; no implants failed to osseointegrate, and no implants exhibited bone loss more than 1.2 mm.[57] Nadine Brodala et al.(2009) reviewed similar literature published from 1966 to 2008 reported a mean radiographic bone loss ranging from 0.7 to 2.6 mm after 1 year of implant placement with flapless technique.[32] Thus the success rate and aesthetic outcome of single tooth implants placed either in maxilla or mandible region had a favourable clinical and radialogical outcome using the two different placement methods.

One explanation for the high success rate may be that when flaps are not reflected, the periosteum is preserved, which may help to optimize the healing of the peri-implant tissue and preserves the bone vascularization.

When teeth are present, blood is supplied to the bone from 3 different paths: the periodontal ligament, the connective tissue above the periosteum, and inside the bone. When a tooth is lost, the blood supply from the periodontal ligament disappears, and blood is supplied only from soft tissue and bone. Cortical bone is poorly vascularized in

contrast to marrow bone. When soft tissue flaps are reflected for implant placement, the blood supply from the soft tissue to the bone (supraperiosteal blood supply) is also removed, leaving only poorly vascularized cortical bone without a part of its vascular supply, ultimately prompting bone resorption during the initial healing phase. [82-84]

On the contarary, Malo and Nobre et al.(2008) conducted prospective cohort study on the rehabilitation of partial edentulism with immediate functional implants placed in predominantly soft bone in which overall average marginal bone resorption was with 1.4 mm and 2.0 mm for the flap and flapless surgical techniques respectively. And here the flapless technique revealed more marginal bone resorption compared with the flap technique.[53]

One more study showed the contrary result with no significant difference in crestal bone resorption between flapped and flapless group during 3 months of healing period.[58]

The finding of present study were also in opposition to DeBruyn et al. (2009) which compared single implants installed with flap or flapless with respect to survival and marginal bone preservation after atleast 3 years. radiographic data recorded at baseline and after 1 and 3 years of function. Overall mean bone loss after an average of 38 months was 1.35 mm. both flapped and flapless showed increasing bone loss during the first year with higher bone loss for flapless (1.9 mm) than for flapped sites (1.5 mm) Afterward no further bone loss occurred and both groups were statistically equal.[10]

## IMPLANT STABILITY QUOTIENT (ISQ)

RFA is a non invasive method which is designed to assess the implant stability. The value of RFA can be used as the diagnosis of primary as well as secondary stability of implant.[85] It is also beneficial for doctors with limited experience in implant placement. RFA measurements taken at implant placement may provide doctors with confidence in determining if implants can be loaded early.[38] as well as for documenting implant stability at the time of implant placement and also during healing.[85]

The present study showed no significant differences in ISQ values between Group A and Group B at the time of implant placement, presenting with no bias with the sites selected for implant placement.

Implant stability at 9 months after the procedure was expected to be biological due to bone remodeling after implant placement. Following the placement of an endosseous implant, primary mechanical implant stability is gradually replaced by biological stability several weeks after placement.[86] This was observed in our study, as the RFA value obtained at 9 months was slightly higher than that obtained at the time of implant placement using both the conventional and flapless technique. This increase was statistically non significant for both the group. However, slight increase of ISQ value in Group B suggests, that the bone remodeling rate in the group B was faster than that in the group A. This may be due to the rich blood supply that was provided by the preserved periosteum around the bone in the group B, which can control bone turnover and bone formation around the implant.[87, 88]

There were no significant differences in ISQ values between the group A and Group B after 9 months of implant placement. In group A, the pre to post changes in ISQ ranged from -6 to 11 whereas in group B it ranged from -6 to 5. The ISQ of group B is slightly higher than group A which is non significant suggestive of bone remodeling and bone maturation that were continuous in both groups during this period but may be slightly higher in the flap group.This might be the reason for slight increase of RFA values and implant stability in the group B.

From the pre (at the time of implant placement) to post ( after 9 months) , the mean ISQ value slightly increased ( non significant) in both the group. This finding may be explained by the increased reinforcement from the woven bone scaffold that consists of lamellar bone.

Implants with a high primary implant stability at the time of surgery had high values throughout the healing period and sometimes showed an increase in their ISQ value. This is in agreement with a previous study [89] indicating that high primary implant stability at the time of implant placement resulted in ISQ values that remained high during the healing period.

In our study, there were no significant differences in implant stability between

implants placed via conventional and flapless techniques during the healing period, which is in agreement with a study by Becker *et al.(2006)* by Al juboori et al.(2015), Cannizarro et al.(2011). When the ISQ values were compared between flapped and flapless procedures, they were similar and from one another with non significant difference.[38,85,2]

On the contarary,Katsoulis et al.(2011) observed the mean ISQ values which were statistically significant in both the flapless and flapped group. The ISQ value was significantly higher in flapless group at both time-points wehereas the flap-group showed a moderate, but insignificant decrease.[90]

The study is also in apposition to *Hassan AF et al.(2016)* After three months interval of surgery the mean implant stability of the study (flapless) group achieved significant higher implant stability than control (flapped) group ($P< 0.05$) and the difference in measured implant stability was (5.05) implant stability quotient(ISQ).[65]

**PAPILLARY INDEX (PPI)**

The Pappilary index was evaluated using the index described by Jemt *et al.* (1997)[61] Generally, the cause for papilla reduction after implant placement could be due to elevation of adjacent papilla during implant surgery.[13] A clinical study by Gomez Roman GG(2001)[7] showed that the elevation of adjacent papilla caused more bone loss compared to a technique that does not include the papilla.

In the present study it showed that there is increase in the mean PPI from 6 to 9 months in both the group. In group A, after 6 months PPI score ranged from 1-3, whereas it ranged from 2-3 at 9 months thus significantly higher PPI score observed at 9 month when compared from 6 months interval.

Similarly, in group B PPI score at 6 month ranged from 1 to 2 whereas at 9 months it ranged from 2 -3 and inferred with a significantly higher score of PPI at 9 months when compared with the 6 months of interval.

When compared between the two groups i.e. group A and group B there is a significant difference between the two groups. In group B, the change in PPI was comparatively higher than group A. The improved papilla fill was observed more in flapless group than

that of conventional group. This finding is in accordance with the previous study found in the literature Jemt 1997, Chang et al. 1999; Choquet et al. 2001.

The study done by Choquet et al. (2001) in the regeneration of gingival papilla shows that bone level is directly interrelated to papilla regeneration. [91-93]

Bashutski et al.(2013) conducted similar study and observed that the implant placed using flap approach had an initial decrease in the PPI, whereas patients assigned to the flapless group had a significant increase in PPI during the first 6 months. PPI increased over time in both groups, although the flapless group had a significantly larger increase at 6 and 9 months .The difference was no longer significant at the 15-month time point.[94]

In the present study flapless implant showed papilla fill faster during 6-9 month period compared to that of conventional group. This might be due to raising a flap temporarily results in greater recession compared to using the flapless technique also the transient change in marginal tissue level may be a result of suturing.

This can be considered as an important point in the esthetic zone which may have better emergence profile in flapless group.

Several studies have highlighted the importance of adequate bone thickness and small contact to interproximal distance in optimizing papilla fill and minimizing gingival recession.[95-97] It was also reported that patients with a thick biotype had better early esthetic results when the flapless technique was employed.[98] Recent studies showed that thin biotypes were at an increased risk for incomplete papilla fill and marginal recession.[98, 99]

The limitations of the study is small sample size, smaller time duration, and implant placed irrespective of maxillary or mandibular arch. Split mouth design should have been taken.

Within the confines of the study, it can be concluded that both flapless and flap implant placement protocols result in high success rates, although a flapless protocol may provide a better short term esthetic result, however it can be used with proper preoperative planning based on advanced radiographic imaging.

# CONCLUSION

# CONCLUSION

With the rapid advancement of dental implant therapeutics, the current trend is more geared toward enhancing esthetics and patient comfort and satisfaction. Keeping this into mind flapless approach has been included in the study to overcome the problems faced in conventional approach.

Following conclusions were drawn from the studies:-

1. The Crestal bone loss was observed in both the group after 9 months interval. however, flapless group showed lesser crestal bone loss as compared to conventional group which was statistically significant with p value <0.001
2. The ISQ value obtained at 9 months was slightly higher than that obtained at the time of implant placement using both the conventional and flapless technique. This increase was statistically non significant for both the group.
3. PPI index showed improved papilla fill in both the group from 6 to 9 months however the PPI index showed higher papilla regeneration in flapless group when compared with conventional group which was statistically significant

In this clinical study implant placed with flapless surgery showed equal clinical success, as those placed with conventional flap surgery. CBL, an important clinical parameter was significantly less in the flapless approach as compared to conventional approach , so it can be considered as a good alternative to conventional surgery.

Although flapless implant surgery has many advantages like

- less invasive procedure.
- less trauma to soft and hard tissues
- less bleeding in the surgical field resulting in faster and more comfortable work.

Despite of all the above mentioned advantages, only a planned pre –operative assessment using advanced imaging techniques and proper diagnosis can favour uneventful flapless surgery. We wish to emphasize that proper case selection is of utmost importance in flapless implant placement. Since it is a blind procedure, fenestration and dehiscence may not be detected leading to implant complications. Hence, it should be performed by an experienced clinician with precise surgical skill.

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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 **Comparison of Soft and Hard Tissue Parameters in Flapless versus Conventional Implant Surgery: A Clinico – Radiographic Study** submitted by **Dr. Sumaiya** 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**
Chairperson Institutional Research Committee

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

# 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: 05** **BBDCODS/03/2017**

**Title of the Project:** Comparison of Soft and Hard Tissue Parameters in Flapless versus Conventional Implant Surgery: A Clinico-Radiographic Study.

**Principal Investigator:** Dr. Sumaiya **Department:** Periodontology

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

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

Dear Dr. Sumaiya

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 20/4/17
(Dr. Lakshmi Bala)
Member-Secretary
IEC

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

(Dr. Vivek Govila)
PRINCIPAL 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 _____

रोगी के पूर्ण नाम _____

उम्र लिंग / आयु _____

पता _____

1. मेरी पुष्टि है कि मैंने अध्ययन हेतु सूचना पत्र दिनांक _____ को पढ़ व समझ लिया तथा मुझे प्रश्न पूछने का मुझे अध्ययन अन्वेषक से सभी तथ्यों को समझा दिया है तथा मुझे प्रश्न पूछने के समान अवसर प्रदान किए गये।

2. मैं यहाँ स्पष्ट लिखा कि अध्ययन में मेरी भागीदारी पूर्णत: स्वैच्छिक है और मैं किसी भी समय किसी भी कारण के लिए, मेरे इलाज या कानूनी अधिकारों को प्रभावित किए बिना, अध्ययन में भाग न लेने के लिए स्वतंत्र हूँ।

3. मैं यह स्पष्ट किया 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 नहीं है, चाहे मैंने इस अध्ययन से नाम वापस ले लिया है। हॉलाकि मैं यह समझता हूँ कि मेरी पहचान को किसी भी तीसरे पक्ष या प्रकाशित माध्यम में नहीं दी जायेगी।

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

5. भविष्य के अनुसंधान के लिए भंडारित नमूना (ऊतक/रक्त) पर अध्ययन के लिए अपनी सहमति देता हूँ। हाँ [ ] नहीं [ ] अनउपयुक्त [ ]

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

मैंने सभी जानकारी सूचना पत्र को पढ़ तथा समझ लिया है।

प्रतिभागी / कानूनी तौर पर स्वीकार्य प्रतिनिधि का हस्ताक्षर ( या अंगूठे का निशान _____ अन्वेषक के हस्ताक्षरकर्ता का नाम _____ दिनांक _____

हस्ताक्षर _____ दिनांक _____

अध्ययन अन्वेषक का नाम _____ दिनांक _____ गवाह के

गवाह के हस्ताक्षर _____ मेरे हस्ताक्षर युगल

नाम _____

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**

COMPARISION OF SOFT AND HARD TISSUE PARAMETERS IN FLAPLESS VERSUS CONVENTIONAL IMPLANT SURGERY: A CLINICO-RADIOGRAPHIC STUDY.

**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 foll owing 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 loss, implant stability and soft tissue profile around implant when comparing conventional and flapless implant surgery.

**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?**

Partially edentulous patient will be randomly divided into group A and group B. Crestal bone loss around implants at the time of placement & at 9 months, Implant stability at time of placement and 9 months & the health & soft tissue profile of the periimplant tissues at 6 months & after 9 months will be evaluated. The obtained data will be subjected to statistical analysis.

**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 loss, implant stability and soft tissue profile around implant when comparing conventional and flapless implant surgery. This will help in determining their use in surgical procedure.

**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?**

The results of the study will be used to evaluate the changes in crestal bone loss, implant stability and soft tissue profile around implant when comparing conventional and flapless implant surgery. This will help in determining their use in surgical procedure.

**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 .....

## प्रतिभागी जानकारी दस्तावेज़ -पीआईडी

1. अध्ययन शीर्षक

फ्लैशलेस वर्सेज में सॉफ़्टवेयर और हार्ड टिस्सू पैरामीटर की तुलनात्मक कार्यात्मक सर्जरी: एक क्लिनिको-रेडियोग्राफिक स्टडी

2 निमंत्रण पैरा?

आप एक शोध अध्ययन में भाग लेने के लिए आमंत्रित किये जा रहा है, ये समझना आपके लिए महत्वपूर्ण है की ये अध्यन क्यों किया जा रहा है, और इसमें क्या क्या सम्मलित होगा, कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने के लिए समय ले। किसी भी स्पष्टीकरण या अधिक जानकारी के लिए पूछे । यह आपका निर्णय रहेगा की आप इसका हिस्सा बनाना चाहते है या नहीं

3. अध्ययन का उद्देश्य क्या है?

इस अध्ययन का उद्देश्य जब पारंपरिक और flapless प्रत्यारोपण सर्जरी की तुलना crestal हड्डी स्तर, प्रत्यारोपण स्थिरता और प्रत्यारोपण के आसपास नरम ऊतक प्रोफ़ाइल में परिवर्तन का मूल्यांकन करने के लिए है

4. मैं क्यों चुना गया है?

आप इस अध्ययन के लिए चुने गए हैं क्योकि आप इस अध्ययन के लिए आवश्यक मानदंडों को पूरा कर रहे हैं।

5 .क्या मेरा भाग लेना अनिवार्य है?

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

6. यदि मैं भाग लेने के लिए मुझे का क्या होगा?

प्रत्यारोपण edentulous क्षेत्र में रखा जाएगा

7. क्या मैं ऐसा करने की क्या ज़रूरत है?

आप अध्ययन की जांच के लिए अपने नियमित जीवन शैली बदलने की जरूरत नहीं है।

8. प्रक्रिया है कि परीक्षण किया जा रहा है?

आंशिक रूप से edentulous रोगी बेतरतीब ढंग से समूह ए और समूह बी Crestal हड्डी स्तर में प्रत्यारोपण के आसपास प्लेसमेंट के और 9 महीनों में, प्रत्यारोपण स्थिरता समय में नियुक्ति के समय और 9 महीने और स्वास्थ्य और कोमल ऊतकों में periimplant ऊतकों की प्रोफाइल पर विभाजित किया जाएगा नियुक्ति के समय, 6 महीने और बाद में 9 महीने का मूल्यांकन किया जाएगा। प्राप्त आंकड़ों के सांख्यिकीय विश्लेषण के अधीन हो जाएगा।

9. अध्ययन के लिए हस्तक्षेप कर रहे हैं?

आंशिक रूप से edentulous मरीज में प्रत्यारोपण प्लेसमेंट

10. भाग लेने के दुष्प्रभाव क्या हैं?

इस अध्ययन के मरीजों पर कोई दुष्प्रभाव नहीं हैं।

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

वहाँ कोई खतरा नहीं इस अध्ययन में शामिल किया है,

12. भाग लेने के संभावित लाभ क्या हैं?

इस अध्ययन जब पारंपरिक और flapless प्रत्यारोपण सर्जरी की तुलना crestal हड्डी स्तर, प्रत्यारोपण स्थिरता और प्रत्यारोपण के आसपास नरम ऊतक प्रोफ़ाइल में परिवर्तन का मूल्यांकन करेंगे। यह शल्य प्रक्रिया में उनके उपयोग का निर्धारण करने में मदद मिलेगी

13. यदि क्या नई जानकारी उपलब्ध हो जाता है?

अतिरिक्त जानकारी के अनुसंधान आप इन के बारे में बताया जाएगा के दौरान उपलब्ध हो जाता है और आप अपने शोधकर्ता के साथ इस पर चर्चा करने के लिए स्वतंत्र हैं, अपने शोधकर्ता आपको बता देगा कि आप अध्ययन में जारी रखना चाहते हैं। आप वापस लेने का फैसला करते हैं, तो आपके शोधकर्ता अपनी वापसी के लिए व्यवस्था कर देगा। आप अध्ययन में जारी रखने का फैसला करते हैं, तो आप एक अद्यतन सहमति पत्र पर हस्ताक्षर करने के लिए कहा जा सकता है।

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

अध्ययन बंद हो जाता है / निर्धारित समय से पहले खत्म, इस मरीज / स्वयंसेवक के लिए समझाया जाएगा।

15. क्या कुछ गलत हो जाता है?

किसी भी गंभीर प्रतिकूल घटना होती है, या कुछ और अध्ययन के दौरान गलत हो जाता है, शिकायतों संस्थानों के लिए रिपोर्टिंग द्वारा नियंत्रित किया जाएगा, और संस्थागत नैतिक समुदाय और उपचार लागत प्रमुख अन्वेषक द्वारा सहन
दिया जाएगा।

16. इस अध्ययन में मेरी एक हिस्से को गोपनीय रखा जाएगा?

हाँ, यह गोपनीय रखा जाएगा।

17. शोध अध्ययन के परिणामों का क्या होगा?

अध्ययन के परिणामों जब पारंपरिक और flapless प्रत्यारोपण सर्जरी की तुलना crestal हड्डी स्तर, प्रत्यारोपण स्थिरता और प्रत्यारोपण के आसपास नरम ऊतक प्रोफ़ाइल में परिवर्तन का मूल्यांकन करने के लिए इस्तेमाल किया जाएगा। यह शल्य प्रक्रिया में उनके उपयोग का निर्धारण करने में मदद मिलेगी

18. जो अनुसंधान का आयोजन किया जाता है?

इस शोध अध्ययन शैक्षणिक संस्था द्वारा आयोजित किया जाता है। आप किसी भी शामिल प्रक्रियाओं के लिए भुगतान करने की जरूरत नहीं है।

19. अध्ययन के परिणामों को उपलब्ध कराया जाएगा के बाद अध्ययन खत्म हो गया है?

हाँ।

20. कौन अध्ययन की समीक्षा की है?

अध्ययन की समीक्षा की और विभाग के प्रमुख, और संस्था के आईईसी / आईआरसी द्वारा अनुमोदित किया गया है।

पीआई के हस्ताक्षर .....

नाम .....

तारीख .....

## ANNEXURE V

## CASE HISTORY PROFORMA

**COMPARISION OF SOFT AND HARD TISSUE PARAMETERS IN FLAPLESS VERSUS CONVENTIONAL IMPLANT SURGERY: A CLINICO-RADIOGRAPHIC STUDY**

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:**

**TYPE OF PLACEMENT:**

Conventional ☐ Flapless ☐

Implant Region:

Duration:

Implant Dimensions:

## CLINICAL PARAMETER

**Papillary Index Score: (Jemt T 1997)**

| At 6 months | At 9 months |
|---|---|
| | |

**Radiological Assessment:**

**Crestal Bone loss (mm)**

| | Mesial | Distal |
|---|---|---|
| At baseline (after implant placement) | | |
| At 9 months | | |

**Implant Stability**

| At Baseline | At 9 months |
|---|---|
| | |

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

***Paired t-test***

Paired t-test was used to calculate the differences between two paired samples i.e. when in each observation in Sample 1 is in some way correlated with an observation in Sample 2, so that the data may be said to occur in pairs and calculated as

$$t = d/S_d$$

where d is the mean of difference within each pair of measurements and $S_d$ the standard error of the difference. The degrees of freedom (DF) is calculated as

$$DF = n-1$$

**Student's t Test**

Student's t-test was used to calculate the differences between the means of two groups

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

where,

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

$S^2$ is the pooled variance and $n_1$ and $n_2$ are number of observations in group 1 and 2 respectively. The degrees of freedom (DF) is calculated as

$DF = n1 + n2 - 2$

**Chi-square test**

The chi-square ($\chi^2$) test is used to compare the categorical data as

$$\chi^2 = \Sigma\Sigma \frac{(Fij - fij)^2}{fij}$$

where, $F_{ij}$ is the observed frequency while $f_{ij}$ the expected frequency. The degrees of freedom (DF) is calculated as

$DF = (r-1)(c-1)$

**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 (***) |

# ANNEXURE VII

## MASTER CHART

| CRESTAL BONE LOSS (mm) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group A (Conventional Implant) | | | | | Mesial | | Distal | |
| SNO | PATIENT NAME | OPD NO. | Age (yrs) | Sex | At the time of implant | After 9 month | At the time of implant | After 9 month |
| 1 | Abhay Tiwari | 1876 | 28 | M | 0 | 0.6 | 0 | 1.1 |
| 2 | Sangeeta Patel | 7321 | 25 | F | 0 | 0.8 | 0 | 1.1 |
| 3 | Sangeeta Patel | 7321 | 25 | F | 0 | 0.4 | 0 | 0.6 |
| 4 | Sangeeta Patel | 7321 | 25 | F | 0 | 0.5 | 0 | 0.8 |
| 5 | Sangeeta Patel | 7321 | 25 | F | 0 | 0.4 | 0 | 1.1 |
| 6 | Sangeeta Patel | 7321 | 25 | F | 0 | 0.6 | 0 | 0.8 |
| 7 | Shakuntala | 9172 | 45 | F | 0 | 1.1 | 0 | 0.8 |
| 8 | Shakuntala | 9172 | 45 | F | 0 | 1.1 | 0 | 0.8 |
| 9 | Pankaj yadav | 2588 | 27 | M | 0 | 0.72 | 0 | 1.13 |
| 10 | Ashwini yadav | 9576 | 32 | M | 0 | 0.9 | 0 | 0.8 |
| | | | | | | | | |
| Group B (Flapless Implant) | | | | | | | | |
| 1 | Chandrika | 2291 | 40 | M | 0 | 0 | 0 | 0 |
| 2 | Sarojini Devi | 3175 | 40 | F | 0 | 0.5 | 0 | 0.8 |
| 3 | Sarojini Devi | 3175 | 40 | F | 0 | 0 | 0 | 0.5 |
| 4 | Sarojini Devi | 3175 | 40 | F | 0 | 0 | 0 | 0.5 |
| 5 | Sarojini Devi | 3175 | 40 | F | 0 | 0 | 0 | 0.5 |
| 6 | Shilpi Verma | 2827 | 36 | F | 0 | 0 | 0 | 0.5 |
| 7 | Shilpi Verma | 2827 | 36 | F | 0 | 0 | 0 | 0.5 |
| 8 | Rahul Shah | 1763 | 27 | M | 0 | 0.5 | 0 | 0 |
| 9 | Ashwini kumar | 5432 | 25 | M | 0 | 0 | 0 | 0 |
| 10 | Anvita | 7345 | 28 | F | 0 | 0 | 0 | 0 |

| Group A (Conventional Implant) | | | | | Osstell values (ISQ) | | Papillary index (PPI) | |
|---|---|---|---|---|---|---|---|---|
| SNO | Name | OPD NO. | Age (yrs) | Sex | At the time of implant | After 9 month | After 6 months | After 9 month |
| 1 | Abhay Tiwari | 1876 | 28 | M | 64 | 71 | 1 | 2 |
| 2 | Sangeeta Patel | 7321 | 25 | F | 76 | 77 | 2 | 2 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3 | Sangeeta Patel | 7321 | 25 | F | 74 | 73 | 1 | 2 |
| 4 | Sangeeta Patel | 7321 | 25 | F | 70 | 70 | 3 | 3 |
| 5 | Sangeeta Patel | 7321 | 25 | F | 75 | 79 | 1 | 2 |
| 6 | Sangeeta Patel | 7321 | 25 | F | 68 | 62 | 1 | 2 |
| 7 | Shakuntala | 9172 | 45 | F | 73 | 74 | 2 | 2 |
| 8 | Shakuntala | 9172 | 45 | F | 53 | 64 | 2 | 3 |
| 9 | Pankaj yadav | 2588 | 27 | M | 73 | 77 | 1 | 2 |
| 10 | Ashwini yadav | 9576 | 32 | M | 72 | 67 | 2 | 3 |

| Group B (Flapless Implant) | | | | | Osstell values (ISQ) | | Papillary index (PPI) | |
|---|---|---|---|---|---|---|---|---|
| SNO | Name | OPD NO. | Age (yrs) | Sex | At the time of implant | After 9 month | After 6 months | After 9 month |
| 1 | Chandrika | 2291 | 40 | M | 76 | 70 | 2 | 3 |
| 2 | Sarojini Devi | 3175 | 40 | F | 66 | 68 | 1 | 2 |
| 3 | Sarojini Devi | 3175 | 40 | F | 67 | 69 | 2 | 3 |
| 4 | Sarojini Devi | 3175 | 40 | F | 70 | 73 | 2 | 3 |
| 5 | Sarojini Devi | 3175 | 40 | F | 68 | 72 | 1 | 2 |
| 6 | Shilpi Verma | 2827 | 36 | F | 74 | 79 | 2 | 3 |
| 7 | Shilpi Verma | 2827 | 36 | F | 73 | 75 | 1 | 3 |
| 8 | Rahul Shah | 1763 | 27 | M | 68 | 68 | 2 | 3 |
| 9 | Ashwini kumar | 5432 | 25 | M | 70 | 71 | 1 | 3 |
| 10 | Anvita | 7345 | 28 | F | 65 | 69 | 2 | 3 |