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A 3D Radiographic Evaluation of Crestal Bone Changes Around Immediately Loaded Endosseous Implants

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LOMA LINDA UNIVERSITY
School of Dentistry
in conjunction with the
Faculty of Graduate Studies

A 3D Radiographic Evaluation of Crestal Bone Changes Around Immediately
Loaded Endosseous Implants

by

Keerthi Senthil

A Thesis submitted in partial satisfaction of
the requirements for the degree of
Master of Science in Implant Dentistry

December 2015 ·

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Each person whose signature appears below certifies that this thesis in his/her opinion is adequate, in scope and quality, as a thesis for the degree Master of Science

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ABBREVIATIONS

BIC	Bone to implant contact
IP	Implant platform
BHIP	Buccal bone height from Implant platform
BWIP	Buccal bone width from Implant platform
BW4IP	Buccal bone width 4mm from implant platform
LHIP	Lingual bone height from implant platform
LWIP	Lingual bone width from implant platform
BWBIC	Buccal bone width at first bone to implant contact
LWBIC	Lingual bone width at first bone to implant contact
MBI	Modified bleeding index
MPI	Modified plaque index
RFA	Resonance frequency analysis
ISQ	Implant stability quotient
CBCT	Cone beam computed tomography
Y1	Mesial bone level on a periapical radiograph
Y2	Distal bone level on a periapical radiograph
NIH	National Institute of Health
IRB	Institutional Review Board
DICOM	Digital communication in Medicine

ABSTRACT OF THE THESIS

A 3D Radiographic Evaluation of Crestal Bone Changes Around Immediately Loaded Endosseous Implants

by

Keerthi Senthil

Master of Science, Graduate Program in Implant Dentistry

Loma Linda University, December 2015

Dr. Jaime Lozada, Chairperson

The purpose of this clinical investigation is to evaluate and compare the 3-dimensional radiographic crestal bone changes around 4 immediately placed and loaded implants supporting full arch fixed mandibular prosthesis in 2 groups of patients. The Test group comprises of patients with failing mandibular teeth needing extraction. (due to caries, periodontal disease, fractures or prosthetic reasons).The Control group comprises of patients with a fully edentulous mandible presenting for fixed implant supported prosthesis with at least 6 months after the last extraction or bone grafting procedure. Stereolithographic bone model obtained from the patient's DICOM files was used to fabricate the bone reduction guide and surgical guide.

This was a prospective non-randomized controlled clinical study in which the subjects were recruited by strict inclusion and exclusion criteria. Seventeen subjects were recruited for the study. 9 patients for the test group and 8 patients for the control group were treated. Four parallel implants were placed and a fixed provisional was placed within 24 hours after surgery. CBCT and periapical radiographs were taken at baseline, 3, 6 and 12 months and were compared between the 2 group. No clinically significant difference was found in the 3D crestal bone levels between the 2 groups for the different

time intervals evaluated at a significance level $P < 0.05$. The study yielded important guidelines for implants placed in sites where extraction s were combined with alveoloplasty and immediately loaded. Crestal bone changes are minimal when these implants are placed greater than 2mm below the bone crest and when the buccal bone is greater than 3mm wide.

CHAPTER ONE

INTRODUCTION

The evolving trend of implant dentistry towards accelerated treatment protocol calls for predictable pre-surgical planning. Clinicians are compelled to search for new methods of treatment to deliver care in shorter time periods without sacrificing quality and accuracy.

The conventional treatment protocol for rehabilitation of a complete dental arch with dental implants includes four phases: a healing phase of 3-6 months after teeth extraction, during which a removable prosthesis is worn to maintain function and esthetics; the surgical phase which involves the placement of dental implants; and an integration phase of 3 to 6 months to allow stress-free osseointegration and finally the prosthetic phase when the final prosthesis is delivered. This results in almost a year of reduced quality of life and for many patients great psychological stress. Through the years immediate and early loading protocols¹⁻⁷ have reduced the treatment time. But one must carefully evaluate the effect these accelerated treatment protocols have on the stability of both the buccal and interproximal crestal bone.

Earlier Studies

Testori et al⁶ conducted a multicenter prospective study to measure the bone loss around immediately loaded implants in the edentulous mandible. The greatest amount of bone loss occurred during the first 6 months. Histological evaluation of the bone 2 and 4

months after loading revealed that bone loss around immediately loaded implants was not significantly different from that of submerged non-loaded implants.

Jaffin et al⁷ conducted a 5 year prospective study comparing the radiographic bone changes around implants placed in fresh extraction sockets without alveoloplasty and immediately loaded with fixed full arch provisional restoration to implants placed in native bone following the same loading protocol. They further subdivided the extraction sockets into those with residual vertical defect adjacent to the implants and those without residual vertical defect adjacent to the implants. Standardized periapical radiographs revealed that in the first 6 months implants placed in extraction sockets had less bone loss than implants placed in native bone. However this difference was not evident one year after placement. Another important observation was that implants with a residual defect showed more crestal bone loss than implants without residual defects. 3-dimensional evaluation of the crestal bone could have revealed valid information about the buccal bone which recently has gained a lot of attention especially in the esthetic zone.

Immediate implant placement in fresh extraction sockets takes advantage of the residual cortical plate and osteogenic potential of the healing socket^{8,9} which may be lost when socket remodeling is complete. Clinical experience has shown that in most patients alveoloplasty/alveolectomy has to be done to have the required prosthetic space. By performing alveoloplasty following extraction, although we may lose some of the residual cortical plate, we eliminate the vertical residual defect and take advantage of the osteogenic potential of the healing socket. .

In a 6 year follow up clinical study by Tolman et al,¹⁰ implants were placed immediately following extraction and alveoloplasty in the mandible. The inferior cortical

plate was engaged for optimal initial implant stability due to lack of the superior cortical plate following alveoloplasty. The result of the study showed high patient satisfaction and overall treatment time was substantially reduced. However, no comparison to implants placed in healed sites was made and the implants were not immediately loaded. It will be intriguing to find out the fate of the buccal bone in cases where radical alveolectomies is combined with immediate implant placement and loading.

In a prospective study of 3-6 years duration by Barnett et al¹¹ implants were immediately placed after extraction and radical alveolectomies. The implants were immediately loaded. Comparison was made to a control group. Periapical radiographs were used to measure the bone changes. No attempt to measure the buccal bone changes was made. Although there was a difference between the test and the control group it was not clinically significant.

Rationale

Proper treatment planning should consist of a thorough assessment of the intraoral hard and soft tissue via direct examination, periapical and panoramic radiography, mounted study models and diagnostic wax-patterns. Other available diagnostic tools for preoperative assessment include 2-dimensional cephalometric analysis, cone beam computed tomography(CBCT) images,^{12,13} tissue or bone mapping techniques¹⁴ to assess underlying bone geometry and model surgery to simulate intraoral implant positioning.¹⁵ Recently emphasis has shifted from arbitrary implant placement to placing implants with consideration of the final prosthetic outcome.^{15,16}

In patients for whom following extraction of teeth reduction of alveolar bone height is necessary for optimal prosthodontic treatment, immediate placement and loading of implants can be an attractive treatment approach.^{3, 10, 16} This eliminates the need to wear a removable prosthesis which may cause micromotion of the implants during the integration phase. Alveolar bone removal generally extends to the depth of the tooth alveolus so as to have adequate bone width for implant placement and most importantly adequate prosthetic space. A 3D stereolithographic bone model enables this bone reduction precisely. The 3D model helps in the identification of important anatomic landmarks such as the inferior alveolar nerve, mental foramen and the topography of the maxillary sinus. Implant placement can be planned outside the mouth and possible complications can be minimized leading to a favorable treatment outcome.^{17, 18} One might raise a question that due to the loss of the superior alveolar crest with alveoloplasty, if the result of treatment is as predictable as when compared to implant placement and immediately loading in healed sites.¹⁹⁻²¹

It is essential to establish the predictability of the treatment with the demand of immediate placement and immediate loading of full arch prosthesis. This study assessed 3D crestal bone changes around implants placed in extraction sockets following alveoloplasty. It helps answer questions such as - Does extensive alveoloplasty dramatically affect the bone remodeling? Does lack of crestal cortical bone in the test group affect implant success in immediately loaded implants? Does the level of implant placement compensate for the bone loss due to remodeling following alveoloplasty? Is there a true benefit for the patient to undergo this extensive surgery or wait till bone remodeling is complete as in the control group?

Purpose

The purpose of this study was to evaluate the 3D radiographic crestal bone changes over 12 months around implants placed following tooth extraction and simultaneous alveoplasty, using stereolithographic bone reduction copings and drill guides and immediately loading with fixed transitional prosthesis. This was compared to the 3D crestal bone changes over 12 months around implants placed in healed sites using the same surgical and restorative protocol.

The null hypothesis was there is no difference in the crestal bone changes between implants immediately placed and loaded after alveoplasty when compared to implants placed in healed sites using guided surgery.

CHAPTER TWO

MATERIALS AND METHODS

Patient Selection

20 Patients seeking treatment at Loma Linda University School of Dentistry, Center for Implant Dentistry were recruited for the study – 10 patients in control group and 10 patients in test group. The study was approved by the Institutional Review Board of Loma Linda University. (IRB # 5120028)

Design of the Clinical Investigation

This was a prospective controlled study design. Patients were selected to the test and the control groups based on strict inclusion and exclusion criteria. The study patients were followed for 12 months after implant placement. All implants were immediately loaded on the day of surgery or within a week of implant placement^{22,23}. Crestal bone changes were evaluated at 3 months, 6 months and 12 months using standardized radiographs and CBCT sections. Success criteria of implants were evaluated using Albrektsson criteria 1986.²⁴

Inclusion Criteria

1. Control group – fully edentulous healed mandible not requiring alveoloplasty and presenting for fixed implant supported prosthesis with at least 6 months after the last extraction or bone grafting procedure

2. Test group - patients with remaining mandibular teeth needing extraction due to hopeless prognosis (caries, periodontal involvement, fractures or prosthetic reasons) Patients with knife edge edentulous mandible requiring alveoloplasty at the time of implant placement were also included in this group.

Criteria Common to Both Groups

- The patient be above 21 years of age and capable of signing the informed consent
- Patients in good systemic health without conditions that will alter the treatment outcome.
- Patients who smoke less than 10 cigarettes per day. Smokers who are included in the study must participate in the smoking cessation protocol.^{25,26}
- The occlusion should be stable with opposing natural dentition or any type of prosthesis
- Interforaminal distance adequate to place a minimum of 4 implants, 3 mm apart and 2mm from the mental foramen²⁷
- Have adequate bone to place a standard diameter implant with a minimum of 1mm of bone surrounding the implant buccally and lingually as seen on CBCT
- Implants will be placed as per manufacturer's recommendation (Neodent USA, Inc)

Exclusion Criteria

- A medical history that would complicate the outcome of study such as alcohol or drug dependency, poor health, uncontrolled diabetes, immunodeficiency diseases

or any other medical, physical or psychological reason that might affect the surgical procedure or the subsequent prosthodontic treatment and required follow-up examinations.

- Patients who smoke more than 10 cigarettes per day
- History of head and neck radiation therapy
- Pregnancy
- Dental history of known bruxism or other parafunction habits
- Poor patient compliance

Clinical examination and all treatment were performed at LLUSD Center for Prosthodontics and Implant Dentistry.

Success Criteria

At 3months and 12months follow-up appointment, the success of each implant will be evaluated according to the criteria proposed by Albrektsson et al. 1986²³ and recorded. The Albrektsson criteria for success are:

- No clinically detectable mobility when tested with opposing instrument pressure
- No evidence of peri-implant radiolucency on periapical radiographs
- No recurrent or persistent peri-implant infection
- No complaint of pain at the site of treatment
- No complaint of neuropathies or paresthesia
- Crestal bone loss not exceeding 1.5mm by the end of the first year of functional loading, and less than 0.2mm/year in the following years

Informed Consent

In accordance with the standards of conduct established by the Institutional Review Board of Loma Linda University, participants will be required to sign an informed consent. The purpose and the nature of the study were explained to the subjects and they were then being invited to participate in the study. Subjects were required to read, understand and sign the consent form before being enrolled in the study.

CHAPTER THREE

SEQUENCE OF TREATMENT FOR CONTROL GROUP

Preoperative Protocol

- A preliminary impression of the arches was made with polyvinylsiloxane (PVS) material (Exafast Heavy Body, GC, Japan) and diagnostic models were fabricated with Type III dental stone (Microstone, Whip Mix, Louisville, KY).



Figure 1 Preoperative view

- Custom trays (Triad, Denstply) were fabricated, border molding was performed and final impressions were made. The intermaxillary relationship (Centric relation record) was recorded using wax bite rims and transferred to an articulator (Panadent, Panadent Co., Colton CA) with the use of a face-bow record and polyvinylsiloxane bite registration material (Exabite, GC America Inc, Alsip, IL).
- Denture teeth for interim complete denture were set up using either canine guidance/group function or bilateral balanced occlusal scheme, depending on the opposing occlusion.

- The first CBCT Scan (i-CAT ISI, Hatfield,Pa) at 120 kV and 3-7 mA pulsed, was taken. The CBCT¹⁴ images were obtained in a DICOM format. These files were sent to a Bone modeling company (Neodent USA, Inc) for the fabrication of a 3D Stereolithographic acrylic resin model.



Figure 2 Stereolithographic bone model

Lab Steps for Surgical Guide Fabrication

- Interim complete denture was fabricated with high impact heat cure acrylic resin. (Lucitone 199)
- A vacuum formed matrix of the interim denture on the bone model will help determine the available prosthetic space
- Implant positions were marked on the bone model before drilling into the model. Implants were positioned 3mm apart and 2mm from the mental foramen.²⁷ Special attention was paid towards inter-implant parallelism to facilitate subsequent restoration.
- Implant positions were finalized with a 2mm twist drills; cylindrical guiding sleeves placed and surgical guide fabricated using salt and pepper technique (Splint Resin Polymer, Great Lake Orthodontics, Tonawanda, New York)

- Implant osteotomies were enlarged using sequential drills and lab implants were placed. The multiunit abutments were placed and temporary abutments were affixed. The interim denture was then altered to fit over the temporary abutments.
- Denture occlusion extended from left second premolar to right second premolar. Cantilever on the interim complete denture did not exceed more than 5mm from the distal implant

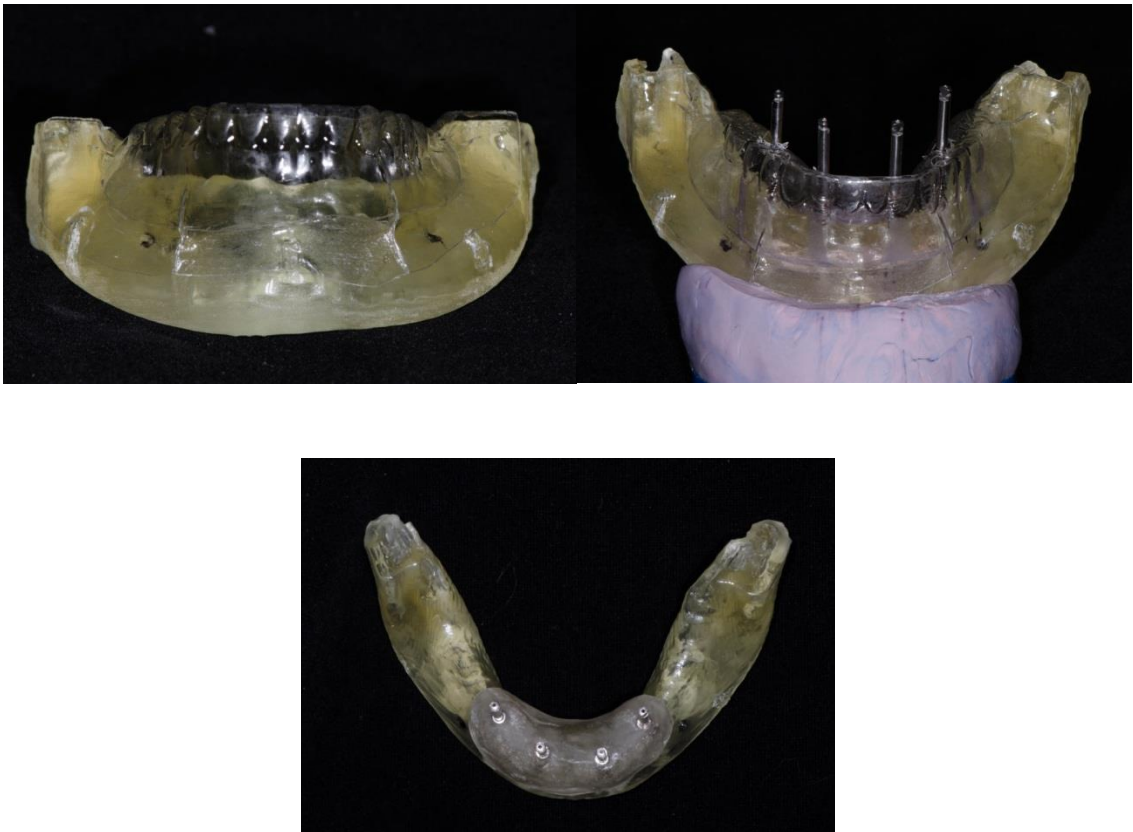


Figure 3 Fabrication of surgical guide



Figure 4 Placement of implant analogs



Figure 5 Alteration of interim denture

Photographic Records

Extraoral photos; full-facial frontal and lateral views, intraoral photos; maximum intercuspation, protrusive, lateral excursion, occlusal and lateral views of the surgical sites were taken at the time of the pre-operative appointment and throughout the treatment with a same camera (Canon 5D Mark II) and at the same setting

Pre-surgical Appointment

At pre-surgical appointment, the patient's vital signs (blood pressure, pulse rate, respiration) were recorded and medical history was updated. Patients were given choices of anesthesia during the surgery as follows:

1. Local anesthesia (LA) only
2. LA in conjunction with Oral sedation (Halcion 0.25 mg)
3. LA in conjunction with Intravenous (IV) sedation

Patient who chose IV sedation had a pre-surgical interview with the anesthesiologist or IV sedation specialist.

All patients were questioned regarding drug allergy and were prescribed appropriate antibiotics. All patients were pre-medicated with antibiotics 1 hour prior to surgery. (Amoxicillin 2 grams 1 hour before surgery or Clindamycin 600mg 1 hour prior to surgery). Patients were instructed to continue prescribed antibiotics for 7 days after surgery. (Amoxicillin 500 mg 1 tablet every 8 hours or Clindamycin 300mg, 1 tablet every 12 hours if allergic to amoxicillin for 7 days). Patients were given analgesic (Motrin 800 mg, every 8 hours as needed for pain) for post-operative usage. Patients were instructed to rinse with 0.12% chlorhexidine gluconate solution (Peridex, Zila Pharmaceuticals Inc., Phoenix, AZ) twice a day, one week before the surgery and 2 weeks after surgery.

Surgical Procedure

On the day of surgery, the patients were escorted to the operating room at LLUSD Center for Implant Dentistry. The patients were asked to rinse their mouth with 0.12% chlorhexidine gluconate mouthrinse (Peridex)²⁸ for 60 seconds prior to the surgery. Monitors for blood pressure, pulse rate, oxygen level were placed and circumoral area was painted with a Povidone-Iodine swab (Aplicare, Aplicare Inc., Branford, CT) and patients were draped for sterile protocol. Oxygen was provided to the patient through the nasal cannula at minimal of 3 liters/minute.

Following administration of local anesthesia a full thickness mucoperiosteal flap was elevated and extended distal to the mental foramina. Distal releasing incision and a mid-line vertical incision was used when needed to have adequate exposure of the underlying bone. The initial drill guide was placed on the exposed bone and secured with a bone screw. The initial 2mm drill was taken to depth through the guide. Then the guide was removed and position of the osteotomies was verified. The implant osteotomies were sequentially enlarged with copious saline irrigation. Implants were placed parallel to each other without tilting. Transmucosal abutments (Minipilar, Neodent, USA, Inc) were placed and hand tightened. Flaps were approximated using 4-0 Vicryl suture (Ethicon Johnson & Johnson, Livingston, UK). Implants were numbered 1, 2, 3 and 4 from right to left for the study.



Figure 6 Flap Elevation



Figure 7 Surgical guide in place



Figure 8 Initial drill to depth



Figure 9 Verification of implant positions

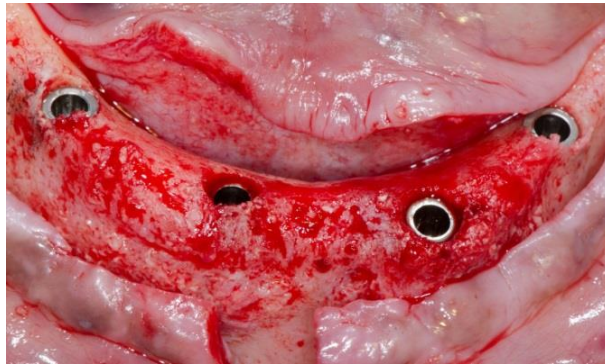


Figure 10 Implant placement

Interim Denture Conversion

Transmucosal abutments were placed and torqued in place. The torque applied was 5 Ncm less than the torque applied to place the implants. The implant stability was evaluated using the Resonance Frequency Analysis device (Osstell, Osstell AB, Gothenburg, Sweden).²⁹⁻³¹ Only implants with an ISQ of 55³² and above were loaded. Temporary abutments were then screwed on to the transmucosal abutments. The altered interim denture was placed and checked for any binding against the temporary abutments. Necessary changes were made to the interim denture to ensure maximum intercuspation in centric relation position. Rubber dam was applied to shield suture line and tissue from acrylic resin. Autopolymerising resin (Rebase, Tokoyama, Japan) was syringed around

the temporary abutments and patient was asked to close into maximum intercuspation. After the final set Interim denture was removed, contoured and polished. The cameo surface of the interim fixed prosthesis was made smooth and convex to ensure better cleansability and comfort.

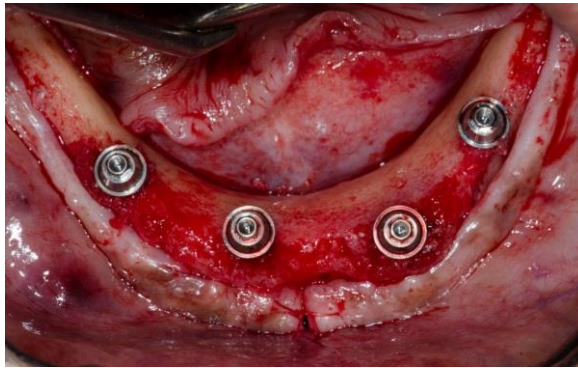


Figure 11 Fixation of transmucosal abutment



Figure 12 Measuring the ISQ



Figure 13 Fixation of temporary abutments



Figure 14 Interim denture Conversion

Immediate Loading Protocol

Occlusion was extended to first premolar area. Light centric contact and no posterior contact especially on the cantilever segment in excursive and non-excursive movements were ensured. Canine guided occlusal scheme or bilateral balanced occlusal scheme developed based on the opposing arch restoration. Converted interim fixed prosthesis screwed in place within one week^{22,23}. In this study for all patients interim prosthesis was screwed in on the same day as surgery except for one patient, it was inserted the following day due to medical reasons.



Figure 15 Immediate loading

Post-operative Instructions

Patients were advised to be on liquid diet for 2 weeks after the surgery and on soft diet for the remaining duration of the implant healing phase (3 months). Patients were advised to continue prescribed antibiotics and analgesics and were instructed to gently rinse with 0.12% chlorhexidine gluconate solution for 2 weeks. Patients were asked to return to the LLUSD Center for Prosthodontics and Implant Dentistry in 2 weeks for suture removal and subsequent follow-up examinations. Oral Hygiene was reinforced using water irrigation devices, proximal brushes and super floss at follow up visits.

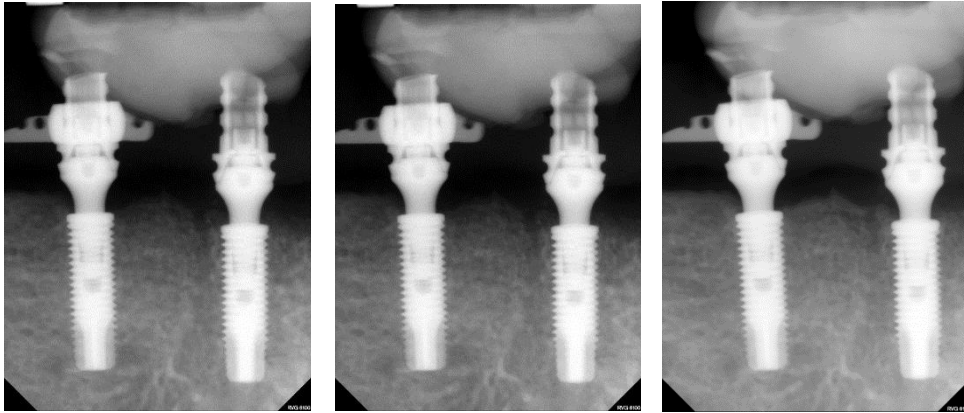
Prosthetic Phase

Following a healing phase of 3 months, abutment level impressions, facebow transfer and centric relation record were obtained and screw retained fixed complete denture prosthesis was fabricated and seated. Appropriate occlusal scheme established and occlusal plane extended to first molar.

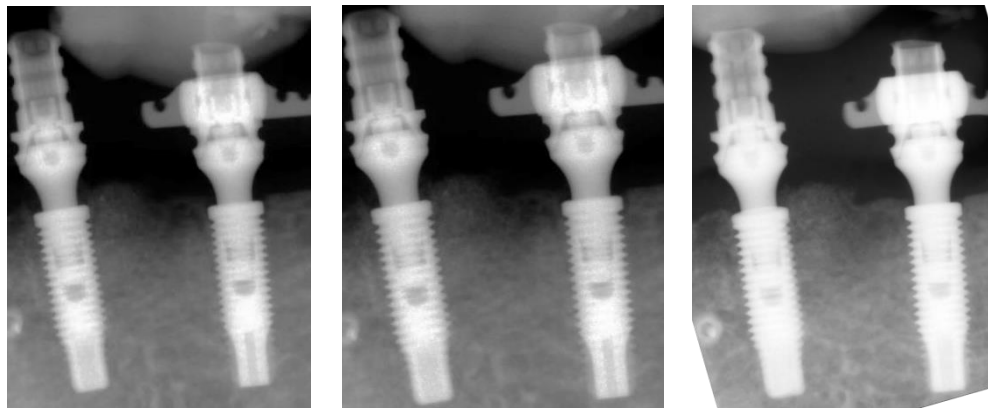
Follow-up and Maintenance

Follow up assessments were performed at 3 months, 6 months and 1 year counted from the day of loading (i.e. implant insertion). At baseline, 3 months and 12 months standardized radiographs with customized jigs fabricated at the day of surgery were taken. At baseline, 6 months and 12 months focused view J Morita scans (Vera viewepocs 3De , 60-80KV, 1-10mA) were taken.

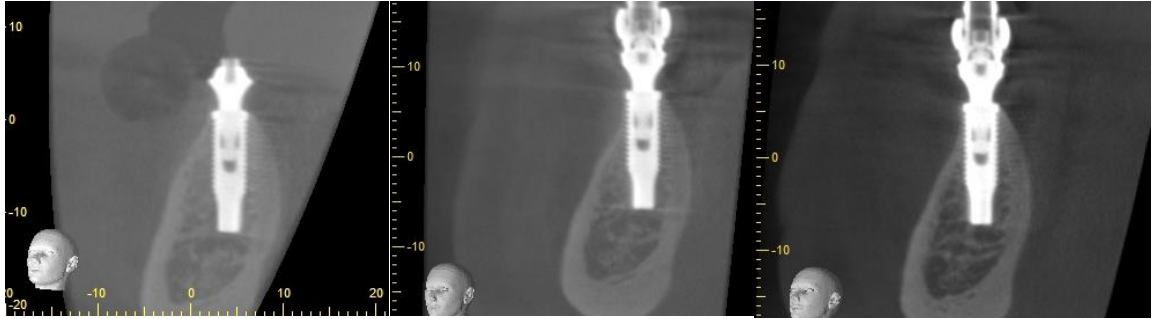
Prophylaxis was done every 6 months. Oral Hygiene was reinforced and Oral Hygiene instructions given at each follow up appointment.



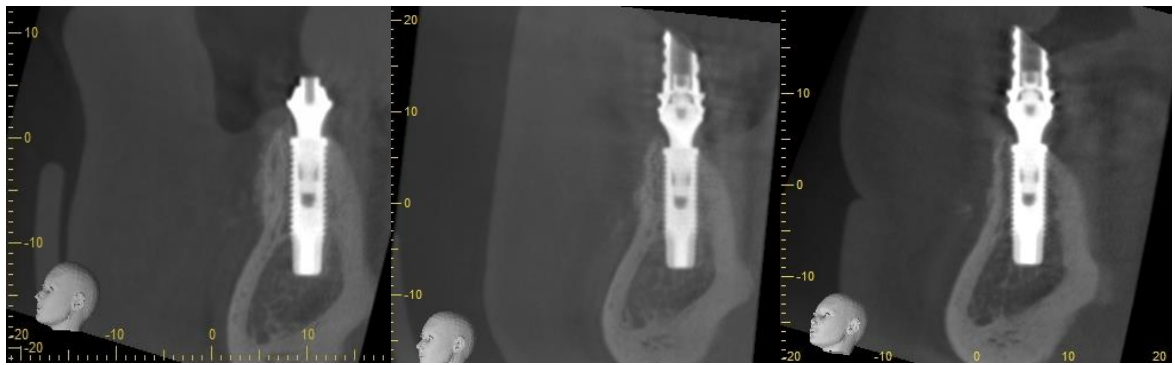
Baseline radiograph 3 month radiograph 12 month radiograph
Figure 16 Comparison of radiographs of different time periods for implants 1 and 2



Baseline radiograph 3 month radiograph 12month radiograph
Figure 17 Comparison of radiographs of different time periods of implants 3 and 4



Baseline CBCT 6 month CBCT 12 month CBCT
Figure 18 Comparison of CBCT of different time periods for implant 1



Baseline CBCT 6 month CBCT 12 month CBCT
Figure 19 Comparison of CBCT of different time periods for implant 2



Baseline CBCT 6 month CBCT 12 month CBCT
 Figure 20 Comparison of CBCT sections of different time periods of implant 3



Baseline CBCT 6 month CBCT 12 month CBCT
 Figure 21 Comparison of CBCT sections different time periods of implant 4



Figure 22 One year follow up

CHAPTER FOUR

SEQUENCE OF TREATMENT FOR THE TEST GROUP

The sequence of treatment for the test group is similar to the control group with a few exceptions. The difference between the groups is explained through examples of Test group 1 and Test group 2.

Example of Test Group 1



Figure23. Pre-operative view

In the above patient example all remaining natural teeth were failing due to advanced periodontal disease and required extraction. Patient desired to have a maxillary complete dentures and a mandibular fixed hybrid denture on 4 implants. Immediate dentures were fabricated and an CBCT scan(i-CAT ISI,Hatfield,Pa) was taken. The DICOM files were sent to a Bone modeling company (Neodent, USA Inc) for the fabrication of a 3-Dimensional Stereolithographic acrylic resin model.

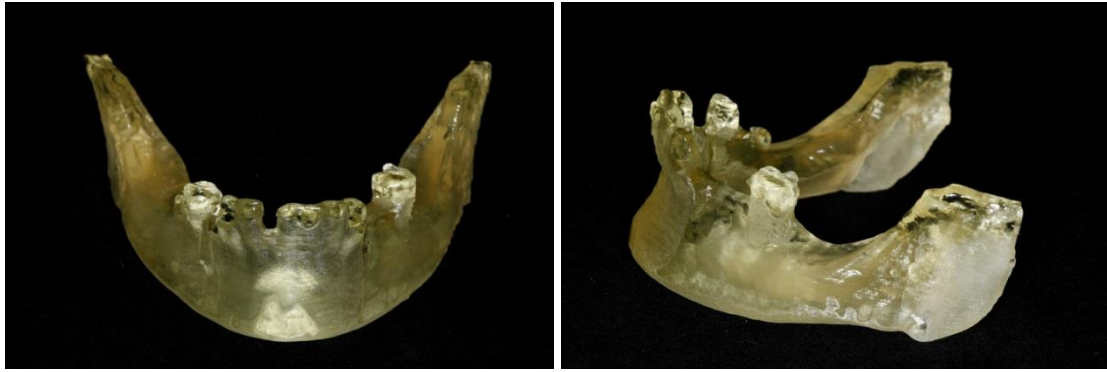


Figure 24. Stereolithographic bone model

In the test group 1, teeth were extracted and bone is reduced to allow adequate prosthetic space. This is planned in the bone model. Bone reduction guide is fabricated in pattern resin (GC dental products,corp).

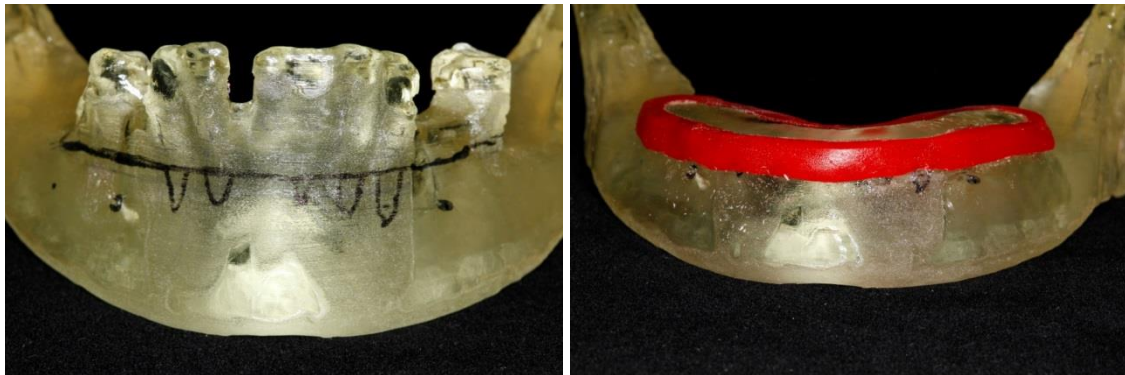


Figure 25 Fabrication of bone reduction guide

The Amount of reduction is based on the distance between the processed interim denture held in place with centric bite with the opposing denture and the bone model. A minimum of 15mm reduction is done to allow for prosthesis fabrication. This is verified with the help of a vacuum suck down of the interim denture on the bone model



Figure 26 Verification of bone reduction

The steps for fabrication of the surgical guide and retrofitting the interim denture to the implants is as described for the control group.



Figure 27 Fabrication of surgical guide Figure 28 Lab alteration of the interim denture

The pre-operative procedure is the same as that for the control group. After local anesthetic administration remaining mandibular teeth were extracted with care to limit socket expansion or cortical bone fracture. Full thickness mucoperiosteal flaps were elevated and extended distal to the mental foramina. Using the bone reduction coping alveoloplasty was performed. Implant osteotomies were prepared using the initial drill surgical guide. Surgical guide enables precise implant placement. Four Implants were placed parallel to each other without tilting. Implants were numbered 1 – 4 from right to

left. The space between the implant and the socket wall was grafted with autogenous bone from the alveoloplasty. Transmucosal abutments were placed and hand tightened. Flaps are approximated using 4-0 Vicryl suture (Ethicon Johnson & Johnson, Livingston, UK).

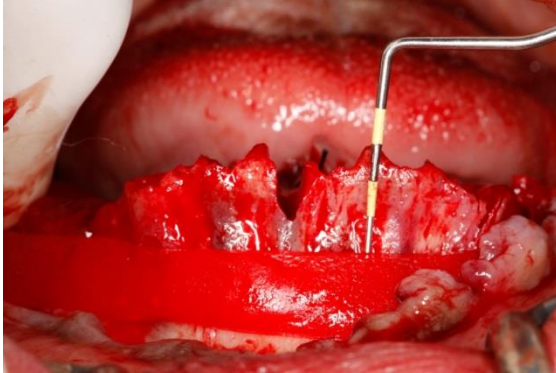


Figure 29 Amount of bone reduction



Figure 30 Surgical guide in place



Figure 31 Implant Insertion

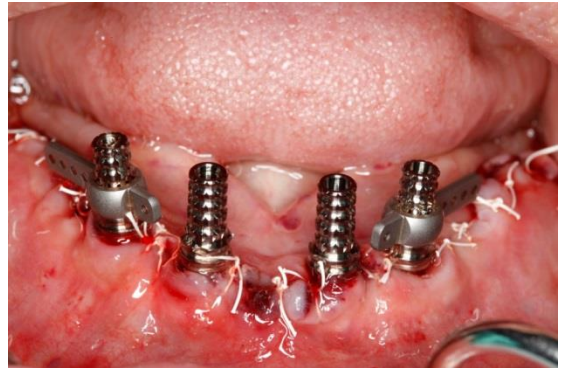


Figure 32 Fixation of Temporary abutments

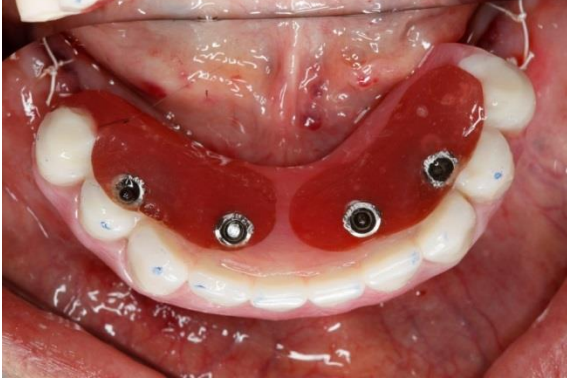
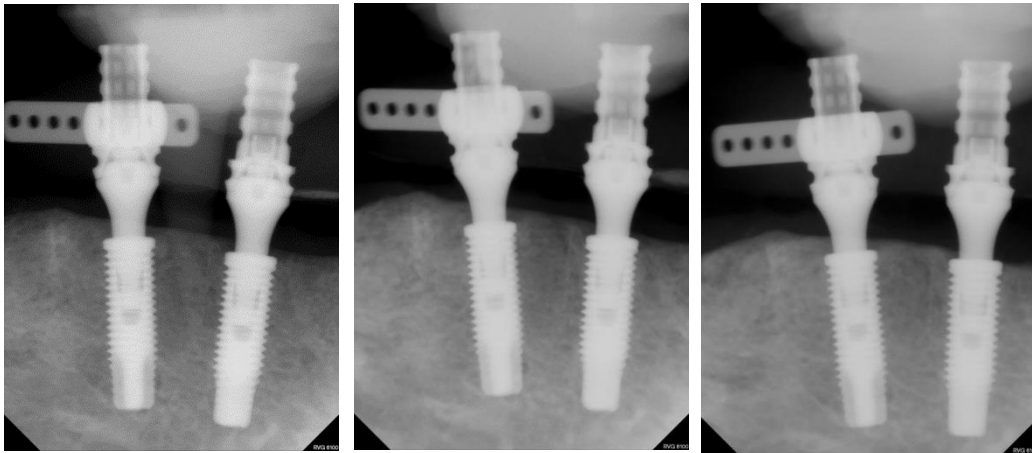


Figure 33 Alteration of the interim denture Figure 34 Immediate Post-operative view

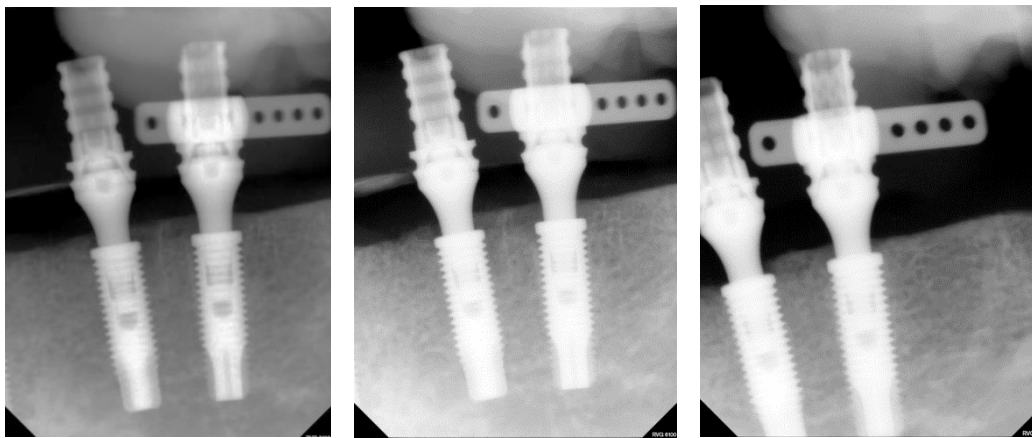
Post-operative instructions, prosthetic phase and follow up and maintenance were the same as that of the control group



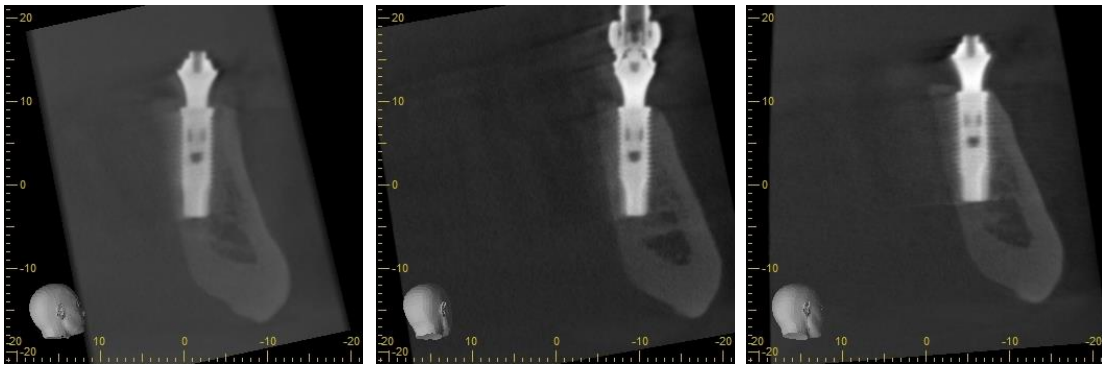
Figure 35 One year follow up



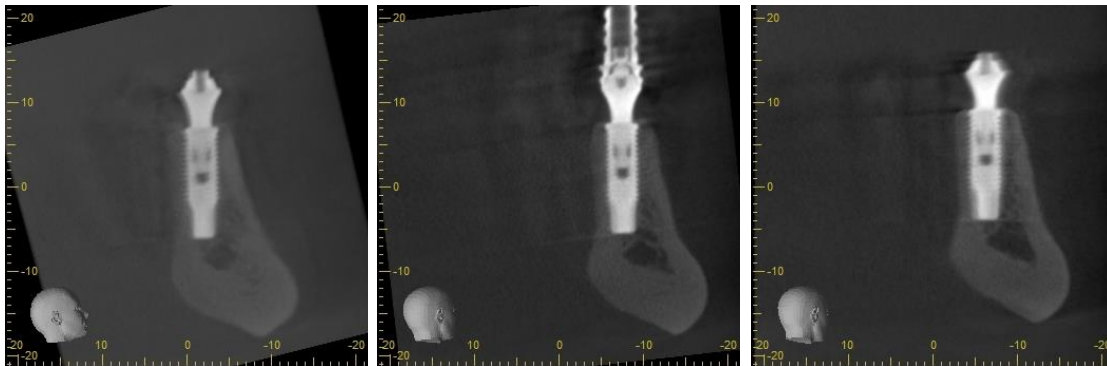
Baseline Radiograph 3 month Radiograph 12 month Radiograph
Figure 36 Comparison of standardized radiographs of different time periods for the implants 1 and 2



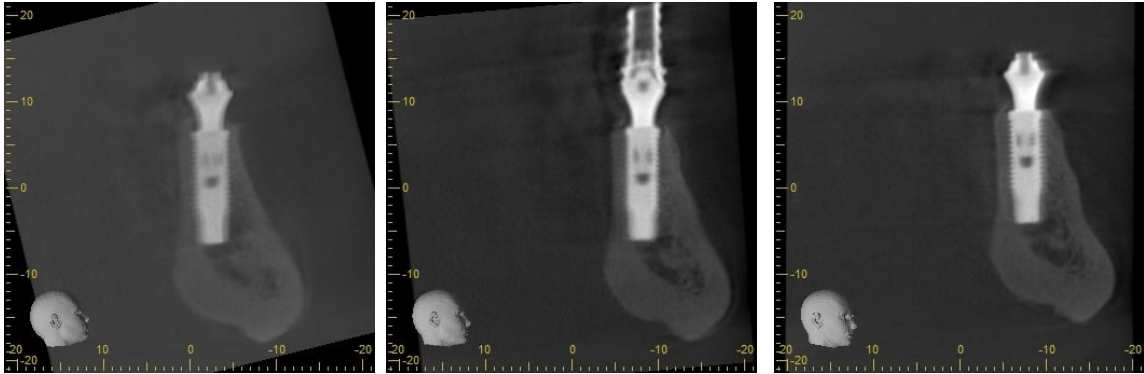
Baseline Radiograph 3 month Radiograph 12 month Radiograph
Figure 37 Comparison of Periapical Radiographs of different time periods for the implants 3 and 4



Baseline CBCT 6 month CBCT 12 month CBCT
Figure 38 Comparison of CBCT sections of different time periods for implant 1



Baseline CBCT 6 month CBCT 12 month CBCT
Figure 39 Comparison of CBCT sections of different time periods for implant 2

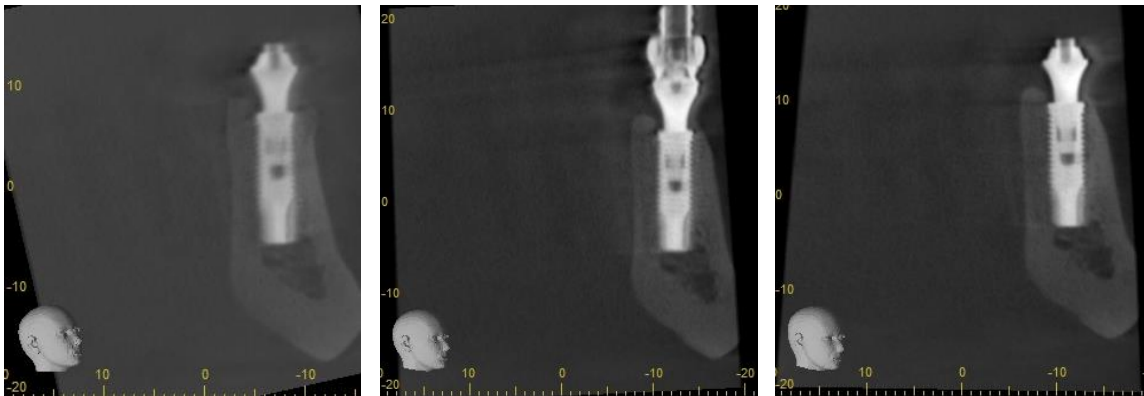


Baseline CBCT

6 month CBCT

12 month CBCT

Figure 40 Comparison of CBCT sections for different time periods for implant 3



Baseline CBCT

6 month CBCT

12 month CBCT

Figure 41 Comparison of CBCT sections for different time periods for implant 4

Example of Test Group 2

There were 3 patients in the study who belonged to this group. These patients had “knife edge” ridges and required extension bone reduction prior to implant placement to gain adequate width to place a standard size implant and/or to have adequate prosthetic space.

The sequence of treatment is similar to test group 1. The amount of bone reduction was planned on the stereolithographic bone model and a reduction guide was fabricated. The difference between this group and the control group is that in the control group there is no alteration /reduction of bone at the time of implant placement. Below are photos of a patient belonging to this group.

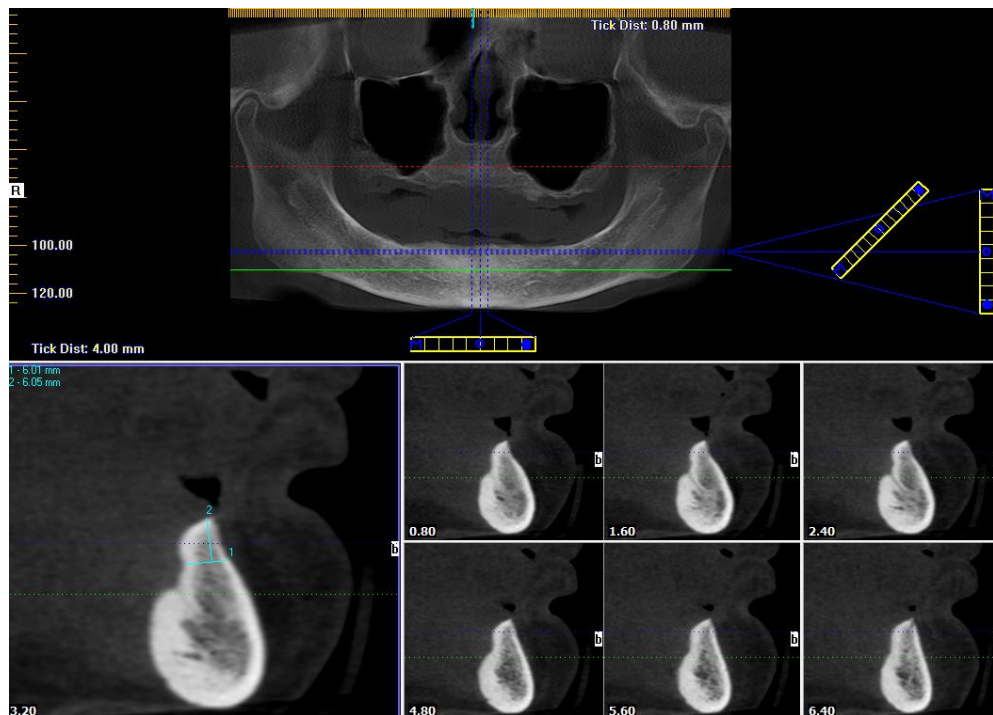


Figure 42 CBCT section showing “knife edge” ridge

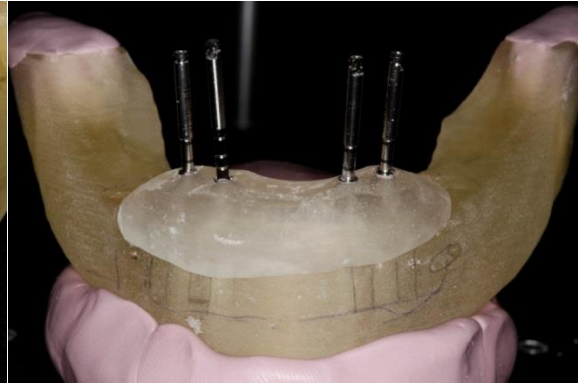


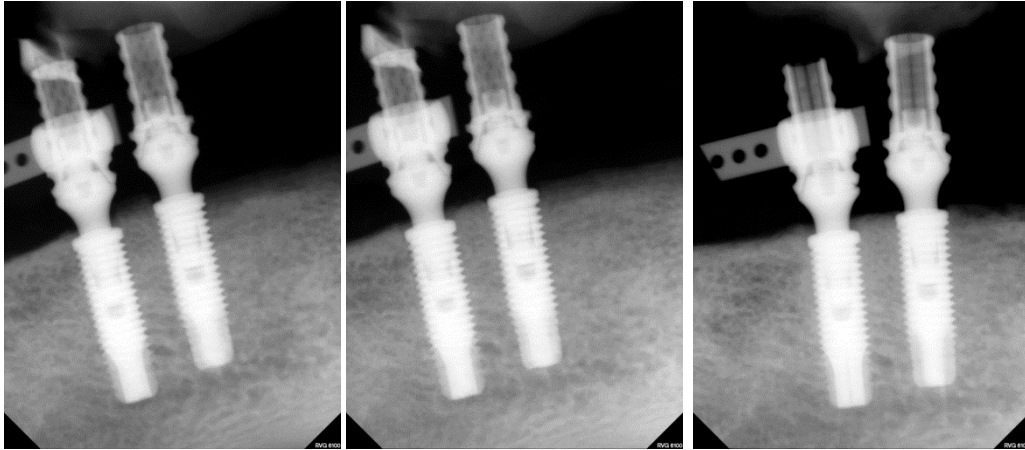
Figure 43 Bone model with reduction guide Figure 44 Fabrication of surgical guide



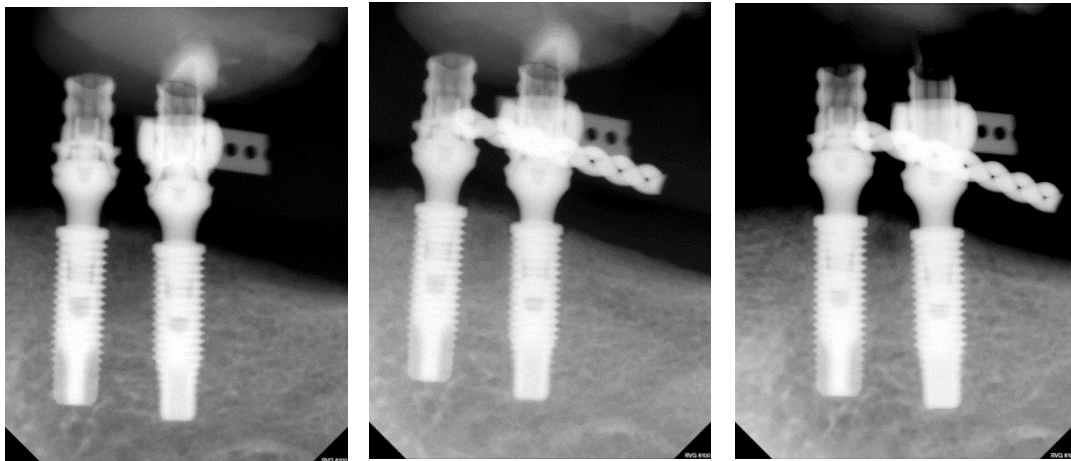
Figure 45 Immediate post-operative photo



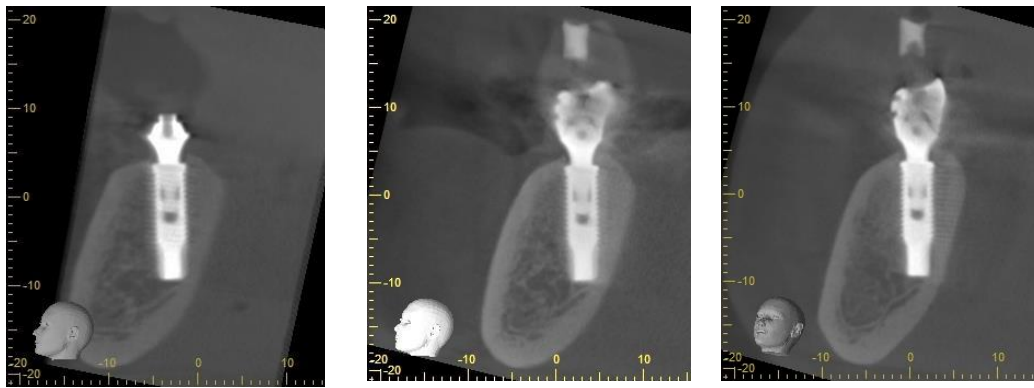
Figure 46 One year follow up



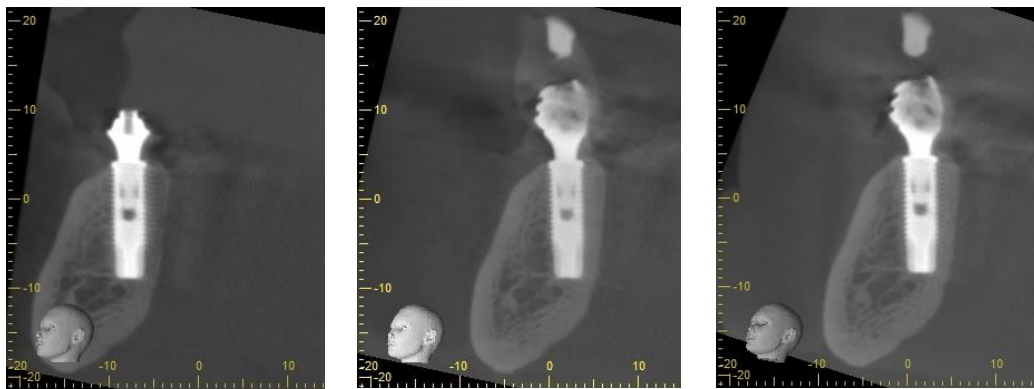
Baseline Radiograph 3 month Radiograph 12 month Radiograph
 Figure 47 Comparison of standardized radiographs of different time periods for implants 1 and 2



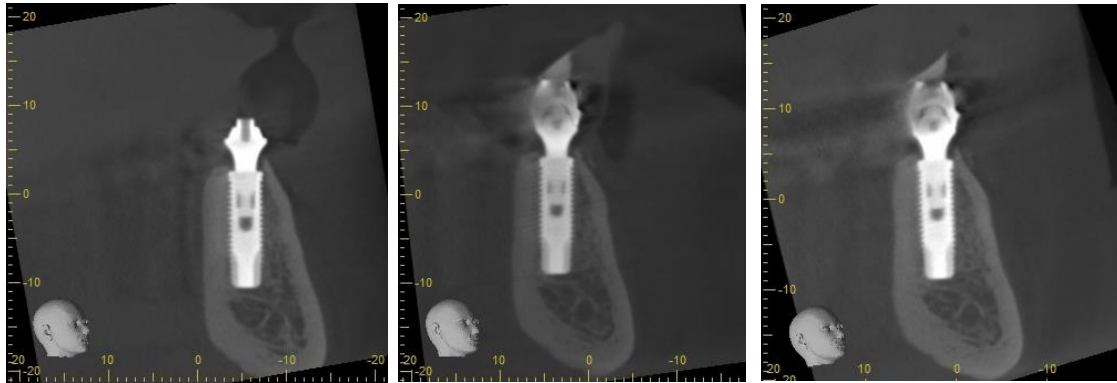
Baseline Radiograph 3 month Radiograph 12 month Radiograph
 Figure 48 Comparison of standardized radiographs of different time periods for implants 3 and 4



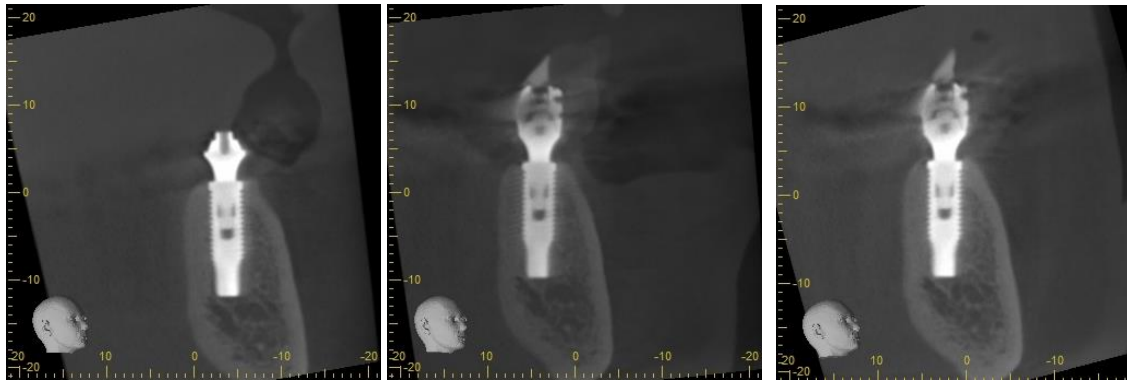
Baseline CBCT 6 month CBCT 12 month CBCT
 Figure 49 Comparison of CBCT sections of different time periods for implant 1



Baseline CBCT 6 month CBCT 12 month CBCT
 Figure 50 Comparison of CBCT sections of different time periods for implant 2



Baseline CBCT 6 month CBCT 12 month CBCT
Figure 51 Comparison of CBCT sections of different time periods for implant 3



Baseline CBCT 6 month CBCT 12 month CBCT
Figure 52 Comparison of CBCT sections of different time periods for implant 4

CHAPTER FIVE

DATE COLLECTION, MEASUREMENTS AND STATISTICAL ANALYSIS

Data Collection and Measurements

All re-care clinical examination and data collections were performed by a single examiner (Keerthi Senthil DDS). The following parameters were recorded at baseline, 3months, 6 months and 12month:

1. Implant success/failure
2. Buccal and Lingual crestal bone changes using CBCT
3. Interproximal crestal bone changes using standardized radiographs
4. Bone quality at baseline
5. Resonance frequency analysis (RFA)
6. Modified plaque index at 3, 6 and 12 months
7. Modified sulcus bleeding index at 3, 6 and 12 months
8. Surgical and Prosthetic complications

Implant Success/Failure

At 3months and 12months follow-up appointment, the success of each implant was evaluated according to the criteria proposed by Albrektsson et al. 1986²³ and recorded. The Albrektsson criteria²³ for success are:

- No clinically detectable mobility when tested with opposing instrument pressure
- No evidence of peri-implant radiolucency on periapical radiographs
- No recurrent or persistent peri-implant infection

- No complaint of pain at the site of treatment
- No complaint of neuropathies or paresthesia
- Crestal bone loss not exceeding 1.5mm by the end of the first year of functional loading, and less than 0.2mm/year in the following years

Buccal and Lingual Crestal Bone Changes Using CBCT Sections

CBCT (J Morita Vera viewepocs 3De)³³ scan taken immediately following implant placement was used as a baseline for buccal and lingual crestal bone changes and compared with CBCT(J Morita Vera viewepocs 3De) scan taken at 6 and 12months. With this scan the radiation is ~ 15 micro Siverts, duration of the scan is 9.4 second, voxel size is 0.125mm and resolution is greater than 2 lines per mm.

Image J software (NIH Image Program Software (<http://rsb.info.nih.gov/nih-image>) was used for measurements.

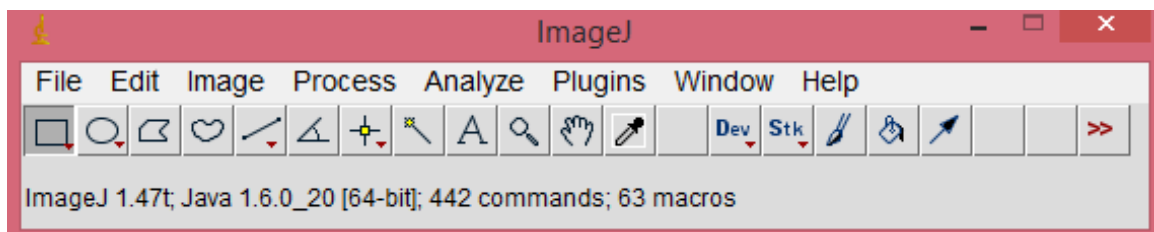
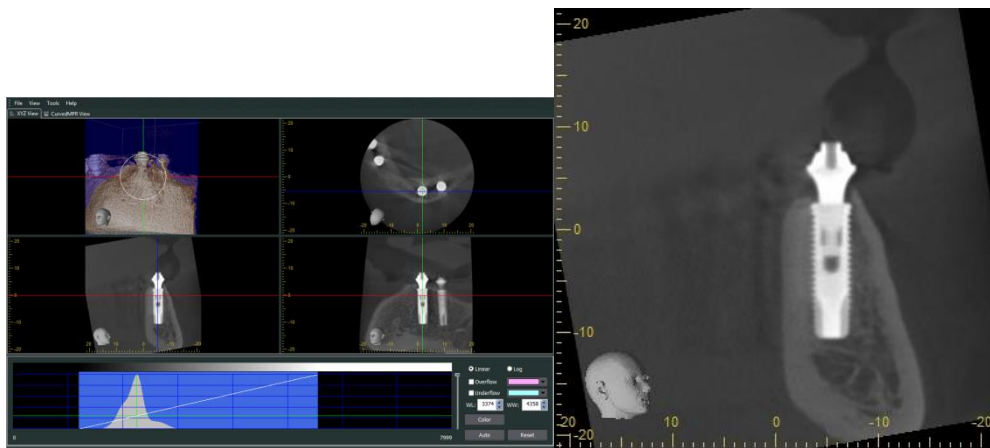


Figure 53 Image J Software

An example of a CBCT Measurement is as below -

The x and y coordinates were centered on the implant. The CBCT section was imported into the Image J software. The image was processed to remove background noise, accentuate details and bring out obscure details and help in quantitative measurements. The image scale was calibrated based on the known distance of the implant diameter. The most apical corner of the implant platform was used as a reference point.



Centering of x and y coordinates
Figure 54 Image Standardization

CBCT section

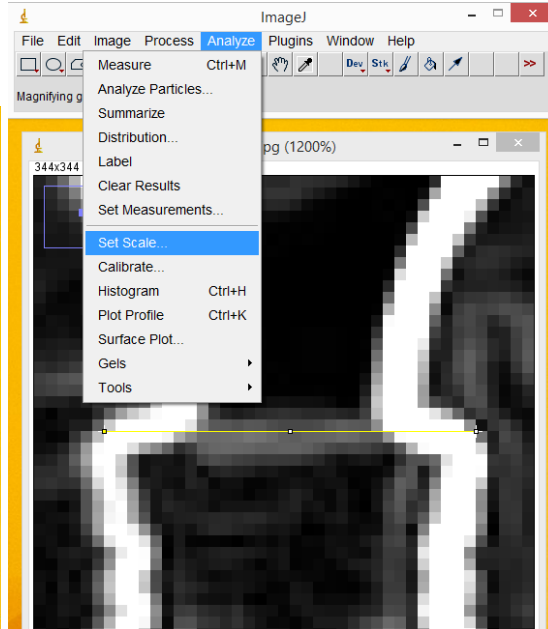
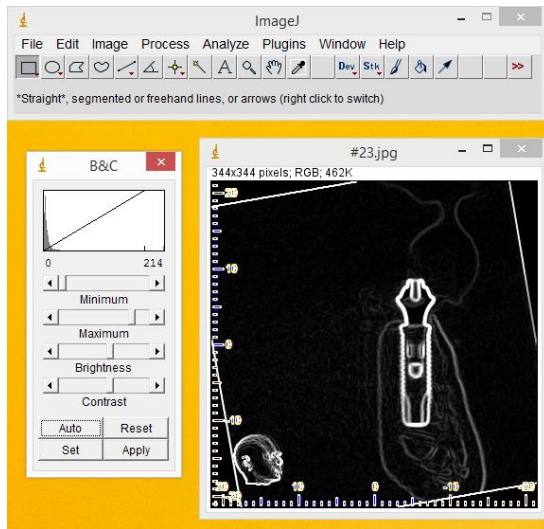


Image Processing

Image Calibration

Figure 55 Image processing and Calibration

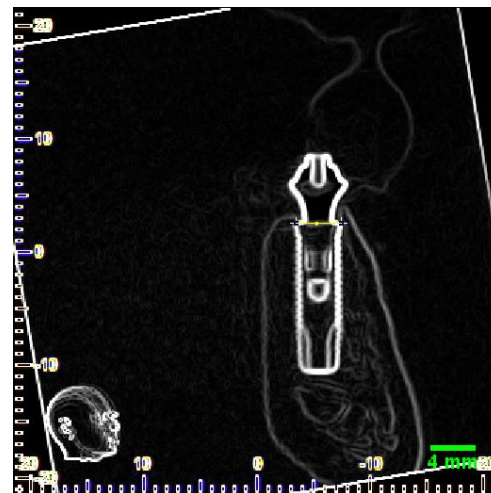
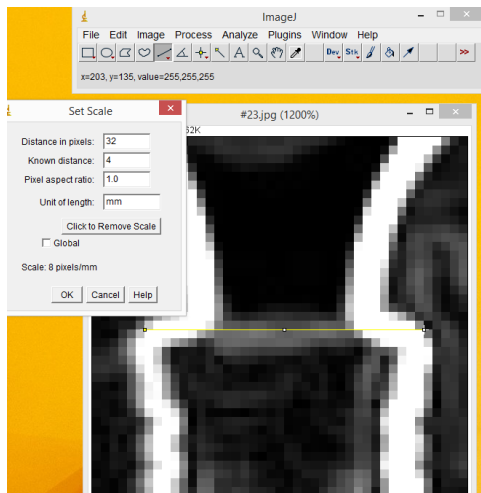


Image Scale set to implant diameter

Processed and calibrated image

CBCT Measurements made were-

- BHIP - buccal bone height from the implant platform
- BWIP - buccal bone width at the implant platform
- BW4IP - buccal bone width 4mm below the implant platform measured along the implant length
- LHIP - lingual bone height from the implant platform
- LWIP - lingual bone width at the implant platform
- BWBIC - buccal bone width at the first bone to implant contact
- LWLIC – Lingual bone width at the first bone to implant contact

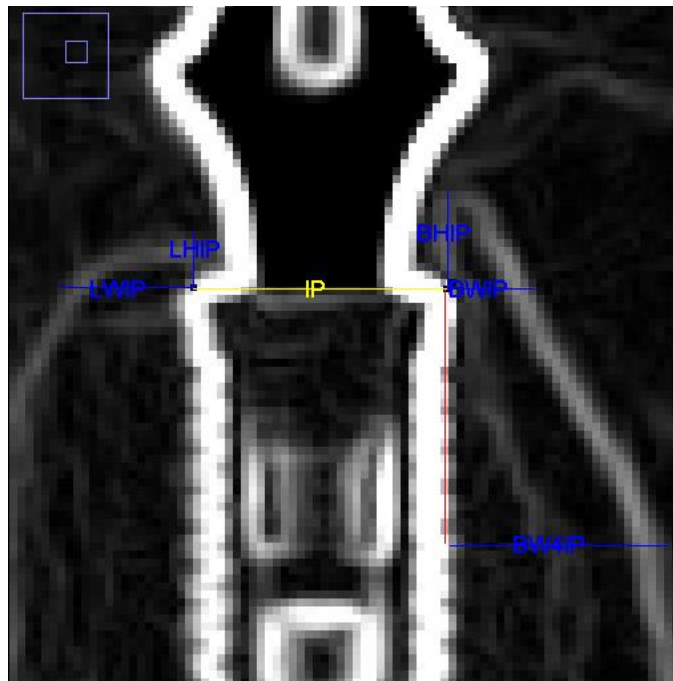


Figure 56 An example of CBCT measurement

After repeated measurements parameters were set to distinguish bone and soft tissue. Any value greater than 30 was considered bone and less than 30 was considered soft tissue. An honest attempt to retract the lips during the scan was made with plastic retractors but due to the edentulous nature of the subject and no occlusion at the time of the scan the lips could not be adequately retracted.

Interproximal Crestal Bone Changes Using Standardized Radiographs

Standardized radiographs using transmucosal abutment level customised jig and long cone paralleling technique, using Rinn Film holders (Dentsply, Germany) were taken at baseline, 3 months and 12 months. Changes in interproximal crestal bone levels were measured and recorded using NIH Image Program Software (<http://rsb.info.nih.gov/nih-image>). The image was imported into the Image J software in a TIFF format. It was then processed to reduce noise and accentuate the details of the image. The image was then calibrated to the known width of the implant diameter. The diameter of implant at the implant platform was measured with NIH Image Program software and labeled IP. The most apical corner of the implant platform was used as a reference point. The distance between the reference point and the bone height was measured both mesially (Y1) and distally (Y2). The true value of bone loss was obtained when dividing the “Y1 or Y2” by “IP” and then times the real diameter of implant platform (d) (True value in mm= dY/IP). The value was recorded as positive when the bone height was coronal to the reference point and negative when it was below the reference point.

Below is an example of a periapical radiograph processed, calibrated and measured using the Image J Software.

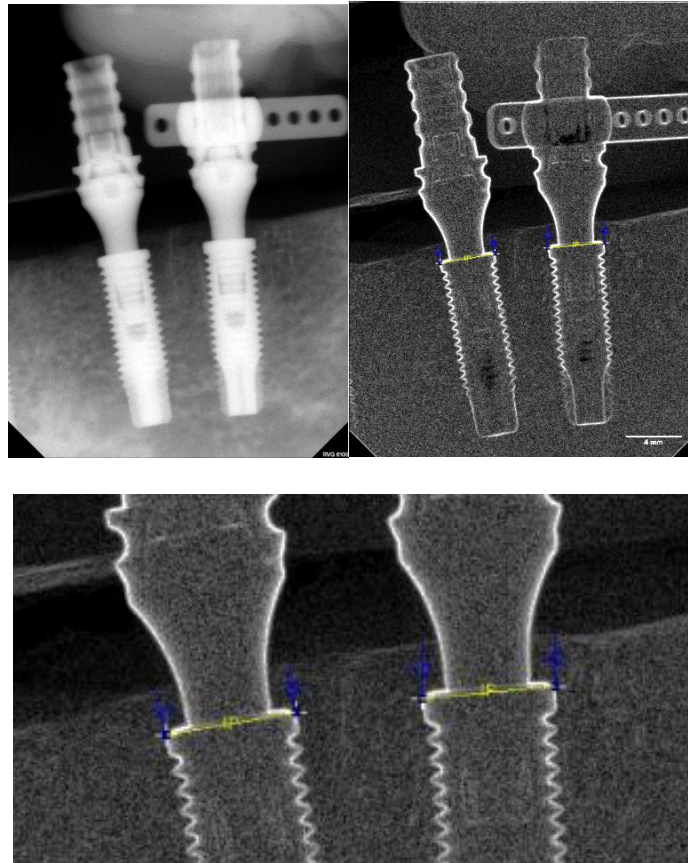


Figure 57 An Example of Periapical radiograph measurements

Bone Quality at Baseline

Bone quality was assessed pre-operatively using initial CBCT according to Lekholm and Zarb classification³⁴

Class 1: Almost the entire jaw is comprised of homogenous compact bone

Class 2: A thick layer of compact bone surrounds a core of dense trabecular bone

Class 3: A thin layer of cortical bone surrounds a core of dense trabecular bone of favorable strength

Class 4: A thin layer of cortical bone surrounds a core of low density trabecular bone

Resonance Frequency Analysis (RFA)²⁹⁻³¹

The implant stability was evaluated using the Resonance Frequency Analysis device (Osstell, Osstell AB, Gothenburg, Sweden)²⁹⁻³¹ at baseline, 3months and at 12months. Two measurements were made for each implant, in the bucco-lingual and mesio-distal axis and the average was recorded.

- The SmartPeg was attached to the transmucosal abutment
- The hand-held probe stimulates it magnetically and gives a digital readout

The displayed ISQ value reflects the degree of stability. The scale ranges from 1 to 100, the higher the ISQ, the more stable the implant. For this study implants with an ISQ values 55 and greater were immediately loaded.

Modified Plaque Index

Presence of plaque was assessed at the mesiolabial, labial, distolabial, mesiolingual, lingual, and distolingual of the definitive restoration with a periodontal probe (South Dakota 4 Color Vision Probe, Hu-Friedy, Chicago, IL) using the Modified Plaque Index by Mombelli et al³⁵.

Score 0: No detection of plaque

Score 1: Plaque only recognized by running a probe across the smooth marginal surface of the implant.

Score 2: Plaque can be seen by the naked eye

Score 3: Abundance of soft matter

Modified Sulcus Bleeding Index

The bleeding tendency of the marginal peri-implant tissues was evaluated at 6 sites (mesiolabial, labial, distolabial, mesiolingual, lingual, and distolingual of the definitive restoration) by running a periodontal probe around the implant circumference 1 mm into the gingival sulcus and assessed using the Modified Sulcus Bleeding Index by Mombelli et al³⁵.

Score 0: No bleeding when a periodontal probe is passed along the gingival margin adjacent to the implant.

Score 1: Isolated bleeding spots visible.

Score 2: Blood forms a confluent red line on margin.

Score 3: Heavy or profuse bleeding.

Surgical and Prosthetic Complication

Complications were recorded and included but not limited to soft tissue problems, bone loss, peri-implant radiolucency, and prosthodontic incidents. The most common complication was fracture of the distal cantilever of the interim prosthesis.

Statistical Analysis

Descriptive statistics were used to characterize the demographics and clinical presentation of the study patients. Twenty (20) patients were recruited for the study in order to have at least 80% power to detect a difference in the crestal bone changes between implants. However, due to patient dropout due to non-compliance we lost 3 patients. A single calibrated examiner measured crestal bone changes using CBCT images and the periapical radiographs. The Intraclass Correlation Coefficient (ICC) was used to determine the reliability of the measurements made by the examiner. Approximately 30% of the total measurements were randomly selected and measured twice, 1 week apart.

The primary hypothesis tested was that there was no significant difference in the crestal bone changes between implants placed immediately and loaded after alveoplasty as compared to implants placed in healed sites using guided surgery. An Analysis of Covariance of ranked data was used to test the primary hypothesis, with implant placement strategy as a fixed independent variable, and crestal bone change as the dependent variable. The secondary hypotheses tested included: (1) there is no difference over time in the bone changes for different depths of implant placement using nonparametric Friedman tests stratified by implant placement depth; (2) there is no difference over time in the bone changes for different widths of crestal buccal bone at the time of implant placement using nonparametric Friedman tests stratified by crestal buccal bone width; (3) there is no correlation between RFA and Torque values recorded using Spearman Rank correlation. The hypotheses were two-sided, and tested at an alpha level of 0.05 using SAS v 9.3 and SPSS v22.

CHAPTER SEVEN

RESULTS

Patient Characteristics

20 patients (11 female and 9 male) were recruited for this study using strict inclusion and exclusion criteria. The mean age was 55.5 years (28 to 78 years). A summary of the control and test group patients' general information is presented in Table 1 and Table 7. All patients were screened by the primary investigator to confirm their eligibility.

Data Screening

The surgeries were performed during the period of 10/18/2012 – 12/5/2014. No serious complication was noted during the period of recovery after surgery or during periodic recall examination. Screw loosening and fracture of the distal extension of the provisional prosthesis were minor complications that were recorded and dealt with. The average time elapsed from the time of implant insertion to prosthetic delivery was about 6 months. All included patients reported on the assigned appointments for periodic exams. One year follow up exams were performed from 10/18/2013 – 12/5/2015. During the course of the study implant #4 belonging to control patient #5 failed. Failure occurred at 3months after implant placement. The implant was removed and another implant was placed distal to it. This implant was submerged and not loaded for the patient's benefit and hence was not included in the study. The other 3 implants supported the interim prosthesis during the healing period of implant 4 without any complications.

Following a healing period of 4 months the implants were restored with fixed hybrid prosthesis.

With one implant lost during the course of the study the cumulative survival rate of the implants is 98.52%. For this study success rate is determined by using Albrektsson's criteria. Based on this criterion an implant is considered a success if the crestal bone loss as seen on periapical radiographs does not exceed 1.5mm at the end of one year of functional loading. The cumulative success rate of the implants is 94.11% .If we include patient #8 from the control group in the analysis the overall success rate will decrease to 88.23%. But considering the fact that the patient did not report his bruxism habit prior to placing the implants and the implants had good primary stability at placement it will be fair to exclude this patient from the analysis. None of the implants in the control group showed crestal bone loss greater than 1.5mm at the end of one year of function. Therefore the success rate of the control group is 100%. In the test group, 3 implants showed bone loss in excess of 1.5 mm at the end of one year of function and one implant failed. This brings the success rate for the test group down to 88.9% .All patients were restored successfully and the survival rate of the prosthesis is 100% at one year.

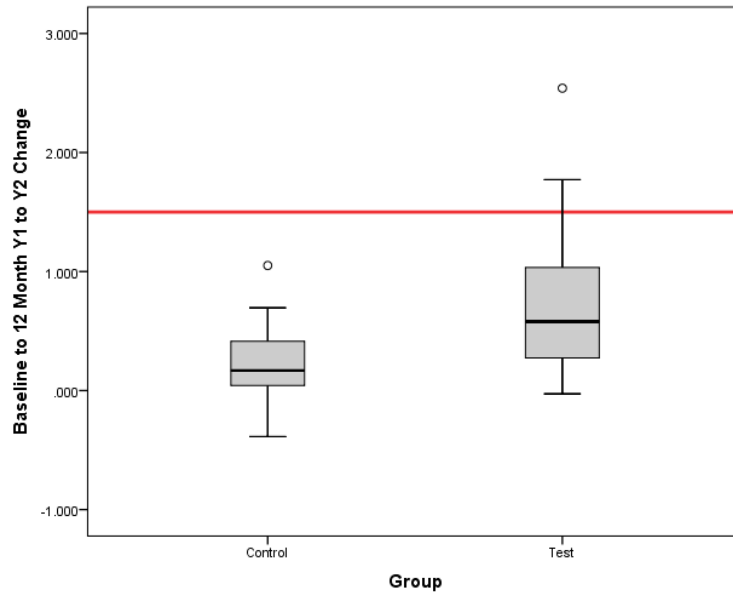


Figure 58 Baseline to 12 month change of interproximal crestal bone levels

Results from CBCT and Periapical Radiograph Measurements

There is a significant difference in the BHIP, BWIP, BW4IP, LHIP and LWIP measures between different time periods for both the control and the test group. This difference is statistically significant between baseline and 6 months and baseline and 12months. The difference is not significant between 6 months and 12 months. But when the same measures are compared between the two groups no significant difference was seen for the different time intervals.

There is a significant difference in the mesial bone height Y1 and distal bone height Y2 between baseline and 12 months for both the control and the test groups. But when the measures are compared between the two groups no significant difference is observed for the time intervals tested.

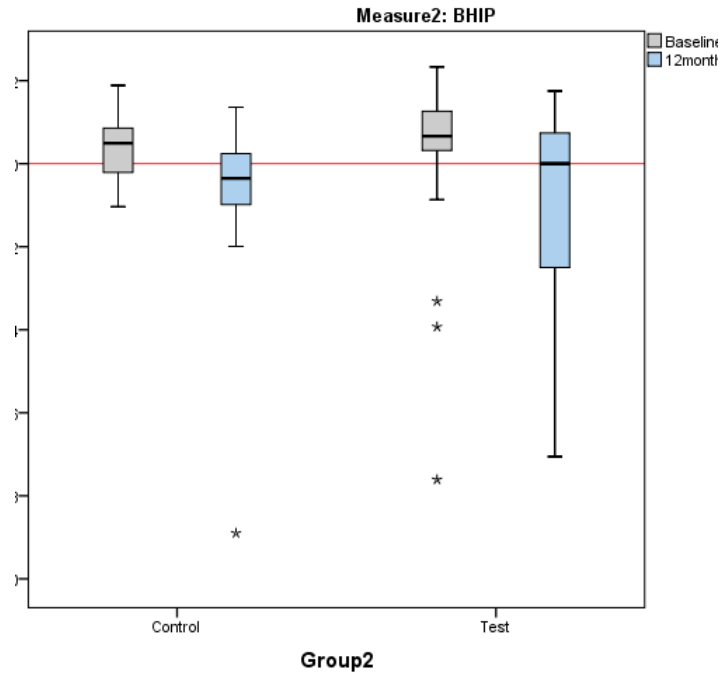


Figure 59 Comparison of Control and Test group for the measure BHIP at baseline and 12months

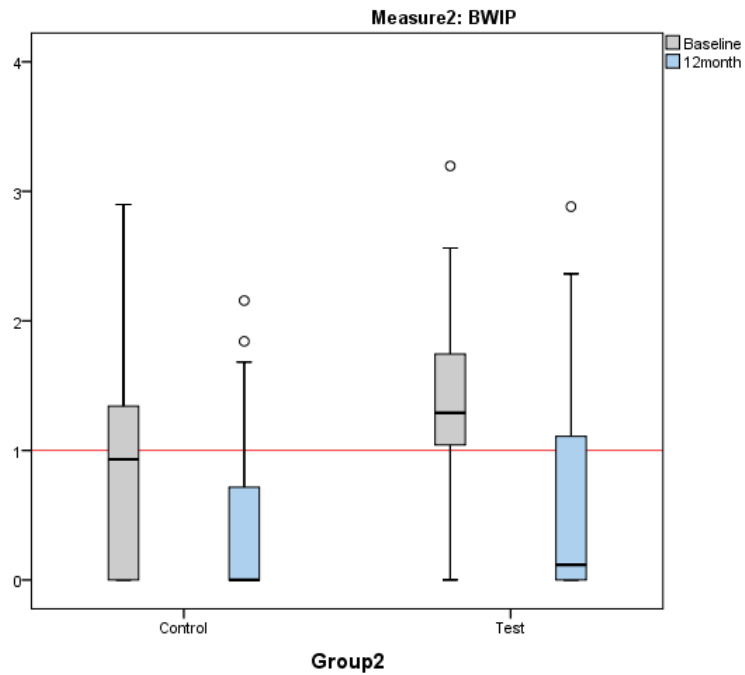


Figure 60 Comparison of Control and Test groups for the measure BWIP at baseline and 12months

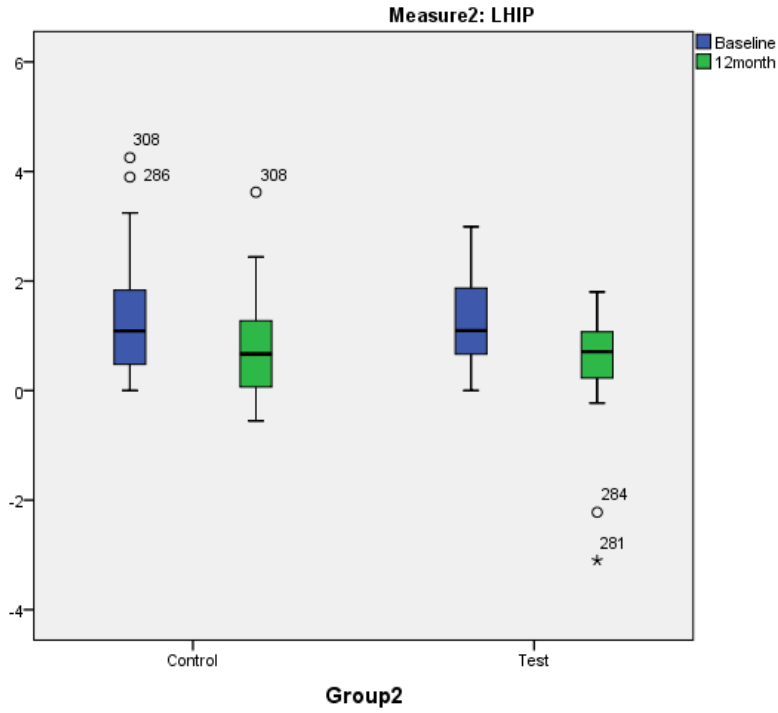


Figure 61 Comparison of control and test group for the measure LHIP at baseline and 12 months

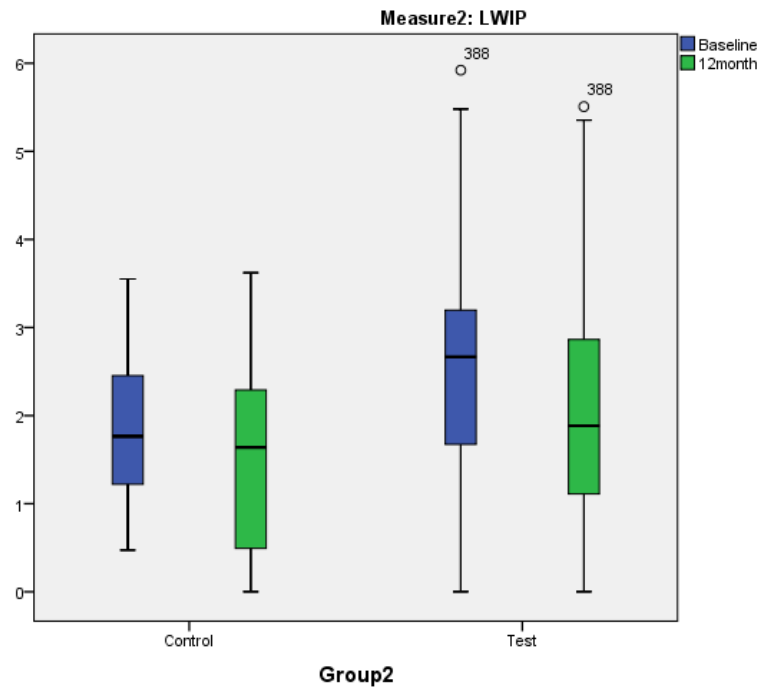


Figure 62 Comparison of Control and Test group for the measure LWIP at baseline and 12 months

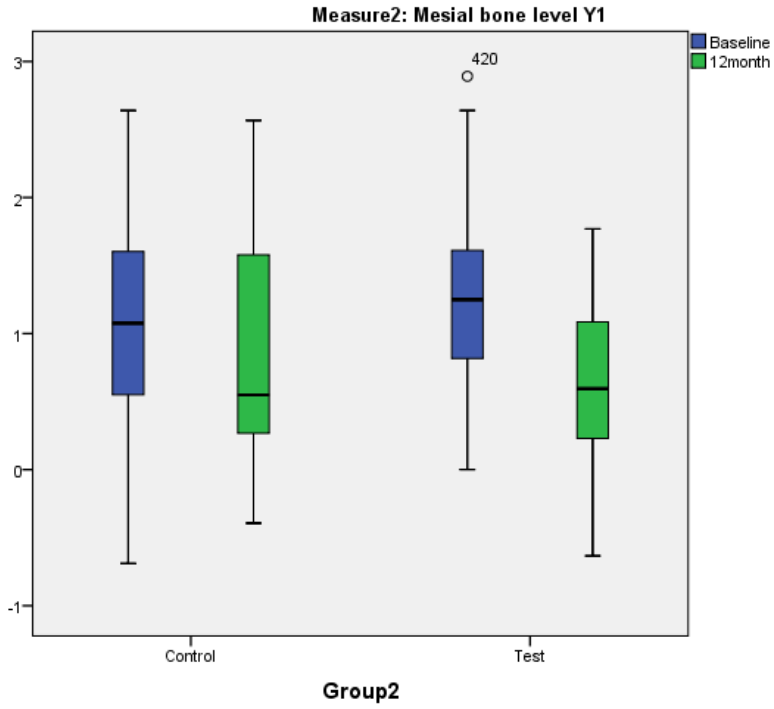


Figure 63 Comparison of Control and Test groups for the measure Y1 at baseline and 12 months

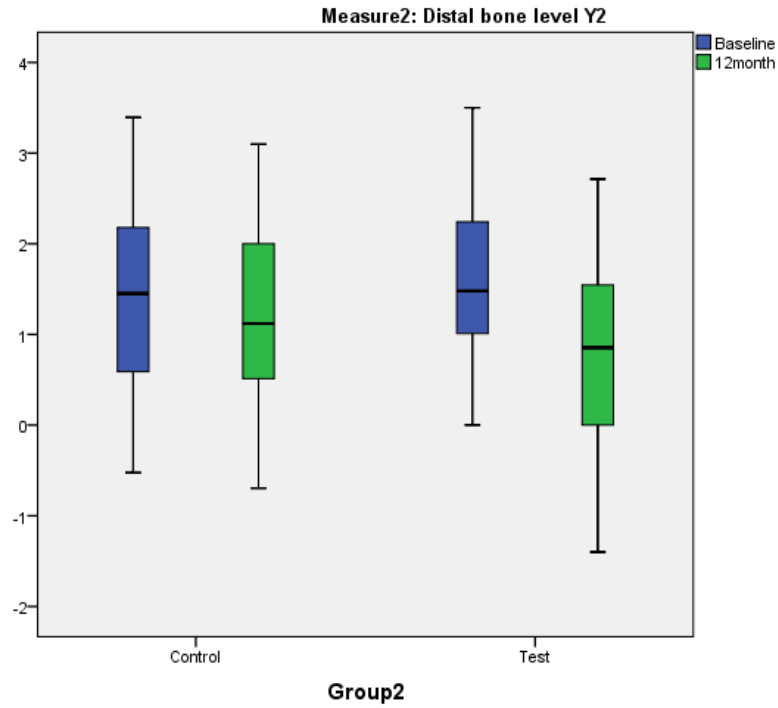


Figure 64 Comparison of Control and Test groups for the measure Y2 at baseline and 12 months

Will there be a difference in the crestal bone changes over time for different depths of implant placements or for different widths of the buccal bone between the two groups? The hypotheses were tested using Friedman's two way analysis of Variance by ranks at a p value of 0.05. Based on this analysis the conclusions that were obtained were-

1. In healed sites placing implants greater than 1mm below the crest causes less crestal bone changes over 12months than when they are placed at the level bone crest.
2. Placing implants greater than 2mm below the crest is beneficial for implants placed in extraction sites followed by alveoloplasty. This probably compensates for the changes due to extensive bone remodeling
3. For the control group, when the buccal bone width is between 1-2 mm there is a significant difference in crestal bone changes which disappears at widths greater than 2mm. Hence to compensate for bone remodeling a buccal width of greater than 2mm is preferred
4. For the test group, when the buccal width is between 1.1-2 mm and 2.1-3mm there is a significant difference in the crestal bone changes which disappears at widths greater than 3mm. Hence to compensate for bone remodeling a buccal width of greater than 3mm is preferred for implants placed in extraction sockets that need extensive alveoloplasty

Results from MPI and MBI Data

1. There is a significant difference in the modified bleeding index between different time periods for the test group. The bleeding index was greater in the test group at the end of one year.
2. There is a significant difference in the modified plaque index between different time periods for the test group. The plaque index was greater in the test group at the end of one year.
3. There is no significant difference in the modified bleeding index between different time periods for the control group.
4. There is no significant difference in the modified plaque index between different time periods for the control group.

Results of Comparison of RFA and Torque Values at Baseline

- There is no significant difference between baseline RFA and torque values for both the test and the control group using the Spearman's rho correlation stratified by groups
- For the Control group the rho was 0.114 at p value of 0.05
- For the Test group the Spearman's rho was 0.112 at p value of 0.05

Table 1: General information for control group

Patient	Age	Sex	Health status	Medical History	Reason for toothloss	Habits	Opposing Arch Occlusion	Bone Type
1	65	M	ASA I	NS	Periodontal disease	NS	Complete denture	Class 2
2	54	F	ASA I	NS	Periodontal disease	NS	Complete denture	Class 2
3	58	F	ASA I	Hyper tension	Periodontal disease	Smoker	Over denture	Class 3
4	45	F	ASA I	NS	Decay	Smoker	Fixed Complete denture	Class 2
5	37	F	ASA I	NS	Decay	NS	Complete denture	Class 3
6	68	F	ASA II	Diabetic	Periodontal disease	NS	Complete denture	Class 2
7*	78	M	ASA II	Hyper Tension	Periodontal disease	NS	Complete denture	Class 4
8*	45	M	ASA II	Gastric Bypass	Periodontal disease	Smoker Unknown bruxer	Complete denture	Class 4
9	72	F	ASA II	Diabetic	Periodontal disease	NS	Complete Denture	Class 4
10	66	M	ASA II	Hyper Tension	Periodontal disease	Smoker	Complete Denture	Class 2

7* patient was excluded from the study as implants could not be immediately loaded

8* patient was excluded as all implants failed due to emergence of previous unknown bruxing habits. Implants were included for assessment of success rate

Table 2: Implant Characteristics for Control group

Patient	Implant 1	Implant 2	Implant 3	Implant 4
1	4x13	4x13	4x13	4x13
2	4x13	4x13	4x13	4x13
3	4x13	4x13	4x13	4x13
4	3.5x13	3.5x13	3.5x13	3.5x13
5	4x11	4x13	5x11	4x11
6	3.5x13	3.5x13	3.5x13	3.5x13
7*	—	—	—	—
8	5x11	5x11	5x11	4x13
9	5x11	5x11	4x13	5x11
10	4x13	4x13	4x13	4x13

* Patient was excluded due to lack for adequate primary stability for immediate loading.

Table 3: Comparison of Torque and RFA values for control group

Patient	Implant	Baseline torque	Baseline RFA	3 month RFA	12 month RFA
1	1	45	69	70	71
	2	45	67	68	71
	3	45	66	69	71
	4	45	70	70	70
2	1	20	68	63	67
	2	45	69	68	70
	3	25	69	66	69
	4	30	69	71	67
3	1	32	71	72	72
	2	20	68	70	69
	3	32	58	67	68
	4	60	72	71	71
4	1	60	70	63	70
	2	60	65	63	69
	3	32	66	70	72
	4	60	70	70	71
5	1	30	69	65	73
	2	32	69	70	73
	3	60	70	70	73
	4	25	68	69	71
6	1	50	62	62	67
	2	60	59	59	63
	3	60	68	60	58
	4	45	66	65	65
8*	1	50	72	-	-
	2	20	72	-	-
	3	32	69	-	-
	4	32	70	-	-
9	1	22	61	70	71
	2	32	68	71	73
	3	22	65	68	71
	4	32	63	71	70
10	1	60	70	69	71
	2	50	67	71	70
	3	45	68	66	69
	4	60	68	70	71

*All implants were lost 4months and 12 days after loading due to emergence of previous unknown boxing habit

Table 4 CBCT measurements over different time periods for control group
(following page)

Patient	Implant	Time	BHIP	BWIP	BW4IP	LHIP	LWIP
1	1	Baseline	0.856	0.995	3.085	0.776	1.201
	1	3 month					
	1	6 month	0.527	1.22	3.165	0.763	1.608
	1	12month	0	0.756	3.045	-0.215	0
	2	Baseline	0.493	2.899	3.237	0	0.473
	2	3 month					
	2	6 month	0.373	2.045	3.672	0	0.577
	2	12month	0.49	1.682	3.11	-0.555	0
	3	Baseline	0.8553	2.726	4.119	0	1.2
	3	3 month					
	3	6 month	0.636	2.226	3.862	0	0.533
	3	12month	0.835	1.842	3.784	0.129	0.63
	4	Baseline	0	0.392	3.623	0.141	1.238
	4	3 month					
	4	6 month	0.358	0.806	3.811	0.858	1.453
	4	12month	-0.089	0	4.178	0.726	1.57
2	1	Baseline	1.653	0.903	2.687	3.243	3.48
	1	3 month					
	1	6 month	0	0.75	1.8	2.86	3.5
	1	12month	-0.231	0	1.805	2.44	3.405
	2	Baseline	0.832	1.015	2.3	1.74	2.687
	2	3 month					
	2	6 month	-1	0	2	0.25	2.39
	2	12month	-1.02	0	2.015	0.221	1.843
	3	Baseline	0.768	1.304	2.024	2.9	3.221
	3	3 month					
	3	6 month	-0.91	0	1.8	1.4	3.1
	3	12month	-1.9	0	1.486	0.723	3.1
	4	Baseline	-0.198	0	3.644	1.364	1.964
	4	3 month					
	4	6 month	-1.1	0	2.79	1.1	1.9
	4	12month	-0.93	0	2.432	1.05	1.824
3	1	Baseline	0.754	0.646	2.431	0.892	0.872
	1	3 month					
	1	6 month	0	0.494	1.175	0	0.484
	1	12month	0	0.474	0.967	-0.356	0
	2	Baseline	1.886	1.758	3.793	0.602	0.82
	2	3 month					
	2	6 month	1.782	1.792	2.921	-0.594	0
	2	12month	1.316	2.157	2.167	-0.34	0
	3	Baseline	1.567	1.821	2.229	0.627	1.095
3	3 month						

Patient	Implant	Time	BHIP	BWIP	BW4IP	LHIP	LWIP
4	3	6 month	0.711	1.778	1.289	-0.178	0
	3	12month	-0.09	0	1.041	0	0.357
	4	Baseline	0	0.333	1.907	0	0.591
	4	3 month					
	4	6 month	-0.099	0	1.624	-0.938	0
	4	12month	0.622	0.721	1.393	-0.207	0
	1	Baseline	-0.685	0	2.606	1.265	2.397
	1	3 month					
	1	6 month	-0.78	0	2.61	1.255	2.054
	1	12month	-0.719	0	2.733	1.273	2.39
	2	Baseline	-0.218	0	1.743	1.45	2.51
	2	3 month					
	2	6 month	-0.575	0	1.616	1.492	2.515
	2	12month	-0.351	0	1.618	1.277	2.32
	5	3	Baseline	-0.204	0	1.4	1.031
3		3 month					
3		6 month	-0.34	0	1.857	0.554	2.324
3		12month	0	0.71	1.765	0.612	2.367
4		Baseline	-0.566	0	1.677	1.925	2.469
4		3 month					
4		6 month	-1.273	0	1.822	1.475	3.167
4		12month	-1.163	0	1.867	1.486	2.669
1		Baseline	-1.036	0	1.5	4.253	3.388
1		3 month					
1		6 month	-1.699	0	1.484	4.013	3.632
1		12month	-1.994	0	1.623	3.622	3.622
2		Baseline	0.495	1.29	1.643	1.93	2.37
2		3 month					
2		6 month	-0.2	0	1.238	1.521	1.726
2	12month	-0.794	0	1.242	1.279	1.639	
6	3	Baseline	0	0.961	1.264	2.09	1.666
	3	3 month					
	3	6 month	0	0.572	0.909	1.14	1.496
	3	12month	-0.36	0	1.01	1.031	1.432
	4	Baseline	0	1.051	2.088	3.897	1.765
	4	3 month					
	4	6 month	-1.887	0	1.83	2.71	1.75
	4	12month	-1.74	0	1.614	2.081	2.042
	1	Baseline	0.52	0.957	2.663	0.505	1.11
	1	3 month					
	1	6 month	0.228	1.217	2.798	0.487	0.821
	1	12month	0.219	1.112	2.84	0.366	0.811

Patient	Implant	Time	BHIP	BWIP	BW4IP	LHIP	LWIP
9	2	Baseline	1.668	3.082	3.689	0	1.694
	2	3 month					
	2	6 month	1.012	2.48	3.611	0	1.556
	2	12month	0.952	2.42	3.514	0	0.739
	3	Baseline	1.118	1.586	3.202	0	1.11
	3	3 month					
	3	6 month	0.828	1.327	3.204	-0.13	0
	3	12month	0.601	1.141	3.213	-0.23	0
	4	Baseline	1.602	2.736	5.343	0	0.858
	4	3 month					
	4	6 month	1.444	2.758	5.303	0	0.606
	4	12month	1.119	2.852	5.403	0	0.603
	1	Baseline	1.102	1.5	2.311	1.612	3.551
	1	3 month					
	1	6 month	1.231	0.851	2.168	0.866	2.082
	1	12month	1.361	1.101	1.916	1.203	2.141
	2	Baseline	0.859	0.982	1.084	0.644	1.334
	2	3 month					
	2	6 month	0	0.662	0.983	-0.283	0
	2	12month	0	0.363	1.132	-0.262	0
	3	Baseline	1.039	1.38	1.075	1.147	1.519
	3	3 month					
	3	6 month	0.661	1.228	0.976	1.09	1.123
	3	12month	0.651	1.269	0.988	1.12	1.221
4	Baseline	0.613	0.644	2.126	1.183	1.332	
4	3 month						
4	6 month	-0.765	0	2.069	-0.352	0	
4	12month	0.876	0.611	1.813	1.446		
10	1	Baseline	-0.469	0	2.949	0.357	1.694
	1	3 month					
	1	6 month	-0.5	0	2.458	0.125	1.854
	1	12month	-0.972	0	2.532	0.142	1.57
	2	Baseline	0.652	1.407	1.857	0.844	1.615
	2	3 month					
	2	6 month	-1.625	0	2.5	0.469	1.6
	2	12month	-0.995	0	2.426	0.376	1.632
	3	Baseline	-0.346	0	2.2	0.2	2.36
	3	3 month					
	3	6 month	-0.719	0	2.117	0.26	2.344
	3	12month	-0.374	0	2.096	0.249	2.262
	4	Baseline	-0.358	0	2.48	0.125	2.288
	4	3 month					

Patient	Implant	Time	BHIP	BWIP	BW4IP	LHIP	LWIP
	4	6 month	0.487	0	2.5	0.6	2.426
	4	12month	-0.377	0	2.513	0.141	1.869

Table 5 Standardized radiographs measurements over different time periods for control group

Patient	Implant	Time	Mesial bone level Y1	Distal bone levelY2
1	1	Baseline	1.2	0.6
	1	3 month	1.159	0.511
	1	6 month		
	1	12month	1.15	0.412
	2	Baseline	0.62	0.7
	2	3 month	0.614	0.699
	2	6 month		
	2	12month	0.6	0.67
	3	Baseline	0.48	0.58
	3	3 month	0.441	0.559
	3	6 month		
	3	12month	0.346	0.416
	4	Baseline	0.45	0.28
	4	3 month	0.424	0.254
	4	6 month		
	4	12month	0.4	0.208
2	1	Baseline	1.638	1.785
	1	3 month	1.661	1.734
	1	6 month		
	1	12month	1.6	1.7
	2	Baseline	1.252	1.252
	2	3 month	1.24	1.18
	2	6 month		
	2	12month	1.18	1
	3	Baseline	2.64	2.878
	3	3 month	2.556	2.78
	3	6 month		
	3	12month	2.4	2.6
	4	Baseline	2.231	3.21
	4	3 month	2.1	3.13
	4	6 month		
	4	12month	2	3.1
3	1	Baseline	0.735	1.842
	1	3 month	0.545	1.695
	1	6 month		
	1	12month	0.497	1.679

Patient	Implant	Time	Mesial bone level Y1	Distal bone level Y2
4	2	Baseline	1.539	2.274
	2	3 month	1.452	1.256
	2	6 month		
	2	12month	1.182	1.24
	3	Baseline	1.397	1.659
	3	3 month	1.075	0.573
	3	6 month		
	3	12month	0.46	1.799
	4	Baseline	0.903	0.628
	4	3 month	0.83	0.351
	4	6 month		
	4	12month	0.699	0.501
	1	Baseline	0	0
	1	3 month	0.287	0.701
	1	6 month		
	1	12month	0.247	0.526
	2	Baseline	0	0.553
	2	3 month	0.51	0.714
	2	6 month		
	2	12month	0.289	0.603
3	Baseline	0	0	
3	3 month	-0.1	0	
3	6 month			
3	12month	0	0.237	
4	Baseline	1.061	1.204	
4	3 month	0.698	0.914	
4	6 month			
4	12month	0.431	0.62	
5	1	Baseline	2.579	3.395
	1	3 month	2.6	3.4
	1	6 month		
	1	12month	2.44	3.035
	2	Baseline	1.021	2.246
	2	3 month	0.433	2.22
	2	6 month		
	2	12month	0.374	1.704
	3	Baseline	1.228	2.253
	3	3 month	-0.112	1.334
	3	6 month		
	3	12month	0	1.38
	4	Baseline	2.169	2.067
	4	3 month	2.028	1.768

Patient	Implant	Time	Mesial bone level Y1	Distal bone levelY2
6	4	6 month		
	4	12month	1.557	2.023
	1	Baseline	1.854	0.921
	1	3 month	0.4	0.16
	1	6 month		
	1	12month	0.92	0.704
	2	Baseline	2.163	1.983
	2	3 month	1.33	1.04
	2	6 month		
	2	12month	1.223	0.948
	3	Baseline	1.546	1.162
	3	3 month	0.553	-0.404
	3	6 month		
	3	12month	1.094	0.441
	4	Baseline	2.673	1.728
	9	4	3 month	1.39
4		6 month		
4		12month	2.131	1.375
1		Baseline	1.092	1.652
1		3 month	0.962	1.662
1		6 month		
1		12month	1.061	2.011
2		Baseline	2.631	2.778
2		3 month	2.387	2.335
2		6 month		
2		12month	2.566	2.475
3		Baseline	1.849	2.111
3		3 month	1.655	2.033
3		6 month		
3		12month	1.714	1.99
10		4	Baseline	1.567
	4	3 month	1.57	1.93
	4	6 month		
	4	12month	1.684	2.171
	1	Baseline	0.19	0.99
	1	3 month	0	1.091
	1	6 month		
	1	12month	-0.394	0.618
	2	Baseline	0.666	0.768
	2	3 month	0.448	0.766
	2	6 month		
	2	12month	-0.331	0.42

Patient	Implant	Time	Mesial bone level Y1	Distal bone level Y2
	3	Baseline	0.685	-0.524
	3	3 month	0.554	-0.641
	3	6 month		
	3	12month	0	-0.698
	4	Baseline	-0.689	0.517
	4	3 month	-0.416	0.5
	4	6 month		
	4	12month	-0.39	0.613

Table 6 MBI and MPI for different time periods for the control group

Patient	Implant	Time	MBI	MPI
1	1	Baseline		
	1	3 month	1	1
	1	6 month	0	1
	1	12month	0	0
	2	Baseline		
	2	3 month	0	0
	2	6 month	0	0
	2	12month	0	0
	3	Baseline		
	3	3 month	0	0
	3	6 month	0	1
	3	12month	0	0
	4	Baseline		
	4	3 month	0	0
	4	6 month	0	0
	4	12month	0	0
2	1	Baseline		
	1	3 month	0	1
	1	6 month	0	1
	1	12month	0	1
	2	Baseline		
	2	3 month	0	1
	2	6 month	0	1
	2	12month	0	1
	3	Baseline		
	3	3 month	0	1
	3	6 month	0	1
	3	12month	0	1
	4	Baseline		

Patient	Implant	Time	MBI	MPI
3	4	3 month	0	1
	4	6 month	0	1
	4	12month	0	1
	1	Baseline		
	1	3 month	0	0
	1	6 month	0	0
	1	12month	0	1
	2	Baseline		
	2	3 month	0	0
	2	6 month	0	0
	2	12month	1	1
	3	Baseline		
	3	3 month	0	0
	3	6 month	1	0
	3	12month	1	1
	4	4	Baseline	
4		3 month	0	0
4		6 month	0	0
4		12month	1	0
1		Baseline		
1		3 month	1	0
1		6 month	1	0
1		12month	2	0
2		Baseline		
2		3 month	1	0
2		6 month	1	0
2		12month	2	0
3		Baseline		
3		3 month	1	0
3		6 month	1	0
3		12month	2	0
5	4	Baseline		
	4	3 month	1	0
	4	6 month	1	0
	4	12month	1	0
	1	Baseline		
	1	3 month	0	0
	1	6 month	0	0
	1	12month	0	0
	2	Baseline		
	2	3 month	0	0
2	6 month	0	0	

Patient	Implant	Time	MBI	MPI
6	2	12month	0	0
	3	Baseline		
	3	3 month	0	0
	3	6 month	0	0
	3	12month	1	0
	4	Baseline		
	4	3 month	0	0
	4	6 month	1	0
	4	12month	1	0
	1	Baseline		
	1	3 month	0	1
	1	6 month	0	1
	1	12month	0	0
	2	Baseline		
	2	3 month	0	1
	2	6 month	0	0
	2	12month	0	0
	3	Baseline		
	3	3 month	0	1
	3	6 month	0	0
3	12month	1	0	
9	4	Baseline		
	4	3 month	0	1
	4	6 month	0	1
	4	12month	1	0
	1	Baseline		
	1	3 month	3	3
	1	6 month	2	2
	1	12month	1	0
	2	Baseline		
	2	3 month	3	3
	2	6 month	2	2
	2	12month	1	0
	3	Baseline		
	3	3 month	3	3
	3	6 month	2	2
	3	12month	0	0
4	Baseline			
4	3 month	3	3	
4	6 month	3	3	
4	12month	0	0	

Patient	Implant	Time	MBI	MPI
10	1	Baseline		
	1	3 month	2	1
	1	6 month	0	1
	1	12month	0	1
	2	Baseline		
	2	3 month	2	1
	2	6 month	0	1
	2	12month	0	1
	3	Baseline		
	3	3 month	0	1
	3	6 month	0	1
	3	12month	0	1
	4	Baseline		
	4	3 month	0	1
	4	6 month	0	1
	4	12month	0	1

Table 7: General information for Test group

Patient	Age	Sex	Health status	Medical History	Reason for toothloss	Habits	Opposing Arch Occlusion	Bone Type
1	55	F	ASA II	Hyper Tension h/o Fosamax	Periodontal disease	NS	Complete denture	Class 2
2	62	M	ASA II	NS	Periodontal disease/ Decay	NS	Complete denture	Class 2
3	64	M	ASA II	Hyper tension	Decay	NS	Fixed Complete denture	Class 2
4	54	F	ASA I	NS	Periodontal disease	NS	Natural teeth	Class 3
5	59	M	ASA I	NS	Periodontal Disease/ Decay	NS	Complete denture	Class 3
6	37	F	ASA I	Gastric Bypass	Periodontal Disease/ Decay	Smoker	Complete denture	Class 2
7	56	F	ASA I	NS	Periodontal Disease/ Decay	Smoker	Complete denture	Class 2
8	45	M	ASA I	NS	Periodontal disease/ Decay	NS	Complete denture	Class 3
9*	28	M	ASA I	NS	Decay	Smoker h/o past drug abuse	Complete Denture	Class 2
10	61	F	ASA II	Hyper Tension	Periodontal disease	NS	Complete Denture	Class 2

9* Patient increased the number of cigarettes he smoked to a pack a day after implants were placed. Implants exhibited some bone loss. He failed to come in for his appointments and was lost to follow up.

Table 8: Implant Characteristics for Test group

Patient	Implant 1	Implant 2	Implant 3	Implant 4
1	4x13	4x13	4x13	4x13
2	4x13	4x13	4x13	4x13
3	4x13	4x13	4x13	4x13
4	4x13	3.5x13	3.5x13	3.5x13
5	4x13	4x13	4x13	4x13
6	4x13	4x13	4x13	4x13
7	4x13	4x13	4x13	4x13
8	4x13	4x13	4x13	4x13
9	3.5x13	3.5x13	3.5x13	3.5x13
10	4x13	4x13	4x13	4x13

Table 9 Comparison of Torque and RFA values for Test group

Patient	Implant	Baseline torque	Baseline RFA	3 month RFA	12 month RFA
1	1	45	68	61	69
	2	45	68	69	72
	3	45	58	61	64
	4	45	63	69	72
2	1	45	58	66	72
	2	45	63	70	70
	3	45	61	70	70
	4	45	64	70	70
3	1	32	64	69	70
	2	32	63	68	71
	3	32	61	63	67
	4	30	61	67	71
4	1	45	55	65	68
	2	40	63	69	72
	3	45	65	69	70
	4	40	64	68	70
5*	1	45	61	65	66
	2	35	57	62	69
	3	35	56	64	70
	4	20	55	-	-
6	1	40	69	69	69
	2	40	64	65	67
	3	30	60	61	61
	4	60	64	64	65
7	1	32	66	69	70
	2	45	67	71	73
	3	25	67	71	72
	4	25	68	71	73
8	1	45	61	66	70
	2	40	68	64	68
	3	45	61	66	68
	4	45	58	65	69
9*	1	50	64	-	-
	2	50	66	-	-
	3	50	63	-	-
	4	50	57	-	-
10	1	60	66	66	68
	2	60	64	64	65
	3	50	66	64	69
	4	35	58	61	67

5* in this patient implant 4 failed before prosthetic phase. The implant was removed and another implant was placed distal to it. But this implant was not loaded immediately and hence was excluded from the study

9* this patient failed to come in for his appointments after the implants were placed and loaded. He was lost to follow up

Table 10 CBCT measurements over different time periods for test group

Patient	Implant	Time	BHIP	BWIP	BW4IP	LHIP	LWIP
1	1	Baseline	0.635	3.196	6.159	1.28	2.519
	1	3 month					
	1	6 month	1.397	3.302	6.111	1.545	2.921
	1	12month	1.37	2.882	6.142	1.743	3.108
	2	Baseline	0	0.356	4.816	0.519	1.763
	2	3 month					
	2	6 month	0	0.624	4.921	0.921	2.042
	2	12month	0.391	1.109	4.95	0.729	1.885
	3	Baseline	1.529	1.351	3.44	0.859	2.115
	3	3 month					
	3	6 month	1.627	0.982	3.637	1.105	2.23
	3	12month	1.749	1.372	3.843	1.099	2.147
	4	Baseline	0.884	1.974	4.391	0.391	1.219
	4	3 month					
	4	6 month	0.665	1.713	3.669	0.54	1.444
	4	12month	0.836	1.879	3.838	0.728	1.191
2	1	Baseline	0	0.523	8.041	0.8	3.031
	1	3 month					
	1	6 month	-0.243	0	8.063	0.55	2.54
	1	12month	-0.221	0	7.872	0.443	2.096
	2	Baseline	-0.868	0	4.138	0.775	4.806
	2	3 month					
	2	6 month	-0.708	0	4.538	0.513	3.815
	2	12month	-0.736	0	4.245	0.49	4
	3	Baseline	-0.473	0	3.769	0.756	5.921
	3	3 month					
	3	6 month	-0.46	0	3.55	0.737	5.381
	3	12month	-0.46	0	3.436	0.708	5.508
	4	Baseline	0.415	1.997	4.044	0	4.346
	4	3 month					
	4	6 month	0.851	2.564	3.923	0	4.103
	4	12month	0.848	2.364	3.727	0	3.697
3	1	Baseline	2.01	1.744	2.232	1.892	3.015

Patient	Implant	Time	BHIP	BWIP	BW4IP	LHIP	LWIP
		1 3 month					
		1 6 month	0	0.488	2.022	0.965	2.527
		1 12month	0	0.371	1.583	0.354	2.437
		2 Baseline	-3.313	0	0.731	1.388	3.567
		2 3 month					
		2 6 month	0	0.238	1.4	1.23	3.326
		2 12month	0	0.233	1.4	1.053	3.018
		3 Baseline	2.023	1.475	3.011	0.867	1.567
		3 3 month					
		3 6 month	0	0.385	3.062	0.612	0.849
		3 12month	0	0.235	2.876	0.233	0.729
		4 Baseline	2.06	1.313	3.642	1.672	2.507
		4 3 month					
		4 6 month	0.897	1.583	3.863	1.414	2.047
		4 12month	0.98	1.409	3.712	0.848	2.081
4		1 Baseline	0.396	1.043	1.386	0.502	0
		1 3 month					
		1 6 month	-3.54	0	0.79	-0.218	0
		1 12month	-3.941	0	0.551	-0.226	0
		2 Baseline	-3.93	0	0.798	0	0.389
		2 3 month					
		2 6 month	-2.896	0	0.673	0	0.366
		2 12month	-3.213	0	0.987	-0.229	0
		3 Baseline	-7.611	0		0.73	1.282
		3 3 month					
		3 6 month	-3.349	0	0.536	0.461	1.129
		3 12month	-3.616	0	0.34	0.45	1.089
		4 Baseline	0.357	1.248	1.812	0.599	1.607
		4 3 month					
		4 6 month	0.12	0.788	1.286	0.598	0.987
		4 12month	0	0.702	1.375	0.351	1.131
5		1 Baseline	0	1.259	2.835	2.133	1.738
		1 3 month					
		1 6 month	-1.491	0	1.857	1.689	1.793
		1 12month	-1.5	0	1.894	0.45	0.984
		2 Baseline	1.241	1.733	1.969	2.462	3.282
		2 3 month					
		2 6 month	-1.747	0	2.099	1.34	2.144
		2 12month	-2.353	0	1.618	1.147	2.109
		3 Baseline	1.448	1.322	2.515	2.495	2.837
		3 3 month					
		3 6 month	-2	0	1.647	1.021	1.1

Patient	Implant	Time	BHIP	BWIP	BW4IP	LHIP	LWIP	
6	3	12month	-3.424	0	0.797	0	0.944	
	4	Baseline	0.512	2.322	2.077	1.005	2.471	
	4	3 month	This implant was lost at 3 months					
	4	6 month						
	4	12month						
	1	Baseline	0.506	1.072	1.985	1.653	5.479	
	1	3 month						
	1	6 month	-2.472	0	1.8	1.203	5.39	
	1	12month	-2.646	0	1.917	0.727	5.354	
	2	Baseline	0.291	0.531	0.571	0.952	1.003	
	2	3 month						
	2	6 month	-1.441	0	0.439	0.74	1.246	
	2	12month	-1.485	0	0.44	0.731	1.24	
	3	Baseline	1.06	1.045	1.781	1.96	1.328	
	3	3 month						
	7	3	6 month	0.979	1.02	1.65	2	1.32
3		12month	0.884	0.844	1.375	1.8	1.32	
4		Baseline	1.287	1.42	1.893	0.473	3.831	
4		3 month						
4		6 month	-2.702	0	1.5	1.302	3.72	
4		12month	-2.715	0	1.397	1.088	3.7	
1		Baseline	1.238	2.314	2.649	1.096	5.46	
1		3 month						
1		6 month	-1.463	0	1.608	0.384	1.722	
1		12month	-1.477	0	1.675	0.224	1.699	
2		Baseline	1.625	1.121	1.342	2.242	2.468	
2		3 month						
2		6 month	-3.046	0	0.609	-0.142	0	
2		12month	-3.121	0	0.599	-0.222	0	
3		Baseline	0.852	1.097	0.818	0	0.767	
3		3 month						
3		6 month	-7.047	0	0	-3.066	0	
3		12month	-7.055	0	0	-3.102	0	
8		4	Baseline	0.349	1.394	1.588	0.155	2.963
		4	3 month					
	4	6 month	-5.028	0	0	-2.214	0	
	4	12month	-5.102	0	0	-2.223	0	
	1	Baseline	0.46	1.596	1.811	2.23	3.315	
	1	3 month						
	1	6 month	1.031	0.75	1.74	1.708	2.854	
	1	12month	0.372	0.745	1.419	1.711	2.737	
	2	Baseline	0.66	1.604	2.056	1.207	2.21	

Patient	Implant	Time	BHIP	BWIP	BW4IP	LHIP	LWIP
10	2	3 month					
	2	6 month	-0.232	0	2.055	0.379	1.326
	2	12month	-0.333	0	2.054	0.253	1.192
	3	Baseline	2.332	1.964	2.905	2.992	2.946
	3	3 month					
	3	6 month	0.909	1.36	1.675	1.722	2.556
	3	12month	1.109	1.211	2.708	1.703	2.875
	4	Baseline	1.695	2.351	3.155	2.321	3.053
	4	3 month					
	4	6 month	0.664	1.628	3.122	1.128	2.775
	4	12month	1.19	1.382	3.02	1.167	2.618
	1	Baseline	0.824	2.511	3.335	1.33	3.077
	1	3 month					
	1	6 month	0.222	0.937	3.023	0.831	2.569
	1	12month	0.637	1.016	3.033	1.032	2.854
	2	Baseline	0.878	1.214	2.88	0.771	2.667
	2	3 month					
	2	6 month	0.754	1.2	2.717	0.618	1.351
	2	12month	0.388	1.512	2.818	0.136	1.155
	3	Baseline	1.237	1.237	2.122	1.695	2.168
	3	3 month					
	3	6 month	0.258	1.063	2.122	1.104	1.448
	3	12month	0.522	1.264	2.601	0.888	1.483
	4	Baseline	0.411	2.562	2.432	1.849	3.114
4	3 month						
4	6 month	0	1.246	2.639	2	3.016	
4	12month	1.018	0.956	2.836	1.371	3.055	

Table 11 Standardized radiograph measurements over different time periods for control group

Patient	Implant	Time	Mesial bone level Y1	Distal bone level Y2
1	1	Baseline	1.562	0.945
	1	3 month	1.461	0.976
	1	6 month		
	1	12month	1.33	1.05
	2	Baseline	0.681	0.548
	2	3 month	0.64	0.4
	2	6 month		
	2	12month	0.6	0.49
	3	Baseline	1.24	0.82
	3	3 month	1.29	0.86
	3	6 month		
	3	12month	1.16	0.45
	4	Baseline	1.59	0.264
	4	3 month	1.36	0
	4	6 month		
	4	12month	1.04	0.22
2	1	Baseline	0.9	0.755
	1	3 month	0.96	0.164
	1	6 month		
	1	12month	0.386	0.289
	2	Baseline	0	0
	2	3 month	0	0
	2	6 month		
	2	12month	-0.298	-0.203
	3	Baseline	0.233	0.719
	3	3 month	0	0.389
	3	6 month		
	3	12month	0	-0.237
	4	Baseline	1.545	1.768
	4	3 month	1.5	1.6
	4	6 month		
	4	12month	1.216	1.6
3	1	Baseline	2.131	1.762
	1	3 month	1.283	1.491
	1	6 month		
	1	12month	1.142	0.443
	2	Baseline	1.572	1.728
	2	3 month	1.098	0.925
	2	6 month		

Patient	Implant	Time	Mesial bone level Y1	Distal bone levelY2
4	2	12month	0.591	0.93
	3	Baseline	1.196	0.844
	3	3 month	0.231	0.115
	3	6 month		
	3	12month	0.229	0.251
	4	Baseline	1.407	1.477
	4	3 month	0.887	1.337
	4	6 month		
	4	12month	0.503	-0.162
	1	Baseline	0.817	0.88
	1	3 month	0.968	0.959
	1	6 month		
	1	12month	0.71	0.517
	2	Baseline	0	0
	2	3 month	-0.3	0
	2	6 month		
	2	12month	-0.445	-0.38
	3	Baseline	0.602	0.35
	3	3 month	0	-0.772
	3	6 month		
3	12month	0.226	-1.4	
4	Baseline	1.2	0.99	
4	3 month	0	-0.614	
4	6 month			
4	12month	-0.138	-0.79	
5	1	Baseline	2.303	3.408
	1	3 month	1.417	2.319
	1	6 month		
	1	12month	1.402	2.3
	2	Baseline	2.497	2.99
	2	3 month	0.797	1.71
	2	6 month		
	2	12month	0.494	1.448
	3	Baseline	2.891	3.015
	3	3 month	1.027	0.809
	3	6 month		
	3	12month	0.337	0.488
	4	Baseline	2.39	0.845
	4	3 month	-	-
	4	6 month	-	-
	4	12month	-	-
6	1	Baseline	2.1	3.5

Patient	Implant	Time	Mesial bone level Y1	Distal bone levelY2
7	1	3 month	1.548	2.958
	1	6 month		
	1	12month	0.561	2.714
	2	Baseline	0.73	1.01
	2	3 month	0.668	0.462
	2	6 month		
	2	12month	0.807	0.453
	3	Baseline	1.85	1.64
	3	3 month	0.79	1.64
	3	6 month		
	3	12month	0.819	1.6
	4	Baseline	0.827	2.241
	4	3 month	0.39	1.58
	4	6 month		
	4	12month	0.396	1.545
	1	Baseline	1.2	1.165
	1	3 month	0.592	1.057
	1	6 month		
	1	12month	0.588	1.033
	2	Baseline	1.682	2.06
	2	3 month	1.268	0.4
	2	6 month		
	2	12month	1.277	0.54
	3	Baseline	0.687	1.047
	3	3 month	-0.574	-0.157
	3	6 month		
	3	12month	-0.632	-0.255
	4	Baseline	0.291	0.233
	4	3 month	-0.574	-0.157
	4	6 month		
4	12month	-0.633	-0.255	
8	1	Baseline	1.611	1.748
	1	3 month	1.158	1.4
	1	6 month		
	1	12month	0.914	0.845
	2	Baseline	1.259	1.291
	2	3 month	1.146	0.47
	2	6 month		
	2	12month	0.65	0
	3	Baseline	2.64	2.87
	3	3 month	1.833	2.426
	3	6 month		

Patient	Implant	Time	Mesial bone level Y1	Distal bone level Y2
10	3	12month	1.351	2.677
	4	Baseline	2.23	3.2
	4	3 month	1.36	2.465
	4	6 month		
	4	12month	1.77	2.383
	1	Baseline	0.926	1.678
	1	3 month	1.176	2.007
	1	6 month		
	1	12month	1.086	1.573
	2	Baseline	0.819	1.135
	2	3 month	0.646	1.246
	2	6 month		
	2	12month	0	0.862
	3	Baseline	1.308	1.393
	3	3 month	1.19	1.5
	3	6 month		
	3	12month	0.806	1.177
	4	Baseline	1.562	1.481
	4	3 month	1.66	1.55
	4	6 month		
4	12month	1.103	0.915	

Table 12 MBI and MPI for different time periods for the test group

Patient	Implant	Time	MBI	MPI
1	1	Baseline		
	1	3 month	0	2
	1	6 month	0	0
	1	12month	0	1
	2	Baseline		
	2	3 month	0	2
	2	6 month	0	0
	2	12month	0	1
	3	Baseline		
	3	3 month	0	2
	3	6 month	0	0
	3	12month	0	1
	4	Baseline		
	4	3 month	0	2
	4	6 month	0	1
	4	12month	0	1
2	1	Baseline		
	1	3 month	0	3
	1	6 month	1	3
	1	12month	0	3
	2	Baseline		
	2	3 month	0	3
	2	6 month	1	3
	2	12month	0	3
	3	Baseline		
	3	3 month	0	3
	3	6 month	1	3
	3	12month	0	3
	4	Baseline		
	4	3 month	0	3
	4	6 month	1	3
	4	12month	0	3
3	1	Baseline		
	1	3 month	0	0
	1	6 month	0	0
	1	12month	0	0
	2	Baseline		
	2	3 month	1	0
	2	6 month	1	0
	2	12month	1	0
	3	Baseline		

Patient	Implant	Time	MBI	MPI
4	3	3 month	0	1
	3	6 month	0	1
	3	12month	0	1
	4	Baseline		
	4	3 month	0	1
	4	6 month	0	1
	4	12month	0	0
	1	Baseline		
	1	3 month	1	3
	1	6 month	1	2
	1	12month	1	1
	2	Baseline		
	2	3 month	2	3
	2	6 month	1	2
	2	12month	1	1
	3	Baseline		
	3	3 month	2	3
	3	6 month	1	2
	3	12month	1	1
	4	Baseline		
4	3 month	2	2	
4	6 month	1	1	
4	12month	0	1	
5	1	Baseline		
	1	3 month	0	0
	1	6 month	0	0
	1	12month	0	0
	2	Baseline		0
	2	3 month	0	0
	2	6 month	0	0
	2	12month	0	0
	3	Baseline		0
	3	3 month	0	0
	3	6 month	0	0
	3	12month	0	0
	4	Baseline		
	4	3 month		
	4	6 month		
	4	12month		
6	1	Baseline		
	1	3 month	1	0
	1	6 month	1	0

Patient	Implant	Time	MBI	MPI
7	1	12month	0	0
	2	Baseline		
	2	3 month	1	0
	2	6 month	1	0
	2	12month	0	0
	3	Baseline		
	3	3 month	1	0
	3	6 month	1	0
	3	12month	0	0
	4	Baseline		
	4	3 month	1	0
	4	6 month	1	0
	4	12month	0	0
	1	Baseline		
	1	3 month	0	0
	1	6 month	0	0
	1	12month	0	0
	2	Baseline		
	2	3 month	0	0
	2	6 month	0	0
	2	12month	0	0
	3	Baseline		
	3	3 month	0	0
	3	6 month	0	0
	3	12month	0	0
	4	Baseline		
	4	3 month	0	1
	4	6 month	0	0
4	12month	0	0	
8	1	Baseline		
	1	3 month	0	1
	1	6 month	0	0
	1	12month	0	0
	2	Baseline		1
	2	3 month	0	1
	2	6 month	0	0
	2	12month	0	0
	3	Baseline		
	3	3 month	1	1
	3	6 month	1	0
	3	12month	1	0
	4	Baseline		

Patient	Implant	Time	MBI	MPI
10	4	3 month	1	1
	4	6 month	1	0
	4	12month	1	0
	1	Baseline		
	1	3 month	0	0
	1	6 month	0	0
	1	12month	0	0
	2	Baseline		
	2	3 month	0	0
	2	6 month	0	0
	2	12month	0	0
	3	Baseline		
	3	3 month	0	0
	3	6 month	0	0
	3	12month	0	0
	4	Baseline		
	4	3 month	0	0
	4	6 month	0	0
	4	12month	1	0

CHAPTER EIGHT

DISCUSSION

Earlier studies have proved that immediate implant placement and immediate loading is a viable option. Jaffin et al in 2007 conducted a 5 year prospective study comparing the radiographic bone changes around implants placed in fresh extraction sockets and immediately loaded with fixed full arch provisional restoration to implants placed in native bone following the same loading protocol. No alveoloplasty was done following extraction. No significant difference was seen between the two groups. Placing an implant immediately after tooth extraction offers several advantages. It reduces the treatment time, fewer surgical sessions, ability to place the implant in a ideal position and above all psychological benefit to the patient. Barnett et al in 1991 conducted a prospective study for 3-6 years comparing the success rate of implants placed immediately and loaded after tooth extraction and radical alveolectomies to a control group. Periapical radiographs were used to measure bone changes. Although there was a difference between the two groups it was not significant.

However, some studies have shown that implants placed in fresh extraction sites have higher failure rates when compared to implants placed in mature healed sites. A recent systematic review by Ramos Chrcanovic et al in 2014 concluded that implants placed in extraction sockets have a higher failure rates than implants placed in healed sites. Why is there a difference in the outcome of various studies? Some of the reasons could be the criteria used to evaluate success and the method used to measure the bone changes around implants. A more accurate way will be to measure the change in the bone dimension 3-dimensionally using standardized radiographs along with high resolution

CBCT sections. We are stepping into a 3D world but still determine implant success using peri apical radiographs. We know from various studies that the buccal bone is most subject to change. It undergoes resorption even after a simple flap reflection. The stability of the labial gingiva is based on the underlying buccal bone. Hence it is crucial during implant placement to ensure that adequate buccal bone remains following remodeling. When extraction of teeth is combined with extensive alveoloplasty, the 3- dimensional fate of the buccal crestal bone has not been evaluated. Do we have to accommodate for the changes that take place due to bone remodeling has not been spelled out. In this study we measured the crestal bone changes 3-dimensionally using standardized periapical radiographs and high resolution CBCT section. A brief discussion of the study results follows.

In this study 20 patients were recruited for the study. Two patients from the control group and one patient from the test group were excluded from the study. Patient #7 belonging to the control group was excluded from the study. At the time of implant placement the implants exhibited inadequate primary stability (a minimum ISQ of 55 required for the study) for immediate load. So the implants were submerged and patient was treated using a conventional protocol and restored.

Patient #8 belonging to the control group was excluded from the study due to the emergence of previous unknown bruxism habit. Implants had good primary stability at the time of immediate load. At 3 month follow visit the patient reported movement of the prosthesis and related it to his bruxism habit. He failed to report this at the time of his initial appointment. When the prosthesis was removed all four implants exhibited

mobility and had to be removed. The circumferential bone defect was pathognomonic of occlusal overload.

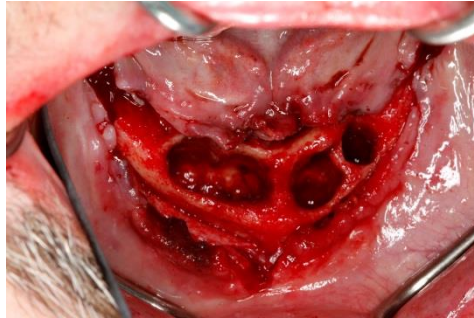


Figure 65 Circumferential defect left after implant removal

In clinical practice it is important to recognize a bruxism habit even in an edentulous patient. It is prudent to do a detailed questionnaire of para-functional habits when teeth were present as this might recur when a fixed prosthesis is delivered. Patient #9 belonging to the test group dropped out of the study. Patient failed to come to his follow up appointments after implant placement. Also he failed to comply with the inclusion criteria of the study and started smoking a pack of cigarettes per day. This reduced the total number of patients included in the study to 17. A total of 68 implants were placed, 32 implants in the control group and 36 implants in the test group. In this study Albrektsson's criteria were used to determine success rate of the implants. The Albrektsson's criterion describes ideal implant health which is of great academic value. But one drawback of this criterion is that it does not take into account those implants which are stable after a brief episode of bone loss. Therefore, although the implants in the test group showed a lesser success rate than the implants in the control group it is not

clinically significant. The success rate of the implants of the control group is 100% and the success rate of implants of the test group is 88.9%.

In the test group one implant (Test patient 5, implant 4) failed 3 months after placement. It had an insertion torque of 20 Ncm and an ISQ of 55 at placement. This reiterates the importance of primary stability for immediate loading. Although the implant met the minimum RFA value for immediate loading a higher value is preferred especially in extraction sites with extensive alveoloplasty. Of the three implants in the test group that exhibited > 1.5mm of bone loss after one year of function two of them belonged to the same patient (Test patient 5 implants 2 and 3) whose implant failed. The ISQ values were 56 and 57 respectively but showed an increasing trend at 3 months and 12 months indicating increasing implant stability. The initial bone loss stabilized without further complications.

The third implant exhibiting > 1.5mm of bone loss after one year of function was a distal implant in a patient (Test patient 4, implant 1) who had a full arch of opposing natural teeth indicating excess occlusal load. The initial bone loss stabilized as evidenced by the increasing RFA values.

Another interesting finding is that the autogenous bone placed in the gap in extraction sockets between the implant and the buccal bone in the test group failed to maintain the width of the buccal bone. Placing a xenograft with a low substitution rate might have reduced the bone volume changes seen.

In the test group there was significant difference in the modified plaque index and the modified bleeding index during the observation period. This might have contributed to the greater amount of bone loss seen in some patients. A reasonable

speculation for higher indices could be due to the fact that the test group patients did not have an edentulous period and continued their previous oral hygiene practices. On the other hand the control group patients were edentulous and realized that this is a second chance for having a fixed option and tried their best to keep the teeth clean.

This is one of the first studies that looked into the 3-dimensional crestal bone changes around implants placed in extraction sockets combined with extensive alveoloplasty. The BHIP, BWIP, BW4IP, LHIP, LWIP, were measured at baseline, 6 months and 12 months. Y1 and Y2 were measured at baseline, 3 months and 12 months. Based on this study the initial buccal bone height and width determine the long term stability of the buccal bone. The buccal bone underwent extensive remodeling when subjected to the trauma of extraction and alveoloplasty. Implant sites with thin facial bone lost more vertical bone height than sites with thicker facial bone irrespective of the type of placement. Spray et al in 2000 conducted a prospective study in healed sites where they measured the changes in vertical dimension of facial bone between implant insertion and uncover and compared these changes to facial bone thickness. As the facial bone thickness approached 1.8 to 2mm bone loss decreased significantly and evidence of bone gain was seen. A similar trend was seen in this study as well. In the control group where the implants were placed in healed sites when the buccal bone thickness after implant placement was between 1-2 mm a significant difference in the crestal bone width was seen between baseline and 12months. However, when the crestal bone width was greater than 2mm this difference was not significant. In the test group where the implants were placed in extraction sites combined with alveoloplasty a significant difference in the crestal bone width was seen up to 3mm of initial bone width. However this significance

disappeared at initial widths greater than 3mm. Therefore, in order to compensate for the bone remodeling following extraction and alveoloplasty an initial buccal width greater than 3mm is preferred.

Veis et al 2010 in a randomized prospective clinical study evaluated the crestal bone changes around platform matching and platform switched implants placed at supracrestal, crestal and subcrestal levels. He concluded that platform switched implants showed less vertical bone loss when placed in a subcrestal position than when placed at crestal or supracrestal positions. In Veis's study the implants were placed in 1-2mm subcrestally.

In this study, platform switch morse taper implants (Neodent, USA Inc) were used. We observed less bone changes when implants were placed greater than 1mm subcrestally in the control group. Whereas in the test group implants placed greater than 2mm below the crest showed better bone stability.

We can summarize by saying that although there were more failures in the test group than in the control group it was not clinically significant. While placing implants in sites where extraction is combined with extensive alveoloplasty, we have to accommodate for bone remodeling by placing implants at least 2mm below the bone crest and have a minimum of 3 mm of facial bone at implant placement. It is of paramount importance that implants that will be immediately loaded must have RFA values greater than 55 especially when they are the most distal implant. A higher MPI and MBI in the test groups calls for a good maintenance program as plaque is a one of the key contributors of bone loss³⁶.

Conclusions and Future Directions

Within the limits of this study, the conclusions that can be drawn are –

1. When implants are placed following extraction and alveoloplasty placing them at least 2mm below the crest will compensate for bone remodeling with platform switch implants
2. A buccal bone width of 3mm in the test group undergoes the least changes over 12months
3. Healed sites undergo changes as well. Best outcome is seen when the implants are placed greater than 1mm below the crest and buccal bone width is greater than 2mm
4. No difference in the mesial and distal bone changes as seen on radiographs between the test and the control group for the different time periods evaluated
5. Buccal bone stability should be used as the new standard for determining implant success rather than the periapical bone levels as buccal bone loss precedes the interproximal bone loss.

With the advent of improved implant surfaces and designs implant survival is not a concern. Success of an implant based on 3D bone stability should be the new future direction as it dictates long term implant health and esthetics. Future studies aiming at measuring mesial and distal bone changes in coronal CBCT sections will be promising.

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