"EVALUATION OF IMPLANT STABILITY, BONE IMPLANT CONTACT AND CRESTAL BONE LOSS WITH SQUARE THREAD FORM IMPLANTS"

Dissertation

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BABU BANARASI DAS UNIVERSITY,

LUCKNOW, UTTAR PRADESH

In the partial fulfilment of the requirements for the degree

of

MASTER OF DENTAL SURGERY

In

PROSTHODONTICS AND CROWN & BRIDGE

By

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Under the guidance of

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BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

(Faculty of Babu Banarasi Das University)

YEAR OF SUBMISSION: 2021 **BATCH: 2018-2021**

CERTIFICATE

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"EVALUATION OF IMPLANT STABILITY, BONE IMPLANT CONTACT AND CRESTAL BONE LOSS WITH SQUARE THREAD FORM IMPLANTS"** is a bonafide and genuine research work carried out by me under the guidance of ***Dr. Swati Gupta*** **,** Professor, Department of Prosthodontics and Crown & Bridge, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

Date: 07/07/2021

Place: Lucknow

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This is to certify that the dissertation entitled **" EVALUATION OF IMPLANT STABILITY, BONE IMPLANT CONTACT AND CRESTAL BONE LOSS WITH SQUARE THREAD FORM IMPLANTS "** is a bonafide work done by **Dr. Georgee Sharun Philip**, under my direct supervision and guidance in partial fulfilment of the requirement for the degree of MDS in Department of Prosthodontics and Crown & Bridge.

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Dr.GeorgeeSharun Philip

Naan Veezhven Endru Ninaithayo Aandavane Namba Pakkam Da !!

CONTENT

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ABSTRACT

BACKGROUND

Macrodesigns and microdesigns are some of the factors that maximize initial contact, improve initial stability, enlarge implant surface area,and favour dissipation of interfacial stress. Out of these, thread depth, thread thickness, thread face angle, thread pitch, and thread helix angle are few of the varying geometric patterns of a thread form that influence the functional thread surface and affect the biomechanical load distribution of the implant .Thread shapes in dental implant designs include square, V-shaped, reverse buttress and buttress. Under axial loads to a dental implant, a V-thread face is comparable to the buttress thread when the face angle is similar and is usually. A square thread design (as opposed to the standard V-shaped or buttress thread) has been suggested to reduce the shear component of force by taking the axial load of the prosthesis and transferring a more axial load along the implant body to compress the bone .Hence, it was suggested to avoid nonaxial, shear loading whenever possible.

AIM AND OBJECTIVE

Evaluation of the implant stability ,bone implant contact and crestal bone loss after placement of square thread form implants at pre-specified intervals.– in vivo study

MATERIAL AND METHOD

The selected patient as per the inclusion criteria‟s and treated with 2 endossteal implants in the region in relation to 22 and 12.Changes in crestal bone level, implant bone contact and implant stability were assessed with the help of CBCT.

OBSERVATION

The follow up of the patient after the initial implant placement had no signs of inflammation or any abnormalities which can cause bone loss. The RFA value taken at the initial stage for both the implant was 57 ISQ.

CONCLUSION

It needs to be understood that each implant site has different bone density, bone mechanics and following the same treatment plan for all the sites will affect the long time prognosis of implant after loading. The review of square thread form implants reveals its larger surface area and the compressive forces generated will improve the osseointegration even in condition where bone has lower density. It can be concluded that combination of square thread form implants with the CBCT diagnostic images will help in improving the success rate of the implant prosthesis.

Key Words: Square thread implants, implant mechanics, CBCT.

Branemark in 1950 coined the term osseointegration with reference to placement of titanium implants in the knee[1]. The introduction of dental implants was done much later inthe year of 1965 by Branemark[1, 2]. Implants have come a long way and since then, it has successfully helped in the rehabilitation of the root structure of the missing tooth/teeth. Tremendous research intoevery aspect of the implants has been done from the placement to the loading of implants, surface treatment to the mechanical forces generated during placement and the loading forces after its been put into function and the implant failures[3].

The success of the implant placement largely depends on the amount of bone loss and the amount of the bone which is been newly formed around the implant. These phenomena are the key features of the osseointegration[4]. Most accepted bone loss during the initial healing of one year was considered to be 1.02mm and every consecutive year of about 0.2mm[5]. The active bone formation and bone resorption are mere act of forces generated into the bone while osteotomy, and while loading the implant into the site. The generation of these forces viz. compressive forces, tensileforces, shear forces, form one of the key to success. The initiation of these forces starts with placement of implants and continues thereafter. Besides factors like the surgical technique of implant placement, the healing phase, type of prosthesis, occlusion; the generation of these forces depends on implant geometry as well[6]. Implant geometry can be classified into microscopic features which include the surface treatment and the surface conditioning and the macroscopic features which include the implant thread form, body type, thread pitch and depth. Unlike the microscopic features, the macroscopic features play more active role in almost all the three types of bones during both initial healing and mature healing which is inter related to forces[7].

Based on the thread form, the implant systems are broadly divided into 4 type"s namely V–shaped thread, Square thread, buttress and reveres buttress[8]. Literature has identified each thread with its disadvantages based on the evaluation tools and it has been observed that most of the studies have evaluated V- shaped threads and are commonly used[9]. The forces generated on bone by the V-shaped threads when compared to square shaped

threads have least amount of compressive forces[10]. One of the major role of compressive forces is to generate stress which will later initiate bone formation around the implant body. The other two major forces are set to be tensile and shear forces. These forces when act upon the bone reduce the bone strength by 70%[11].

The surface area of the implant varied with various macroscopic implant design it was found that the square thread had larger surface area in comparison to the V- shaped, buttress and reveres buttress[12]. Studies until now have showed that bone loss during the initial healing in relation to square thread was 0.8mm to 1 mm and less than .2mm for every consecutive year[13]. The bone loss was considered to be way lesser than the gold standard set by Branemark[14].

To prove the clinical significance of square thread implants, the imaging technique chosen to be Cone bean Computed Tomography (CBCT). Until now imaging of head and neck or any imaging system was based on ALARA criteria which stated "as low as reasonably achievable "meaning diagnostic imaging technique selected should include the lowest possible radiation dose to the patient. But these criteria should not jeopardize the image quality[15]. This was one of the reason panoramic imaging was so commonly used for implant treatment option; this imaging has its own limitation which blinds the dentist in keeping the treatmenttwo dimensional[16]. CBCT has come a long way since American Academy Of Oral Maxillofacial Radiology had started its venture to make the implant treatment a three dimensional study reducing failures and selection of the ideal site for implant placement which was done solely by the help of advance techniques like conventional or computer tomography[17].

To our knowledge, there was no pervious study that has assessed the implant stability, bone implant contact and crestal bone loss in relation to square thread form implant. Therefore the purpose of this study is to evaluate implant stability, bone implant contact and crestal bone loss with square thread form implant at pre-specified intervals.

WORKING HYPOTHESIS

There is a correlation between the thread shape of implants with crestal bone loss, bone implant contact and Resonance frequency analysis and implant stability.

NULL HYPOTHESIS

There is no correlation between the thread shape of implants with crestal bone loss, bone implant contact and Resonance frequency analysis and implant stability.

AIM

Evaluation of the implant stability, bone implant contact and crestal bone loss after placement of square thread form implants – in vivo study

OBJECTIVES

- To evaluate stability using resonance frequency analysis (ISQ), at the time of the placement.
- To evaluate stability using resonance frequency analysis (ISQ), after three months of placement.
- To evaluate stability using resonance frequency analysis (ISQ), 3 months post prosthesis placement.
- To compare the above three values of RFA.
- To evaluate crestal bone loss around implant after 3 months of placement.
- To evaluate crestal bone loss around implant after 3 months of placement and also after 3 months of prosthesis loading.
- To compare the above three values of crestal bone loss.
- To evaluate BIC at different periods of observation and to compare them.
- To evaluate bone implant contact at the time of the placement.
- To evaluate bone implant contact after 3 months of implant placement.
- To evaluate bone implant contact after 3 months of prosthesis loading.

Wlike ,H-J,Claes,L&Steinemann,S.(1990)[18]

Drew attention to an increase resistance to interfacial shear between implant and bone, when the surface of the implant was in some way roughened and that the morphology and dimensions of the surface roughness would also influence the implant "holding power".

Lawrence A. Weinberg (1993)[19]

evaluated all three major forces been acted by the implant system while loading it was briefly explained the properties of all three main types of forces been generated such as the compressive forces which makes the bone more stronger which in turn will help the bone formation. Tensile and shear forces makes the bone 30% to 60% weaker respectively when compared with compressive forces.

CaptGherME(1995)[20]

Conducted a study in which periapical, panoramic, linear tomographic, and computerized tomographic radiographs were made of a partially dentate human mandible with four implants in place. Measurements taken from the radiographs and computer generated images were compared to measurements made directly on the cross-sectional test specimen. Computerized and linear tomographic images provided the unique advantage of cross-sectional views of anatomic structures, but image blurring inherent to linear tomography and volume-averaging error inherent to computerized tomography affected the accuracy of measurements made from these images. They concluded by stating that computerized tomographic when used with dentascan produced the most accurate measurement.

Jung YC et al.(1996)[21]

Conducted a study to evaluate the alveolar bone loss during the first 12 months after implant abutment connection. Marginal bone loss around 62 endosseous root-form implants in 62 patients was measured on periapical radiographs. Changes in bone density were measured by the digital subtraction image radiographic method. At 3-month intervals for 1 year, bone loss around the four types of implants used (standard series, square thread , and hexlock implants of the Steri-Oss system; and 3i standard

implants) was investigated. Rapid bone loss around all four implant types occurred in the first 3 months. Most of the implants showed resorption of alveolar bone beyond the polished neck at 12 months. The bone level stabilized at the first thread of the implants with no correlation to either the time of exposure of the polished neck or the type of implant. Bone density decreased at the marginal bone and increased at the newly formed alveolar crest.

BarbierL et al.(1997)[22]

Suggested that square thread design as opposed to the standard V-shaped or buttress thread has been suggested to reduce the shear component of forces by taking the axial load of the prosthesis and transferring a more axial load along the implant body to compress the bone.

Reddy M et. al(1999)[23]

Reviewed and compared the strengths and weaknesses of radiographic techniques including periapical, occlusal, panoramic, direct digital, motion tomography, and computed tomography. Practical considerations for each method, including availability and accessibility, are discussed. To date, digital subtraction radiography is the most versatile and sensitive method for measuring boss loss. It can detect both bone height and bone mass changes on root-form or blade-form dental implants.

Bumgardner JD et al (2000)[24]

Square- thread design implants showed , in a 4 beagle dog animals study , that bone grew between the thread , closely adapted to the implant, and that the inferior aspect of the test implant threads were opposed by more bone that the coronal aspect. These results suggest a biologic advantage for the compressive load transfer mechanism for this thread design .

O'Sullivan D et. al(2000)[25]

Compared the primary stability characteristics of five different implant designs, specifically the standard Branemark, Mark II self-tapping implant and Mark IV self-tapping tapered implant (Nobel Biocare AB Goteburg, Sweden), Osseotite (Biomet 3I), and Tioblast, implant (AstraTech AB, Molndahl, Sweden). The study demonstrated higher RF analysis and insertion torque values for Tioblast implant

square thread than for tapered implants, suggesting increased stability in square thread implant had better results.

Lars Rasmusson et al.(2001)[26]

Resonance frequency analysis indicated that all implants in the test and control groups were osseintegrated after4months, with a tendency toward higher implant stability for the Astra Tech implants. There was a statistically significant higher increase in resonance frequency for the square thread form implants compared with their corresponding controls. Histology and histomorphometry showed well-integrated implants with varying degrees of bone repair at the defect sites. The greater bone-implant contact for the square thread implants was statistically significant.

Chun (2002)[27]

Performed finite elimite analysis (FEA) study and suggested that the square thread form had the least stress concentration when compared with other thread shapes.The force decapitated by the implant produced more of compressive forces which initiated the bone remodeling.

Engquist B et al. (2002)[28].

Conducted a study to compare the two systems (Astra Tech and branemark system) primarily with regard to marginal bone changes, but also with regard to other clinical variables of interest. The marginal bone level was radiographically examined at fixture insertion, at abutment connection, at baseline (delivery of the prosthetic construction) and at 1- and 3-year follow-up examinations. Between fixture insertion and the baseline examination, the pattern of marginal bone resorption differed between the two systems. However, there was no significant marginal bone change between baseline and the 1-year examination or between the 1 and 3-year examinations. Nor were there any differences between the systems. The implant system used by astra tech was the square thread form.

Steigenga, J. et al (2004)[29]

Performed a study on animals and it showed square thread implants had better bone implant contact and higher reverse torque.

Geng et al (2004a)[30] concluded that the square thread dissipated lesser amount of stress over the surrounding bone on loading when compared to the V-shaped implants.

Geng, J.P.et. al (2004b)[31]

Using FEA, compared different thread configurations for V-shape and the broader square experimental stepped screwed implant. Out of these different thread designs broader square thread form generated significantly less stress compared with the thin V- shape thread form in thin and narrower cancellous bone.

Schwartz-Arad D (2005)[32]

Evaluated the implant success criteria, regarding marginal bone loss and other parameters, which were first suggested in 1986 and today are still frequently referred to as the gold standard for implant success. They concluded by suggesting new criteria‟s which are as follows:Four hypothetical patterns of implant marginal bone loss after the first year: A low-rate marginal bone loss over the years (Albrektsson's pattern); low-rate marginal bone loss in the first few years followed by a rapid loss of bone support; high-rate marginal bone loss in the first few years followed by almost no bone loss; and continuous high-rate marginal bone loss leading to a complete loss of bone support .This was seen in various thread forms of the implants and the lowest amount of bone loss was seen around square thread form.

Chia-Ching Lee et al (2010)[33]

Concluded that among the three implant thread shapes, the contact area of the symmetrical thread was the least, and its first thread was subjected to the greatest stresses. If the wall thickness of the square thread was kept structurally reasonable, the square thread possessed a higher contact area and lower stress value than the buttressed one.

MychelleVianna dos Santos(2011)[34]

In their study compared two different implant system using RFA device for the primary stability. These two implant system included were V- shaped thread and square thread form and concluded maximum implant insertion torque depends on the implant geometry, thread form and surface roughness which was found in squared thread form.

Vieira Feijó C (2012)[35]

Statistically concluded that CBCT when used in the boney disease in comparison to the 2D imaging technique showed all the wall defects and the marginal bone lose which was clinically accurate.

Shashikala k. and Shekhar V. (2013)[36]

Concluded that advantage of (small field of view) CBCT scanner ,it produced relatively low –effective radiation dose to the patient been exposed .It yields radiation doses similar to that from two or three intraoral radiographs.

The present study was conducted in the Department of Prosthodontics, Crown And Bridges,Babu Banarasi Das College Of Dental Sciences, BBD University, Faizabad Road, Lucknow, India. The aim of the study was to **evaluate implant stability, bone implant contact and crestal bone loss with square thread form implants – in vivo study**

Patients requiring implant supported fixed prosthodontic treatment were selected for the study sample as per the inclusion and exclusion criteria‟s. The study was approved by the ethical committee of Babu Banarasi Das College Of Dental Sciences, BBD University. The number allotted to the study IEC CODE 42. Patients were provided with a consent form with written explanation regarding the nature of treatment, associated procedures and risks involved with the treatment.

Only one patient requiring two implants in the maxillary anterior region was treated with titanium endosteal transmucosal square thread type fixtures "AlphaBio" (Israel). Due to the imposed lockdown for bringing down the onset of Covid from March‟20, the study had to be put on hold and could not be further progressed.

1 Materials

1.2 Materials used for diagnosis and pre clinical assement fig 3,4

Mouth mirror (API AshoosonsPvt Ltd New Delhi, India)

Periodontal probe (GDC Marketing , India)

Tweezer(API AshoosonsPvt Ltd New Delhi, India)

Metal scale

Hard tissue caliper (GDC Marketing , India)

Digital CBCT (PreXion3D Exercisior CBCT scanner) with an image field of view 4x4.

Additional Materials used for implant placement fig3,4

Syringe 3 ml(Dispo Van, Hindusatan Syringe and medical Device Ltd, Faridabad, India)

Local anesthesia (Xicaine ,ICPA Health Products LTD,Ankleshwar, India)

Saline (Gibson Sri Durga import (P)Ltd,-ESPB, Chennai)

Bard parker handle(API AshoosonsPvt Ltd New Delhi, India)

Blade (no.12) (API AshoosonsPvt Ltd New Delhi, India)

Periosteal elevator (GDC Marketing , India)

Tissue holding forceps (GDC Marketing , India)

Needle holder (GDC Marketing , India)

Suture 3-0 silk (Ethicon , Johnson and Johnson ltd.,Baddi, H.P.India)

Suture cutting scissors (API AshoosonsPvt Ltd New Delhi, India)

Physio dispenser (NSK, NSK India sales Pvt.Ltd, Delhi ,india)**Fig. 5**

Implant system (spiral square thread form, Israel)**Fig. 6**

Implant surgical kit (Alphabiobiotec,Sark Healthcare PvtLTd Delhi, India)**Fig. 7**

Osteotomes(GDC Marketing, India)**Fig. 7**

Betadine (Win- medicate Pvt Ltd, Nehru Place New Delhi , India)

Equipments Used for Crestal Bone loss Analysis fig 1, 2

CBCT with FOV of 4_X4 view finder

CBCT viewer soft window software

Equipments Used For Implant Stability Analysis Fig. 8

RFA (AW&H Company)

2 METHOD

Selection of patient depends on a thorough evaluation of the following points

MEDICAL HISTORY:

It is one of the most important and revealing aspect of patient evaluation. The patient was given a detailed questionnaire and a thorough medical history was obtained. The following were evaluated.

1. Whether the patient is under the care of a physician. If so, determine the nature of the disease and therapy to be known.
2. History of cardiac problems.
3. History of kidney, urinary tract, GIT system, respiratory system, endocrine system and nervous system disorders.
4. History of abnormal bleeding tendencies.
5. Any allergic reactions to drugs and dental materials.
6. Any drug abuse alcohol or chemical substances.
7. History of psychological problems.

Detailed medical history will help us asses the patients with underlying medical conditions and any complications which will affect the implant prognosis.

Vital signs:

The recording of vital signs such as blood pressure, pulse, temperature, respiration, weight and height was noted. It was found to be within the normal range.

DENTAL HISTORYAND EXAMINATION:

Cause and duration of tooth loss:

Patients were asked for the cause of tooth loss which may be due to periodontal disease, caries, malocclusion, trauma, periapical pathology or gross neglect on the patient‟s part. The duration of edentulism and the cause of tooth loss are useful to estimate the quantity and quality of bone.

ASSESSMENT OF ORAL HEALTH:

Number of teeth and health of each remaining tooth was evaluated. Any source of infection present in the mouth was treated prior to implant therapy. Treatment of periodontal disease, dental caries, was carried out prior to the implant therapy. The present status of oral hygiene and patient‟s attitude is an important factor considered for better prognosis of the therapy.

Extra and Intra oral examination:

Detailed extra oral examination was done. Palpation of sub mental, submandibular, parotid and cervical area was done for lymphadenopathy and any other swellings. Intra oral examination of lips, labial and buccal mucosa, hard and soft palate, tongue and oral pharynx were done.

LABORATORY EVALUATION:

Laboratory screening is of benefit in recognizing oral manifestations of systemic diseases. Blood investigation was done as it may influence the implant surgery protocol or long term success rate. The test done from the sample of venous blood

includes total blood cell count, testing the member erythrocytes, leukocytes, hemoglobin leveland platelet count. Bleeding test were also done such as bleeding time and clotting time. Random blood sugar level was investigated.

RADIOGRAPHIC INVESTIGATION:

It plays an important role in developing the patient‟s treatment planning and diagnosis. The main role of the radiographic imaging is to identify the quality and quantity of bone.The imaging system used is cone bean computed tomography (field of view) CBCT (FOV).

Pre-fixture placement: Cone beam computed tomography (CBCT): for pre implant alveolar bone dimensional assessment of the implant site. In the study, small FOVs of 4x4 is been used patients wearing thyroid collar and lead apron for overall protection.

Inclusion Criteria-

Patient who :

1. Have good periodontal health in the remaining dentition, and age above 18 years.
2. Are relatively healthy to ensure uneventful healing and osseiontegration of implants.
3. Have partially edentulous and completely healed alveolar sockets.
4. Are willing to take up implants as a treatment options

Exclusion Criteria-

Patients who :

1. Are unable /unwilling to undergo a minor oral surgical procedure.
2. Have allergy to any drugs and /or material used in study.
3. Are current smokers or consumes any form of tobacco.
4. Have insufficient inter- arch spaces to accommodate the required restorative component.
5. Are unable to maintain adequate oral hygiene.
6. Have Para- functional habits.
7. All the patients with compromised health conditions were excluded.

Case 1

The selected patient as per the above mentioned criteria's was treated with 2 endossteal implants in relation to 22 and 12.

The various phases are discussed as follows

I. **PHASE I Surgery :**

Flapless technique

Osteotomy Preparation: Osteotomy site was prepared by using a series of drills precisely and incrementally and as per the manufacturer's instructions and site requirement along with profuse irrigation. Bone drilling was performed at revolutions per minute recommended by Branemark i.e. 1000-1500 rpm. The depth and angulation was checked continuously with the help of depth gauge, paralleling pins and by intra-operative radiographs. After the

angulation and depth of osteotomy was established, use of following drills for final osteotomy preparation capable of accepting the implant dimension was accomplished. The implant site was liberally irrigated with sterile saline to ensure no debris or bone debris left at the base or affixed to the vertical walls of the osteotomy site following preparation.**Fig. 11, 12, 13**

Implant Placement**(Fig.14):** Implant (Alphabio Dental Implant Systems LTD: Touareg^{TM}-S) was inserted using torque controlled wrench, insertion torque was kept above 45 Nm followed by placement of 15 degree abutment been placed on either side.

II. PHASE II Surgery:

After 3 months of implant placement, 15 degree abutment is been removed and the RFA Measurements were obtained then a healing abutment or gingival former (Alphabio Dental Implant Systems LTD: RS Healing Abutment) was placed on the implant for 2 weeks. **Fig. 15**

III. Impression

After the two weeks of healing abutment been placed, it was then loosened and the impression coping (Alphabio Dental Implant System LTD: Impression coping) were placed for the final impression using the light body and heavy body impression materials (Ivoclar impression light and heavy body impression materials).

III. Placement Of Prosthesis

The final restoration was constructed using the 15 degree abutment to get single path of insertion and the axial load was placed at 30 degree angle for the forces to be distributed evenly through the implant body into the adjacent bone. **Fig. 16.** The restoration given for this case was temporary

IV. **Post fixture placement:** A radiographic follow up was conducted during the following periods.

1. Immediately post operative.
2. 3 months(CBCT post secondary surgery)
3. 3 months after prosthesis been placed

IMAGING

criteria for the post operational implant imaging after placement are as follow, after implants has been placed , implant images are obtained using a complementary metal-oxide semiconductor flat panel detector, variable FOV CBCT unit (3D Accuitomo 170; J Morita Mfg. Corp., Kyoto, Japan) operating at 90 kVp, 5.0 mA and an exposure time of 17.5 s to image each specimen before and after defect preparation at three different FOVs and voxel sizes [nominal cubic millimetre resolution (mm3)]:**Fig. 1, 2**

(1) 40×40mm FOV, 0.080mm3 (FOV40)

(2) 80x80mm FOV,0.160mm(FOV_{80})

(3) 50x50mm FOV, 0.09mm(FOV_{50})

IMAGE ANALYSIS:

- **To Measure Crestal Bone Loss**

The image data was retrieved and analyzed on the Adobe photoshop® Ver 8 software. Prior to the analysis the image characteristics were enhanced (contrast, density, brightness) to optimal levels by the software itself. Images were resized wherever magnification errors were found. A filter tool was used to create an embossed effect on the image to highlight the bone details of the image and minimize errors.

Metric analysis was performed on an mm scale using the measuring tool available in the software. Markings made on the CBCT which was the site of reference for the calculation of bone loss :-

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 distal alveolar bone crest.

The determined values of each fixture were compared over the follow up period of 3 months separately for the mesial and the distal, and the average of these values which were taken during the given time frame will help us to find the amount of bone loss which had happened during the initial stage and after placement of the prosthesis.

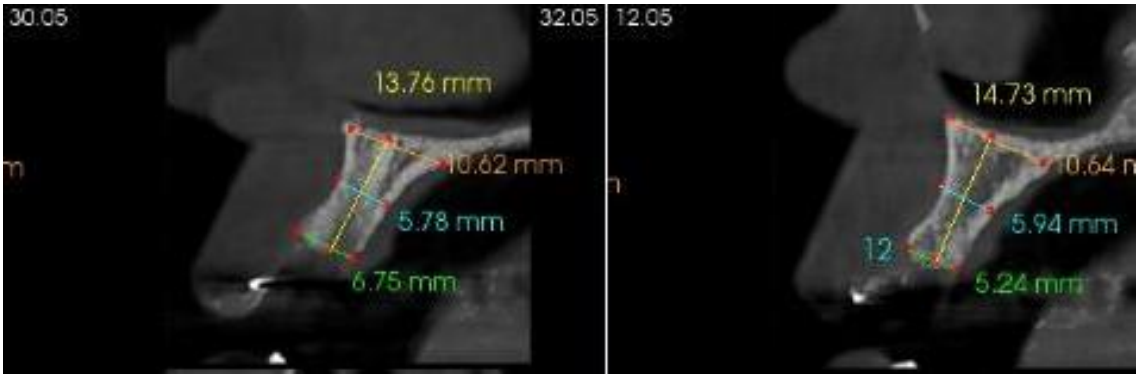

Figure 1.Pre operation CBCT

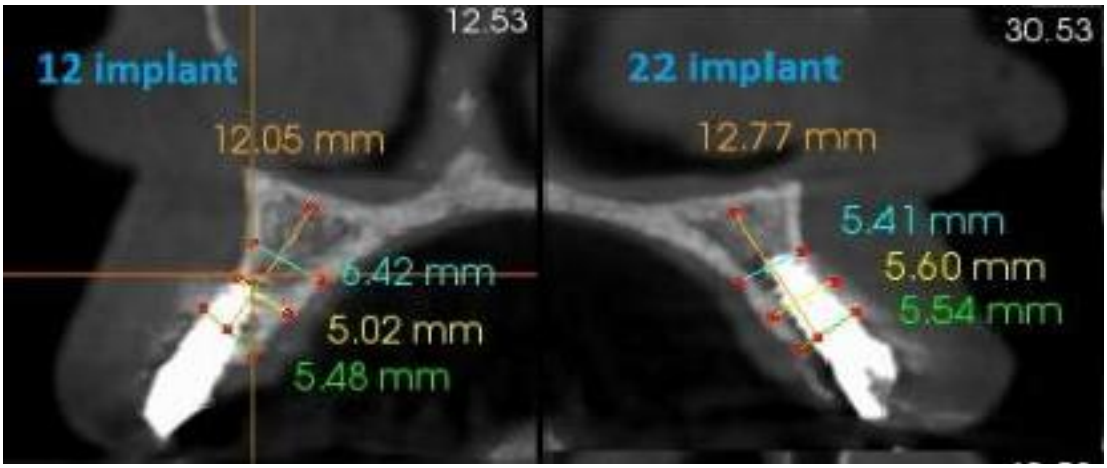

Figure 2.Post operationCBCT

- **Bone Implant Contact**

Bone implant contact was calculated by the help of CBCT (FOV_{40}) taken at three intervals which were immediately after placement of implant and 3 months after second stage surgery and 3 months after prosthesis was placed. A thin layer of metal artifact around an metallic dental implant was present along the whole implant surface. To reduce this artifact CBCT was done with lesser distortion and the image was downloaded into the Softwindowsoftware for more precise imaging. The covered mesial and distal lengths were measured using longitudinal images . The rate of bone-to-implant contact (%) was calculated as the

Length of the implant covered by bone ⁄ the actual length of the implant × 100.

The average of three values were taken as average.

RESONANCE FREQUENCY ANALYSIS:

Implant stability was measured using an OsttellMentorTM(Osttell AB, Gothenburg ,Sweden)

The measuring technique used does not require any contact with the implant and is noninvasive. A SmartPeg is attached to the implant orabutment and is dependent on the implant manufacturer and implant diameter. The Osstell Mentor is then placed at 2 different directions, as recommended by the manufacturer. An resonance frequency anylasis reading showed the implant stability quotient (ISQ) value, which is dependent on the stability of the implant. The clinical range of ISQ has been found to be normally between 50 to 80 for implant stability. Readings were taken for each implant were then averaged.

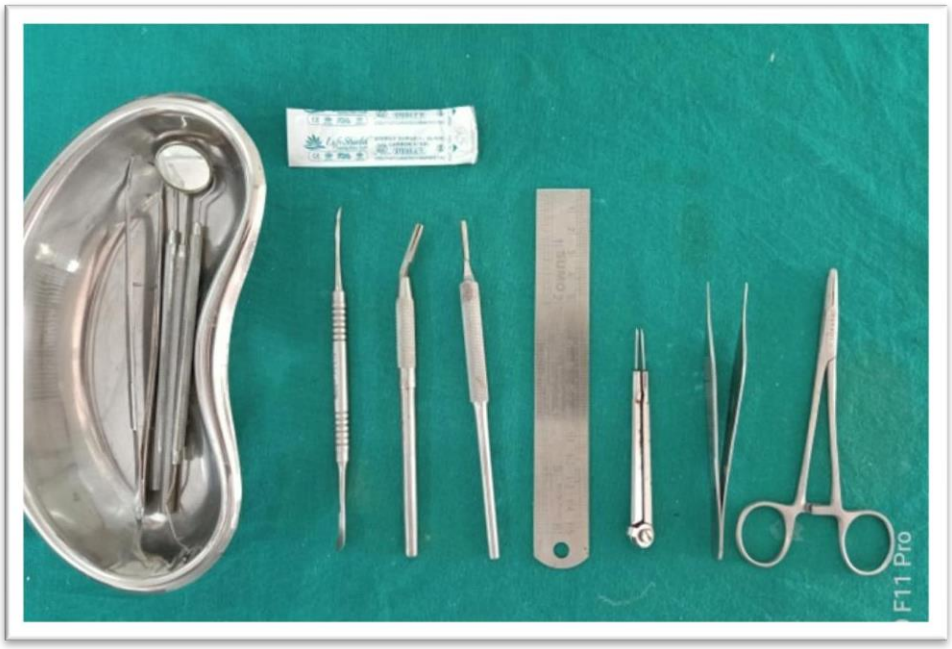

Figure 3 materials used for diagnosis, incision and suturing

Figure 4 Local Anasthesia, syringe, saline &betadine

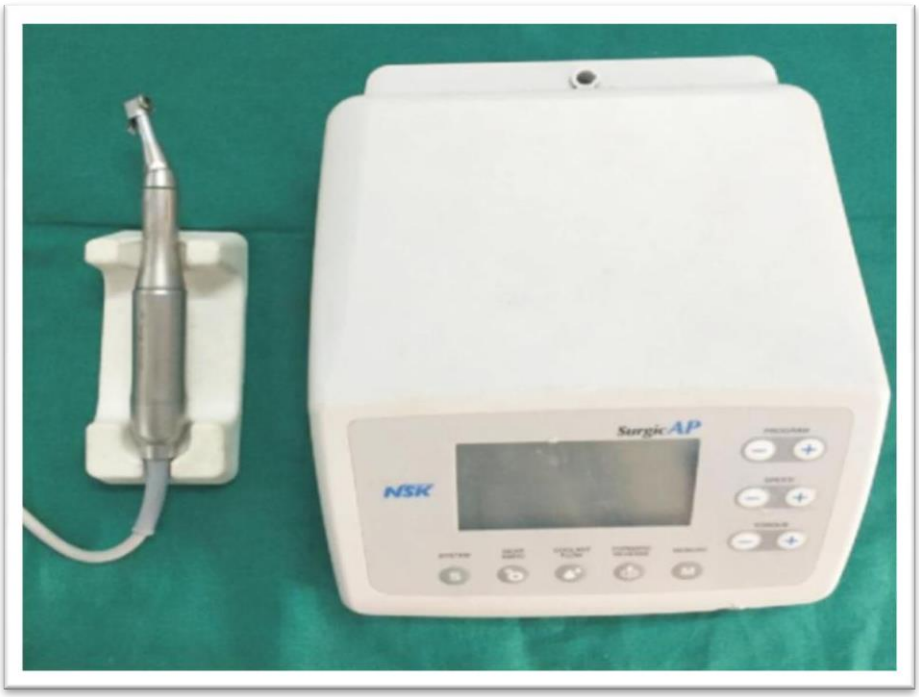

Figure 5physio dispenser

Figure 6Alpha Bio Square Thread Implant

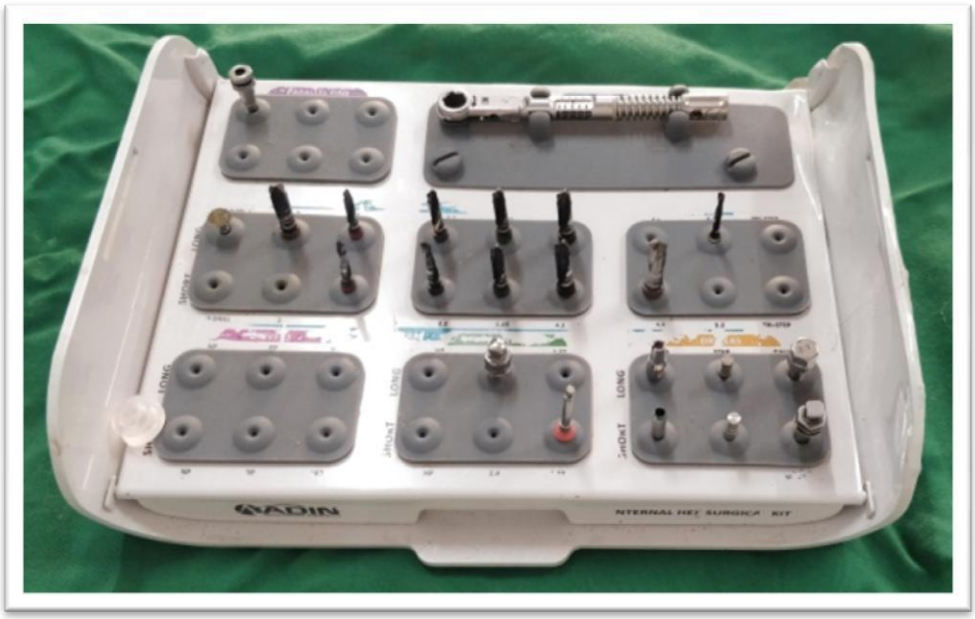

Figure 7 Implant Surgical Kit

Figure 8 RFA (OSTELL)

PRE-OPERATIONAL

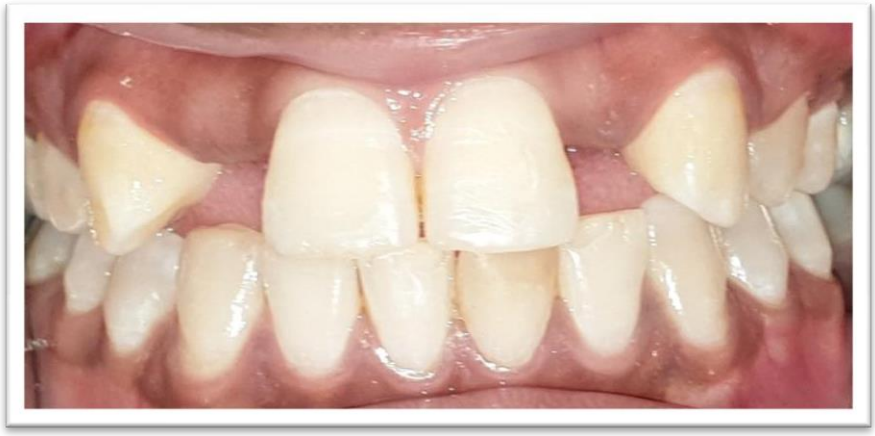

Figure9Labial View

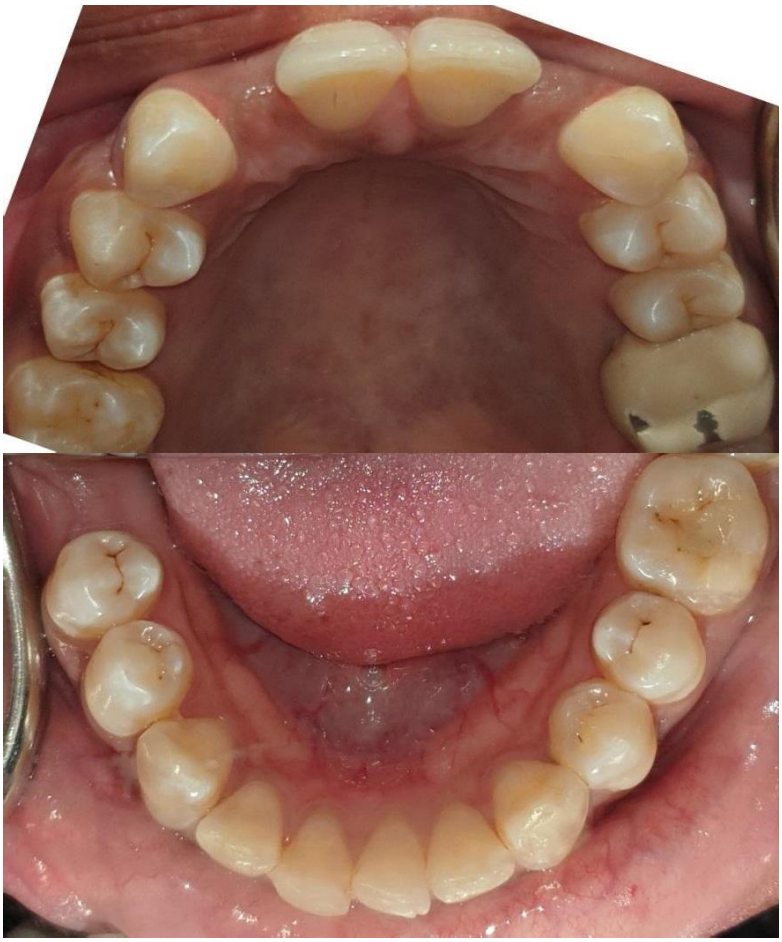

Figure 10 Maxillary and mandibular Dentition

SURGICAL PHASE

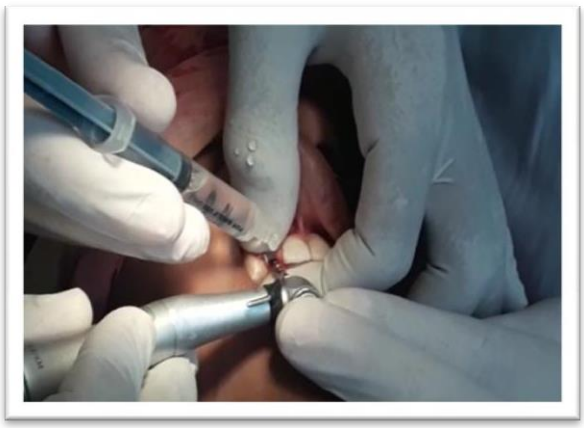

Figure 11 Placement of Pilot Drill

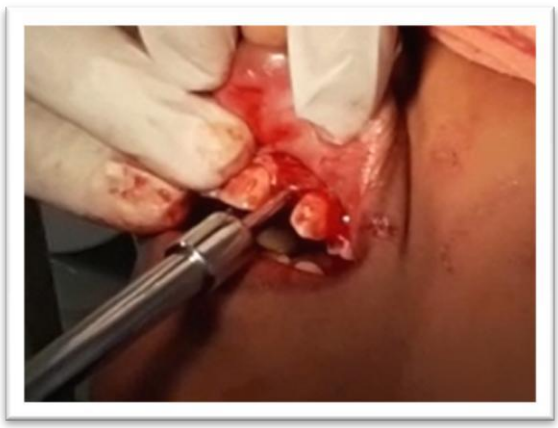

Figure 12Osteotomy Drill

Figure 13 use of guide pin

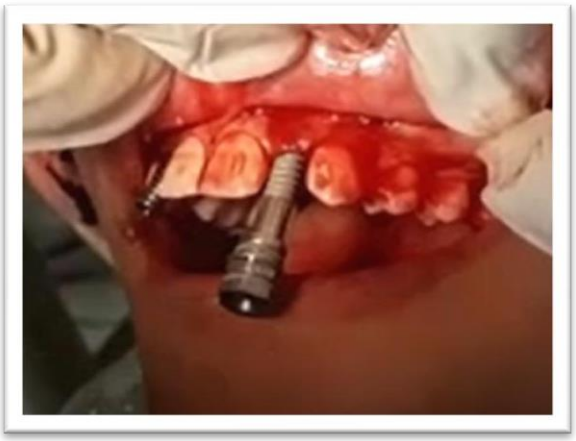

Figure14 placement of implant in implant bed

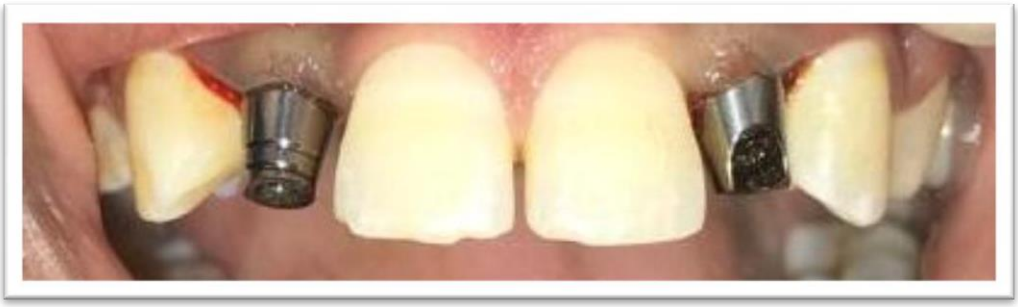

Figure 15 implant with 15 degree abutment (alpha bio abutment system, Isreal)

OBSERVATIONS

Clinical experience

The two implants used were of 4x11 mm in size. The osteotomy preparation did not require any additional drilling for the square thread shaped implant to be accommodated. RFA readings of 57 ISQ on both implants were noted after its been loaded into the implant site. The post-operative CBCT revealed no changes in bone level. When the pre- and post-op CBCTs were compared. It was very evident that the implant failure is not just mere failure in surgical phase but also the selectionof right implant system for the implant region been selected to be treated. The study used the most conservative technique to preserve the crestal bone from surgical phase that is opting for flapless technique and placing the abutment attachment which in turn did not require second surgical intervention for cover screw exposure for various attachments placement. CBCT imaging played a crucial role in identifying the bone type and seeing the trabecular pattern distribution which suggested the density of the bone. The adjacent landmarks were well defined with these images and when combined with Dentacan software helped in three dimensional treatment planningfor accurately assessing the available bone.

THE FOLLOW UP IN THE STUDY TO BE DONE :-

1. Clinically by using RFA for assessing implant stability

2. Radiographically by using Cone beam computed tomography (CBCT) for assessing crestal bone loss (CBL) and bone implant contact (BIC)

The different periods of observation:

- First stage surgery – RFA, CBCT
- Second stage implant surgery- RFA, CBCT
- Three months post prosthesis - RFA, CBCT

The data was collected and tabulated as follows:

Table1- collective data for assessing implant stability, crestal bone loss and bone implant contact.

	Immediately after placement(12,22)	After 3 months (12,22)	After 3 months post prosthesis (12,22)
RFA	57	57	
CBL	1	1	
BIC	113.3	113.3	

STATISTICAL TOOL

Parametric tests

The parametric tests assume that the data are on a quantitative (numerical) scale, with a normal distribution of the underlying population. The samples have the same variance (homogeneity of variances). The samples are randomly drawn from the population, and the observations within a group are independent of each other. The commonly used parametric tests are the Student's *t*-test, analysis of variance (ANOVA) and repeated measures ANOVA[43].

The statistical analysis was done using SPSS(statistical package for social sciences) version 16.0 statistical analysis

Student's *t*-test

Student's *t*-test is used to test the null hypothesis that there is no difference between the means of the two groups. It is used in three circumstances:

1. To test if a sample mean (as an estimate of a population mean) differs significantly from a given population mean (this is a one-sample *t*-test)

   The formula for one sample *t*-test is $t = \frac{X - u}{\mathrm{SE}}$

where X = sample mean, u = population mean and SE = standard error of mean

2. To test if the population means estimated *by two independent samples* differ significantly (the unpaired *t*-test). The formula for unpaired *t*-test is:

$$t = \frac{X_1 - X_2}{\mathrm{SE}_{x_1 - x_2}}$$

where $X_1 - X_2$ is the difference between the means of the two groups and SE denotes the standard error of the difference.

3. To test if the population means estimated *by two dependent samples* differ significantly (the paired *t*-test). A usual setting for paired *t*-test is when measurements are made on the same subjects before and after a treatment.

The formula for paired *t*-test is:

$$t = \frac{d}{\mathrm{SE}_d}$$

where *d* is the mean difference and SE denotes the standard error of this difference.

The group variances can be compared using the *F*-test. The *F*-test is the ratio of variances (var l/var 2). If F differs significantly from 1.0, then it is concluded that the group variances differ significantly[44].

Analysis of variance

The Student's *t*-test cannot be used for comparison of three or more groups. The purpose of ANOVA is to test if there is any significant difference between the means of two or more groups.

In ANOVA, we study two variances – (a) between-group variability and (b) within-group variability. The within-group variability (error variance) is the variation that cannot be accounted for in the study design. It is based on random differences present in our samples.

However, the between-group (or effect variance) is the result of our treatment. These two estimates of variances are compared using the F-test.

A simplified formula for the *F* statistic is:

$$F = \frac{MS_b}{MS_w}$$

where MS_b is the mean squares between the groups and MS_w is the mean squares within groups.

Repeated measures analysis of variance

As with ANOVA, repeated measures ANOVA analyses the equality of means of three or more groups. However, a repeated measure ANOVA is used when all variables of a sample are measured under different conditions or at different points in time.

As the variables are measured from a sample at different points of time, the measurement of the dependent variable is repeated. Using a standard ANOVA in this case is not appropriate because it fails to model the correlation between the repeated measures: The data violate the ANOVA assumption of independence. Hence, in the measurement of repeated dependent variables, repeated measures ANOVA should be used[45].

Due to the outbreak of COVID-19 pandemic in India on March 2020 and the lockdown imposed thereafter, this study fell short of time to reach a definite conclusion. The aim of the study was to compare the literatures published regarding square thread implants and the other thread forms in relation to their crestal bone loss and bone implant contact during the period of the 3 months after the prosthesis has been loaded. Present study assessed the implant status at 3 months which was based on previous studies[46,47,].All the patients who had fulfilled the inclusions criteria were involved in the study. However, the present study involved one patient for the treatment due to Covid 19 pandemic.

In an oral cavity three different types of forces are applied over a restoration which are termed as compression, tension and shear. Bone when subjected to compressive forces is strongest in comparison to tensile which makes the bone 30% weaker and 65%weaker when loaded in shear[48]. Hence it is advised to limit shear forces on bone, as it is more prone to fracture the bone. These conditions are most valued when the implants are loaded in regions of decreased bone density, as the density is directly related to strength **fig(17)**[49] .

Implant design or surface condition showed an effect on initial stability. Implant design functions to dissipate and distribute biomechanical loads to optimize the implant- supported prosthesis function. Biomechanical load management is predicted on two factors: The characteristics of the applied force and functional surface area over which the load is dissipated. Keeping in the account of scientific principles related to force and surface area may then be combined with engineering principles to pursue the desired clinical goals[50]. A clinical study done based on correlation between the functional occlusion and peri-implant bone level evaluation concluded that the implant geometry plays an important role in the stress and force distribution around the supporting bone[51].

Implant design are divided into macroscopic and microscopic components. Microscopic features include surface characteristics like surface treatment and surface conditioning whereas the macroscopic features include the complete design of the implant which include thread design , thread depth, thread form. These two features are usually independent but are relevant for better clinical behavior .The microscopic

features are mostly crucial for initial implant healing and the initial loading period. The macroscopic design components are important for early loading and mature loading periods[52].

Surface conditions may enhance the bone-implant contact and adhesion qualities to the bone -implant interface at initial healing[53]. However surface coating over the cylinder body do not permit compressive forces to be effectively transmitted to the bone cells, this is because the compressive forces when applied through microscopic features does not produce sufficient forces to be applied[54]. Therefore, the surface area-bone contact percentage is higher during initial healing; however functional surface area over which loads are effectively dissipated for long term loading to the surrounding bone is mainly dependent on the macroscopic design[55]. Under axial load on an implant - bone interface, a buttress or square-shaped thread would transmit compressive forces on the bone. Study using the square thread implant showed that the upper part of the implant had lesser bone covering in comparison to the lower half of the implants in addition bone bridges were found from one square thread to the other thread[56]. These bridges improve the bone density between the upper and lower part of the implants. The bone modeling and remodeling are primarily controlled by the mechanical environment of strain.

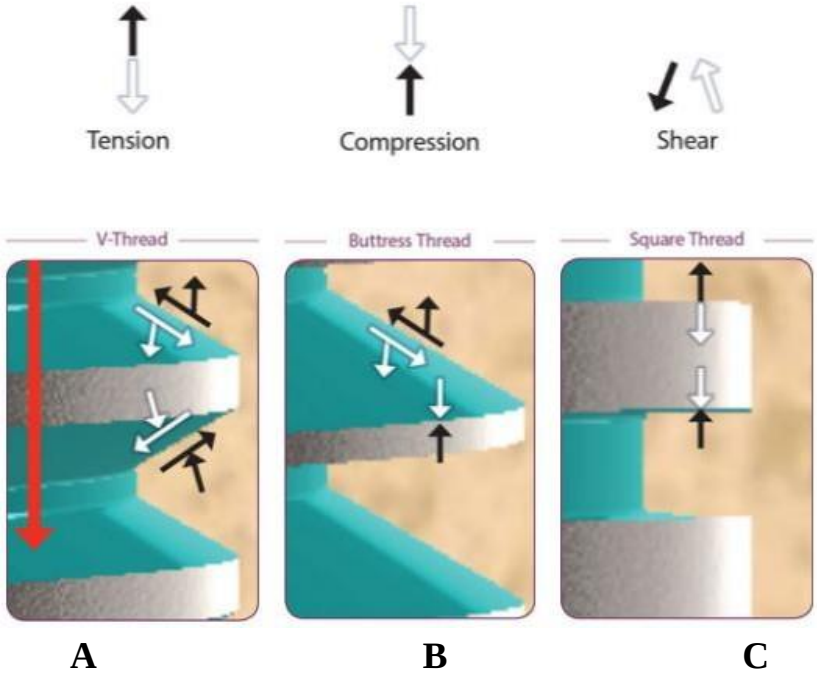

Figure 17 ABC various thread forms and stress distribution

1.Thread Geometry

Threaded implant plays an important role in increasing mechanical osseointegration and influence stress around implant loading.Huang et al[57] reported that "threaded implant could reduce both stress and implant-bone sliding distance, thus potentially improving initial implant stability and long term survival".Chun et al[58] stated that square thread shape with small radius distributes stresses more effectively.

The design of the thread maximizes initial contact, enhance surface area, and facilitate dissipation of loads at the bone-implant interface. Functional surface area of the implants which help in load dissipation can be modified based on the three geometric thread parameters- Thread pitch, Thread shape and Thread depth[59].

A. Thread Pitch

The smaller the pitch, more number of threads can be accommodated which will increase the functional surface area. Thread pitch is the distance measured between adjacent thread of an implant. Stress is directly related to magnitude of the force and indirectly related to the area over which the force is applied[60]. Surgical ease of implant placement is related to the numberof threads in the implant. The fewer the thread easier to insert the implant. This concept is best applied in case of denser bone for its difficulty in implant placement. Of all the design variables, pitch has been

proved to be most effective in changing the surface area on a threaded implant. Kong et al emphasized that thread pitches exceeding 0.8mm were optimal selections for a screwed implant by biomechanical consideration[61]. Lee et al showed that square thread with a 0.6 mm pitch has optimal contact area and stress values. Chung et al found that implants with a pitch distance of 0.6 mm exhibited more crestal bone loss as compared with implants with pitch distance of 0.5mm[62]. Lan et al in their study concluded that the loading type is the main factor of influence on stress distribution, and that in biomechanical consideration, thread pitches exceeding 0.8mm are more appropriate for screwed implants[63].The thread pitch value used for this study is about 0.6mm Alphabio (spiral square thread form , Israel)[64] .

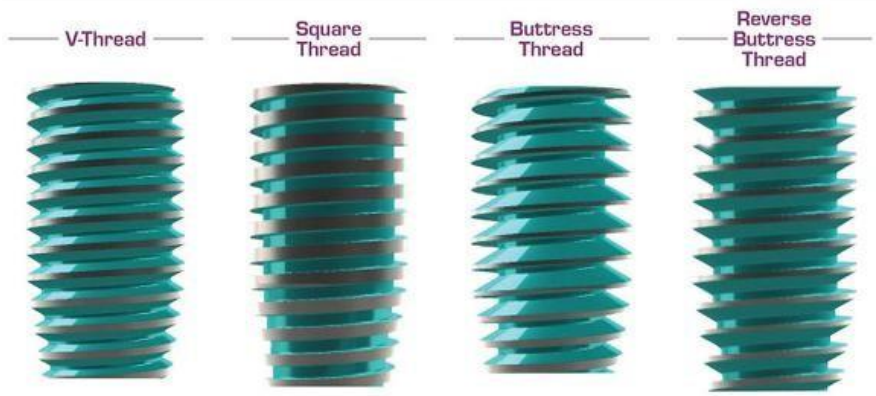

Figure 18. Depiction of basic classification of thread forms for screw- type dental implant

Thread Shape

The next important component which affects the implant prognosis is the thread shape[65]. In relation to thread shape, the implants have been classified into four types: square, V-shaped, revere buttress and buttress **fig(18)**[66] . In conventional engineering application, the V- thread design is called a *fixture* and it‟s primarily used for fixating metal parts together[67]. The buttress and reverse buttress thread shape were initially designed for pullout loads by Krupp[68]. The square or power thread provides an optimized surface area for intrusive, compressive load transmission.

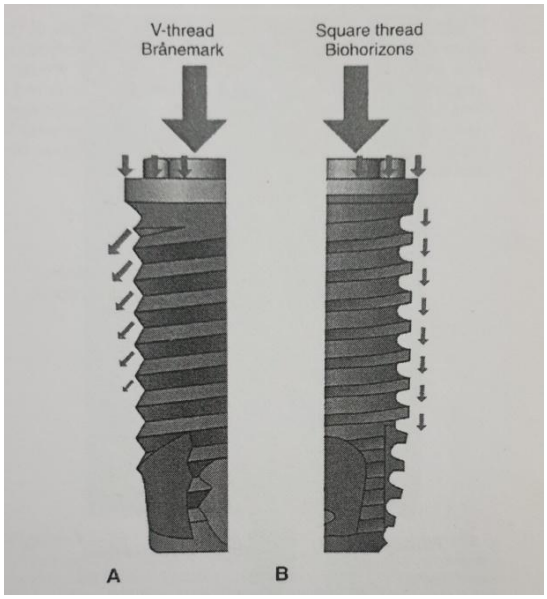

Figure 19- A, A long axis load to an implant body with V-thread with a 30 – degree thread face converts the load direction to a 30-degree angle at the implant interface.B, A square thread design can deliver compressive force to the bone when the implant is loaded in the long axis

Face angle of the thread or plateau in an implant body can modify the direction of the occlusal load imposed on the prosthesis and abutment connection to a different direction at the bone interface. The face angle of the V- shaped implants is about 30 degree of the long axis whereas the square thread may be perpendicular to the long axis[69]. Due to this 30 degree correlation to the long axis, the v-shaped thread implants exhibit shear force which are 10 times greater than square thread**fig (19)**[70]. A finite study done by the Kim et al on four different shapes of the implant showed that square shape thread had less stress in both compressive and also in shear forces[71]. Chun et al used finite element analysis to evaluate design parameter of osteointegrated dental implants also concluded the square-thread design has a beneficial shape for occlusal loading compared with other thread design[72]. The reduction in shear loading at the thread bone interface provides for more compressive load transfer, which is important in lower bone density. Different thread shapes with the similar pitch indicate that implant with different total contact areas at the implant –bone interface affects the initial stability[73].

In account of all the researches done until now, they revealed that stress loading of threaded implants is maximal at the interface between the first pitch of implant and

the cortical bone[74]. The thickness of the cortical bone ranges between 0.8 and 2.0mm on average with thicker bone having a higher load- bearing capacity[75].

Thread Depth

The thread depth is the distance between the major and minor diameter of the thread[76]. Usually the implants have a uniform thread depth throughout the implant length. Due to this the implant surface area increases by 15% to 25% for every 1mm increase in diameter[77]. A straight minor diameter results in uniform cross- sectional area throughout parallel –walled implant length. A tapered implant has similar minor diameter, but the outer diameter reduces towards the apical region. This design reduces the surface area which is more favorable to shorter implants. The greater the thread depth, the greater is the surface area of the implant, if all the parameters are equal. However, with increase in the implant diameter, the depth of the thread may be deeper without decreasing the body wall thickness between the inner diameter and the abutment screw space within the implant[78]. The depth of the each thread in an implant increases the surface area for the bone to grow over. Thread depth selected for the implants is of 0.5mm.Hence thread depth helps the implant to improve its overall surface area for the bone implant contact[79].

Reports from Zechner et.al.evaluated the peri-implant bone over 3 to 7 years period with functionally loaded, screw-type implants with a machined surfaced V- thread and sandblasted, acid-etched, square thread design with their identical crest module and external hex connection[80]. The results showed range of bone loss for V-shaped thread was from 0.1 to 8.5mm and in case of square thread implants it was between 0.2 to 4.8mm[81]. It has been established from the literature that variations in the implant thread designs and the implant surface plays an important role in enhancing anchorage and increasing the surface area of the implant which helps to reduce stress distribution to adjacent bone[82].Hence, the implant used was from Alphabio spiral square thread, Israel which had an thread pitch distance of 0.6mm and the thread depth of about 0.2 to 0.5mm[83].

In the field of oral implantalogy, there are numerous radiographic modalities available to assist the rehabilitation with dental implants from diagnosis phase till follow up. These various imaging technique used in dentistry are as follows

1. Intraoral PeriapicalRadiograph (IOPA).
2. Panoramic (OPG).
3. Computed Tomography (CT).
4. Cone bean Computed Tomography (CBCT).

Up till recently, most reliable imaging system of choice was Intraoral Periapical radiographs along with panoramic images which produced two – dimensional imaging systems. However, these techniques provided limited information with respect to bone quality and quantity. These deficiencies in imaging were attributed to some percentage of implant failures. The advancements in the radiographic imaging systems and increased availability to use have significantly contributed to more predictable implant dentistry[84].

The goal of the radiographic evaluations is to assess the available bone quality and quantity, angulations of bone, selection of the potential implant site and to verify absence of pathology[85]. However there exists no such ideal radiographic imaging technique in the fields of oral implantalogy that would be acceptable to all patients[86].All the radiographic imaging techniques which is been applied in the dentistry has its own advantages and disadvantages and have been shown to exhibit false – negative and false – positive images[87,].

2 IMPLANT IMAGING TECHNIQUES

Intraoral Periapical Radiograph (IOPA)

Periapical radiography generates a high-resolution planar picture of a specific area of the jaws. These methods can resolve more than 20 line pairs per millimeter, which is more than twice as much as digital intraoral imaging or extraoral radiography[88]. The use of nonscreen films, a short object-film distance, and a lengthy source are all elements that affect image quality. They provide evidence of aetiology, an assessment of the quality of trabecular bone, and the approximate position of anatomic features related to the intended implantation site, such as the maxillary sinus[89]. Periapical radiography can be used to determine the alveolar bone's approximate height, the distance between the potential implant locations and important anatomic structures,

and more. Radiation exposure is less in periapical radiography, and accurate details are obtained. It is also easily available and can be used in any clinical setup[90].

Distortion and magnification may be present in periapical radiographs. Over the film, millimeter radiopaque grids, which are sometimes employed in endodontics, can be overlaid. Prior to being exposed, however, they have limited quantitative value andthey give false information since they lie in the film and do not compensate for the underlying anatomy and its maganification[91]. Opposing landmark for the implant placements are usually in mandible is beyond the lingual muscle attachment and beyond the palatal vault in the maxilla. Usually the image most often must be foreshortened to visualize the opposing cortical plate, this foreshortening leads to reduction in the bone height[92].

The periapical radiography imaging field is generally narrow, and its reproducibility is poor. Furthermore, this modality is not efficient for displaying the edentulous ridge's buccolingual width. Hence they are most commonly effective for the single-tooth implant replacement.

In terms of the objectives of preprosthetic imaging, periapical radiography is:

1. A high-yield technique for confirming the absence of local bone or dental disease.

2. The picture is enlarged, may be distorted, and does not represent the third dimension of bone width, thus it is of limited utility.

3. It is of limited value in determining bone density or mineralization (the lateral cortical plates prevent accurate interpretation and cannot differentiate subtle trabecular bone changes).

4. It is used in identifying critical structures but is of little use in depicting the spatial relationship between the structures and the implant site[93].

Film-based radiography is being phased out in favor of direct digital intraoral imaging. Its benefits include quick picture collection, storage, retrieval, and transmission to remote locations. Direct measurements of height and width can be obtained. These radiographs can be easily sent to other operator sites, i.e. teleradiography[94].

Direct digital intraoral imaging has the same constraints as IOPA radiography. As a result, its application is contingent on the operator's ability to modify picture density and contrast in order to assess bone density at specific places and then use the information for treatment planning[95].

Panoramic Radiography (OPG)

The imaging approach should be capable of evaluating normal anatomic features from all angles, evaluating potential pathogenesis locations, and indicating viable surgical routes for implantation, as well as assisting with postoperative assessments and providing, documentation of diagnosis and therapy. Panoramic images is one modalities that will allow a practitioner to meet these goals[96]

A panoramic radiograph is useful in the diagnosis of gross pathogenesis within the jaw as well as sinuses, canals, fossae and foraminae to the implant site.

Some of the panoramic machines have unreliable magnifications (25% to 30%) and Its more pronounced in the posteriors than in anterior areas. This will present with false sense of availability of bone between the alveolar crest to nearest anatomic landmark. The patient positioning may further contribute to image distortion[97]. The unavailability of conventional panoramic radiography to provide cross-sectional pictures of the alveolar ridge is a severe drawback.

Advantages

1. It‟s simple to spot opposing landmarks.

2. The vertical height of the bone can be measured at first.

3. Can be completed with ease, speed, and convenience.

4. The jaws' gross anatomy, as well as any associated pathologic abnormalities, can be assessed[98].

The following are some of the shortcomings of panoramic imaging:

1. Does not demonstrate bone quality/mineralization.

2. Because of the magnification and the lack of a third dimension, cross-sectional perspective, the data is quantitatively misleading.

3. Depicting the spatial relationships between the structures and dimensional quantification of the implant site isn‟t significant.[99]

Tomography

For dental implant, high quality complex motion tomography demonstrates the alveolus and taking magnification into consideration enabling quantification of the geometry of the alveolus. This technique determinates the spatial relationship between the critical structures and the implant site. Ideally image spaced every 1 to 2 mm assists in evaluation of the implant site and with mental integration, enable appreciation of the quasi-three dimensional appearance of the alveolus[100]. Post imaging digitization of topographic implant images allows use of a digital ruler to aid in the determination of alveolar bone for implant placement[101].

Computer Tomography (CT

CT is a digitalized and mathematical imaging technique that creates tomographic sections where the tomographic layer is not contaminated by blurred structures from adjacent anatomy. This helps the CT image differentiation and quantification of soft and hard tissues. The power and usefulness of CT for maxillofacial imaging and diagnosis were apparent as soon as high resolution CT was introduced in early 1980s.It was used for imaging the temporomandibular joint, dental –bone lesions, assessing maxillofacial deformities, and preoperative and postoperative evaluation of maxillofacial region[102]. CT also provides unique three dimensional images, using tangential and cross – sectional tomographic images of the implant site. With various advances in the imaging techniques, the reformatted images are characterized by a section thickness of 1 pixel (0.25mm) and an in plane resolution of 1 pixel by the scan spacing (0.15 to 1.5mm) this produces a geometric resolution similar to that of planar imaging. The density of structures within the image is absolute and quantitative and can be used to differentiate tissues in the region and characterize bone quality[103].

As the CT images recorded more details in comparison to other imaging tools combined it led to an new imaging system called the **Dentascan** imaging[104] .Dentascan imaging provides programmed reformation, organization and display of the imaging study. Limitations of Dentascan was that the images were not true to the size and required compensation for magnification , and the examined patients head position was also crucial. To overcome some of the limitations of the conventional CT

scans, a new type of CT developed called the cone bean volumetric tomography (CBVT)[105]. As the conventional imaging was associated with high dosage of radiation, which was the one of the major criticism in implant treatment planning. However with this new device this criticism was overcome as it followed ALARA principle[106].

Various designs of CBCT have been developed which are divided into two types:-

1. Small field-of-view (FOV) CBCT that could acquire only a limited volume of the oral and maxillofacial region (diameter < 50 mm), but could also achieve two-dimensional (2D) dental panoramic imaging. In general, these kinds of architecture are low-cost systems.

2. Large FOV CBCT, which is able to acquire complete Oral and maxillofacial region (diameter > 16 cm)[107].

The patient radiation dose is closely related to field of view (FOV) and exposure parameter used for CBCT.
For the study, small FOVs(less than 10 cm useful for dento-alveolar imaging) were taken with patient wearing thyroid collar and lead apron for overall protection. The study was conducted on adults so the exposure risk to growing tissues as in children (Orthodontics) is eliminated [108].
Studies have reported that exposure by small FOVs is equal to 2-3 IOPA X-rays.

The following are the advantages of CT-based systems:

1. Magnification that is consistent.

2. A well-defined image layer with a high-contrast image without getting blurred.

3. Bone grafts or hydroxyapatite materials used to enhance maxillary bone in the sinus area are easier to identify than with conventional tomography[109].

4. Views in several planes.

5. Reconstruction in three dimensions.

6. Investigation of numerous implant locations at the same time.

7. The availability of picture analysis software[110].

The following are some of CT's drawbacks:

1. Reconstructive software is scarce.

2. Expensive.

3. Higher radiation exposures as compared to traditional tomography and CBCT.

4. The radiologic technicians and medical radiologists who acquire and analyze the CT pictures do not comprehend the dentist's imaging needs.

5. Inapplicability for implant-interface follow-up due to the presence of metallic streak artifacts

6. Restoration artifacts made of metal.[111]

CONE BEAM COMPUTED TOMOGRAPHY

A CBCT scan combined with software modeling may be utilized to create a virtual planning environment for prosthesis placement, occlusion, and other factors in a virtual environment with accompanying supporting implants

For each implant site CBCT can :-

1. Determine bone height and breadth (bone dimensions) for each implant location.

2. Compare bone density to determine bone quality analysis in three dimensions.

3. Locate internal anatomies such as nerves and sinus cavities by identifying and locating them.

4. Determine the maxilla and mandible boundaries.

5. Determine the magnitude and dimension of pathology in 3dimenional.

6. Information on radiographic planning can be transferred.

7. Determine the alveolar bone's long axis[112].

The operator will be able to overcome the flaws and drawbacks of the different other procedures with the aid of CBCT.

To ensure precise implant placement, CBCT can be used in conjunction with surgical templates and virtual implant placement software for placement of the implant[113].

CRESTAL BONE LOSS ANALYSIS

The reference point of the fixture was the border between the titanium oxide-blasted surface and the machined surface of the fixture . Calibration was performed with known fixture length (Bra¨gger et al. 1998). The distance was measured to the nearest 0.01mm with UTHSCSA image tool[114]. Only the amount of vertical bone loss was measured. Thus, in case of coronal bone gain, bone loss was considered to be zero.[115]

The determined values of each fixture were compared over a three-month, follow-up period for the mesial and distal, side respectively. The average of these readings will help us determine the amount of bone loss that occurred during the initial stage and after the prosthesis was placed. For several implant systems, there were correlations between the amount of bone loss after 12 months and the length of the machined surface, thereby linking bone loss with the level of the „first thread' (Jung et al.)[116].In studies on the marginal bone loss of the square thread form implant, bone loss varied from 0.05 to0.6mm during 1 year of loading[117]. Thus, relatively uneven degrees of bone loss measurements were reported in the studies, that dealt with marginal bone loss of square thread form implants (Norton 1998; Palmer et al. 2000; Puchades-Roman et al. 2000; Engquist et al. 2002)[118].These studies used the above points as a reference to check for the bone loss in the initial first year after loading of the implant. The compressive forces generated on bone by the V-shaped threads when compared to square shaped threads is less[10]. There is more crestal bone loss in V-shaped implants when compared to square threaded implants.

4 IMPLANT STABILITY

The mechanical characteristics of the bone tissue at the implant site, as well as how effectively the implant is engaged with that bone tissue, are the major determinants of implant stability[119].As a result, implant stability is determined at the time of surgery

by bone density, surgical technique, and implant design[120].The implant is first held in place by bone compression. Secondary stability develops over time as a result of bone healing, in which newly produced bone bridges and fills voids in the interface zone and grows into surface irregularities and macroscopic undercuts, resulting in secondary stability. As a result, the implant interlocks and becomes more stable[121].On the other hand, because the implant is surrounded by fibrous scar tissue, a failed implant exhibits clinical movement on the macro-scale fibrous tissue can develop as a result of

(i) Failure osseointegration following initial healing or

(ii) Progressive "disintegration" of an originally successfully integrated implant due to adverse circumstances during the process of functional loading[122].

4.1 Factors related to bone properties

Numerous studies have demonstrated that bone density is a key predictor of RFA measurement[123].The Lekholm&Zarb index, insertion torque measurements, and quantitative CT have all demonstrated that ISQ units have a positive relationship with bone density[124].Because mandibular bone is generally denser than maxillary bone, implant stability is usually better in the mandible than in the maxilla. When comparing anterior and posterior locations inside each jaw, differences can also be seen.

RFA readings are influenced by the characteristics of the marginal bone. For example, Myiamoto et al found a significant, positive association between cortical bone thickness and initial ISQ values for 225 screw-shaped implants implanted in the maxilla and mandible, as determined by computed tomography images[125].In cadaver investigations, Nkenke et al and Gedrange et al discovered a favorable relationship between the height of the crestal cortical bone and ISQ values[126]. Tözum and colleagues 36 found that lowering bucco-lingual thickness from 8 to 0 mm resulted in a lower ISQ value in an in vitro study[127]. The reading for both the implants was 57 ISQ.

The resonance frequency analysis approach could not successfully identify mobile implants, according to Nedir and coworkers, who compared implants loaded

immediately with implants loaded after 3 months of healing. Implant stability, on the other hand, could be accurately assessed for implants with an ISQ greater than 47[128].

5 BONE IMPLANT CONTACT

The deeper the thread depth, the larger the implant's surface area[129]. Greater thread depth may be beneficial in areas of softer bone because it induces bone condensation and forms a thicker lining along the implant surface, as well as in areas of greater occlusal force because to the increased functional surface area in contact with bone[130]. Threading the implant is easier when the shallower thread depths are used .For every 1 mm increase in diameter, thesurface area of the implant increases by 15 to 25%. However, as an implant becomes wider, the thread depth can be increased without reducing the thickness of the body wall between the inner diameter and the abutment screw gap[131]. As a result, the thread depth may be adjusted in relation to the implant's diameter; increasing the overall surface area by 150 percent for every 1mm increase in diameter[132].The surface area of each implant support system is proportional to the implant's width and height[133]. Because of their higher circumferential bone contact regions, wider root-form implants have a larger area of bone contact than narrow implants of equal height and shape[134]. As the crest of the ridge is where the occlusal load on the implant generates the most stresses, it is where the initial bone loss occurs. As a result, once a minimal or ideal height has been achieved for initial attachment and resistance, the diameter of the implant appears to be more significant than the height[135].

The bone implant contact is calculated by the help of the formula been framed by the Mish which is as follows

Total surface area of the bone/ total length of the implant been placed x 100. This formula helps to find out the total bone implant contact. Bone Implant when viewed under CBCT produce an artifact layer around the image which is later transferred to Adobe Photoshop to reduce the contrast and the markings were placed[135].

6 SURGICAL PHASE Fig 11, 12.

The surgical phase was decided bases on the two techniques of implant placement - Two stage techniques and single stage. Two stage technique involved complete flap exposure, one of the biggest disadvantage of this method was the bone loss associated with the flap elevation[136]. This not only increased the patient discomfort but also increased the chances of soft tissue losing its contour later leading to recession and bone loss. The second technique which was followed in this study that is single stage implant placement here the flap is not displaced but an punch out is been made adequate enough for the pilot drill to be placed directly above the bone[137]. Flapless technique was preferred as the bone density was considerably low. Flapless technique prevents bone loss usually caused in the second stage technique as the abutment would be placed in the implant during the initial healing[138].

LIMITATION

The sample size and the follow up criteria one of which being CBCT scan. CBCT even though being one of the best diagnostic tool it hasn‟t yet be fully accepted by the patients completely. The next challenge in terms of image viewing also has its limitations. The parameters needed to be analyzed couldn‟t be asses with precision because of lack of human skills. Analysis such as Finite element analyses (FEM) and micro-pet ct scans and histopathology could have taken this analysis to microscopic level of amount of bone formations and various changes over the period of time.

From this present study it was concluded:

- It needs to be understood that each implant site has different bone density, bone mechanics and following the same treatment plan for all the sites will affect the long time prognosis of implant after loading.
- The review of square thread form implants reveals its larger surface area and the compressive forces generated will improve the osseointegration even in condition where bone has lower density.
- It can be concluded that combination of square thread form implants with the CBCT diagnostic images will help in improving the success rate of the implant prosthesis.
- Using combination of various radiographic images to assess the prognosis of each implant which can be done with starting the multi-unit treatment plans to have CBCT as one of the main imaging criteria followed by digital IOPA as the follow up imaging aids which will reduce the treatment price.

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

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"Evaluation of Implant Stability, Bone Implant Contact and Crestal Bone Loss With Square Thread Form Implants."** submitted by **Dr Georgee Sharun Philip** Post graduate student from the **Department of Prosthodontics and Crown & Bridge** as part of MDS Curriculum for the academic year 2018-2021 with the accompanying proforma was reviewed by the Institutional Research Committee present on **26th November 2018** at BBDCODS.

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

Prof. Vandana A Pant
Co-Chairperson

Prof. B. Rajkumar
Chairperson

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

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

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

IEC Code: 42 **BBDCODS/01/2019**

Title of the Project: Evaluation of Implant Stability, Bone Implant Contact and Crestal Bone Loss with Square Thread Form Implants.

Principal Investigator: Dr. Georgee Sharun Philip **Department:** Prosthodontics and Crown & Bridge

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

Type of Submission: New, MDS Project Protocol

Dear Dr. Georgee Sharun Philip,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 10th January 2019.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Amrit Tandan Member	Prof. & Head, Department of Prosthodontics and Crown & Bridge, BBDCODS, Lucknow
3.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics & Dentofacial Orthopedics, BBDCODS, Lucknow
4.	Dr. Sumalatha M.N. Member	Reader, Department of Oral Medicine & Radiology, BBDCODS, Lucknow

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.
The comments were communicated to PI thereafter it was revised.

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

Lakshmi Bala
21/01/19

(Dr. Lakshmi Bala)
Member-Secretary
IEC

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

Forwarded by:

(Dr. B. Rajkumar)
Principal
BBDCODS

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

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Consent Form (English)

Title of the Study ……..

Study Number……..
Subject's Full Name…….
Date of Birth/Age ……
Address of the Subject……..
Phone no. and e-mail address……
Qualification ……
Occupation: Student / Self Employed / Service /
Housewife/ Other (Please tick as appropriate)
Annual income of the Subject……
Name and of the nominees(s) and his relation to the subject…… (For the purpose of compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document dated ……..for the above study and have had the opportunity to ask questions. **OR** I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3. I understand that the sponsor of the project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
5. I permit the use of stored sample (tooth/tissue/blood) for future research. **Yes [ ]** **No [ ]**

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

Representative:……..
Signatory's Name……. Date …….
Signature of the Investigator…… Date……..
Study Investigator's Name..... Date……..
Signature of the witness…… Date……..
Name of the witness……
Received a signed copy of the PID and duly filled consent form
Signature/thumb impression of the subject or legally Date……..

Acceptable representative

Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

सहमति पत्र

अध्ययन शीर्षक.....
अध्ययन संख्या.....
प्रतिभागी के पूर्ण नाम.....
जन्म तिथि / आयु.....
प्रतिभागी का पता .....
फोन नं. और ई-मेल पता .....
योग्यता .....
व्यवसाय: छात्र / स्व कार्यरत / सेवा / ग्रहिणी .....
अन्य (उचित रुप मे टिक करें) .....
प्रतिभागी की वार्षिक आय .....
प्रत्याशीयो के नाम और प्रतिभागी से संबंध...(परीक्षण से संबंधित मौत के मामले मे मुआवजे के प्रयोजन के लिए)

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

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

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

4. मै इससे सहमत हूँ कि कोई भी डेटा या परिणाम जो इस अध्ययन से प्राप्त होता है उसका वैज्ञानिक उद्देश्य (ओं) के उपयोग के लिए मेरी तरफ से कोई प्रतिबंध नही है।
5. भविष्य के अनुसंधान के लिए भंडारित नमूना (ऊतक/रक्त) पर अध्ययन के लिए अपनी सहमति देता हुँ।

हॉ [ ] नही [ ] अनउपयुक्त [ ]

6. मै परीक्षण की अनुमति देता हुँ। मुझे इसके द्वारा यदि कोई परेशानी होती है, इसके बारे में जानकारी दे दी गई है। मैने रोगी जानकारी सूचना पत्र को पढ तथा समझ लिया है।

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

हस्ताक्षरकर्ता का नाम..... दिनांक .....अन्वेषक के हस्ताक्षर ..... दिनांक .....

अध्ययन अन्वेषक का नाम .....

गवाह के हस्ताक्षर ..... दिनांक .....गवाह के नाम .....

मैनें पीआईडी और विधिवत भरे सहमति फार्म का एक हस्ताक्षर की नकल प्राप्त की.

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

Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
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Guidelines for Devising a Participant / Legally Acceptable Representative Information Document (PID) in English

Guideline for preparation of the participant information document	
While submitting your project report to the Institutional Ethics Committee, ensure that you have included participant information document and an informed consent form that is prepared as per the guidelines for Good Clinical Practice-Centre for Drug Candidate Optimization (GCP-CDCO2001), International Conference on Hormonization-Good Clinical Practice (ICH – GCP), ICMR ethical guidelines 2006, and the Declaration of Helsinki. The document is important because it enables the participants to make an informed choice. It also has got to be unique because no two research projects are identical. **The participant information document (PID should include only those headings listed below which are relevant to that study. Any further information you wish to add, is your choice.**	
1.	Participant information document and an consent form **in English and Hindi** (other languages if required)
2.	Font: Arial spacing of lines with 1.5
3.	Size: 12
4	All the consent forms must have Version No, Date, Page no **in the footer**
5.	In the case of participants with age≥ 18 yrs, PID and consent form should be attached while in the case of participant's age≤ 18 yrs and ≥ 8 yrs the above along with information document and assent form for children (minor) should be attached. In the case of ≤ 8 it will be signed by the guardian.

Potential recruits to your research/trial study must be given sufficient information to allow them to decide whether or not they want to take part. The Information Document should contain information under the headings given below, and preferably in the order specified. It should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs.

1. **Study Title**
   Is the title self-explanatory to a lay person? If not, an additional simplified title may also be included.

2. **Invitation Paragraph**

You should explain that the patient is being asked to take part in a research/trial study.

States:

–You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

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

The background and aim of the study should be given here.

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

You should explain how and why the patient/volunteer was chosen and how many other patients will be studied. Explain if the patient/volunteer with the following can be included in the study for e.g. pacemaker, pregnant women, breast feeding women, surgical clips, artificial heart valve, small bowel endoscopy capsule, metallic implants in the body, prosthesis orthopaedic devices, mentally retarded etc.

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

You should explain that taking part in the research is entirely voluntary. States:

–It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still are free to withdraw at any time and without giving a reason.

6. **What will happen to me if I take part?**

You should say how long the patient/volunteer will be involved in the research, how long the research will last, how often and what interval they will need to visit the centre and how long these visits will be. You should explain how long the volunteer will need to come for the study for conducting one experiment and how many experiment/study will be performed each day and if travel expenses are available for each visit. If the volunteer is illiterate then compensation for his/her wage/livelihood for a day is met, if he/she participates in the study? What exactly will happen e.g. blood tests, interviews etc.?

Whenever possible please draw a simple flow chart or plan indicating what will happen at each visit. What are the volunteer's/patient's responsibilities? Set down clearly what you expect of them in the form of simple instructions, for example asking them to come to the Institute at 9.00 am without having eaten anything/on an empty stomach/fasting. You should explain simply and briefly the research methods you intend to use.

7. **What do I have to do?**

Are there any lifestyle restrictions? You should tell the patient/volunteer if there are any dietary restrictions. Can the patient drive? Drink? Take part in sport? Can the patient continue to take his/her regular medication? Should the patient refrain from giving blood? What happens if the volunteer/patient becomes pregnant after performing first visit? Will she still be included in the research study if she needs to come after an interval of months? When and to whom this information has to be passed?

8. **What is the procedure that is being tested?**
   You should include a short description of the drug device. Patients/volunteers entered into study should preferably be given a card (similar to an identity card) with details of the study they are in. They should be asked to carry it if they need to visit a second time.

9. **What are the interventions for the study?**
   For interventional research study the patient/volunteer should be told what is the type of the intervention.

10. **What are the side effects of taking part?**
    For the procedure you should explain to the patients/volunteer the possible side effects. If they suffer these or any other symptoms they should report immediately. You should also give them a contact name and number to phone if they become in any way concerned or in case of emergency. The known side effects should be listed in terms the patient will clearly understand.

11. **What are the possible disadvantages and risks of taking part?**
    For studies where there could be harm to an unborn child if the patient were pregnant or became pregnant during the study, States:
    –It is possible that if the study is performed to a pregnant woman it will harm the unborn Child. Pregnant women must not therefore take part in this study, neither should woman who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the investigator.
    Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.
    You should clearly state what will happen if you detect or find a condition of which the patient was unaware. It is treatable? What are you going to do with this information?

12. **What are the possible benefits of taking part?**
    Where there is no intended clinical benefit to the patient/volunteer from taking part in the study, this should be stated clearly.
    It is important not to exaggerate the possible benefits to the patient during the course of the study/intervention, e.g. saying they will be given extra attention.

13. What if new information becomes available?

If additional information becomes available during the course of the research you will need to tell the patient about this. States:

–Sometimes during the course of a research project, new information becomes available about the research being studied. If this happens, your researcher will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your researcher/investigator 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 finishes/stops before the stipulated time, this should be explained to the patient/volunteer. Occasionally the company sponsoring the research may stop it. If this is the case the reasons should be explained to the patient/volunteer.

15. What if something goes wrong?

You should inform patients/volunteers how complaints will be handled and what addresses may be available. Is there a procedure in place? You will need to distinguish between complaints from volunteers as to their treatment by members of staff (research scolars etc.) and something serious happening during or following their participation in the trial, i.e. a reportable serious adverse event.

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

You will need to obtain the patient‘s permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential. States:

–If you consent to take part in the research any of your medical records may be inspected by the company sponsoring (and/or the company organizing) the research for purposes of analyzing the results. They may also be looked at by people from the company and from regulatory authorities/IEC to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the laboratory/centre.

–All information collected about you during the course of the research will be kept strictly confidential. Any information which leaves the laboratory will have your name and address removed so that you cannot be recognized from it.

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

You should be able to tell the patients/volunteers what will happen to the results of the research. You might add that they will not be identified in any report/publication.

18. Who is organizing the research?

The information should include the organization or company sponsoring/collaborating/organizing/funding the research (e.g. Govt. agency, NGO, academic institution).

The patient should be told whether the investigator conducting the research is being paid extra for including and conducting the study. This means who is bearing the cost of the tests/experiments? Is it free? Do the patients/volunteers have to pay for the experiments or results?

19. Will the results of the study be made available after study is over?
Please explain to participant regarding this query.

20. Who has reviewed the study?
You may/should mention that HOD /IRC/IEC of the institution has reviewed and approved the study (you should not however list the members of the Committee).

21. Contact for further information
You should give the patient a contact address for further information. This can be your name or that of another scientist/investigator involved in the study. **Name of the PI, Address, e-mail address, Telephone Numbers and name, Member Secretary of Ethics Committee of the institution (Dr. Lakshmi Bala, Member Secretary, bbdcods.iec@gmail.com) with address, e-mail address with telephone numbers (ext. no. 1291).**

Remember to thank your patient for taking part in the study!

The patient information sheet should be dated
The Participant Information document should state that the participant will be given a copy of the information sheet and the signed consent form.

Signature of PI……

Name……..

Date……..

Babu Banarasi Das College of Dental Sciences
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प्रतिभागी के लिए सूचना पत्र

1. अध्ययन शीर्षक

क्या आप का अध्ययन शीर्षक एक आम आदमी के समझने योग्य है ? यदि नही,, तो आप एक अतिरिक्त सरल शीर्षक शामिल कर सकते हैं।

2. निमंत्रण अनुच्छेद

आपको समझाना चाहिए कि मरीज को एक अध्ययन/शोध परीक्षण में भाग लेने के लिए कहा जा रहा है. निम्नलिक्षित एक उदाहरण है.:
आप को एक अध्ययन/शोध परीक्षण में भाग लेने के लिए आमंत्रित किया जा रहा है। इससे पहले आपके लिए यह समझना जरूरी है कि यह अध्ययन क्यों किया जा रहा है और उसमें क्या चीजे शामिल है। कृप्या अपना समय निकालकर इस सूचना को पढें तथा अपनी इच्छानुसार अपने मित्रों , परिजनो तथा अपने चिकित्सक के साथ चर्चा करें। अगर आपको कोई जानकारी समझ में नही आती है या और चाहिए तो हमें बताए। आप अपना समय निकालकर इस सूचना को पढें और बताए कि आप अध्ययन में भाग लेना चाहते है कि नहीं

3. अध्ययन का उद्देश्य क्या है ?

पृष्ठभूमि और अध्ययन के उद्देश्य की जानकारी सरल शब्दों में यहॉ देनी चाहिए।

4. मुझे इस अध्ययन के लिए क्यों चुना गया है ?

कृप्या आप प्रतिभागी को बताए कि उसे क्यों चुना गया है और इस में और कितने लोगो का चुनाव किया जाना है।

5. क्या इसमें मुझे भाग लेना चाहिए ?

कृप्या आप भागी को समझाए कि अनुसंधान / परीक्षण में भाग लेने के पूरी तरह स्वैच्छिकता है। आप निम्नलिखित पैराग्राफ का इस्तेमाल कर सकते है :–
'' यह आप पर निर्भर है कि आप को भाग लेना चाहिए की नहीं । यदि आप भाग लेने का फैसला करते है तो आप को अपने पास रखने के लिए एक सूचना पत्र दिया जाएगा और एक सहमति फार्म पर हस्ताक्षर करने के लिए कहा जाएगा। यदि आप ने भाग लेने के लिए फैसला किया फिर भी किसी भी समय बिना कारण वापस भाग न लेने के लिए स्वतंत्र है।

6. मुझे क्या होगा यदि मैं इस अध्ययन में भाग लेता हूँ।

आपको यह बताना चाहिए कि प्रतिभागी को कितने समय के लिए अध्ययन में भाग लेना है और यह अध्ययन कितने समय चलेगा। प्रतिभागी को यह भी बताना होगा कि भागी को कितनी बार और कितने दिनों के लिए परीक्षण के लिए सी0 बी0 एम0 आर0 आना होगा। आप प्रतिभागी को यह भी बताए कि उसे सी0 बी0 एम0 आर0 आने जाने का खर्च किसे देय होगा ? आप भागी को यह भी बताए की उसे आने पर हर बार कौन सी जॉच करनी होगी। आप प्रतिभागी को यह भी बताए कि उसकी क्या जिम्मेदारी होगी। प्रतिभागी को यह लिखकर दीजिए की उसे क्या सावधानी बरतकर आना चाहिए। आप प्रतिभागी को अध्ययन के विभिन्न पहलू के बारे में जानकारी दीजिए।

7. मुझे क्या करना है ?

क्या अध्ययन में भाग लेने से जीवन शैली पर किसी तरह का फर्क पडेगा ? आप भागी को यह भी बताए कि उसे आहार में कोई सावधानी बरतनी होगी। आप प्रतिभागी को यह भी बताए कि क्या वह रोज कि तरह गाडी चला सकता है ? क्या वह खेलखूद में भाग ले सकता है ? क्या वह रोज की तरह दवाए ले सकता है? क्या उसे रक्त देने से बचना चाहिए ? आप यह भी बताए कि उसे गर्भवती हो जाने पर क्या करना चाहिए ।

8. किस प्रक्रिया का परीक्षण किया जा रहा है ?

आप को प्रक्रिया या डिवाइस का एक संक्षिप्त विवरण देना चाहिए। आप को उनके विकास के बारे में जानकारी देना चाहिए। आप को दवा की खुराक और और उसे देने की विधि के बारे में जानकारी देना चाहिए। यदि मरीज को दवा के परीक्षणों में शामिल किया जाता है तो उसे अध्ययन की जानकारी का एक पहचान पत्र जैसा कार्ड देना चाहिए।

9. इस शोध में कौन से हस्तक्षेप दिए जायेगें ?

शोध के लिए रोगी को आप यह बताए कि उसे कौन से हस्तक्षेप दिए जायेगे।

10. इस अध्ययन में भाग लेने के क्या दुष्प्रभाव है **?**

किसी भी नई शोध या प्रक्रिया के लिए आप प्रतिभागी को उसके संभव दुष्प्रभाव को समझा जाना चाहिए। यदि वे इन या किसी भी अन्य लक्षण से पीडित है तो उन्हें अगली बार जब आप से मिलने आए तो उन्हे बताना चाहिए। आप भी उन्हे अपना नाम और फोन नंबर देना चाहिए ताकि यदि वे किसी भी आपातकालीन

स्थिति में आप से संपर्क कर सके । ज्ञात दुष्प्रभाव को भागी को सरल भाषा में समझकर तथा लिखकर देना चाहिए। किसी भी नई शोध 1के लिए अज्ञात दुष्प्रभाव के बारे में रोगी को पता होना चाहिए।

11. इस अध्ययन में भाग लेने के सम्भावित जोखिम और नुकसान क्या है **?**

अध्ययन के पहले या उसके दौरान महिला यदि गर्भवती हो जाती है तो बच्चे पर नुकसान हो सकता है, उसे आपको इन शब्दों में बताना होगा:–

'' यह संभव है कि अगर एक गर्भवती महिला को शोध के लिए चुना गया है तो उसे इस अध्ययन में भाग लेना चाहिए या नही ? या जो औरत अध्ययन के दौरान गर्भवती होने की संभावना है और कुछ महीने के बाद दोबारा इस अध्ययन में भाग लेना है या नही । किसी भी औरत को यदि पता चलता है कि वह गर्भवती बन गयी है , तो उसे तुरन्त अन्वेषक को सुचित करना चाहिए। गर्भावस्था के बयान को सावधानी से करें ।

12. अध्ययन में भाग लेने के संभावित लाभ क्या हैं **?**

क्या प्रतिभागी को अध्ययन में भाग लेने से कुछ फायदा है? यह स्पष्ट रूप से कहा जाना चाहिए। यह महत्वपूर्ण है अध्ययन के बारे में प्रतिभागी को बढाचढाकर नही बताना चाहिए । बल्कि उसे इस भाषा में समझाना चाहिए:

हमें आशा है कि परीक्षणों से आपको मदद मिलेगी। हालांकि यह गारंटी नही हो सकती ,इस अध्ययन से प्राप्त जानकारी हमें भविष्य में लोगो की बीमारी के बारे में जानकारी मिल सकती है।

13. क्या होगा यदि कोई नई जानकारी उपलब्ध हो जाती है ?

यदि अनुसंधान / परीक्षण के दौरान अतिरिक्त नई जानकारी उपलब्ध हो जाती है आप इस बारें में प्रतिभागी को बताएँ । आप निम्न शब्द इस्तेमाल कर सकते है:

'' कभी कभी एक अनुसंधान परियोजना / परीक्षण या शोध के दौरान नई जानकारी उपलब्ध हो जाती है। यदि ऐसा होता है तो आपके चिकित्सक आपको इसके बारे में बताएगे और आप के साथ चर्चा करेगे कि क्या आप इस अध्ययन में भाग लेना जारी रखना चाहतें है या नही । यदि आप वापस लेने का फैसला करते है तो आपका चिकित्सक आपके शोध को जारी रखने की व्यवस्था करेगे । यदि आप अध्ययन में जारी रखने का निर्णय लेते तो आपको एक अपडेटेड सहमति फार्म पर हस्ताक्षर करने के लिए कहा जा सकता है।

इसके अलावा नई जानकारी प्राप्त होने पर आपका चिकित्सक आपके हित के लिए अध्ययन से वापस लेने के लिए कह सकता है । वह इन कारणों को आपको बताएगें और इलाज जारी रखने की व्यवस्था करेगें।

14. क्या होता है जब अध्ययन / शोध परीक्षण बन्द हो जाता है ?

अगर यह शोध समय से पहले समाप्त हो जाता है तो इसकी पुरी सुचना प्रतिभागी को देना अनिवार्य है। कभी–कभी जो संस्था शोध को आर्थिक रूप से सहायता प्रदान कर रही होगी उसकी मदद न करने से शोध बन्द हो जाता है । अगर यह एक कारण है तो इसकी जानकारी प्रतिभागी को देनी चाहिए।

15. क्या होगा अगर कुछ गलत हो जाता है ?

प्रतिभागी को सुचित करना चाहिए कि उसकी शिकायतो का निवारण कैसे होगा और जिनके पास शिकायत करनी , उनके पते क्या है ? आपको शिकायत करने की प्रकिया की के विषय में पूर्ण जानकारी देनी होगी एवं शोध के दौरान किसी भी प्रकार के अप्रिय घटना घटने के पश्चात उन्हें कहॉ सम्पर्क करना है उसकी जानकारी उन्हें देनी होगी ।

16. मेरे इस अध्ययन में भाग लेने को गोपनीय रखा जाएगा ?

आपकों प्रतिभागी के चिकित्सीय प्रपत्र की पूर्ण जानकारी देने के लिए प्रतिभागी से आज्ञा लेनी पडेगी। आपको यह बताना होगा जो भी जानकारी प्राप्त की जाएगी वह गोपनीय रखी जाएगी। इसका निम्न वर्णन है।

'' यदि आप शोध में भाग लेने की सहमति देते है परीक्षण के लिए आपके मेडिकल रिकार्ड / परिणामों का विश्लेषण जॉच प्रायोजित कंपनी द्वारा किया जा सकता है । यह कंपनी और नियामक अधिकारियों द्वारा अध्ययन सही ढंग से किया जा रहा है की नही इसे देखने के लिए किया जाता है। आपका नाम का अस्पताल / क्लिनिक और प्रयोगशाला के बाहर खुलासा नही किया जाएगा ''

'' सभी अनूसंधान / परीक्षण के दौरान आप के बारे में एकत्र जानकारी कडाई से गोपनीय रखी जाएगी । कोई भी जानकारी है जो अस्पताल/ क्लिनिक और प्रयोगशाला से बाहर जाएगी , तो उसके ऊपर से नाम और पता हटा दिया जाएगा।

17. अध्ययन / शोध परीक्षण के परिणाम का क्या होगा ?

आप को रोगी के अनुसंधान / परीक्षण के परिणाम को यह बताना होगा कि आगे उसका क्या होगा । आप को यह भी समझाना होगा की उसकी पहचान किसी भी रिपोर्ट /प्रकाशन में नही की जाएगी।

18. इस अध्ययन को कौन आयोजित कर रहा है और इस परीक्षण के लिए धन कहॉ से आएगा ?

कौन सी संस्था या कंपनी शोध कार्य को प्रायोजित/सहयोग/वित्त पोषण (जैसे सरकारी एजेंसी,एन0 जी0 ओ0 , शैक्षिक संस्थान) कर रही है। इसकी जानकारी यहॉ उल्लेखीत होनी चाहिए।

प्रतिभागी को इसकी जानकारी देना होगा कि शोधकर्त्ता जॉच के लिए उन्हें अलग से कोई धनराशि देगे या नही? जिस शोध में वह भाग ले रहे है । इसका तात्पर्य है कि उस जॉच अथवा परीक्षण की जो कीमत है उसका वहन कौन कर रहा है? क्या वह फ्री है ? क्या प्रतिभागी को इस परीक्षण के लिए कोई शुल्क देना होगा या नही?

19. क्या सेवाएं शोध खत्म हो जाने के बाद उपलब्ध रहेगी या नही ?

इस जानकारी की कृप्या आप सूचना पत्र में शामिल करें ।

20. इस अध्ययन का पुर्ननिरिक्षण किसने किया है ?

आप यह बताए कि इसका पुर्ननिरिक्षण या पुर्नावलोकन हमारे संस्थान की नैतिकता / आचार समिति ने किया है तथा अध्ययन करने की सहमति दी है ।

निम्न लोगो से सम्पर्क करें

21. अधिक जानकारी के लिए

आपको प्रतिभागी को अधिक जानकारी देने के लिए मरीज का संपर्क पता देना चाहिए जो अन्वेषक के नाम पर है

प्रमुख अन्वेषक का नाम , पता , ई मेल पता , दूरभाष नं0 और नाम , संस्था की नैतिकता समिति के सदस्य सचिव (डा0 लक्ष्मी बाला , सदस्य सचिव,)

bbdcods_iec@gmail.com) दूरभाष नं0 :– 1233

1 , प्रतिभागी को घन्यवाद अवश्य प्रदान करे।

2 , प्रतिभागी सूचना पत्र में दिनांक लिखित है

3. प्रतिभागी सूचना पत्र में इसकी जानकारी अवश्य हो कि इसकी एक प्रतिलिपि आपने प्रतिभागी को दिया है।

प्रमुख अन्वेषक के हस्ताक्षर

प्रमुख अन्वेषक का नाम ..... दिनांक.....

Tools for statistical analysis:

Data was entered into Microsoft Excel spreadsheet and was checked for any discrepancies. Summarized data was presented using Tables and Graphs. The data was analysed by SPSS (21.0 version). Shapiro Wilk test was used to check which all variables were following normal distribution. Data was found to be normally distributed (p-value was more than 0.05). Therefore, bivariate analyses were performed using the parametric tests i.e. One way ANOVA (for comparing more than two groups) and Paired t test for comparing pre and post difference. Level of statistical significance was set at p-value less than 0.05

The following statistical formulas were used:

1. **The Arithmetic Mean:** The most widely used measure of central tendency is arithmetic mean, usually referred to simply as the mean. To obtain the mean, the individual observations were first added together and then divided by the number of observation. The operation of adding together or summation is denoted by the sign $\sum$.

The individual observation is denote by the sign X, number of observation denoted by n, and the mean by $\bar{X}$

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

2. **The Standard Deviation:** The standard deviation (SD) is the positive square root of the variance, and calculated as

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

where, n= no. of observationsand also denoted by subtracting minimum value from maximum value as below

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

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

where:

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

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

Assumptions are:

a) Response variable must be normally distributed (or approximately normally distributed).
b) Samples are independent.
c) Variances of populations are equal.
d) The sample is a simple random sample (SRS).

Two-way anovais used when we have one measurement variable and two nominal variables, and each value of one nominal variable is found in combination with each value of the other nominal variable. It tests three null hypotheses: that the means of the measurement variable are equal for different values of the first nominal variable; that the means are equal for different values of the second nominal variable; and that there is no interaction (the effects of one nominal variable don't depend on the value of the other nominal variable). When we have a quantitative continuous outcome and two categorical explanatory variables, we may consider two kinds of relationship between two categorical variables. In this relationship we can distinguish effect of one factor from that of the other factor. This type of model is called a **main effect model** or **no interaction** model.

4. **Post-Hoc Tests (Tukey-HSD):** After performing ANOVA, Tukey-HSD (honestly significant difference) post hoc test is generally used to calculate differences between group means as

where, $$q = \frac{X_1 - X_2}{SE}$$

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

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

5. **Level of significance:** "p" is level of significance signifies as below:

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

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SA	**front page.pdf** Document front page.pdf (D99288041)	1
W	URL: https://pocketdentistry.com/7-radiographic-imaging-in-implant-dentistry/ Fetched: 9/25/2019 10:08:06 AM	1
W	URL: https://www.researchgate.net/publication/323612840_Implant_thread_designs_An_overview Fetched: 7/6/2021 4:51:00 PM	1

7/7/21
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