COMPARISION OF BONE REGENERATION AROUND THE DENTAL IMPLANT USING β-TRICALCIUM PHOSPHATE ALONE AND IN COMBINATION OF β-TRICALCIUM PHOSPHATE AND CALCIUM SULPHATE IN IMMEDIATE IMPLANT PLACEMENT

Dissertation Submitted to

BABU BANARASI DAS UNIVERSITY LUCKNOW, UTTAR PRADESH.

In the partial fulfillment of the requirements for the degree

Of

MASTER OF DENTAL SURGERY

In

ORAL AND MAXILLOFACIAL SURGERY

By

Dr. Ashish Pandey

Under the guidance of

Prof. (Dr.) Hemant Gupta

Professor and Head

Department of Oral and Maxillofacial Surgery

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

(Faculty of Babu Banarasi Das University)

BATCH: 2019-2022

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Date: 4th April ; 2022

Place: Lucknow

Dr. Ashish Pandey

Ashish

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This is to certify that the dissertation entitled **"COMPARISION OF BONE REGENERATION AROUND THE DENTAL IMPLANT USING β-TRICALCIUM PHOSPHATE ALONE AND IN COMBINATION OF β-TRICALCIUM PHOSPHATE AND CALCIUM SULPHATE IN IMMEDIATE IMPLANT PLACEMENT"** is a bonafide work done by **Dr. Ashish Pandey,** under my direct supervision and guidance in partial fulfillment of the requirement for the degree of M.D.S. in Oral and Maxillofacial Surgery.

Date : 4th April, 2022

Prof. (Dr.) Hemant Gupta
Professor and Head
Department of Oral and Maxillofacial Surgery
Babu Banarasi Das College of Dental Sciences,
Babu Banarasi Das University,
Lucknow (U.P.)

DR. HEMANT GUPTA
PROF. & HEAD
DEPT. OF ORAL & MAXILLOFACIAL SURGERY
BABU BANARSI DAS COLLEGE OF
DENTAL SCIENCES

CERTIFICATE BY THE CO-GUIDES

This is to certify that the dissertation entitled **"COMPARISION OF BONE REGENERATION AROUND THE DENTAL IMPLANT USING β-TRICALCIUM PHOSPHATE ALONE AND IN COMBINATION OF β-TRICALCIUM PHOSPHATE AND CALCIUM SULPHATE IN IMMEDIATE IMPLANT PLACEMENT"** is a bonafide work done by **Dr. Ashish Pandey,** under our direct supervision and guidance in partial fulfillment of the requirement for the degree of M.D.S. in Oral and Maxillofacial Surgery.

Dr. Hemant Mehra
Reader
Department of Oral and Maxillofacial Surgery
Babu Banarasi Das College of Dental Sciences,
Babu Banarasi Das University,
Lucknow (U.P.)

ENDORSEMENT BY THE HOD / HEAD OF THE INSTITUTION

This is to certify that the dissertation entitled **"COMPARISION OF BONE REGENERATION AROUND THE DENTAL IMPLANT USING β-TRICALCIUM PHOSPHATE ALONE AND IN COMBINATION OF β-TRICALCIUM PHOSPHATE AND CALCIUM SULPHATE IN IMMEDIATE IMPLANT PLACEMENT"** is a bonafide work done by **Dr. Ashish Pandey,** under direct supervision and guidance of **Prof. (Dr.) Hemant Gupta,** Professor and Head, Department of Oral and Maxillofacial Surgery, Babu Banarasi Das College Of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

Prof. (Dr.) Hemant Gupta
Professor and Head

DR. HEMANT GUPTA
PROF. & HEAD
DEPT. OF ORAL & MAXILLOFACIAL SURGERY
BABU BANARSI DAS COLLEGE OF
DENTAL SCIENCES

Prof. (Dr.) Puneet Ahuja
Principal
PRINCIPAL
Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow-226028

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Date : 4th April ;2022

Place : Lucknow

Dr. Ashish Pandey

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LIST OF ABBREVIATION

BIC	BONE – TO IMPLANT CONCEPT
CBCT	CONE BEAM COMPUTERIZED TOMOGRAPHY
CG	CONTROLLED GROUP
EG	EXPERIMENTAL GROUP
IL	IMMEDIATE LOADING
IOPAR	INTRA – ORAL PERIAPICAL RADIOGRAPH
ISQ	IMPLANT STABILITY QUOTIENT
OPG	ORTHOPANTOMOGRAM
RCT	RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background : Immediate dental implants have been gaining popularity during the recent times as it bears the advantage of reduced treatment time and cost but suffers from technical complexitie. It is a challenge to place an implant matching the extracted tooth dimensions and the space between the implant and bone has to be filled in three dimensions with a biocompatible material optimal osseointegration. This study was performed to asses bone regeneration around dental implants placed immediately after extraction.

Aim and Objectives : To compare bone regeneration around dental implants placed immediately after extraction along with grafting using β-Tricalcium Phosphate alone or a combination of β-Tricalcium Phosphate and Calcium Sulphate.

Material and Method : 20 patients were enrolled in the study. Patients were divided in 2 groups.

Group A (n=10) – Placement of implants in sockets grafted with β- tricalcium phosphate alone

Group B (n=10) – Placement of implants in sockets grafted with β- tricalcium phosphate and calcium sulphate in combination.A randomized single center study was conducted on 14 implants to clinically and radiographically compare the primary and final dental implant stability by RFA, crestal bone loss and bone density.

Results : Significant difference was found between the two groups. Group A (Placement of implants in sockets grafted with β- tricalcium phosphate alone) and Group B (Placement of implants in sockets grafted with β- tricalcium phosphate and calcium sulphate in combination). Group B shows better implant stability, bone density, minimal crestal bone loss as compared to Group A.

Conclusion : The study concluded that β- tricalcium phosphate and calcium sulphate in combination shows improved and promising results for bone regeneration aroundimmediate implant placement.

KEYWORDS : Immediate implant, bone density, ISQ, crestal bone loss.

INTRODUCTION

A prerequisite of a successful outcome with regards to dental implants is adequate quantity and quality of bone at the recipient site.[1] However, this is not usually the case due to post-extraction trauma, bone resorption, or periodontal defects. Dental implants are the replacement of missing teeth with long-lasting treatment modality providing functional and esthetic integrity, making dental implants treatment more advanced and ameliorated.[2]

The replacement of a tooth using an implant is derived from an evolution in concepts, technology, and clinical applications, following years of basic research and fundamental studies on the concept of osseointegration. Due to the advantages provided by implant supported prosthesis like improved esthetics, improved function, improved hygiene accessibility, and osseous preservation, all at a comparable cost, the single tooth implant replacement is a more viable option for today's patient than teeth supported fixed partial denture that involves preparation of adjacent teeth. Inspite of advanced diagnostic facilities, it is a real challenge to place an implant matching the extracted tooth dimensions. The space between the implant and bone is required to be filled in three dimensions with a biocompatible material for enhanced osseointegration.

Albrektsson et al.[3] reported that primary implant stability and lack of micro movement are two of the main factors considered necessary for the achievement of predictably high success rates for osseointegrated oral implants. Primary stability of implants placed immediately after extraction strongly influences the long-term success of dental implants.[4]

Grafts are widely used in immediate dental implants for optimal restoration of deficient bone. Immediate implant placement is primarily advocated as it reduces the number of surgical interventions and preserves the dimension of the alveolar ridge.[5] The most predictable way to maintain the alveolar bone and the architecture of the residual ridge is preservation at the time of the tooth extraction by grafting of the extraction socket with bone grafting materials1 (socket grafting) or immediate implant placement with or without grafting.[3]

This concept led to the development of many techniques during the past two decades. Nowadays, a large number of grafting materials are available, among which autogenous bone graft is still considered to be the gold standard. However, harvesting

autogenous bone graft has its disadvantages: secondary donor site surgery, extended operating time, risk of complications as well as a limited amount of graft materials.[1]

As an alternative, bone graft substitutes such as xenografts, allografts, or alloplastic materials have been proposed. Among the most widely used and promising is the tri-calcium phosphate. It is considered to be bioactive and biocompatible. However, TCP cements have a slower resorption rate than bone and are usually too dense to allow bone tissues to grow into the defect in a shorter period. By adding a faster resorbing material like Calcium Sulphate (CS), pores may be created, ensuring new bone tissue grows into the grafted defect.

Clinical and experimental studies have shown that tooth extraction inevitably leads to atrophic changes of the alveolar ridge.[2,7] An average of 40% to 60% of original height and width is expected to be lost, with the greatest loss occurring within the initial 3 months.[2,5] This may render difficult, or sometimes impossible, subsequent rehabilitation with dental implants as the residual bone volume may be insufficient for the placement of an implant in an ideal 3-dimensional position. Chen and Buser [8] reviewed 91 studies and concluded that bone augmentation procedures are effective in promoting bone fill and defect resolution for implants in post extraction sites. Calcium sulphate shows a predictable resorption rate in vivo, presence of minimal trace elements and extremely uniform crystalline structure.

It is a bio-inert material and get resorbed over a period of weeks allowing fibrovascular tissue to take its place which eventually allows neovascularization and bone formation. Addition of calcium sulphate as a bone graft in case of placement of dental implants and pathological bony defects has been shown to improve the clinical outcome. Calcium sulphate also act as a barrier and filling material for the treatment of 'through and through' bony lesions.

Use of calcium sulphate as a bone graft substitute avoids the complications and morbidity associated with autografts like infection, donor site morbidity and is relatively inexpensive as compared to xenograft and alloplastic substitutes.

The rationale of this study is to evaluate and compare the outcomes of bone regeneration around the dental implants using β-Tricalcium Phosphate alone and in combination with Calcium Sulphate in immediate implant placement.

AIM & OBJECTIVES

AIM:

To compare bone regeneration around dental implants placed immediately after extraction along with grafting using β-Tricalcium Phosphate alone or a combination of β-Tricalcium Phosphate and Calcium Sulphate.

OBJECTIVES:

- To evaluate the primary implant stability (compare ISQ value) immediately after implant placement and 6 months postoperatively in both groups.
- To compare the bone density of the sockets, around the implant using specified graft materials immediate post-operative , after 3 months and 6 months postoperatively.
- To assess and compare the crestal bone loss in both the groups at 3 months and 6 months postoperatively.

REVIEW OF LITERATURE

Dean J et al (1995)[9] compared the host-bone response to hydroxyapatite/tricalcium phosphate (HA/TCP)-coated and non-coated titanium fiber metal implants placed in a load-sharing cancellous bone environment of the distal femurs of rabbits. Scanning electron microscopy in the backscatter mode demonstrated that new bone formed directly onto the HA/TCP-coated fibers and did not usually form directly on noncoated fibers. Analysis of fluorochrome labeling revealed that bone formation in weeks 1 through 4 was primarily woven and thereafter lamellar. The study showed that the host response to titanium fiber metal implants is influenced both by HA/TCP coating and by the implantation site.

Rosenquist B et al (1996)[10] conducted a study in 51 patients, a total of 109 implants were placed into extraction sockets immediately following extraction. The follow-up period varied between 1 to 67 months. Osseointegration was determined by clinical stability, lack of symptoms, and lack of peri-implant pathology based on radiographic examination. It was found that immediate placement of implants into extraction sockets is a safe and predictable procedure if certain guidelines are followed.

U.Bragger (1996)[11]conducted a study to compare the peri-implant mucosal conditions 1 year after immediate transmucosal implant placement without or in combination with guided tissue regeneration with the situation after regular placement of transmucosal 1-1 stage procedure implants in partially edentalous patients.15 patients were included in the study and 20 implants were placed. Two groups were created group 1 consisted of 6 patients who received 8 immediate implants group 2 consisted of 9 patients who received 12 standard implants. The immediate implants demonstrated lower frequencies of sites bleeding on probing The study has established that immediate oral implants are a feasible treatment modality with high predictability.

Schwartz A and Chaushu G (1998)[12] evaluated the consequences of submerged implants placed into fresh extraction sites without incisions or primary closure. No barrier membranes were used and the sole grafting material was autogenous bone chips. Complete bony healing was noticed in all cases with high survival rates. Clinical osseointergration was achieved with minimal gingival recession and papilla preservation. They concluded that immediate implant placement can be successful for replacing a single tooth even without primaryclosure.

Meredith N (1998)[13]discussed the parameters necessary to monitor successful implant placement. They discussed various techniques for measuring implant stability and osseointegration, such as cutting resistance, removal torque values, Periotest and Dental Fine Tester. They found that the RFA was easy to use in addition of being capable of eliciting quantitative information related to implant stability and stiffness and hence concluded that RFA has the potential application for predicting the outcome of implant as it yields valuable information of stability, both at placement and during function.

Mayfield L (1999)[14] compared immediate (IIP), delayed and late submerged and transmucosal implants. They observed that the implant survival rate is similar with either an IIP or a delayed placement protocol. They concluded that IIP offers many advantages over delayed placement, these include improve healing without flap advancement and decreased treatment time, surgical procedures, cost and discomfort.

Dario De Leonardis, Gabriele E. Pecora(1999)[15]conducted the study to evaluate the clinical and histologic results of a sinus augmentation procedure performed using calcium sulfate as the grafting material. A group of 12 patients (15 sinuses) formed the pilot group. Based on the experience of the pilot group, the technique of calcium sulfate application was modified, and the second group of 45 patients (50 sinuses) was subsequently treated (test group). In the pilot group, a total of 30 implants was placed. In the test group, a total of 100 implants was placed. The clinical data reported in the present study are related to the 1-year follow-up for both groups. Clinical evaluations, including assessment of implant mobility and probing pocket depth, were recorded on a monthly basis following implant uncovering until final prosthesis placement, and every 6 months thereafter. Radiographs were taken prior to sinus augmentation, monthly until 6 months postoperatively, 9 and 12 months after implantation, and at yearly intervals thereafter. Based on defined criteria, the overall success rate for the 130 placed implants 1-year post-implantation was 98.5%. Clinical and radiographic evaluation revealed that the augmentation procedure resulted in new tissue formation within the sinuses. The application of a resorbable barrier membrane to the access window reduced the invagination of soft tissue at that level. The results of this study support the hypothesis that calcium sulfate may be a suitable material for sinus augmentation.

Orsini M.et al(2001)[16]conducted a study to a total of 12 patients were treated in the study. A split-mouth design was utilized. Twelve 3-wall periodontal defects were treated with calcium sulfate plus autologous bone graft (test) and compared with 12 contra-lateral defects treated with a bioabsorbable membrane plus autologous bone graft (control). Before the surgical procedure, patients were instructed about oral hygiene, and scaling and root planing (SRP) was completed. Probing depth (PD), clinical attachment level (CAL), and bleeding on probing (BOP) were recorded at baseline and 6 months. The mean clinical attachment gain was 3.57 mm for control sites and 3.58 mm for test sites. As there were no sham-operated controls, it is not clear that the healing of these test or control-treated sites was any better than similar 3-walled defects sham-operated.

M. Kelly C.et al(2001)[17]conducted a prospective, nonrandomized, multicentre study, 109 patients with bone defects were treated with a surgical grade calcium sulfate preparation as a bone graft substitute. The calcium sulfate pellets were used in place of morselized cancellous bone graft for the treatment of patients with bone defects who usually would require grafting secondary to trauma, periprosthetic bone loss, tumor, or fusion. Calcium sulfate was used alone or mixed with other materials such as bone marrow aspirate, demineralized bone matrix, or autograft. The defects that were treated were contained and were not necessary for the stability of the bony structure. Radiographic and clinical data were collected at predetermined intervals for 12 months. At 6 months postoperatively, radiographic results for all patients showed that 99% of the calcium sulfate had been resorbed and 88% of the defect was filled with trabeculated bone. There were 13 complications; however, only four (3.6%) were attributable to the product. The results of a subgroup of 46 patients with benign bone lesions treated in the same manner are identical to the results of the overall study population. Surgical grade calcium sulfate pellets are considered a convenient, safe, and readily available bone graft substitute that yield a consistent successful result.

Botticelli D et al (2004)[18]studied dimensional alterations of hard tissues that occur following tooth extraction and immediate placement of implants. Eighteen subjects with a total of 21 teeth scheduled for extraction were included. Following flap elevation and the removal of a tooth and implant installation, clinical measurements were made to characterize the dimension of the surrounding bone walls, as well as the marginal defect. During the 4 months of healing the bone walls of the extraction underwent marked changes. The horizontal resorption of the buccal bone dimension

amounted to about 56%. The corresponding resorption of the lingual/ palatal bone was 30%. The vertical bone crest resorption amounted to 0.3 +/- 0.6mm (buccal), 0.6 +/- 1.0mm (lingual/palatal), 0.2+/- 0.7mm (mesial), and 0.5 +/- 0.9mm (distal).

Guarnieri R. et al(2005)[19]conducteda studyto investigate the influence of MGCSH on the histopathologic pattern of intrasocket regenerated bone and to evaluate histologically the healed MGCSH-grafted extraction socket site at 3 months postextraction. The mean trabecular area was 58.6% ± 9.2% in the coronal sections, 58.1% ± 6.2% in the middle sections, and 58.3% ± 7.8% in the apical sections. The differences in the mean trabecular area between sections were not statistically significant. Significantly, the MGCSH underwent complete resorption and replacement by newly formed bone because the most important negative attribute of other graft materials is the resorption time. Moreover, calcium sulfate shows great potential for guided bone regeneration in surgical sites.

Miyamotto I et al (2005)[20]evaluated role of regional bone structure on the dental implant stability at the time of surgery. CT scans were obtained to measure the cortical bone thickness of cortical bone at the sites of implant placement. The average ISQ value of the implants placed in mandible was higher than those placed in maxilla. They concluded that cortical bone thickness is extremely important for implants' stability andsuccess.

Beer A et al (2006)[21]assessed the correlation between implant primary stability and the diameter of the implant bed. Implants were inserted in three groups based on implant bed diameter. They observed that the insertion torque was inversely proportional to the diameter of the implant bed. They concluded that higher torque values and implant stability can be achieved in poor density bone by under-preparing the insertion site diameter

S. Mamidwar S.et al(2006)[22] conducted the study to characterize the dissolution, morphology, and chemical composition of a calcium sulfate/poly (L-lactic acid) (CS/PLLA) composite material before and after immersion in simulated body fluid (SBF). Twelve groups of experimental samples were prepared by coating CS pellets 1, 2, 3, or 4 times with one of three concentrations of a PLLA solution and wrapping them in the mesh; CS pellets for use as controls were similarly prepared but not coated. The half-life of pure CS pellets was 19 days whereas the half-life of CS/PLLA composite pellets ranged from 30 to 70 days. X-ray microprobe analysis of experimental pellets after immersion in SBF revealed that mineralization occurred in the CS portion of these pellets as well as on the coating; most of the mineral was

calcium phosphate, most of which was on the coating. Further studies will be required to confirm this composite's promise as a clinically effective osteoconductive material.

Intini G. et al(2007)[23]conducted a study to test CS-Platelet in heterotopic (muscle) and orthotopic (bone) bone regeneration bioassays. We then utilized CS-Platelet in a variety of dental and craniofacial clinical cases, where regeneration of bone was needed. The study showed that CS-Platelet is a novel biomaterial able to induce the formation of bone in heterotopic and orthotopic sites, in orthotopic critical size bone defects, and various clinical situations. The discovery of CS-Platelet may represent a cost-effective breakthrough in bone regenerative therapy and an alternative or an adjuvant to the current treatments.

S. Atilgan, F. Yaman, U. Yilmaz, B. Görgün & G. Ünlü(2007)[24]conducted a study to investigate the effect of medical-grade calcium sulphate and β-tricalcium phosphate/ hydroxyapatite on new bone formation. Additionally, the study compared these materials for infection, resorption, biocompatibility, immune reaction, fibrotic encapsulation, foreign body reaction, and physical attachment. The 40 rats in the study were divided into 2 groups. Medical grade calcium sulphate particles were applied to the rats in group 1 and β-tricalcium phosphate/hydroxyapatite to those in group 2, both materials resulted in similar fibrous tissue and inflammation responses, that their biocompatibilities were very good and that they did not cause foreign body reaction. The effects of calcium sulphate on bone formation were faster than those of β-tricalcium phosphate/ hydroxyapatite.

Hasan et al (2008)[25]demonstrated a comparative evaluation of immediate dental implant with autogenous versus synthetic guided bone regeneration. Clinical and radiographic study showed that the autogenous bone graft appeared to be superior and the graft of choice because it maintained bone structure and activated the osteogenesis process.

Evans CJZ and Chen ST (2008)[26] evaluated the esthetic outcomes of immediate implant placement. They observed that even when the clinician follows a correct IIP protocol, the resulting restoration may still present with an unacceptable esthetic outcome. They advocated for a stage approach in those patients with high esthetic expectations.

Brkovic Bozidar M.B. et al(2008)[27]reported the case of immediate implant placement and postextraction alveolar preservation using two different methods to prevent significant postextraction bone loss. Preservation of maxillary tooth extraction

using an alveolar preservation technique involving application of beta-tricalcium phosphate along with type 1 collagen. The study shows new bone formation 9 months after the procedure. The new bone provides adequate bone support for dental implant placement.

Hassan KS, Kasim A, Ogaly AURA, (2008)[28] conducted a study in which he divided the patients into two groups (I) received immediate implants augmented with autogenous bone graft, and the other (group II) received immediate implants augmented with a synthetic bone graft. The results show a significant difference between the groups for pocket depth and clinical attachments there was decreased bone loss in Group 1 compared to Group 2 bone density. The immediate dental implant placement with autogenous bone graft showed a significant superiority to the synthetic bone graft.

Podaropoulos L. et al (2009)[29]In their study aimed to compare the osteogenic potential of β-tricalcium phosphate (β-TCP) alone or in a calcium sulfate matrix histomorphomatically. Three round defects, 10 mm(diameter) 3 5 mm (depth), were created on each iliac crest of 4 dogs. The defects were divided into 3. Group A sites (b-TCP/CS), complete bone formation was observed. Group B (b-TCP) defects were partially filled with new bone. Group C incomplete new bone formation was observed.

Yamauchi K. et al (2009)[30] in their study evaluated the clinical outcome of periosteal expansion osteogenesis for correction of a horizontally deficient alveolar ridge, stability of dental implants placed in the expanded areas, and osteocompatibility of *β*-tricalcium phosphate (*β*-TCP) block areas. The mandibular premolars were extracted and buccal corticotomy was performed in 5 female dogs. The *β*-TCP block was placed at the lateral surface of the mandibular bone and 2 titanium screws were inserted from the lingual aspect to push the block to the buccal side. No problems with the materials were observed at any of the sites of intervention before, during, or at the end of the experimental period. The width increased after expansion and showed stable results on week 8 from the end of the expansion.

Ferrus Jorge et al (2009)[31]conducted a study in 93 patients where single tooth implants were placed immediately after extraction into the socket in the maxilla (tooth location 15-25). The implant sites were evaluated in four factors (i) implant location (anterior/posterior), (ii) cause of tooth extraction (periodontitis/non-periodontitis), (iii) thickness of the buccal bone walls (_1/41mm), and (iv) the

dimension of the horizontal buccal gap (_1/41 mm). The thickness of the buccal bone wall as well as the dimension of the horizontal gap influenced the hard tissue alterations that occur following immediate implant placement into extraction sockets.

Gökçen-Röhlig B.et al(2010)[32]conclude the study to examine the clinical and radiographic results of implants placed in fresh extraction sockets for 2 years of function. Ten patients were presented a treatment protocol involving the extraction of their remaining mandibular teeth and immediate placement of 4 implants (2 in fresh extraction sockets; test group (TG, n 20), 2 in mature bone; control group (CG, n 20). Descriptive statistics for the differences between baseline and follow-up values were assessed by chi-square test. The results none of the implants lost osseointegration. Placement of implants in fresh extraction sockets is a reliable treatment alternative.

Tabassum A et al (2010)[33]assessed the effect of surgical technique and bone density on primary implant stability. Implants were inserted into bone equivalents of different densities by either a press-fit or by an undersized technique. Independent of the surgical technique used they observed a statistically significant increase in mean insertion & removed torque values with increase in bone density. The insertion & removed torque values were significantly higher in undersized osteotomy group. The authors concluded that bone densities play a significant role in implant primary stability and undersized osteotomy technique improves implant success rate.

Shibly O et al (2010)[34]evaluated the bone regeneration around implants in periodontally compromised patients treated by immediate implant with immediate loading. The results suggested that immediate tooth replacement along with IIP demonstrate bone gain and soft tissue outcomes similar to those seen in delayed loading. They also observed decreased marginal recession and bone loss around the implant. They concluded that if strict protocols are followed the results with IIP usually highly predictable.

B.Shilpa et al(2012)[35]conducted a studyto clinically and radiographically evaluate and compare the treatment of intrabony defects with the use of decalcified freeze-dried bone allograft in combination with a calcium sulphate barrier to collagen membrane. They included Twelve patients having chronic periodontal disease aged 20 to 50 years and with a probing depth >6 mm were selected. Classification of patient defects into experimental and control groups was made randomly. In the test group, a calcium sulphate barrier membrane, and in the control group, a collagen

membrane, was used in conjunction with decalcified freeze-dried bone graft in both sides. Ancillary parameters as well as soft tissue parameters along with radiographs were taken at baseline and after 6 months of surgery. The study concluded that a calcium sulphate barrier was comparable to collagen membrane in achieving clinical benefits and hence it can be used as an economical alternative to collagen membrane.

Kutkuta B. et al (2012)[36] evaluated clinical and histologic outcomes of using medical-grade calcium sulfate hemihydrate (MGCSH) mixed with platelet-rich plasma (PRP) for extraction socket preservation graft before implant placement. Sixteen patients with a non-restorable tooth requiring extraction followed by implant placement were enrolled in this study. After extraction of a tooth, eight selected patients randomly received MGCSH mixed with PRP in the extraction sockets (test group), and eight selected patients randomly received collagen resorbable plug dressing material (control group). Bone core samples were retrieved from the center of the healed socket before implant placement for histomorphometric analysis. MGCSH mixed with PRP showed greater vital bone volume at 3 months with the rapid enhancement of bone healing compared to PRP-free collagen resorbable graft.

Vishwamabran et.al(2012)[37]conducted a study in which they included 30 patients(male and female) with a mean age of 23.1 years each having at least 1 tooth indicated for extraction 30 Implants were placed into fresh extraction sockets. The patients were divided into 2 groups Group 1 freeze-dried bone allograft was used and Group 2 modified hydroxyapatite was used. After implant placement, all implants were evaluated clinically and radiographically at baseline, 3 months, 6 months, 9 months, and 12 months. Results show immediate restoration of single tooth implants placed in fresh extraction sockets could be considered a valuable option to replace a missing tooth. The graft materials used in both groups have been found to be equally effective.

INTINI G.et al(2012)[38]conducted a study to define the conditions for the fabrication of a bioactive matrix that induces and supports cell proliferation and tissue regeneration. The proposed hypothesis was that a composite graft could be engineered by the absorption of platelet-rich plasma (PRP) onto calcium sulfate (CS). This combination showed the highest cell proliferation levels (*p*, 0.001). Further evaluations demonstrated that PRP is activated when combined with CS. When tested as a possible carrier for biologically active molecules such as platelet-derived growth factor (PDGF), CS showed increased cell proliferation (*p*, 0.001). SEM revealed

adherent osteoblasts with broad flattened edges on CS–PRP. This study proposes CS as an efficient carrier for PRP or PDGF and supports the use of these combinations as bioactive matrices in clinical or laboratory applications.

S. Soydan S.et al(2012)[39]conducted a study that evaluated the success and survival rates of implants following immediate and early placement. 50 implants were placed in 36 patients. 26 immediate (group I) and 24 early placements (group II) were performed. Pain or tenderness with function, mobility, radiographic bone loss from the initial surgery, and exudate history was evaluated. Mean vertical bone loss in the immediate placement group was 0.55 mm and 0.80 mm in the early placement group. The survival rate for the immediate placement group was 96.16% with 51.6 months follow-up and in the early placement group was 100% with 61.9 months follow-up. The results of this study suggest that although the success and survival rates of early placed implants were a little higher and the follow-up period was longer than immediately placed

Ortega-Martínez J.(2012)[40]write a review about the current state of immediate implants, with their pros and contras, and the clinical indications and contraindications. Twenty studies out of 135 articles from the initial search were finally included, which summed up a total of 1139 immediate implants with at least a 12-month follow-up. The results have been compared with other current available papers in the literature reviewed that obtained similar outcomes. Immediate implants have predictable results with several advantages over delayed implant placement. Few studies report on success rates rather than survival rates in the literature reviewed. Short-term clinical results were described and results were comparable to those obtained with delayed implant placement. Further long-term, randomized clinical trials are needed to give scientific evidence on the benefits of immediate implants over delayed implant placement.

Bee Tin Goh et al (2013)[41]conducted a study in a monkey model, to evaluate peri-implant bone regeneration and implant stability after immediate implant placement into tooth sockets with facial wall defects in two treatment groups. In eight control monkeys, the bony defect was reconstructed with autogenous particulate bone, whereas in 10 test monkeys a polycaprolactone–tricalcium phosphate (PCL–TCP) scaffold was used. Better maintenance of facial bone contour was noted in the test group; however, bone regeneration was seen only at areas adjacent to a bony wall of the defect. The mean bone-to-implant contact was 27.6 6 19.1% (control group)

versus 6.8 6 7.9% (test group).the use of a PCL–TCP scaffold showed better maintenance of the alveolar contour as compared to autogenous particulate bone at 6 months, there was minimal bone regeneration within the defect.

Harel N. et al (2013)[42]carried out a retrospective study to evaluate the crestal bone loss around immediate implant placed in tricalcium phosphate (TCP) grafted extraction sockets.58 patients underwent immediate implant placement into fresh extraction sockets with or without the use of TCP. inserted: In Group A 79 were placed immediately with the use of β-TCP as grafting material. In Group B 175 were placed in healed extraction sites, with 61 implants placed with the use of β-TCP graft material, and in Group C 114 implants were placed without any grafting material. Boneloss recordings were performed using periapical radiographs. Measurements were performed from the neck of the implant to the level of the surrounding bone in the vertical dimension. The use of TCP (Cerasorb) as a grafting material during immediate implant placement allowed no bone loss in 72.1% of the implants, which was very similar to the non-grafted cases for which implants were placed in favorable conditions.

Atalay,B.et al(2013)[43]conducted the study to present the clinical results of 110 cases of immediate implant placement without using graft materials at the end of 5 years. Inclusion criteria for the patients were the presence of at least 2 mm of bone beyond the root apex, the absence of acute signs of infection or inflammation in the treatment area, and the absence of systemic pathologies that would contraindicate bone healing around implants. Healing progressed uneventfully in 105 cases. Four implants were lost as a result of an infection in the first 3 months and 1 implant was lost 1 year after the functional loading of the prosthesis. The soft tissue anatomy was clinically acceptable in all patients. The implants that were placed in the extraction sockets of infectious teeth had also acceptable survival rates and clinical success. With a proper patient selection, immediate implant placement without bone grafting has predictable survival rates and clinical success.

Yashavantha Kumar C1 , Nalini K B2 , Jagdish Menon3 , Dilip Kumar Patro4 , Banerji B H(2013)[44]conducted a study to evaluate the Calcium Sulfate as Bone Graft Substitute in the Treatment of Osseous Bone Defects. The study includes 15 patients with benign bone lesions and chronic osteomyelitis were operated and the osseous defects were filled with calcium sulfate. Thirteen cases out of 15 showed calcium sulphate resorption and new bone incorporation. Calcium sulphate resorption occurred

at an average of 14.5 weeks (range,13- 18weeks) whereas new bone incorporation occurred at an average of 6 months (range 5-7months). The study shows Calcium sulphate is safe, efficient, and easily available bone graft substitute in the treatment of osseous defects.

Leventis M. et al(2014)[45]in their study evaluated the effect of a biphasic synthetic bone graft material composed of β-tricalcium phosphate (β-TCP) and calcium sulfate (CS) in 12 New Zealand rabbits. A circular bicortical critical-size cranial defect was created in each of the 12 rabbits. The defects were grafted with β-TCP/CS. Animals were euthanized at 3 and 6 weeks. Harvested tissue specimens were evaluated histologically and histomorphometrically. Parameters associated with new bone formation and graft resorption were measured and calculated. The results were statistically analyzed using the Mann-Whitney test. In this animal model, synthetic β-TCP/CS proved to be a biocompatible, osteoconductive, and bioresorbable bone graft substitute.

Laino L et al(2015)[46]conducted the study toevaluate bone healing in sinus lift procedure by using calcium sulphate as sinus augmentation material through CBCT in 25 patients before and after 6 months of surgery. The study shows that calcium sulphate produces an enhanced amount of bone production and is safe and provides predictable outcomes post-surgery.

Altintas, F. Taskesen N. Y.et al(2015)[47]conducted a retrospective study to assess the success of immediate and non-immediate implants installed in patients undergoing planned extraction of all remaining teeth and rehabilitation with implant-supported full fixed prostheses. Implant success, complications, and failures were recorded during follow-up. Forty-one patients with 512 implants were included in the study. Healing progressed uneventfully for 501 installed implants, but nine implants were lost in the non-immediate group and two were lost in the immediate group, during a mean follow-up of 44.9 months. This retrospective analysis showed that with thorough patient evaluation, the extraction of all residual teeth and implant installation in a single surgical procedure is a safe and predictable treatment modality for the successful rehabilitation of the edentulous patient with a fixed prosthesis.

TonettiMS et al(2016)[48]conducted the study to compare the need for bone augmentation, surgical complications, periodontal, radiographic, aesthetic, and patient-reported outcomes in subjects receiving implant placement at the time of extraction (Immediate Implant) or 12 weeks thereafter. IMI was unfeasible in 7.5% of

cases. One hundred and 24 subjects were randomized. One implant was lost in the IMI group. IMI required bone augmentation in 72% of cases compared with 43.9% for delayed (p = 0.01), while wound failure occurred in 26.1% and 5.3% of cases, respectively (p = 0.02). At 1 year, IMI had deeper probing depths (4.1 _ 1.2 mm versus 3.3 _ 1.1 mm, p < 0.01). A trend for greater radiographic bone loss was observed at IMI over the initial 3-year period (p-trend < 0.01). Inadequate pink aesthetic scores were obtained in 19% of delayed and in 42% of IMI implant cases (p = 0.03). No differences in patient-reported outcomes were observed. Immediate implant placement should not be recommended when aesthetics are important, IMI should be limited to selected cases. Longer follow-up is needed to assess differences in complication rates.

Iskaros M. et al (2017)[49]conducted a study to improve the surgical site preparation and implant integration when beta-tricalcium phosphate is inserted into extraction sites prior to implant placement. Ridge preservation using the guided bone regeneration technique has been proven to improve ridge height and width dimensions compared to tooth extraction only. The use of beta-tricalcium phosphate shows great osteoconductive potential because of its macroporosity which leads to good bone growth.

Chrcanovic B et al (2017)[50]conducted a systematic review and meta-analysis to compare the survival rate of dental implants, postoperative infection, and marginal bone loss when implants were inserted in bone sites of different quantities and qualities. An electronic search was undertaken in January 2015 for randomized and nonrandomized human clinical trial. The authors observed that dental implants inserted in bone quality 4 demonstrated highest failure rates. They concluded that poor bone quality and quantity are the main risk factors for implant failure, so thinner cortical bone combined with thicker trabecular bone are responsible for implant failure in posterior maxilla.

Baftijari D et al (2018)[51]analyzed the primary and secondary stability of dental implants placed in the maxilla using resonance frequency analysis. An ISQ value of ≥65 was recorded in 78.82% of total implants placed after 3 months of placement. The one year cumulative success rate of the inserted implants was 98.3%. The authors concluded that the ISQ value recorded by RFA is a reliable parameter for evaluating the success of implants, especially in suboptimal density bone.

Singla Nancy et al(2018)[52]conducted the study in which they place 10 immediate implants with the traditional flap technique and 10 other patients with flapless technique. Through radiographic follow-up for three months, they observed that there is comparatively less bone resorption in cases of flapless implants as compared to the traditional flap technique.

Fairbairn Peter et al(2018)[53]conducted a study by using beta TCP and Calcium sulphate as graft material for alveolar ridge preservation resulting in producing an adequate amount of high-quality bone capable to place an implant after 12 weeks post-surgery. It provides functional preservation of the volume and the dimensions of the site.

Sang-Ho Jun et al (2018)[54]conducted a study to evaluate the effect of bone graft procedure on the primary stability of implants placed immediately after extraction into the sockets and assess the vertical alteration of peri-implant bone radiographically. They placed twenty-three implants in 18 patients immediately after tooth extraction. The horizontal gap between the implant and bony wallsof the extraction socket was grafted with xenografts. The implant stability before and after graft procedure was measured as implant stability quotient before bone graft (ISQ bbg) and implant stability quotient after bone graft (ISQ abg). Periapical radiographs were taken to measure peri-implant bone change immediately after implant surgery and 12 months after implant placement. Results show that the bone graft procedure is beneficial for increasing the primary stability of immediately placed implants, especially when the ISQ of implants is below 65 and that bone grafts have some effects on peri-implant bone maintenance.

Wu Dong et al(2019)[55]conducted a study to compare the efficacy of the autogenous tooth bone and xenogenic bone grafted in immediate implant placement with the bone defect. Methods: Thirty patients whose compromised anterior teeth need immediate implant placement were enrolled. Autogenous tooth bone made from the extracted teeth by chair-side or the xenogenic bone was used to repair the bone defect. Clinical examination, radiographic assessment about the horizontal bone change in the level of 0 mm, 3 mm, and 6 mm below the implant neck, and the marginal bone loss were made immediately, 6 and 12 months after implant placement. All implants achieved the success criteria without any complications during the follow-up period. The percent of the horizontal bone change and the marginal bone loss at 6 and 12 months were almost the same between the two groups ($P > .05$). The horizontal bone loss at

the first or the latter 6 months was almost the same (P > .05). But the horizontal bone loss at the 6 mm level was less than the 0 mm and 3 mm levels at 6 and 12 months (P < .05). The bone volume change in the facial part of the implant after immediate placement is almost the same between the two groups. Providing clinical evidence that the autogenous tooth bone made from the compromised tooth can be an acceptable bone graft material.

Dong Wu1et al (2019)[56] conducted a study to compare the efficacy of the autogenous tooth bone and xenogenic bone graft in immediate implant placement with the bone defect. They included 30 patients in the study. Autogenous tooth bone made from the extracted teeth by chair-side or the xenogenic bone was used to repair the bone defect. Clinical examination, radiographic assessment about the horizontal bone change in the level of 0mm, 3mm, and 6mm below the implant neck, and the marginal bone loss were made immediately, 6 and 12months after implant placement. The result shows that the bone volume change in the facial part of the implant after immediate placement is almost the same between the two groups. Providing clinical evidence that the autogenous tooth bone made from the compromised tooth can be an acceptable bone graft material.

Sonalika Kabi et al (2020)[57]conducted a study to evaluate the peri‑implant hard and soft tissue changes following immediate implants placement with a jumping distance of 2 mm with or without autogenous bone grafts. They included 33 patients in the study 16 participants in the study group and 17 in the control group. The study group which received bone graft and the control group which did not receive any graft. The alveolar bone loss was evaluated radiologically using cone‑beam computed tomography, and pain, suppuration, mobility, and periodontal probing depth were evaluated clinically.The alveolar bone loss was greater in the study group; however, pain, suppuration, and mobility showed no difference between the groups.

Gupta R. et al (2020)[58]conducted a study to evaluate the efficacy of the β-tricalcium phosphate (β-TCP) in the stability of immediate implant placement in mandibular first molar cases in twelve weeks period using radiographic aids. The mean densities for coronal buccal and lingual side, sagittal mesial and distal side, axial anterior, posterior, mesial, and distal side were 0.008, 0.115, 0.10& 0.30) respectively. The mean crestal bone loss on the mesial and distal side was 0.60mm with SD of ± 0.6mm (p=0.02) and 0.4mm with SD of ±0.3mm (p=0.02) respectively. The result shows that the β-TCP doesn't seem to be an ideal and highly beneficial bone filler around

immediate implant placement, due to delayed osteoconduction and integration, poor handling, and condensing properties.

Huchim-Chablé M et al(2020)[59]conducted a studyto evaluate the mixture of Calcium Sulfate and Plasma Rich in Growth Factors (CaSO4 + PRGF) as a bone-graft substitute in extracted mandibular third molar (MTM) alveoli during a 4-month period. Bilateral MTM extractions were performed in 10 patients (18–25 years) A CaSO4 + PRGF mixture was placed in the right alveolus (Experimental Group (EG)) and a natural blood clot in the left (Control Group (CG)). Monthly X-ray controls were performed using grayscale to measure Bone Regeneration (BR). A non-parametric Sign Test was used to evaluate Radiopacity/Bone Regeneration (Ro/BR) over 4 months, and Friedman's non-parametric test was used for intra-group analysis over these months. the EG showed significant difference of Ro/BR between groups $p = 0.002$ ($p < 0.05$). Significant differences were observed in all quadrants and areas $p = 0.002$ ($p < 0.05$) except in area A in month 4 ($p = 0.016$), which could be explained by its being the closest to native bone. EG CaSO4 + PRGF showed a higher degree of bone regeneration compared to CG.

Kabi S et al (2020)[60]evaluated the peri-implant hard and soft tissue changes following immediately placed implants with a jumping distance of 2mm with or without autogenous bone grafts. The alveolar bone loss was calculated using CBCT revealed that it was greater in the autogenous bone graft group, but other parameters were similar. They concluded that immediate implants placed with or without bone grafts had similar alveolar hard and soft tissue changes when the jumping distance was less than 2mm.

Zihou Zhao et al(2020)[61]conducted a study to investigate and evaluate the effect of antibiotic-loaded absorbable calcium sulfate/calcium phosphate (CS/CP) composite as a bone substitute in the treatment of chronic osteomyelitis compared with CS. The study includes 31 patients (group A: CS/CP, 21 patients, group B: CS, 10 patients)New bone formation property and resorption were analyzed through X-ray and CT scan. The average follow-up in each group was 61.3 and 86.7 weeks, respectively. In group A (CS/ CP), no patient had a recurrent infection at 17 months after surgery, 1 case had delayed wound healing and healed after dressing change. In group B (CS), 2 patients had a recurrent infection at 18 weeks after surgery, and were managed after further surgical treatment, 3 cases had delayed wound healing and healed after dressing change. The results proved that compared with CS, this novel

antibiotic-impregnated CS/CP composite acted as a superior scaffold for bone formation with a lower rate of infection recurrence, when choosing bone substitutes in the treatment of chronic osteomyelitis.

Jessar AL et al(2021)[62]conducted a study comparing the effectiveness of beta-tricalcium phosphate to other grafting materials in treating periodontal infra bony defects around tooth. The study shows that bone regeneration with beta-tricalcium phosphate was more effective when compared with other bone graft materials in terms of pocket depth reduction and clinical attachment levels implants, the difference was not remarkable. In conclusion, both implant insertion techniques are safe and reliable procedures with considerably high survival rates.

MATERIALS & METHOD

- A prospective, randomized, single-center study will be performed among patients with at least one or more teeth that is/are to be extracted in the patients, reporting to the out-patient department (OPD) of Oral and Maxillofacial Surgery, Babu Banarasi Das College of Dental Sciences, Lucknow.
- Total(n=20) patients will be divided into two groups-
    1. Group A (n=10) – Placement of implants in sockets grafted with β-tricalcium phosphate alone
    2. Group B (n=10) – Placement of implants in sockets grafted with β-tricalcium phosphate and calcium sulphate in combination.

Clearance was obtained from the Research Committee and Institutional Ethical Committee of Babu Banarasi Das College of Dental Sciences. Written informed consent was obtained from each patient.

Eligibility Criteria:

Inclusion criteria

- Patients with one or more teeth is/are to be extracted.
- Patients with acceptable oral hygiene status and no active periodontal disease.
- Patients with no intraoral soft and hard tissue pathology.
- No systemic condition that contradicts implant placement

Exclusion Criteria

- Periapical pathology
- Maxillary sinus pathology
- Smokers
- Patients with systemic disease that may affect normal healing
- Psychiatric problems
- History of radiation therapy to the head and neck neoplasm
- Immunodeficiency pathology, bruxism, stress situation (socially and professionally), unrealistic aesthetic/functional demands.

Materials Required:

- Mouth mirror and probe
- Metallic scale
- Periosteal elevator- Howarths
- Periosteal elevator- Molts
- Tissue holding forceps
- Suture cutting scissors
- Needle holder Bard Parker handle- No. 3
- B. P. Blade- No. 15
- Micromotor and straight handpiece
- Suture materials- 3-0 Silk
- Implant placement drill kit / physio dispenser
- Disposable syringe
- Bone Grafting Kit
- Resonance Frequency Analysis (RFA)
- Others

METHODOLOGY

Mouth rinsing with Chlorhexidine mouthwash (0.2% for 2 minutes) was done just before the surgery. Local anaesthesia (2% Lignocaine hydrochloride with 1:80000 adrenaline) was used to anesthetize the surgical site by suitable nerve block.

As atraumatic extraction as possible was done. Osteotomies were performed using drills in sequence from smaller to larger diameters in accordance with the diameter of the implant to be placed.

Before implant insertion, a periodontal probe was used to check for any bony fenestrations of the osteotomy. The specified graft materials were inserted into the osteotomy following the manufacture's guidelines.

The implants were inserted with a handpiece at the recommended torque (about 40 Ncm for both cortical and root from the dental implant) and speed about 25 to 35 rpm, final seating was done manually with a wrench if the torque exceeded the motor capacity.

The final seating was confirmed when the implant bottomed out at the base of the osteotomy and was not showing any further apical movement. After the implants were placed, the ISQ was measured using Resonance Frequency Analysis (RFA)

Patients were recalled for radiographic evaluations periodically (IOPARs/OPG/CBCT) to assess crestal bone loss after 3 months and 6 months, bone density immediately after implant placement, 3 month and 6 months and primary stability immediately after implant placement and 6 months postoperatively. Patients were prescribed suitable antibiotics, analgesics and anti-inflammatory drugs.

Post-operative care

- All patients were advised medication (Amoxicillin 500 mg TDS), Metronidazole 400 mg TDS, B-complex OD, Analgesics TDS) after surgery for 5 days.
- Patients were advised to maintain oral hygiene by rinsing with 0.2% Chlorhexidine gluconate.
- Patients were advised strictly liquid diet for 24 hours.
- Periodic recall was done and data recording was done as per designed protocol.
- Periodic follow-up was done.

STATISTICAL ANALYSIS

The following statistical tools were employed for the present study:

- **MEAN**
- **STANDARD DEVIATION**
- **CHI-SQUARE TEST**

1. **Chi-square test:** This test was performed to evaluate whether there was a significant difference in frequency of events in one group from that in another. The following formula was used to calculate the proportion.

Chi square test:

$$\chi^2 = \sum \frac{(O-E)^2}{E}$$

Where O = Observed frequency

E=Expected frequency

1. **Mean** : Mean was calculated as the central tendency of a group using the Following formula:

$$\overline{X} = \frac{\Sigma X}{n}$$

Where ΣX= summation of values

n= number of samples

Standard Deviation:Most frequently used, measure of dispersion, denoted by S.D .and was calculated as:

$$SD = \sqrt{\frac{\Sigma(X-\overline{X})^2}{n}}$$

S.D.=Standard Deviation

X = Individual value for the parameter X=Arithmeticmean

N=Number of observations

1. **Student 't' test:** To test between equality of two mean:

$$t = \frac{\bar{x}_1 - \bar{x}_2}{\sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}}$$

$\bar{X}_1$ = Mean 1 X_2=Mean2

SD_1=Standarddeviation1

SD_2=Standard deviation2

n_1=Numberofvaluesingroup1

n_2=Numberofvaluesingroup2

ASSESSMENT PARAMETERS –

Clinical Evaluation:

1. Preoperative (in both groups)
    a. OPG/IOPAR
2. Immediately after implant placement (in both groups)

    IOPAR/OPG/CBCT

    a. Primary Stability of the implant with Resonance Frequency Analysis

    b. To check implant placement level in relation to crestal bone

    c. To compare bone density of the socket around the implant

3. After 3 months postoperatively (in both groups)

- OPG/IOPAR/CBCT

a. To check implant placement level in relation to crestal bone

    b. To compare bone density of the socket around the implant

4. After 6 months postoperatively (in both groups)

- OPG/IOPAR/CBCT
    a. To check implant placement level in relation to crestal bone
    b. To compare bone density of the socket around the implant
    c. Stability of the implant with Resonance Frequency Analysis

Method of investigation

- Hard tissue- X- Ray intra oral periapical radiograph (IOPAR), (Manual/
- digital method using paralleling cone technique with grid)

- Orthopantomogram (OPG) (Fig. 3, 4, 29 &30)
- CBCT (optional)
- Routine blood investigation & viral markers

1- Bone healing

a- Pre-operative OPG & IOPAR

b- Post-operative OPG & IOPAR

Time period	Group1	Group2
At the time of surgery After three months After six months		

2- Primary stability

a- Implant stability quotient (ISQ)

Time period	Group1	Group2
At the time of surgery After six months		

3. Level of crestal boneinrelation to implant

a- Pre-operative IOPAR

b- Post-operativeI OPAR

Time period	Group1	Group2
After three months After six months		

Dental Implant Stability Evaluation:

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

Statistical Analysis

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

Blood investigations -

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

Radiographic investigations - CBCT, OPG, IOPAR

ARMAMENTARIUM

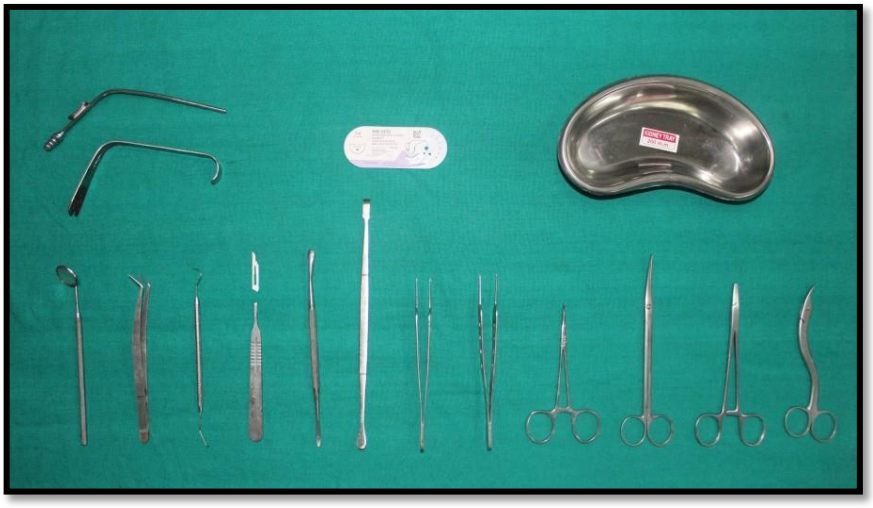


Fig.1.1: Surgical Instruments

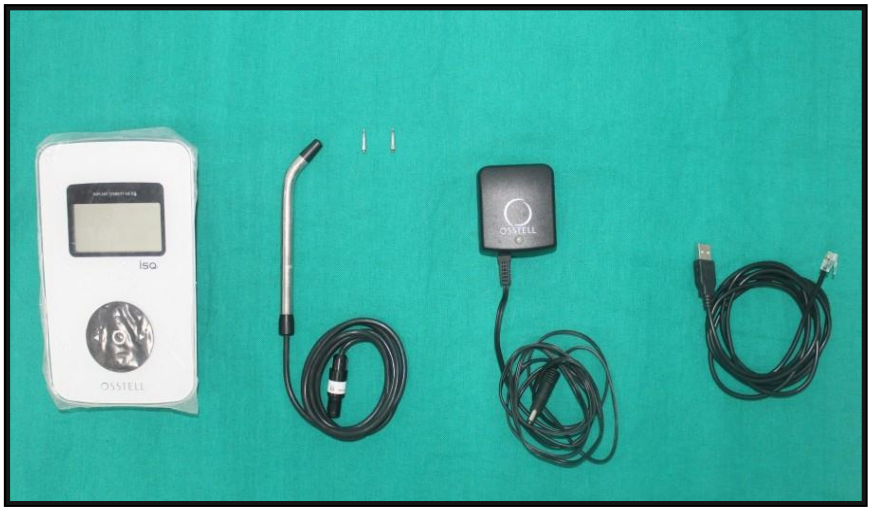


Fig.1.2: Implant Stability Quotient Device

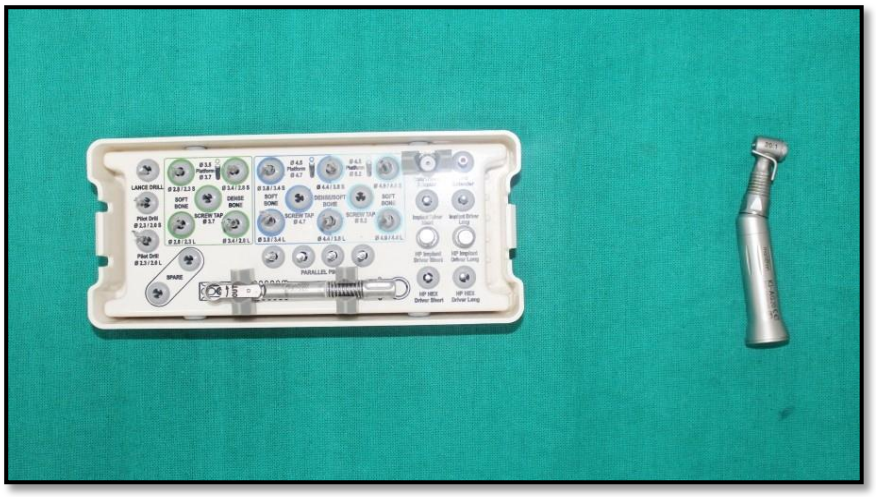


Fig. 1.3: Implant Kit With Hand Piece

GROUP A

PRE-OPERATIVE RADIOGRAPHS

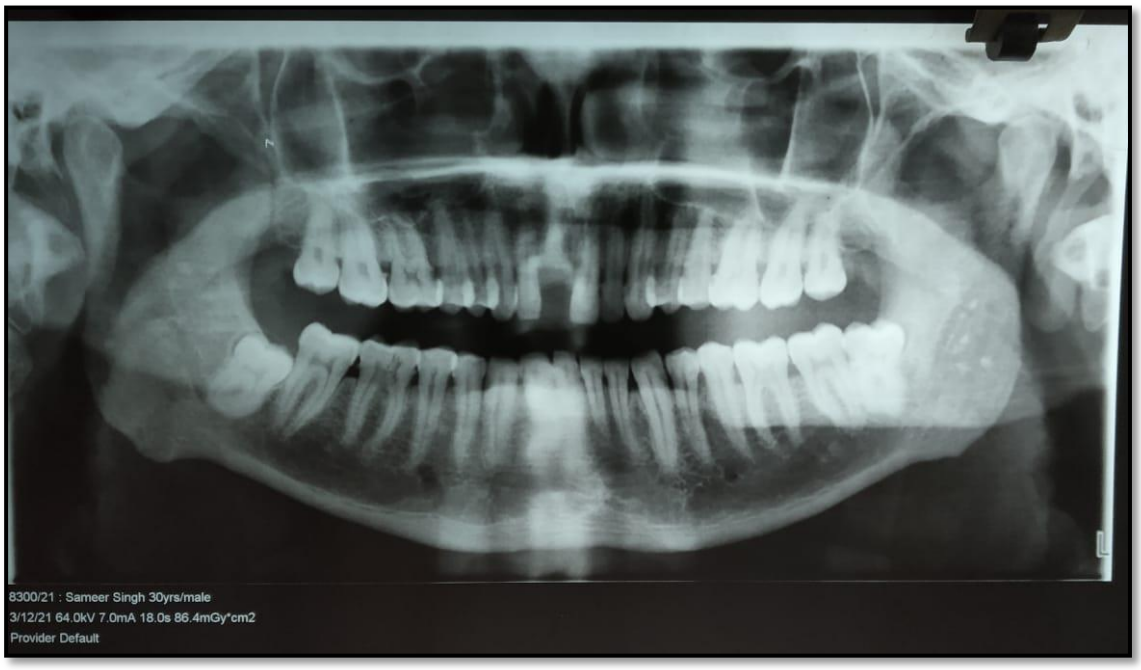


Fig.2.1 : Orthopantomogram

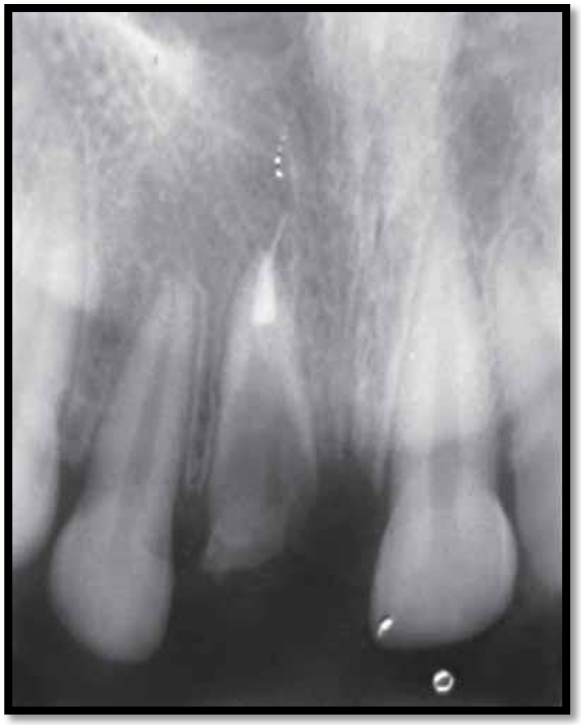


Fig. 2.2 : Pre Op IOPAR

INTRA-OPERATIVE PROCEDURE

Fig. 2.3 : Extraction Socket

Fig. 2.4 : Implant Placement

Fig. 2.5 : Graft Placement

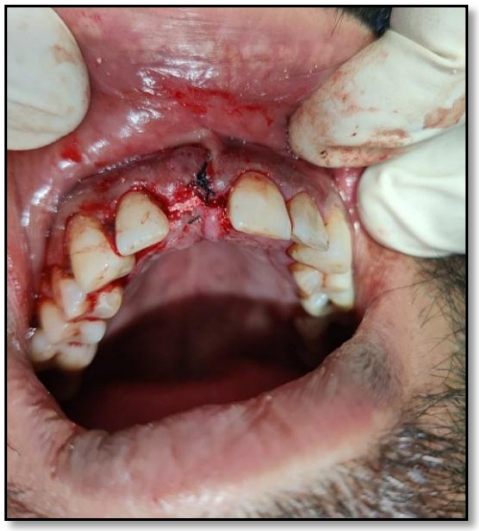


Fig. 2.6 : Closure

Fig. 2.7 : Immediate Post Op ISQ

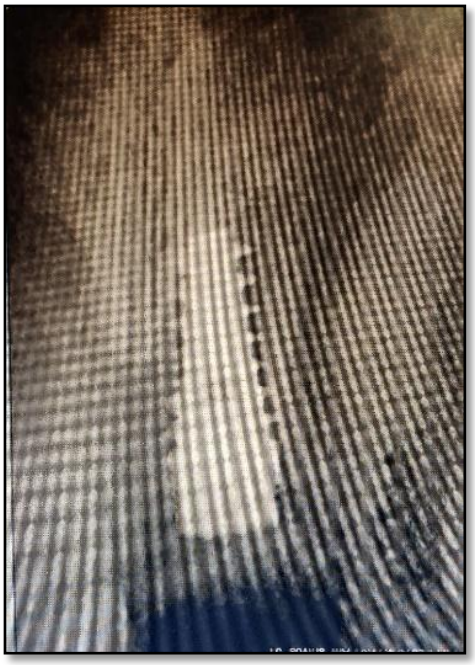


FIG. 2.8: Immediate Post Op IOPAR

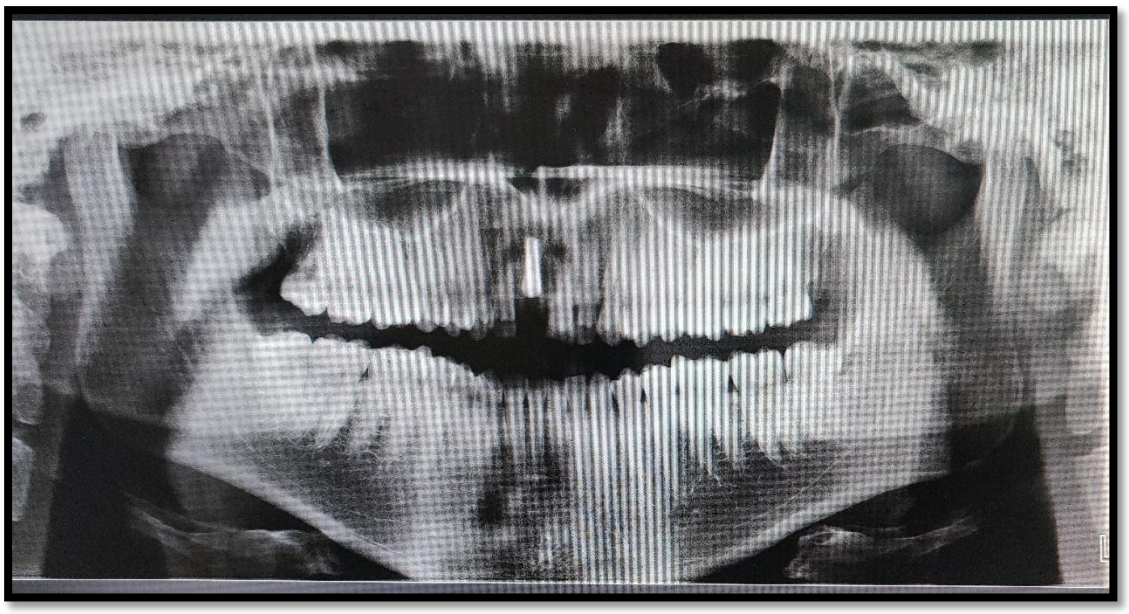


Fig. 2.9 : Immediate Post Op OPG

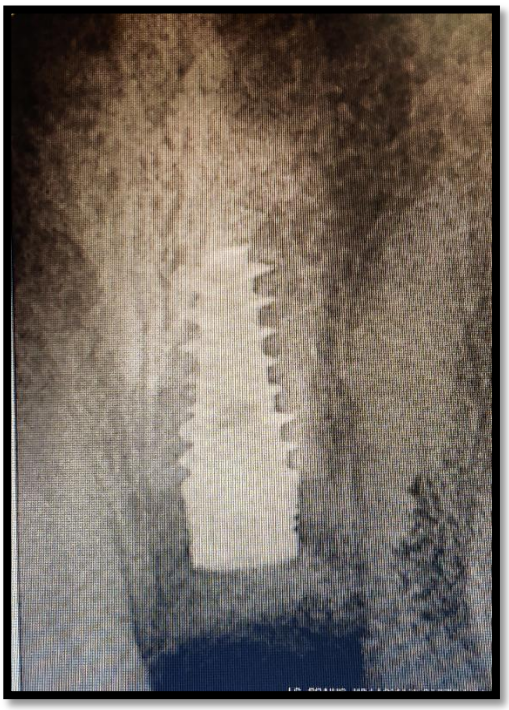


Fig. 2.10 : After 3 Months IOPAR

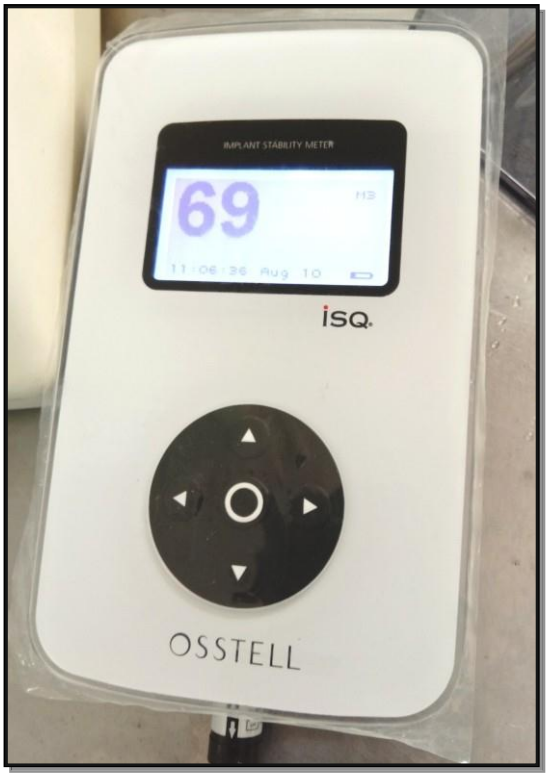


Fig. 2.11 : After 6 Months

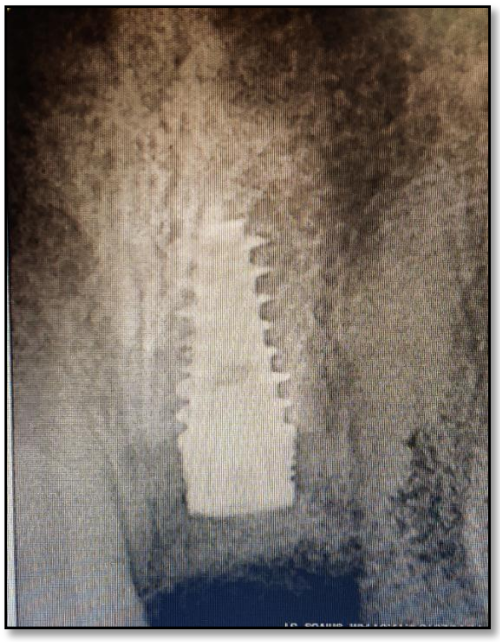


Fig. 2.12 : After 6 Months IOPAR

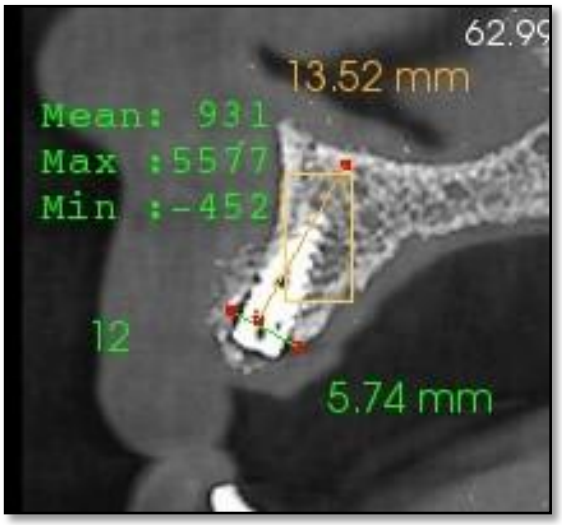


Fig. 2.13 : After 6 Months CBCT

GROUP B

PRE-OPERATIVE RADIOGRAPHS

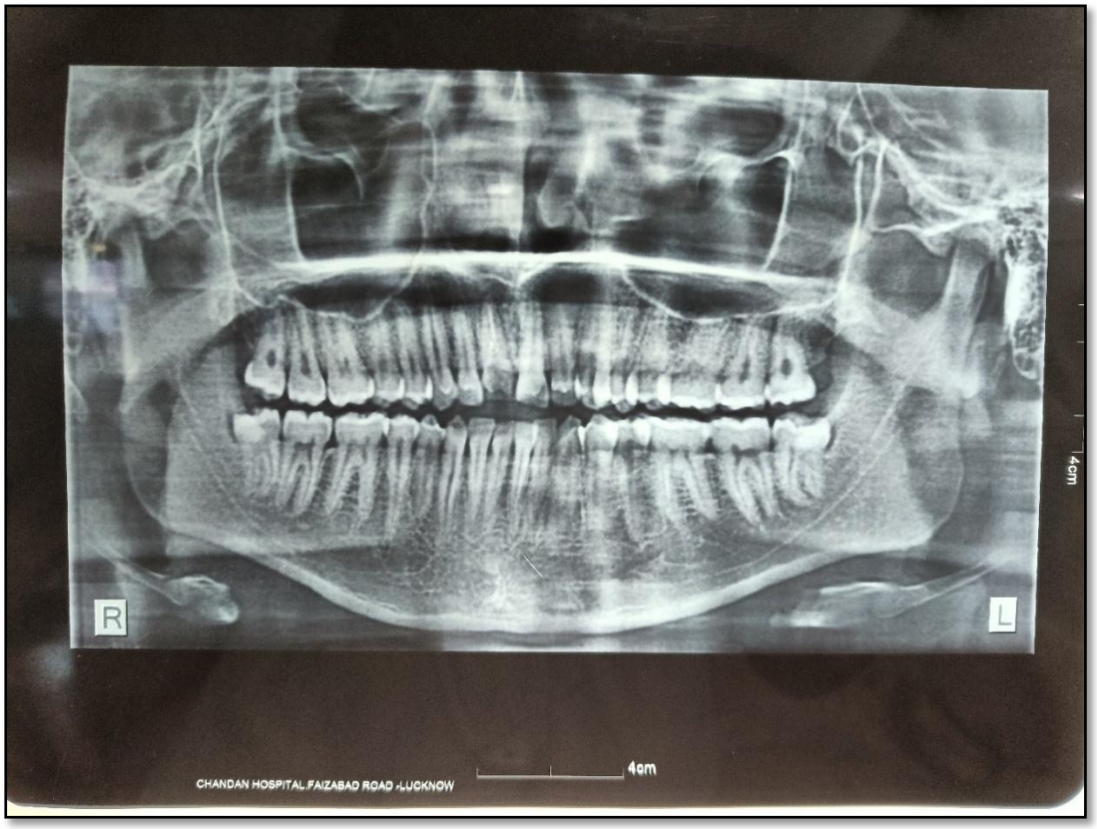


Fig.3.1: Orthopantomogram

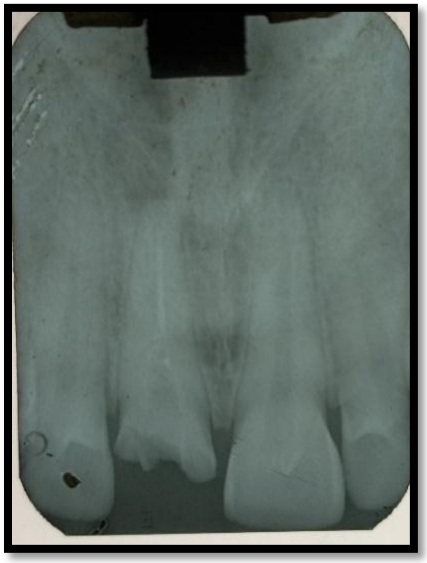


Fig.3.2 : INTRA ORAL PERIAPICAL RADIOGRAPH

INTRAOPERATIVE PROCEDURE

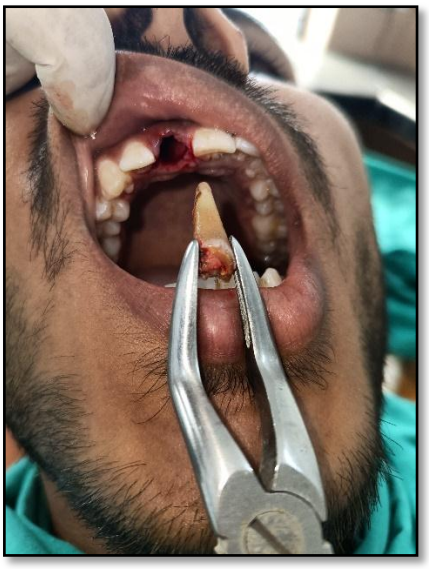


Fig. 3.3 : Extraction Socket

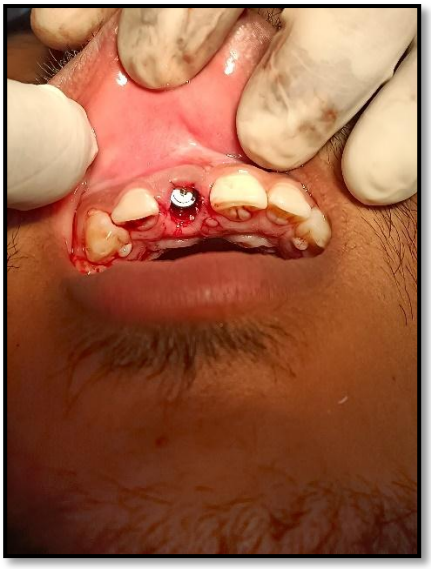


Fig. 3.4 : Implant Placement

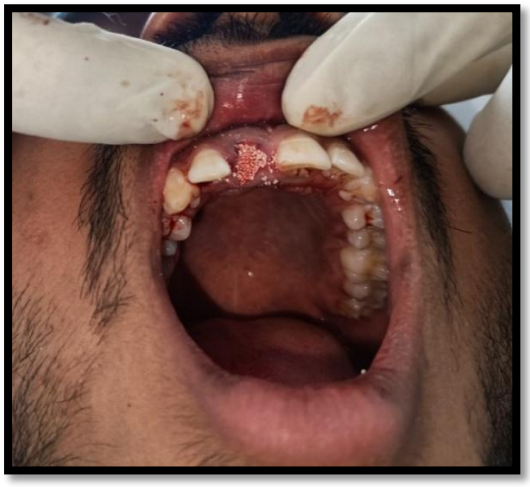


Fig. 3.5 : Graft Placement

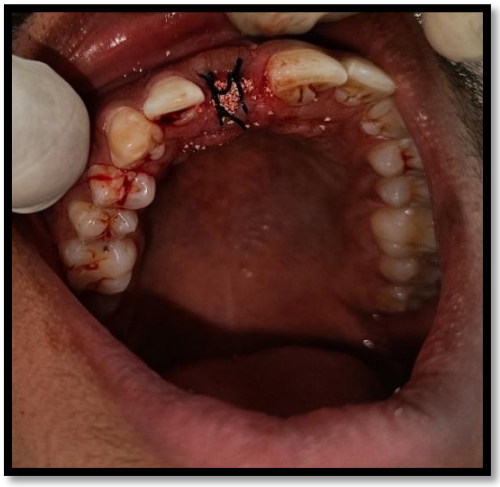


Fig. 3.6 : Suture Placed

Fig 3.7. At the time of Surgery

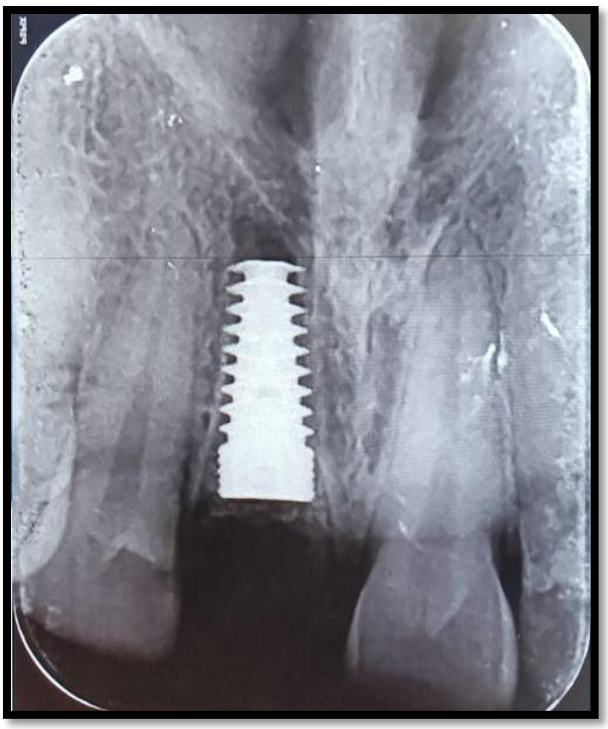


Fig. 3.8 : Immediate Post Op Iopar

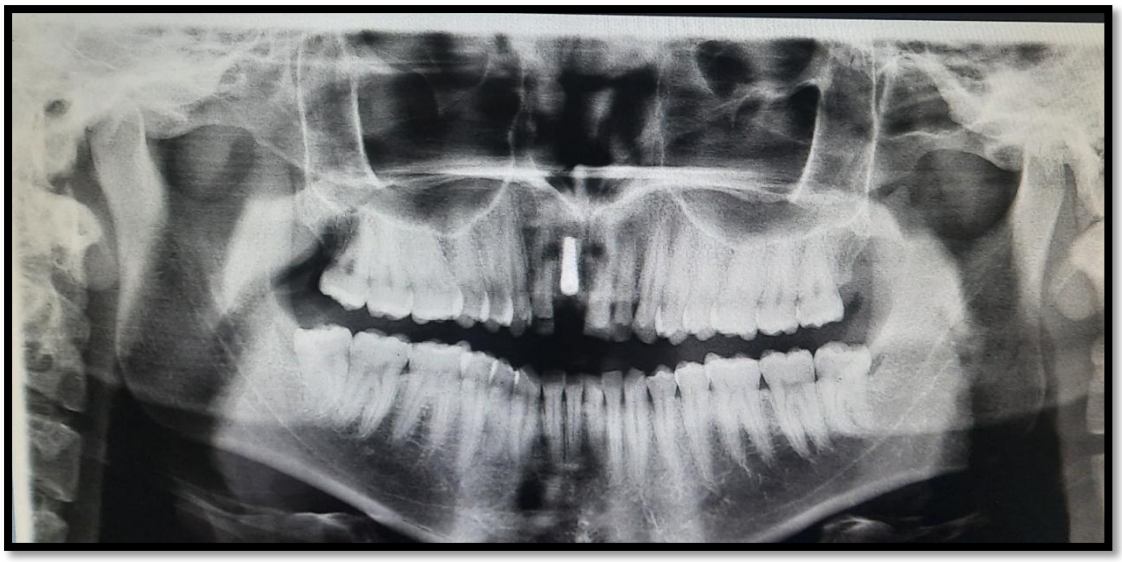


Fig. 3.9 : Immediate Post Op OPG

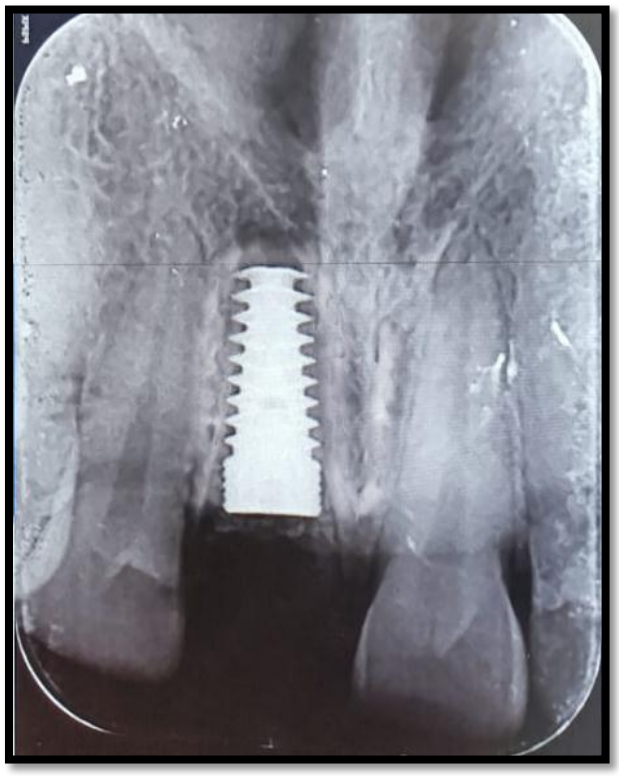
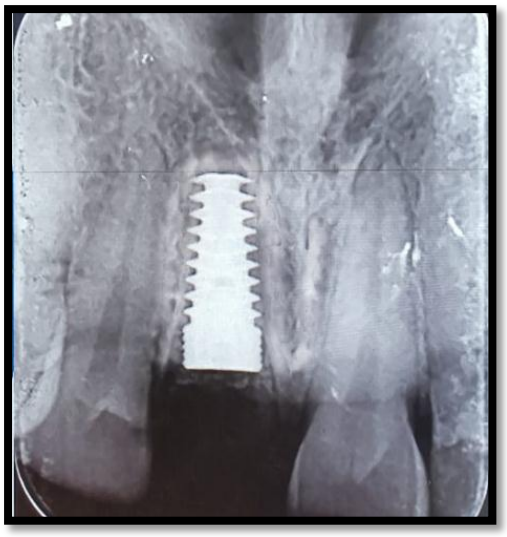


Fig. 3.10 : After 3 Months IOPAR

Fig. 3.11 : After 6 Months



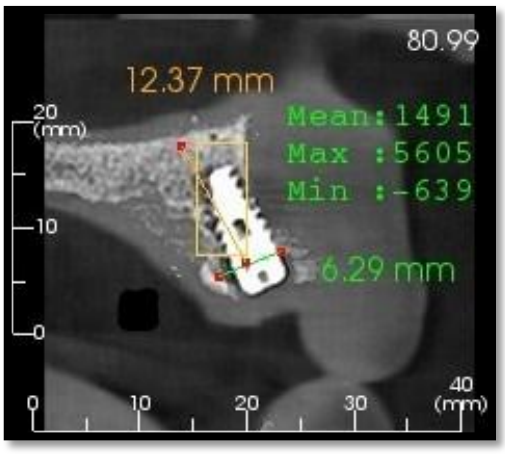


Fig. 3.12 : After 6 Months IOPAR **Fig. 3.13 : After 6 Months CBCT**

RESULT & OBSERVATION

Table 1: Intergroup comparison of Mean Age

Age (years)				
gr	N	Mean	Std. Deviation	P value
Group A	10	37.4000	15.04955	0.741, NS
Group B	10	39.8000	16.91022	

Mean Age of study participants was not found to be significantly different among two study groups

Graph-1 Mean Age

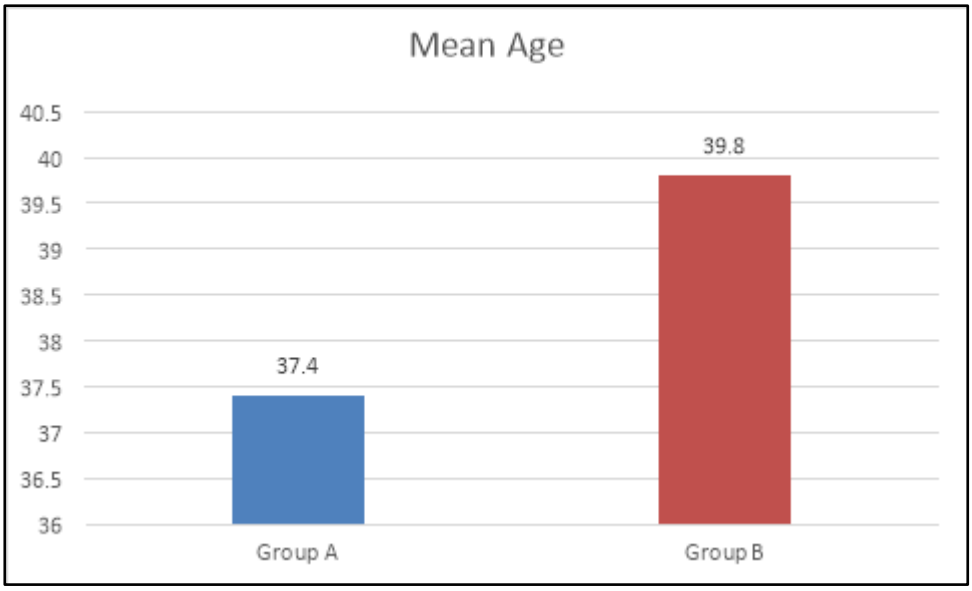


Table 2 : Distribution of males & females among two study groups

			sex		Total
			Males	Females	
gr	Group A	n	8	2	10
		%	80.0%	20.0%	100.0%
	Group B	n	7	3	10

		%	70.0%	30.0%	100.0%
Total		n	15	5	20
		%	75.0%	25.0%	100.0%
P value					0.999, NS

The distribution of males & females was not found to be significantly different among two study groups.

Graph-2 Distribution of males & Females among two study groups

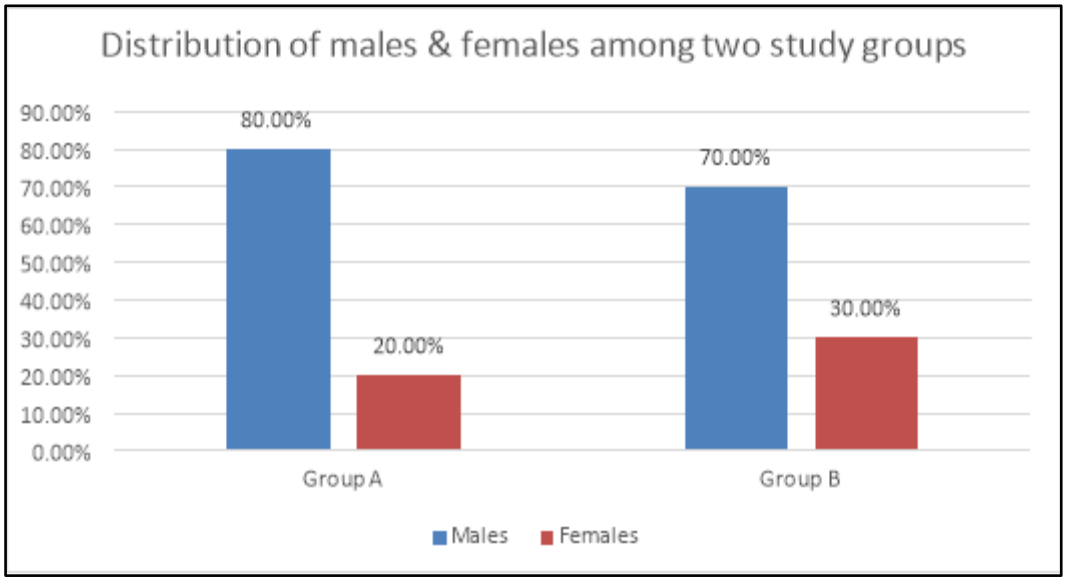


Table 3: Intergroup comparison of Bone Density at different follow up points

Bone Density					
		N	Mean	Std. Deviation	P value
Immediate Post-op	Group A	10	548.6000	23.41035	0.431, NS
	Group B	10	556.6000	20.97724	
At 3 months	Group A	10	587.2000	23.36569	0.016, S
	Group B	10	614.4000	22.24710	
At 6 months	Group A	10	613.3000	23.88886	0.002, S
	Group B	10	647.8000	18.00494	

At immediately post op, no statistically significant could be found in bone density among two study groups.

At 3 months & 6 months, mean bone density among Gr B participants was found to be significantly high as compared to Gr A participants.

Graph-3 Bone Density

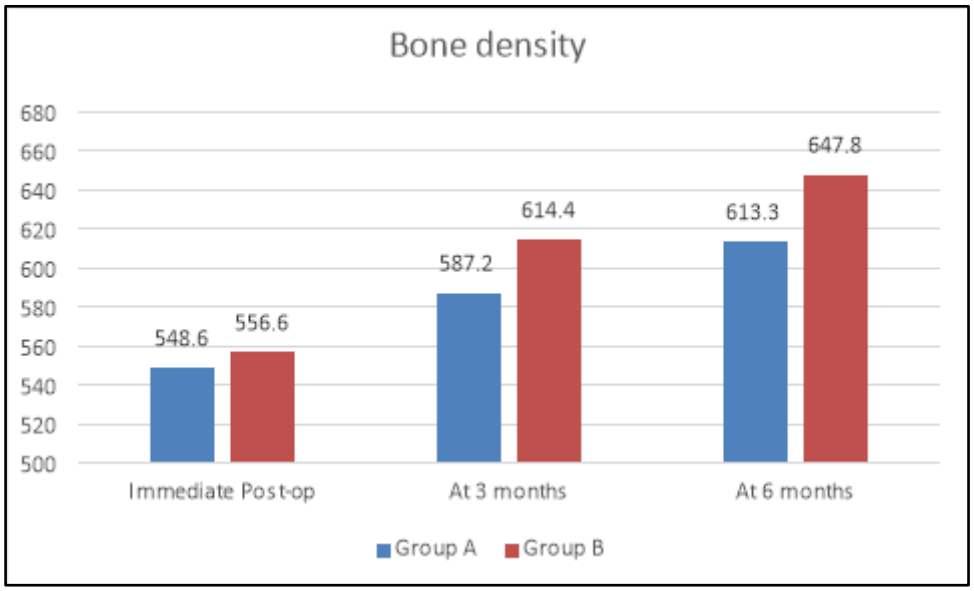


Table 4: Intergroup comparison of Primary Stability at different follow up points

Primary Stability					
	g	N	Mean	Std. Deviation	P value
Immediate Post-op	Group A	10	69.0000	2.86744	0.109, NS
	Group B	10	71.7000	4.16467	
	Group B	10	76.2000	2.78089	
At 6 months	Group A	10	77.1000	1.44914	0.016, S
	Group B	10	79.8000	2.85968	

At immediately post op, no statistically significant could be found in primary stability among two study groups.

At 3 months & 6 months, mean bone density among Gr B participants was found to be significantly high as compared to Gr A participants.

Graph-4 Primary Stability

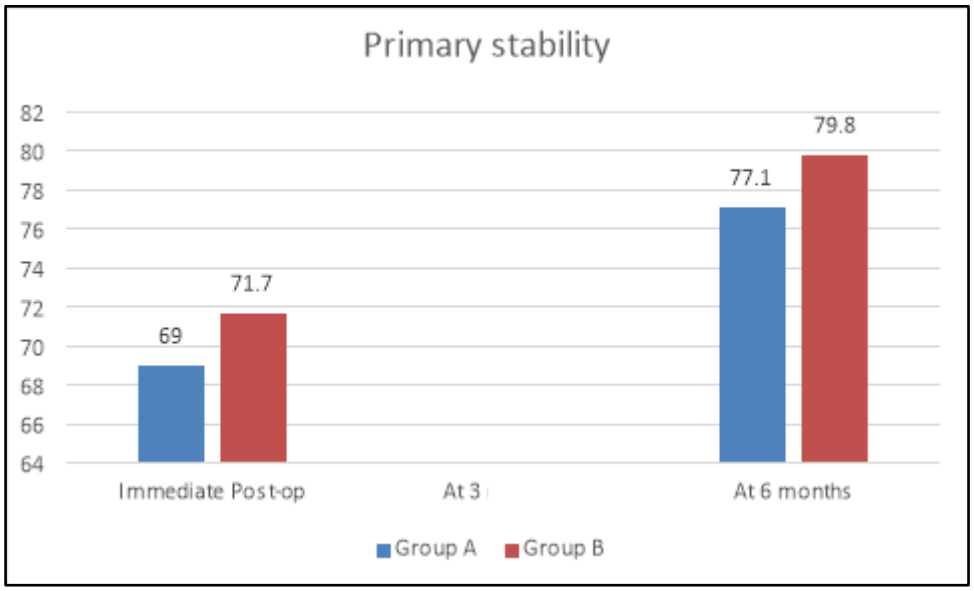


Table 5: Intergroup comparison of Level of Crestal bone at different follow up points

Crestal Bone					
	g	N	Mean	Std. Deviation	P value
Mesial at 3 months	Group A	10	.6760	.03471	0.879, NS
	Group B	10	.6780	.02201	
Distal at 3 months	Group A	10	.6560	.03471	0.822, NS
	Group B	10	.6590	.02283	
Mesial at 6 months	Group A	10	.6780	.02201	0.269, NS
	Group B	10	.6960	.04477	
Distal at 6 months	Group A	10	.6590	.02283	0.052, NS
	Group B	10	.7010	.05953	

Intergroup comparison of Level of Crestal bone at different follow up points was done using Independent t test. No statistically significant difference could be found in the crestal bone level at mesial & distal sides at 3m on as well as 6 m, among two study groups.

Graph-5 Crestal Bone

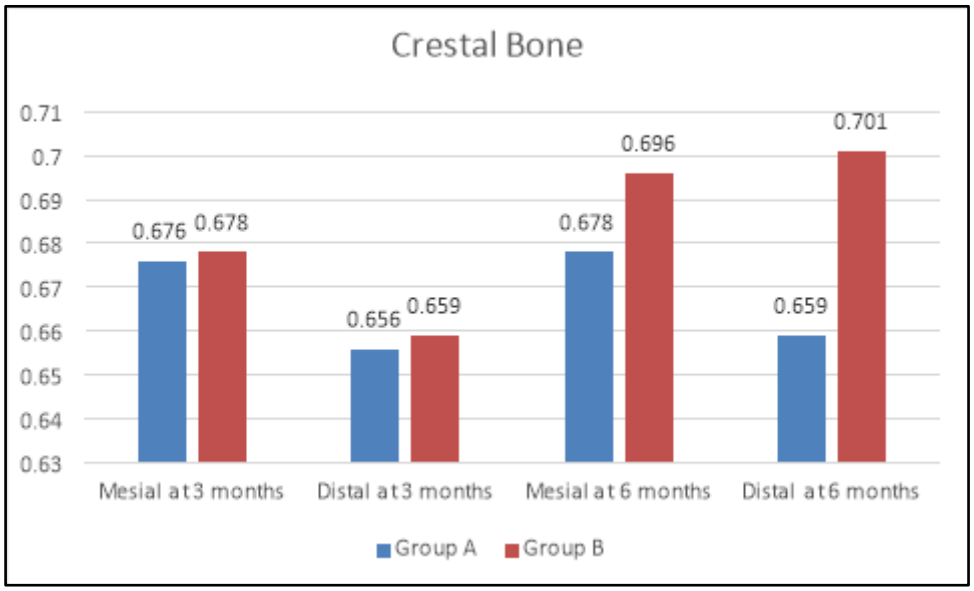


Table 6: Intragroup comparison of Level of Crestal bone at different follow up points

Crestal Bone					
		Mean	N	Std. Deviation	P value
Group A	Mesial at 3 months	0.6760	10	0.03471	0.846, NS
	Mesial at 6 months	0.6780	10	0.02201	
	Distal at 3 months	0.6560	10	0.03471	0.769, NS
	Distal at 6 months	0.6590	10	0.02283	
Group B	Mesial at 3 months	0.6780	10	0.02201	0.222, NS
	Mesial at 6 months	0.6960	10	0.04477	
	Distal at 3 months	0.6590	10	0.02283	0.061, NS
	Distal at 6 months	0.7010	10	0.05953	

Intragroup comparison of Level of Crestal bone at different follow up points was done using Repeated measures of ANOVA test. No statistically significant difference could be found in the crestal bone level at 3 m as well as 6 m, among both the study groups.

Graph-6 Crestal Bone

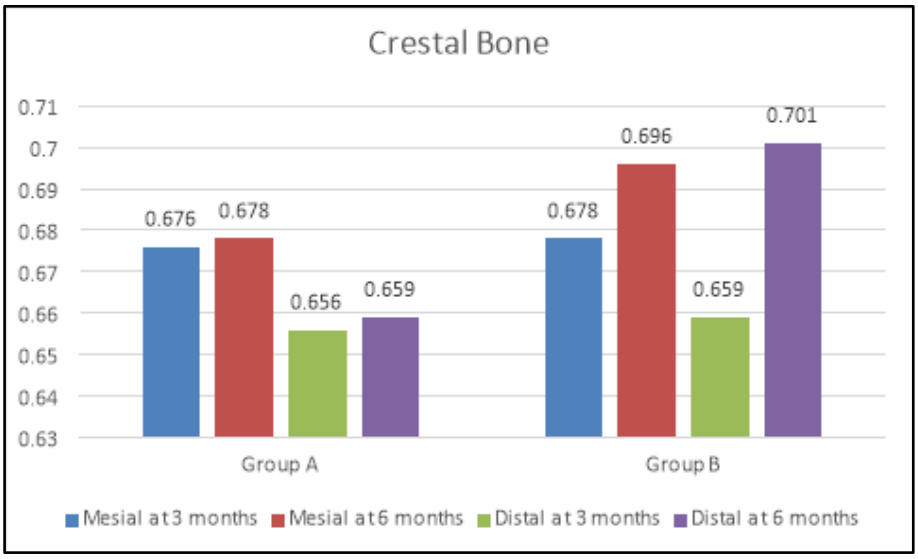


Table 7: Intragroup comparison of Bone Density at different follow up points

Bone density					
		Mean	Std. Deviation	P value	Post hoc pairwise comparisons
Group A	Immediately after post op	548.6000	23.41035	<0.001, S	Imm Post op * 3m - <0.001, S Imm post-op*6m - <0.001, S 3m*6m - <0.001, S
	At 3 months	587.2000	23.36569		
	At 6 months	613.3000	23.88886		
Group B	Immediately after post op	556.6000	20.97724	<0.001, S	Imm Post op * 3m - <0.001, S Imm post-op*6m - <0.001, S 3m*6m - <0.001, S
	At 3 months	614.4000	22.24710		
	At 6 months	647.8000	18.00494		

Intragroup comparison of Bone Density at different follow up points was done using Repeated measures of ANOVA. Bone density was found to increase significantly from imm post op to 6 months among both the study groups.

Graph-7 Bone Density

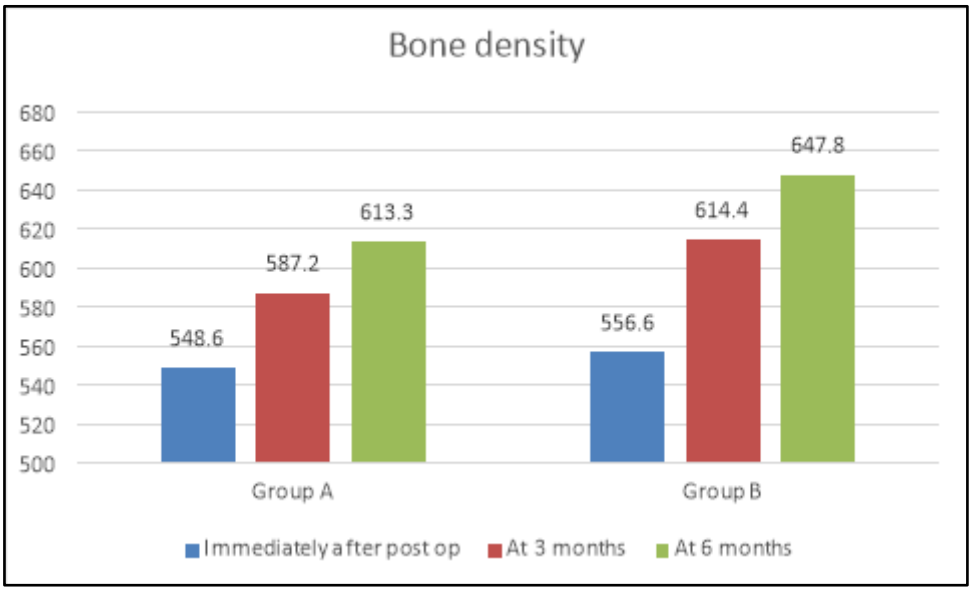


Table 8: Intragroup comparison of Primary stability at different follow up points

Primary Stability					
		Mean	Std. Deviation	P value	Post hoc pairwise comparisons
Group A	Immediately after post op	69.0000	2.86744	<0.001, S	Imm post-op*6m - <0.001, S
	At 6 months	77.1000	1.44914		
Group B	Immediately after post op	71.7000	4.16467	<0.001, S	Imm post-op*6m - <0.001, S
	At 6 months	79.8000	2.85968		

Intragroup comparison of Primary stability at different follow up points was done using Repeated measures of ANOVA. It was found to increase significantly from imm post op to 6 months among both the study groups.

Graph-8 Primary Stability

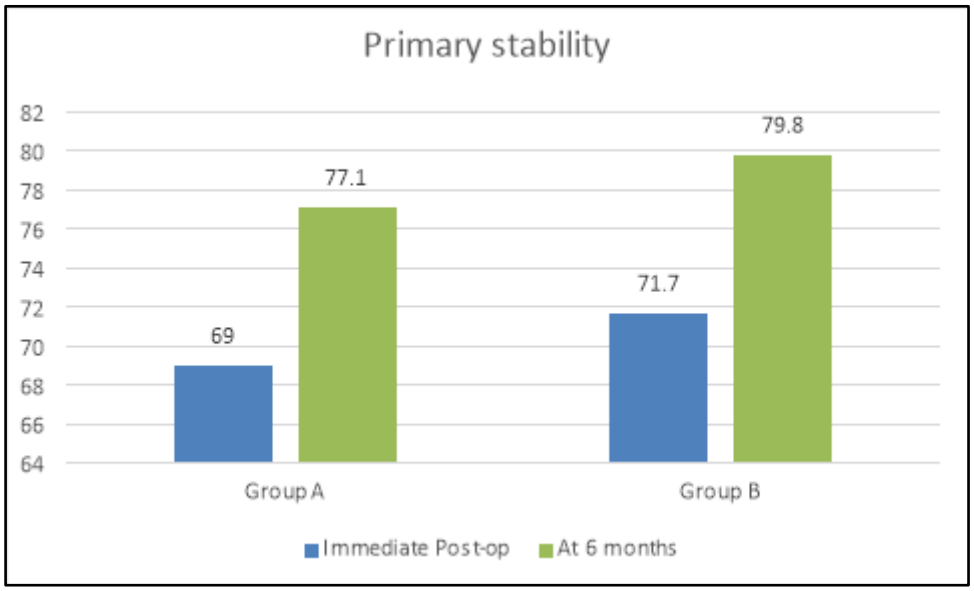


Table 9: Intergroup comparison of Absolute increase in bone density

Absolute Increase in Bone Density					
	gr	N	Mean	Std. Deviation	P value
From immediate post op to 3 months	Gr A	10	38.6000	3.77712	<0.001, S
	Gr B	10	57.8000	7.22342	
From immediate post op to 6 months	Gr A	10	64.7000	6.42996	<0.001, S
	Gr B	10	91.2000	8.33733	

Absolute increase in bone density was found to be significantly more among Gr B as compared to Gr A at both the follow up point

Graph-9 Absolute Increase in Bone Density

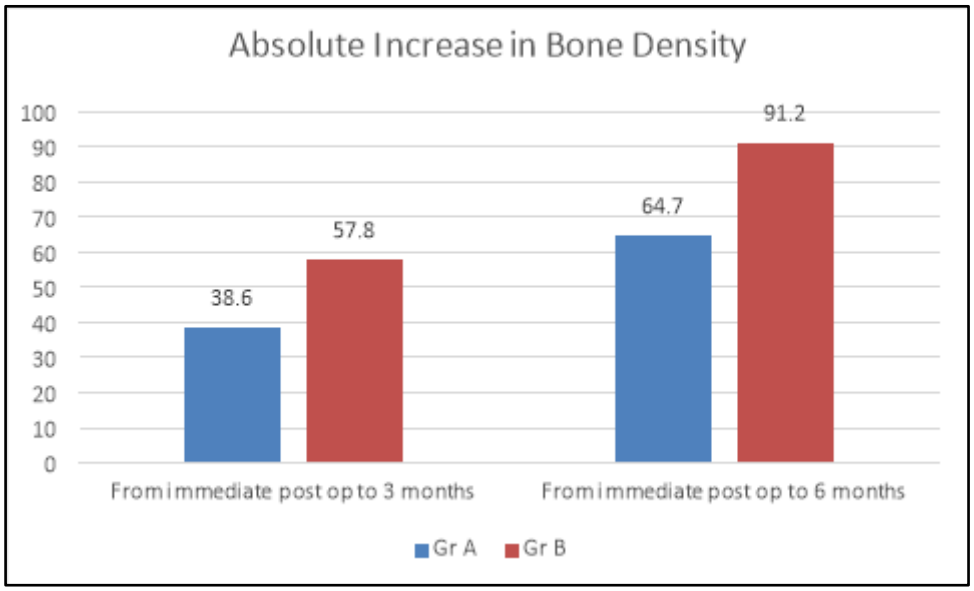


Table 10: Intergroup comparison of Absolute increase in Primary stability

Absolute Increase in Primary Stability					
	gr	N	Mean	Std. Deviation	P value
From immediate post op to 6 months	Gr A	10	8.1000	2.88483	1.000, NS
	Gr B	10	8.1000	1.85293	

Absolute increase in primary stability was found to be significantly more among Gr B as compared to Gr A at both the follow up points.

Graph-10 Absolute Increase in Primary Stability

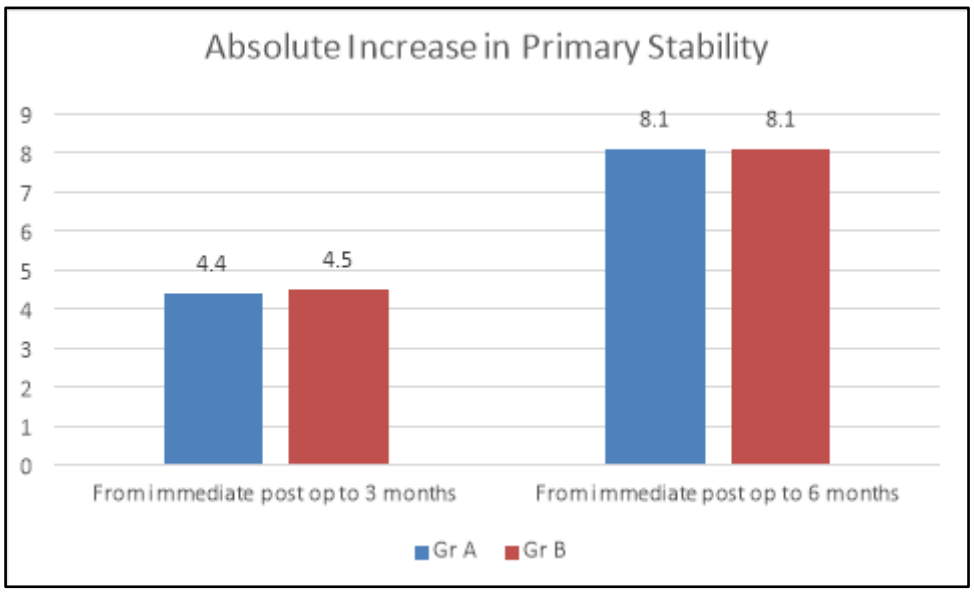
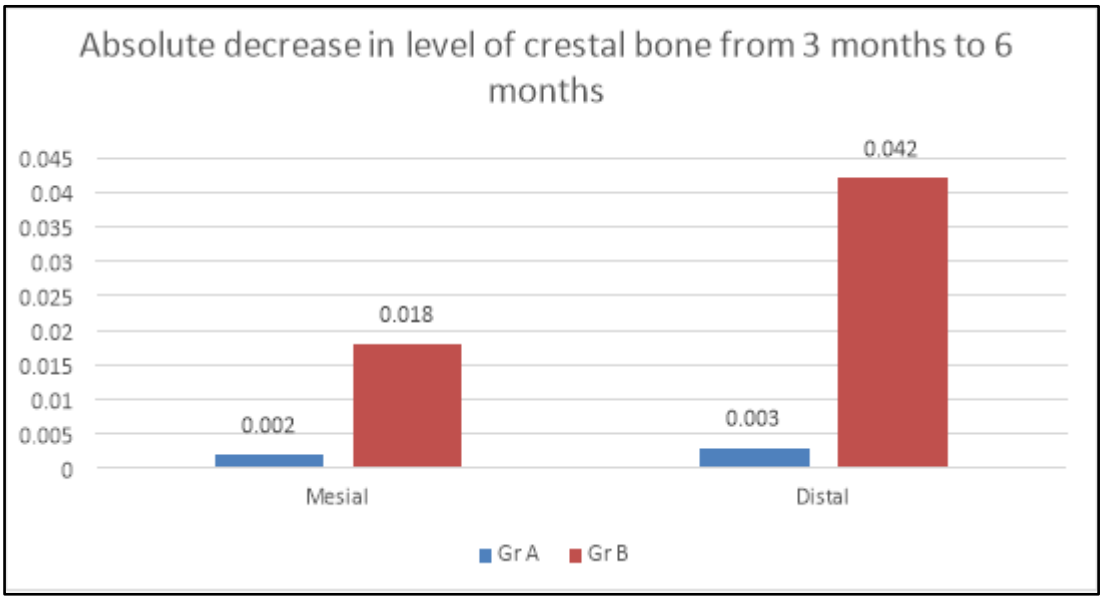


Table 11: Intergroup comparison of Absolute decrease in level of crestal bone from 3 months to 6 months

Absolute decrease in level of crestal bone from 3 months to 6 months					
	gr	N	Mean	Std. Deviation	P value
Mesial	Gr A	10	.0020	.03155	0.358, NS
	Gr B	10	.0180	.04341	
Distal	Gr A	10	.0030	.03129	0.093, NS
	Gr B	10	.0420	.06197	

Absolute decrease in crestal bone level was not found to be significantly different among both the study groups at both mesial and distal sides.

Graph-11 Absolute decrease in level of Crestal bone



DISCUSSION

The concept of "osseointegration" was introduced by Dr. Per-Ingvar Branemark in 1969 [63-65] .It refers to the process that takes place between the living bone and the surface of the implant. Although the direct bone to implant surface connection without intervening connective tissue was described way back in 1939 by Strock, it was Branemark, who scientifically explained the philosophy that the absence of connective tissues at the bone-implant interface is the key to clinical success in dental implantology, for the first time.[63] He defined osseointegration as "Direct structural and functional connection between the ordered, living bone and the surface of load-carrying implant". It was an exemplary milestone in the field of dental rehabilitation. Implant therapy has become a reliable, safe, and highly predictable treatment option for the replacement of missing teeth.[63-65]

The alveolar process is a tooth-dependent tissue, so tooth extraction inevitably results in significant resorption and atrophy,[66,67] leading to significant three-dimensional changes of the alveolar bone, particularly in the first 6 months.[68,69] This not only prevents the placement of the endosseous implant in a favorable prosthetic position but also hinder appropriate fabrication of pontic when conventional fixed prostheses are considered.[70]Along with this natural process of socket healing, several pathologic conditions can locally contribute to damage the integrity of one or more walls of the postextraction alveolus.[71]

The amount of peri-implant bone around the implant plays an important role in the success of the implant. The bone lost during the implant service reduces the total osseointegrated surface area of the implant leading to increase in the stress build up around the peri-implant region which further leads to the failure of implant. Success of an implant is defined as less than 1.5mm of marginal bone loss during first year after insertion of the prosthesis and less than 0.2mm annual bone loss thereafter. Therefore, it is important to minimize bone loss from the initial stage.[72]

Tricalcium phosphate as a bone graft substitute has been evaluated at length in previous studies. It binds to bone by means of mechanical anchorage with no formation of intermediate apatite layer.[73–75] Bioresorption of TCP granules occurs due to chemical dissolution in biological fluids and cellular degradation. Solubilization is induced by mesenchymal cells, which are also actively involved in the degradation process.[76,77]

It seems that the more soluble a CaP ceramic, the more rapidly it is resorbed by osteoclasts. However, the increased number of released calcium ions may, on one hand, inhibit osteoclasts' activity,[80] while on the other hand, it provides a good environment for osteogenesis.[75] Therefore, it seems that TCP resorption is performed at a rather unpredictable rate that does not always correspond to the new bone formation rate. it should be noted that a faster resorbable material might allow soft-tissue cells to prematurely intrude into the defect, while non-resorbable or slowly resorbable materials that remain for a long time may inhibit new bone deposition.[83]

The presence of CS increases the porosity of the grafting material by its early resorption, while it facilitates the circulation of biological fluids and growth factors. Nevertheless, the exact period of time that CS remains in a bony defect without being resorbed has not yet been estimated. It is reported, however, to be approximately 4 to 5 weeks[86,87,109]; Salata et al[96] found that the use of GBR membrane in combination with bone substitutes did not significantly improve bone formation compared with the use of bone substitutes alone.

Calcium sulfate acts as a binder and enhances graft containment, making the mixture more stable and pressure resistant.[98] the combination of b-TCP/CS mixture solidifies in a few minutes time after mixing and creates a stable mass with a surface that is not vulnerable to fractures. In the present study, the b-TCP/CS combination demonstrated complete regeneration while b-TCP alone did not succeed in regenerating.

Among bone-filling materials, calcium sulfate (CS) was one of the first bone substitutes to be used; it was used by Dreesman in 1892.[107] It is totally bioabsorbable [108] and osteoconductive,does not cause an inflammatory or foreign-body reaction[98,109] allows fibroblast migration,[110] and does not elevate serum calcium levels.[83] This osteoconductive material lacks osteoinductive properties; however, an osteogenic activity of CS was reported in the presence of bone and/or periosteum.[111,112]

The final goal of any grafting procedure is to achieve formation of 100% living bone tissue surrounding the implants. Renzo Guarnieri et al 2005 conducted a study that shows the MGCSH seems to be an acceptable graft material for extraction socket bone regeneration because it is completely resorbable and allows new trabecular bone arrangement in a limited 3-month period.

Various studies reported favorable results, both clinically and histologically, when using CS for socket grafting. One prospective clinical trial performed on 10 patients compared the use of CS hemihydrate to natural socket healing in half of the patients.[93]

Histological results reported 100% newly formed living bone in all the analyzed specimens with no residual particles after 3 months of healing. In the sites grafted with CS, the mean trabecular bone was found higher (58% vs. 46%) than nongrafted sites. However, no clinical data were reported in their results and discussion. Another clinical study compared both clinical and histological outcomes between natural healing and CS‐ grafted sockets in the anterior maxilla.[3]

Clinically, the grafted sockets appeared to accelerate the healing process and minimize ridge resorption when compared to non-grafted sites. Those control sites showed greater dimensional changes than sites grafted with CS, with a mean of 0.7 mm and 1.2 mm greater vertical height and horizontal width loss, respectively. Their histological evaluation showed similar statistically greater trabecular and lamellar bone percentages in the grafted sites.

Several animal and human clinical studies have shown promising outcomes when using CS in sinus augmentation for future implant placement. A previously published case series reported new bone formation 8‐ 9 months after grafting with no residual bone grafting. Successful

osseointegration of implants placed in CS grafted sinuses through both staged and simultaneous approaches was noted.[4,87, 116,117]

There have been a limited number of clinical studies reporting the use of CS around dental implants. When compared to other grafting materials, histological and immunohistochemical analyses of animal models report no differences compared to CS when used for bone augmentation around titanium implants.[93] Clinically, case reports on the use of CS in treating peri‐ implant defects at the time of implant placement showed trabecular bone formation with the absence of any CS remnants through light microscopy, while histomorphometry showed 40% of new bone formation.[2] As for peri‐ implantitis treatment, one clinical case reported 2‐ year successful outcomes after using a mixture of CS and inorganic bovine bone following implant surface decontamination.[118]

The present study was designed to compare bone regeneration around dental implants placed immediately after extraction along with grafting using β-Tricalcium Phosphate alone or a combination of β-Tricalcium Phosphate and Calcium Sulphate.

In our study the mean bone density in Group A was 587.2 HU (after three month) and 613.3 HU (after six month). The mean bone density in Group B was 614.4 HU (after three month) and 647.86 (after six month). The mean bone healing score was higher

in Group B than that of Group A.

In our study we measured ISQ at the time of surgery and after three months and 6 months. According to our study primary stability there is absolute increase in primary stability was found to be significantly more among Group B as compared to Group A at the follow up points.

CONCLUSION

Based on the observations, statistical analysis, and evidence based discussion, the following conclusion can be drawn;

1. The use of different grafting materials to fill the gap around immediate implants enhances implant stability and bone density.
2. Placement of implants in sockets grafted with combination of β- tricalcium phosphate and calcium sulphate produces a positive influence in enhancing the primary stability as compared to Implants placed with β- tricalcium phosphate alone.
3. Mean bone density among implants in sockets grafted with combination of β- tricalcium phosphate and calcium sulphate was found to be significantly higher as compared to Implants placed with β- tricalcium phosphate alone.
4. The results of the present study revealed that the crestal bone loss around the implants surrounded by combination of β- tricalcium phosphate and calcium sulphate showed lesser bone loss than the implants inserted with β- tricalcium phosphate alone.

In conclusion, immidiate implant placement and grafting with combination of β- tricalcium phosphate and calcium sulphate has better treatment outcomes with implant stability, bone density and bone loss as compared to those utilizing β- tricalcium phosphate alone.

However, a larger sample size and longer follow up may be required to conclusively validate the results of present study.

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Annexure - 1

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

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"Comparision of Bone Regeneration Around the Dental Implant using β-Tricalcium Phosphate Alone and in Combination of β-Tricalcium Phosphate and Calcium Sulphate in Immediate Implant Placement"** submitted by **Dr Ashish Pandey** Post graduate student from the **Department of Oral & Maxillofacial Surgery** as part of MDS Curriculum for the academic year 2019-2022 with the accompanying proforma was reviewed by the Institutional Research Committee present on **19th December 2019** 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

Annexure -2

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 VIII[th] Institutional Ethics Sub-Committee

IEC Code: 31 **BBDCODS/03/2020**

Title of the Project: Comparison of Bone Regeneration around the Dental Implant using β-Tricalcium Phosphate alone and in Combination of β-Tricalcium Phosphate and Calcium Sulphate in Immediate Implant Placement.

Principal Investigator: Dr. Ashish Pandey **Department:** Oral & Maxillofacial Surgery

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

Type of Submission: New, MDS Project Protocol

Dear Dr. Ashish Pandey,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 18th March, 2020.

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. Sahana S. Member	Reader, Department of Public Health Dentistry, 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.

Forwarded by:

Lakshmi Bala 18/03/20

(Dr. Lakshmi Bala)
Member-Secretary
IEC

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

(Dr. B. Rajkumar)
Principal
BBDCODS

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

Annexure -3

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज

(बाबू बनारसी दास विश्वविद्यालय का एक घटक संस्थान)

बी.बी.डी.सिटी, फैजाबादरोड, लखनऊ - 227105 (भारत)

प्रतिभागी सूचना दस्तावेज (पी.आई.डी)

1-अध्ययन शीर्षक

डेंटल इम्प्लांट के चारों ओर अस्थि उत्थान की तुलना अकेले beta-tricalcium फॉस्फेट का उपयोग करके और तत्काल इंप्लांट प्लेसमेंट में β-ट्रिकैल्शियम फॉस्फेट औरकैल्शियम सल्फेट के संयोजन में।

2- आमंत्रण अनुच्छेद?

आपकोएकशोध / परीक्षण अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है। इससे पहले कि आप तय करें कि आपके लिए यह समझना महत्वपूर्ण है कि शोध / अध्ययन क्यों किया जा रहा है और इसमें क्या शामिल होगा । कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने और दोस्तों, रिश्तेदारों और अपने इलाज करने वाले चिकित्सक / परिवार के डॉक्टर से चर्चा करें। हमसे पूछें कि क्या ऐसा कुछ है जो स्पष्ट नहीं है या यदि आप अधिक जानकारी चाहते हैं। यह तय करने के लिए समय निकालें कि आप भाग लेना चाहते हैं या नहीं।

3- अध्ययन का उद्देश्य क्या है?

निष्कर्षण के तुरंत बाद रखा दंत प्रत्यारोपण के आसपास हड्डी पुनर्जनन की तुलना करने के लिए अकेले β-tricalcium फॉस्फेट और tricalcium sulphate के संयोजन का उपयोग कर ग्राफ्टिंग के साथ फॉस्फेट और कैल्शियम सल्फेट।

4-मुझे क्यों चुना गया है?

इस अध्ययन के लिए आपको चुना गया है क्योंकि आप इस अध्ययन के लिए आवश्यक मानदंडों को पूरा कर रहे हैं।

5- क्या मुझे भाग लेना है?

अनुसंधान में आपकी भागीदारी पूरी तरह से स्वैच्छिक है। यदि आप करते हैं, तो आपको रखने के लिए यह सूचना पत्र दिया जाएगा और सहमति पत्र पर हस्ताक्षर करने के लिए कहा जाएगा। अध्ययन के दौरान आप अभी भी किसी भी समय और बिना कारण बताए वापस लेने के लिए स्वतंत्र हैं।

6- अगर मैं भाग लेता हूं तो मेरे साथ क्या होगा?

आप 6 महीने के लिए मेरे अध्ययन में शामिल होंगे, प्रत्यारोपण प्लेसमेंट के लिए ओस्टियोटॉमी की तैयारी एक मामूली शल्य प्रक्रिया है। प्रक्रिया के परिणाम को सुधारने और रोगी की समस्याओं को कम करने के लिए अध्ययन किया जा रहा है।

7- मुझे क्या करना है?

आपके पास अपनी नियमित जीवन शैली हमेशा की तरह हो सकती है और अध्ययन की जांच के लिए केंद्र में आवश्यक यात्रा कार्यक्रम का पालन कर सकती है।

8- परीक्षण की जा रही प्रक्रिया क्या है?

यह एक मामूली शल्य प्रक्रिया है, जो अस्थि भंग को बढ़ाने के लिए ट्राइकशियम कैल्शियम फॉस्फेट और कैल्शियम सल्फेट द्वारा किए गए सॉकेट ग्राफ्टिंग के साथ एट्रैमैटिक निष्कर्षण के तुरंत बाद स्थानीय संज्ञाहरण के तहत किया जाता है।

9- अध्ययन के लिए हस्तक्षेप क्या हैं?

अध्ययन से संबंधित इस तरह के हस्तक्षेप, जोखिम और प्रतिकूल प्रभाव नहीं हैं। स्वयंसेवक को नैदानिक लाभ है क्योंकि वह हड्डी ग्राफ्ट और मुकुट के साथ प्रत्यारोपण प्राप्त करेगा।

10- भाग लेने के दुष्प्रभाव क्या हैं?

इस अध्ययन के रोगियों पर कोई दुष्प्रभाव नहीं हैं।

11- भाग लेने के संभावित नुकसान और जोखिम क्या हैं?

इस अध्ययन में भाग लेने का कोई जोखिम या नुकसान नहीं है। लेकिन हम प्रत्यारोपण के साथ 100% सफलता की गारंटी नहीं देते हैं। यह व्यक्ति के शरीर की स्वीकृति और अस्वीकृति की प्रतिक्रिया पर निर्भर करता है; प्रत्यारोपण उपचार कभी कभी विफल हो सकता है।

12- भाग लेने के संभावित लाभ क्या हैं?

के रूप में निष्कर्षण हड्डी में voids बनाता है; टिश्यू फॉस्फेट और कैल्शियम सल्फेट के साथ BIC% हड्डी ग्राफ्टिंग को बढ़ाने के लिए रोगी को ओस्टियोइन्ग्रेशन की प्रक्रिया को बढ़ाकर लाभकारी होगा

13- क्या होगा अगर नई जानकारी उपलब्ध हो जाए?

जैसा कि अध्ययन 6 महीने के समय के लिए चलेगा, उसके बाद कृत्रिम अंग तैयार किया जाएगा ।इसके अलावा यदि सभी अध्ययन अपरिहार्य परिस्थितियों के कारण निर्धारित समय से पहले रुक जाते हैं, तो यह आपको समझाया जाएगा।

14- शोध अध्ययन बंद होने पर क्या होता है?

यदि अध्ययन निर्धारित समय से पहले बंद / खत्म हो जाता है, तो यह रोगी / स्वयं सेवक को समझाया जाएगा।

15- क्या होगा अगर कुछ गलत हो जाए?

यदि कोई प्रतिकूल घटना होती है, या अध्ययन के दौरान कुछ गलत हो जाता है, तो शिकायत को सक्षम व्यक्ति द्वारा संस्था और आई ई सी को रिपोर्ट किया जाएगा। गंभीर प्रतिकूल घटना में उपचार के प्रति अध्ययन और व्यक्तिगत हित को ध्यान में रखते हुए व्यक्ति द्वारा सुनने की लागत।

16- क्या इस अध्ययन में मेरा हिस्सा गोपनीय रखा जाएगा?

हां इसे गोपनीय रखा जाएगा।

17- शोध अध्ययन के नतीजों का क्या होगा?

अध्ययन के परिणामों का उपयोग मानक प्रत्यारोपण के साथ लघु प्रत्यारोपण की नैदानिक सफलता दर की तुलना करने के लिए किया जाएगा। किसी भी रिपोर्ट / प्रकाशन के मामले में आपकी पहचान गोपनीय रखी जाएगी।

18- शोध का आयोजन कौन कर रहा है?

यह शोध अध्ययन मौखिक और मैक्सिलोफेशियल सर्जरी विभाग,शैक्षणिक संस्थान (BBDCODS) द्वारा आयोजित किया जाताहै।

19 क्या अध्ययन के परिणाम अध्ययन के बाद उपलब्ध कराए जाएंगे?

हाँ।

20- अध्ययन की समीक्षा किसने की है?

अध्ययन की समीक्षा विभाग के प्रमुख, मार्गदर्शक, सह मार्गदर्शक और आई ई सी द्वारा अनुमोदित की गई है

21- अधिक जानकारी के लिए संपर्क करें

डॉ. आशीष पांडे
एम.डी.एस, मौखिक और मैक्सिलोफेशियल सर्जरी विभाग
ई मेल: draashishpandey01@gmail.com

संपर्क नंबर: 9793334568

डॉ.लक्ष्मी बाला,

सदस्य सचिव, आई.ई.सी

bbdcods.iec@gmail.com

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ 227,105

पी आई का हस्ताक्षर .....

नाम .....

दिनांक.....

Annexure -4

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

Participant Information Document (PID)

1. **Study Title**

   Comparison of bone regeneration around the dental implant using β-tricalcium phosphate alone and in combination of β-tricalcium phosphate and calcium sulphate in immediate implant placement.

2. **Invitation Paragraph**

   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?**

   To compare bone regeneration around dental implants placed immediately after extraction along with grafting using β-tricalcium phosphate alone and in combination of β-tricalcium phosphate and calcium sulphate.

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

   You have been chosen for this study as you have fulfilled the desired inclusion criteria.

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

   Your participation in the research is entirely voluntary. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. During the study you still are free to withdraw at any time and without giving a reason.

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

   You will be involved in my study for 6 months, osteotomy preparation for implant placement is a minor surgical procedure. The study is being conducted to improvise the outcome of the procedure and lessen the patient's problems.

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

   You can have your regular liestyles as usual and to follow the required visiting schedule to the centre for the investigation of the study.

8. **What is the procedure that is being tested?**

   It's a minor surgical procedure carried out in upper jaw under local anaesthesia to enhance the quality of bone in upper jaw to enhance the primary stability of implant.

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

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

10. **What are the side effects of taking part?**

    There are no side effects to the patients of this study.

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

    There are no disadvantages of the study other than the complications associated with implant and graft failure.

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

    As the bone in upper jaw is inferior quality and also less in volume, the process is going to improve the bone quality and volume as well and implants could be placed effectively and in turn rehabilitation could be done.

13. **What if new information becomes available?**

    I additional information becomes available during the course o the research you will be told about these and you are free to discuss it with your researcher and decide accordingly.

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

    As the study will run for 6 months time, after that prosthesis will be fabricated. Moreover if at all the study stops before the stipulated time due to unavoidable circumstances, this will be explained to you.

15. What if something goes wrong?

If any adverse event occurs, or something goes wrong during the study, the complaints will be handled by the competent person reporting to the institution and IEC. Cost to be hear by the person undertaking the study and personal interest towards treatment in severe adverse event.

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

Yes , it will be kept confidential.

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

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

18. Who is organizing the research?

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

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

Yes, only the data obtained will be published.

20. Who has reviewed the study?

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

21. Contact for further information

Dr. Ashish Pandey

MDS, Dept. of Oral & Maxillofacial Surgery,

E- mail : draashishpandey01@gmail.com

Contact no. 9793334568

Dr. Lakshmi Bala

Member Secretary, IEC

bbdcods.iec@gmail.com

Signature of PI……

Name……..

Date……..

Annexure-5

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
2. ……..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.
3. 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.
4. 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.

5. 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).
6. I permit the use of stored sample (tooth/tissue/blood) for future research.
   a. **Yes [ ] No [ ] Not Applicable** [ ]
7. I agree to participate in the above study. I have been explained about the complications and side effects, if any, and have fully understood them. I have also read and understood the participant/volunteer's Information document given to me.

Signature (or Thumb impression) of the Subject/Legally

Acceptable Representative:……..

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

Acceptable representative

Annexure-6

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज
(बाबू बनारसी दास विश्वविद्यालय)
बीबीडी सिटी, फैजाबाद रोड, लखनऊ - 227105 (भारत)

सहमति प्रपत्र (हिंदी)

अध्ययन का शीर्षक ……..

स्टडी नंबर……..
विषय का पूरा नाम …….
जन्म तिथि/आयु ……
विषय का पता…….
फोन नंबर। और ई-मेल पता ……
योग्यता ……
व्यवसाय: छात्र / स्वरोजगार / सेवा / गृहिणी / अन्य (कृपया उपयुक्त के रूप में टिक करें)
विषय की वार्षिक आय……
नाम और नामांकित व्यक्ति (ओं) और विषय के साथ उसका संबंध (के प्रयोजन के लिए)
मुकदमे से संबंधित मौत के मामले में मुआवजा)।

1. **मैं पुष्टि करता हूं कि मैंने प्रतिभागी सूचना दस्तावेज दिनांक . को पढ़ और समझ लिया है ……..उपरोक्त अध्ययन के लिए और प्रश्न पूछने का अवसर मिला है। या मुझे अन्वेषक द्वारा अध्ययन की प्रकृति के बारे में बताया गया है और मुझे प्रश्न पूछने का अवसर मिला है।**

2. **मैं समझता हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और बिना किसी दबाव के स्वतंत्र इच्छा के साथ दी गई है और मैं बिना कोई कारण बताए और अपनी चिकित्सा देखभाल या कानूनी अधिकारों को प्रभावित किए बिना किसी भी समय वापस लेने के लिए स्वतंत्र हूं।**

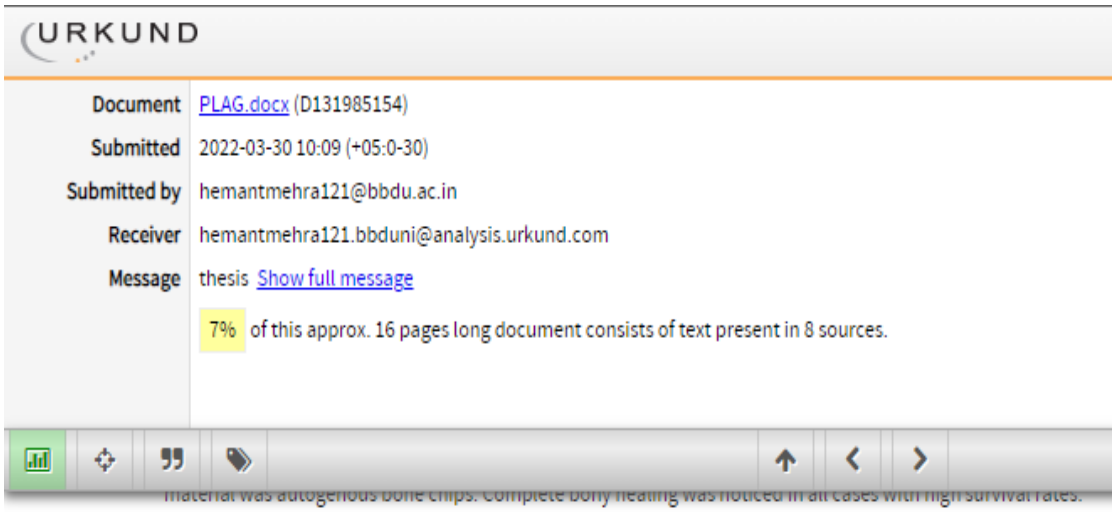
3. **मैं समझता हूं कि परियोजना के प्रायोजक, प्रायोजक की ओर से काम करने वाले अन्य, नैतिकता समिति और नियामक प्राधिकरणों को वर्तमान अध्ययन और किसी भी आगे के शोध के संबंध में मेरे स्वास्थ्य रिकॉर्ड को देखने के लिए मेरी अनुमति की आवश्यकता नहीं होगी। इसके संबंध में आयोजित किया जा सकता है, भले ही मैं परीक्षण से हट जाऊं। हालांकि, मैं समझता हूं कि तीसरे पक्ष को जारी या प्रकाशित किसी भी जानकारी में मेरी पहचान प्रकट नहीं की जाएगी।**
4. **मैं इस अध्ययन से उत्पन्न होने वाले किसी भी डेटा या परिणामों के उपयोग को प्रतिबंधित नहीं करने के लिए सहमत हूं, बशर्ते ऐसा उपयोग केवल वैज्ञानिक उद्देश्यों के लिए हो।**

5. **मैं भविष्य के शोध के लिए संग्रहीत नमूने (दांत/ऊतक/रक्त) के उपयोग की अनुमति देता हूं। हाँ नही** [ ]
लागू नहीं [ ]

6. **मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं। मुझे जटिलताओं और दुष्प्रभावों के बारे में समझाया गया है, यदि कोई हो, और उन्हें पूरी तरह से समझ लिया है। मैंने प्रतिभागी/स्वयंसेवक के मुझे दिए गए सूचना दस्तावेज को भी पढ़ और समझ लिया है।**

विषय/कानूनी रूप से स्वीकार्य प्रतिनिधि के हस्ताक्षर (या अंगूठे का निशान):……..
हस्ताक्षरकर्ता का नाम……. **तारीख** ……**।**
अन्वेषक के हस्ताक्षर …… **तारीख**……..
अध्ययन अन्वेषक का नाम …… **तारीख**……..
गवाह के हस्ताक्षर…… **तारीख**……..
गवाह का नाम ……
पीआईडी की एक हस्ताक्षरित प्रति और विधिवत भरे हुए सहमति फॉर्म विषय के हस्ताक्षर/अंगूठे का निशान या कानूनी रूप से दिनांक……..

स्वीकार्य प्रतिनिधि



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material was autogenous bone chips. Complete bony healing was noticed in all cases with high survival rates. Clinical osseointergration was achieved with minimal gingival recession and papilla preservation. They concluded that immediate implant placement can be successful for replacing a single tooth even without primary closure.

Meredith N (1998)13 discussed the parameters necessary to monitor successful implant placement. They discussed various techniques for measuring implant stability and osseointegration, such as cutting resistance, removal torque values, Periotest and Dental Fine Tester. They found that the RFA was easy to use in addition of being capable of eliciting quantitative information related to implant stability and stiffness and hence concluded that RFA has the potential application for predicting the outcome of implant as it yields valuable information of stability, both at placement and during function.

Mayfield L (1999)14 compared immediate (IIP), delayed and late submerged and transmucosal implants. They observed that the implant survival rate is similar with either an IIP or a delayed placement protocol. They concluded that IIP offers many advantages over delayed placement, these include improve healing without flap advancement and decreased treatment time, surgical procedures, cost and discomfort.

Dario De Leonardis, Gabriele E. Pecora(1999)15 conducted the study to evaluate the clinical and histologic results of a sinus augmentation procedure performed using calcium sulfate as the grafting material. A group of 12 patients(15 sinuses) formed the pilot group. Based on the experience of the pilot group, the technique of calcium sulfate application was modified, and the second group of 45 patients (50 sinuses) was subsequently treated (test group). In the pilot group, a total of 30 implants was placed. In the test group, a total of 100 implants was placed. The clinical data reported in the present study are related to the 1-year follow-up for both groups. Clinical evaluations, including assessment of implant mobility and probing pocket depth, were