"COMPARATIVE EVALUATION OF VITAMIN D LEVELS ON CRESTAL BONE HEIGHT AND IMPLANT STABILITY: AN IN-VIVO STUDY"

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In

PROSTHODONTICS

By

Dr. Aakanksha Pandey

Under the guidance of

Dr. Manoj Upadhyay
Reader
Department of Prosthodontics

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

(Faculty of Babu Banarasi Das University)

BATCH: 2018-2021 **Enrolment No.:**

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"COMPARATIVE EVALUATION OF VITAMIN D LEVELS ON CRESTAL BONE HEIGHT AND IMPLANT STABILITY : AN IN-VIVO STUDY "** is a bonafide and genuine research work carried out by me under the guidance of **Dr. Manoj Upadhyay,** Reader, Department of Prosthodontics, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

Date: 1st July '21
Place: BBDCODS, Lucknow.

Dr. Aakanksha Pandey

CERTIFICATE BY THE GUIDE

This is to certify that the dissertation entitled **"COMPARATIVE EVALUATION OF VITAMIN D LEVELS ON CRESTAL BONE HEIGHT AND IMPLANT STABILITY : AN IN-VIVO STUDY"** is a bonafide work done by **Dr. Aakanksha Pandey** under our direct supervision and guidance in partial fulfilment of the requirement for the degree of Master of Dental Surgery (M.D.S.) in Department of Prosthodontics.

Date: 1st July '21.

Dr. Manoj Upadhyay
Reader
Department of Prosthodontics
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 **"COMPARATIVE EVALUATION OF VITAMIN D LEVELS ON CRESTAL BONE HEIGHT AND IMPLANT STABILITY: AN IN-VIVO STUDY"** is a bonafide work done by **Dr. Aakanksha Pandey,** under the supervision of **Dr. Manoj Upadhyay,** Reader, Department of Prosthodontics, in partial fulfilment of the requirement for the degree of Master of Dental Surgery (M.D.S.) in Department of Prosthodontics, Babu Banarasi Das College Of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

Dr. Amrit Tandan
Professor and Head

Prof. (Dr.) RajkumarB
Principal

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I hereby declare that the **Babu Banarasi Das University** shall have the right to preserve, use and disseminate this dissertation in print or electronic format for academic / research purpose.

Date: 1st July '24
Place: BBDCODS, Lucknow.

Dr. Aakanksha Pandey

Dedicated

to

my father

Sudhir Pandey

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Dr. Aakanksha Pandey

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BACKGROUND: Vitamin D has been seen to play a role in implant dentistry as it affects various stages of osseointegration of intraosseous implants. It has become a vital part of dental surgery and implantology as it plays a role in the metabolism of the bone tissue and the immune system.

AIM: Our aim was to observe the effect of vitamin D supplementation on crestal bone height changes and its effect on implant stability.

METHOD: 18 samples were divided randomly into three groups i.e., Group A, Group B, and Group C. 6 implants in group A (control group; vitamin D sufficient) were placed without supplementation with Vitamin D. Group B (test group I; vitamin D insufficient) had 6 implants placed without supplementation with vitamin D. Group C (test group II; vitamin D insufficient) had 6 implants placed with Vitamin D supplementation. All the groups were evaluated for crestal bone changes at 0,3rd and 6th months of implant placement and implant stability scores at the time of placement (day 0) and after 90 days.

RESULT: For the period of 0 to 6 months, implant group C with vitamin D supplementation showed lesser loss followed by group A and B. Also, post hoc comparison showed bone loss was found to be more in Group B than Group C. There was no significant difference in implant stabilities among the three groups.

CONCLUSION: **T**his study concluded that implants placed in individuals with vitamin D insufficiency supplemented with vitamin D showed very minimal crestal bone loss from a period of 0 to 6 months immediately from implant placement, and comparatively less crestal bone loss when compared to implants placed without Vitamin D supplementation. With regards to implant stability, there was no significant difference among the three groups.

The prime goal of implant therapy is to restore an individual's normal anatomy, function, aesthetics, comfort, and speech regardless of loss of bone either due to diseases or injury to the stomatognathic system. Missing tooth is an absolute problem and for generations, it has affected people worldwide. It is very challenging for a clinician to find the right replacement for the same. Failure to replace missing teeth causes deleterious consequences which may include resorption of alveolar bone, supra-eruption or drifting of adjacent teeth, altered vertical dimension, loss of intercuspation, or occlusal disharmony.

Removable partial dentures are considered a viable option treatment as they are the most inexpensive but they have their own limitations as well which include lack of retention, poor or inadequate adaptation and irritation to denture supporting tissues, dimensional stability, and lastly maintenance. The third modality for missing tooth called dental implants was brought into existence after the discovery of the phenomenon of osseointegration of the dental implants needs to occur i.e., a direct connection between the bone and the implant surface is mandatory, without the interposition of the fibrous tissue. Various factors may enhance or inhibit implant osseointegration. Factors enhancing osseointegration include factors related to implant such as its design and chemical composition, the topography of the its surface, material, shape, length, diameter, the surface treatment and the coatings, the status of the host bone bed and its intrinsic healing potential, quantity, and quality of the bone, the mechanical stability and the loading conditions applied, and lastly the use of adjuvant treatments such as bone grafting, osteogenic biological coatings, and biophysical stimulation and also pharmacological agents such as simvastatin.

Vitamin D was discovered by Mellanbe in 1919. He was the first to show that rickets occurs through nutritional deficiencies[1]. Vitamin D in the 20th century was recognized as a 'pro-hormone'. Vitamin D belongs to the group of four fat-soluble vitamins along with A, E and K. It is proven to be a fundamental element in the mineralization of the bones and the teeth. It comprises of two biologically active compounds which differ structurally named as **vitamin D3 (cholecalciferol)** and vitamin **D2 (Ergosterol)[1]**. Vitamin D2 comes from plants whereas most of the vitamin D3 requirements are from the synthesis in the epidermis as a result of sufficient sunlight exposure, and the remainder is met by diet. Ultraviolet B exposure induces vitamin D3 biosynthesis in the skin where 7-dehydrocholestrol is changed to

previtamin D3 form. Next in the liver, pre vitamin D3 is hydroxylated into 25-OH vitamin D3. Further, in the kidneys, 1alpha hydroxylase converts 25-OH vitamin D3 into 1, 25-dihydroxy vitamin D3, which is known as the biologically active metabolite or Calcitriol. The biologically active form of vitamin D is 1,25 dihydroxy vitamin D3 and it exerts it action on various tissues by binding to the vitamin D receptors and regulating the transcription of specific target genes. Vitamin D receptors have been found in tissues like skin keratinocytes, macrophages, smooth muscles, pancreatic B-cells, and osteoblasts.

The most important prerequisites for successful outcomes of implants are successful osseointegration, minimal crestal bone loss and achievement of primary and secondary stability. Albrekktson et al in 1986 also proposed in the criteria for successful implants that the vertical bone loss should be less than 0.2mm following implants first year of service[2]. The current criterions being used for the success of implants are the measurement levels of bones. They constitute an integral part of routine clinical evaluation which is carried out for the radiographic evaluation of implants. There should also be a simultaneous monitoring objectively and qualitatively to determine the status of the implant stability. Various types of equipment and methods are present to evaluate implant stability at the time of placement or after that at different time periods. In the past, the gold standard method for the evaluation of the degree of osseointegration was microscopic or histologic analysis. It was a very unethical subject for evaluation as it was invasive in nature. The other methods for the evaluation are the perception of the dentist, radiographs like iopar, opgs and cbcts, the cutting torque resistance, the reverse torque testing, the periotest and the resonance frequency analysis (RFA). RFA is an electromagnetic device that has a transducer present and along with it a magnetic peg is attached which is fixed to the implant or the abutment component. Upon its activation, the peg gets activated, it then vibrates and an electric volt is induced which is inturn recorded by magnetic resonance frequency analyzer. The unit's sensor measures the received frequencies and assigns particular numerical values which correspond to the resonance frequencies at the bone-implant interface site. These values are expressed in the form of implant stability quotient (ISQ) ranging from zero to hundred. Higher the ISQ value, the greater is the mechanical stability of the implant placed. During the surgery, it helps in providing a baseline reading for the placement and follow up.

Despite its importance and its effects on the bone metabolism very few studies till date have been done on the Vitamin D and investigation of its effect on the osseointegration of dental implants still needs more research. Almost all these studies have been done on animal models and very few on humans. The purpose of this study is therefore to correlate the effect of different levels of vitamin D on crestal bone height and implant stability with the help of intraoral periapical radiograph using grid and resonance frequency analysis in two-stage implant placement technique at the baseline, 3 months and 6 months respectively.

AIM:

To observe the effect of vitamin D supplementation on crestal bone height changes and its effect on implant stability.

OBJECTIVES:

1. To observe crestal bone height in participants with optimal levels of vitamin D, not supplemented with vitamin D.
2. To observe crestal bone height in participants with borderline levels of vitamin D, not supplemented with vitamin D.
3. To observe crestal bone height in participants with borderline levels of vitamin D, supplemented with vitamin D.
4. To measure implant stability in participants with optimal levels of vitamin D, not supplemented with vitamin D.
5. To measure implant stability in participants with borderline levels of vitamin D, not supplemented with vitamin D.
6. To measure implant stability in participants with borderline levels of vitamin D, supplemented with vitamin D.
7. To compare crestal bone height among the three groups.
8. To compare the implant stability among the three groups.

Structured review of scientific publications in English literature related to dissertation topic "**Comparative evaluation of vitamin d levels on crestal bone height and implant stability: An in-vivo study**" was done.

R. Adell, U. Lekholm, B. Rockler, P.I. Branemark (1981)[3]: in this study, during 15 years, installments of around two thousand seven hundred and sixty eight fixtures were done for three hundred seventy one consecutive patients. These patients were provided with facultative removable bridges and were also examined at continuous yearly controls. Over a pilot period of 5 years the surgical and prosthetic techniques were developed and evaluated. The observation time was maintained around 5-9 years which was thought to properly reflect the potential of this method. In this, hundred and thirty jaws were provided with eight hundred and ninety five fixtures, out of these 81% of the maxillary and 91% of the mandibular fixtures remained stable. Also it was observed that the bridges were continuously stable in 89% of the maxillary cases and 100% of the mandibular cases. During the healing phase and the first year after the connection of the bridge was made, the mean value for the marginal bone loss was around 1.5mm after which only 0.1 mm was lost annually.

Bergman, B (1983)[4]: this study evaluated the results of treatment with osseointegrated implants by a random selection of 20 patients for the observation period of 4 months for one patient to 6 & 1/2 years for two patients. The mean observation period was 3 & 1/2 years. The patients were examined according to periodontal and prosthetic parameters. They were asked to subjectively evaluate their treatment, and radiographic examinations were made. The mean gingival index according to Loe and Silness (1963) was about 1.2, and the mean plaque index according to Silness and Loe (1964) was about 0.6 with the highest value of approximately 0.75. The mean pocket depth was 2.1 mm buccally and 3.7 mm lingually. Seventeen of 18 prostheses were stable, whereas in one patient the prosthesis showed slight mobility on one side. The radiographic examination failed to show any radiolucency between the bone tissue and the implant for 94 implants, a success rate of 97%. In three implants a radiolucent space was detected between implant and bone. Therefore the National Institutes of Health Harvard Consensus Development Conference defined an implant as successful if the bone loss did not

exceed one-third of its length, if symptoms were absent, and if the implant was stable after 5 years.

Branemark P-I, Albrektsson T (1988)[5]: reported that in the mandible there is a success rate of 99.1%. In the maxilla a success rate of 84.9% and in irradiated and grafted mandibles, no implant was lost during a follow-up of five to eight years. It was concluded that the osseointegrated implant, if inserted according to the guidelines of Branemark, results in a very high degree of clinical success, thereby meeting any published oral implant success criteria.

Meredith N, Alleyne. D, Cawley P. (1996)[6]: they stated that implant stability can be evaluated by applying RFA and architectural engineering. RFA involves resonating sine wave with a certain frequency width continuously from high to low or from low to high. So, RFA can reveal the effective length of the implant out of bone and also the stiffness of the bone-implant surface.

Bahat., O(2000)[7]: evaluated Branemark System implants placed in posterior maxillae that have been restored with fixed partial ceramometal restorations and followed for as long as 12 years after loading. The growing success rate was therefore seen to be 94.4% at the end of five to six years and 93.4% after a period of ten years. It was also observed that the quality and quantity of bone seemed to play a little role on the success rate. They emphasised that the surgical techniques were very important for the success of osseointegrated implants placed in the posterior maxilla. In implant surgical procedures careful surgical planning and execution is required which can lead to a success rate of approximately 95% after 5 years.

Claudia Bortolaia, Antonio Barone, Ludovico Sbordone. (2004)[8]: they did a review on implants placed immediately after tooth extraction. It offered several advantages, but many studies had reported problems in filling the residual gap between the implant and the socket walls. Barrier and grafting techniques have been tested and shown to yield varying results, so they stated that the timing of implant placement may be important for success criteria. This study analyzed the bone healing and coronal bone remodelling pattern around thirty five implants, in which twenty implants were immediately placed after tooth removal and fifteen implants were placed after 6 to 8 weeks of extraction. These implants were submerged and placed

within the confines of the alveoli, thereby leaving circumferential defects. Stabilization was observed to be achieved in the bone apically. After the placement, the mean distance from buccal bone to lingual bone was observed to be 10 mm for the immediate implants and 8.86 mm for the delayed implants. No membrane or filling materials were used. Primary flap closure was accomplished in all cases. It was observed that at second-stage surgery all the periimplant defects were filled and the mean distance from buccal bone to lingual bone was observed to be 8.1 mm for the immediate implants and 5.8 mm for the delayed implants. The pattern of coronal bone remodeling, i.e. a narrowing of the bucco-lingual width, was seen to be clinically similar for the two groups, but it was also to be noted that the delayed implants already exhibited smaller bucco-lingual bone width at the first measurement. From this inference, it could be speculated that early remodeling may start immediately after tooth extraction and continue, non-uniformly, even after the delayed implant placement. They concluded by suggesting that circumferential defects could heal clinically without any guided bone regeneration (GBR) in both experimental groups and that the procedure was virtually free from complications in the postoperative period. Histologically it is observed that the peri-implant defects those over 1.5 mm heal by connective tissue apposition, rather than by direct bone-to-implant contact, but clinically this healing may be very successful. In this study, no histological analysis was carried out but even the largest residual gaps were filled with hard tissue that couldn't be probed. Thus, such outcomes can be considered clinically successful.

Araceli Boronat López , Miguel Peñarrocha Diago , Orlando Martínez Cortissoz , Ignacio Mínguez Martínez (2006)[9]. The primary stability of dental implants is related to the bone in contact with the implant and it and can be evaluated by the resonance frequency analysis (RFA). Measurements were made in one hundred and thirty three implants taking sixty two in the upper jaw and seventy one in the mandible. Resonance frequency and insertion force was taken into account to determine implant stability on the day of surgery, with an evaluation of its relationship to different variables. The stability quotient of the implants on the day of surgery was noted to be 62.1 , with an insertion force of 35.7 N. It was observed that the insertion force was proportional to the resonance frequency. The graph showed an increasing stability quotient with growing insertion force. The stability quotient was

seen to be greater in the larger diameter implants, mandibular placed implants, and areas of more compact bone. The stability quotient on the day of implant placement was observed to be greater in higher bone density areas.

Heli T Viljakainen, Anna-Mari Natri, Merja Karkkainen, Minna M, Anette Palssa, Jette Jakobsen, Kevin D Cashman, Christian Mølgaard and Christel Lamberg-Allardt (2006)[10]. It is a proven fact that vitamin D intake in the elderly patients protects them against osteoporosis, but there exists no literature on the fact that vitamin D supplementation would benefit the bone mineral augmentation. This one year study aimed to determine in a randomized double-blinded trial the effect of 5 and 10 g vitamin D3 supplementation on bone mineral augmentation in adolescent girls with adequate dietary calcium intake. Altogether, 228 girls (mean age, 11.4 ± 0.4 years) participated and their BMC was measured by DXA from the femur and lumbar spine. Measurements were made for the Serum 25-hydroxyvitamin D, intact PTH, osteocalcin, and urinary pyridinoline and deoxypyridinoline. Bone mineral augmentation in the femur was 14.3% and 17.2% higher in the groups receiving 5 and 10 g of vitamin D, respectively, compared with the placebo group, but only 10 g increased lumbar spine BMC augmentation significantly. It was concluded that the Vitamin D supplementation decreased the concentration of bone resorption markers but had no impact on bone formation markers, thereby explaining increased bone mineral augmentation.

Ran Zhang, Declan P Naughton 2010[11] ever since the past, vitamin D inadequacy has been a global problem. In the past, vitamin D intake was associated with the prevention of rickets in children but in other areas it has been researched less. Though in recent years, vitamin D deficiency has also been linked with the pathogenesis and progression of several disorders including cancer, hypertension, multiple sclerosis, diabetes yet the evidence for the associations of vitamin D with these conditions is seen to be lesser than it is for bone-related disease. Generally recommendations of daily vitamin D intake have been suggested but higher levels are needed to have real effective or therapeutic effects as numerous studies have advocated. UV-B radiations or sunlight plays an alternating role in improving vitamin D level apart from oral supplementations. Its advantage over supplementations is that it will not cause any intoxication since excessive vitamin D will be broken down by

the ultraviolet. But many factors linked to ultraviolet radiations need to be carefully controlled so as to avoid the erythematic condition. These factors are wavelength and duration of exposure. Despite several associations of vitamin D with human health, it has not been widely recognized as a problem by the doctors and the patients. Greater awareness of this problem and understanding is required among researchers, clinicians, and patients of the high prevalence of vitamin D inadequacy.

Neha Mall, B Dhanasekar, IN Aparna 2011[12] Implant stability is an important implant success criteria for osseointegration and without it, long-term success cannot be achieved. Continuous monitoring quantitatively and objectively is mandatory to determine the status of implant stability. Measurement of implant stability is a valuable tool for making decisions about treatment protocol and they also improve dentist-patient communication. As the histological analysis is seen to be an invasive method in nature, there have been various others methods proposed which include radiographs, cutting torque resistance, reverse torque, modal analysis, resonance frequency analysis, and Implatest.

S. Battault,S. J. Whiting ,S. L. Peltier. S. Sadrin ,G. Gerber,J. M. Maixent 2012[13] Vitamin D has always been considered as an essential element for the skeletal health growth. Recently it has been attracting interest from medical and nutritional communities too due to its biological functions and its association with decreased risk of many chronic diseases. A question in our heads arises as to how much supplementation of vitamin D dowe need for these functions to be performed efficiently. It was reviewed and discussed about the vitamin D physiology and hypovitaminosis D. Two vitamin D dietary policies were presented according to regulatory authorities and that of nutrition scientists. Scientific data states that 25(OH) D serum levels should be above75 nmol/L, if not there would be no beneficial effect of vitamin D on long-latency diseases. The current regulatory authority recommendations have been insufficient to reach this level of adequacy required. Observational and some prospective data showed that vitamin D has a role in the prevention of cancer as well as immunity, diabetes, and cardiovascular and muscle disorders, which supports the actions of 1a,25(OH)2D at the cellular and molecular levels. There have been new claims by the European Food Safety Authority in their new assessments. It was concluded that Vitamin D, is a promising new health

strategy, if fortified and supplemented. It also provides opportunities for the food industry and nutrition researchers to work together towards determining how to achieve this potential health benefit.

Dvorak, G., Fügl, A., Watzek, G., Tangl, S., Pokorny, P. and Gruber, R. (2012)[14]: The purpose of this study was the investigation of the effect of Vitamin D supplementation on peri-implant bone regeneration. Fifty ovariectomized Sprague-Dwaley rats were taken and divided into three groups. The depletion group was fed a vitamin-D-free diet and the repletion group was fed a vitamin -D free diet for 6 weeks then switched to a standard diet. The control group was fed a standard diet. They concluded by saying that vitamin D deficiency has a negative impact on cortical peri-implant bone formation and can be compensated by vitamin D supplementation.

Ali Akhavan, Zahra Noroozi, Amir Abbas Shafi ei, Abbas Haghighat, Gholam Reza Jahanshahi, Sayed Behrouz Mousavi (2012)[15]: The purpose of this research was to compare the effect of vitamin D administration on the bone to implant contact in diabetic rats with a control group. It was a randomized placebo-controlled trial, in which fourty eight Wistar rats were made diabetic by giving intravenous injections of drug Alloxan. Implants were placed in their tibial bones. These rats were then divided intotwo groups namely, study and control group. They received oral vitamin D3 drugs of 160 IUs or placebo respectively for one week. The bone to implant contact values were measured after a period of 3 and 6 weeks. They concluded by saying that it seemed that vitamin D supplement had no significant effect on BIC and was also not time-dependent.

Joseph Choukroun Georges Khoury, Fouad Khoury, Philippe Russe, Tiziano Testori, Yataro Komiyama, Gilberto Sammartino,Patrick Palacci, Mustafa Tunali, Elisa Choukroun (2013)[16]: Excess low-density lipoprotein cholesterol also nown as dyslipidemia is responsible for a slower bone metabolism and thereby inturn lower dental implant osseointegration. Besides, vitamin D has been shown to be a key factor for linking innate and adaptive immunity. Both of these factors get compromised under the conditions of vitamin D deficiency. Therefore, vitamin D deficiency is seen to slow implant osseointegration and also increases the chances of graft infection. Vitamin D is also play an important role in immune

functions and allergic reactions. Vitamin D serum level and LDL Cholesterol levels should be explored systematically in patients who are diabetic, allergic, with hypertension, and previously in a difficult case of implants or bone grafting. This exploration is to be mandatorily done in casesof failure of bone grafst or implant placements. Correcting these detected anomalies is recommended for successful implants.

Beatrice Y. Lau, Bryan D. Johnston, Peter C. Fritz and Wendy E. Ward (2013)[17]: This review discussed findings from studies that had investigated the role of diet, either whole foods or individual dietary components, on periodontal health and their potential role in wound healing after periodontal surgery. Till date, research has always focussed on foods or the dietary components that may attenuate inflammation or oxidant stress, or promote the de novo formation of bone. All the literature available and studies done state that a variety of dietary components are required for optimal periodontal health and conditions. Both macronutrients and micronutrients are needed to accelerate oral wound healing after periodontal procedures. In this review dietary considerations are highlighted to help a patient achieve the best possible healthy outcomes after periodontal procedures.

Schulze-Spate U et al (2015)[18]: In this study, a randomized, double-blind, placebo-controlled clinical investigation was done. The effect of oral supplementation with vitamin D3 and combined calcium on the bone formation and its impact on remodelling after maxillary sinus augmentation compared to a placebo medication containing calcium alone was studied. Serum 25-hydroxyvitamin D (25-OHD) levels were comparable between both groups at the baseline. It was seen that vitamin D3 plus calcium supplementation improved serum 25-OHD levels significantly but no significant difference statistically was seen in bone formation or graft resorption between the groups. But, in the vitamin D3 group, a significant association was found between the increased vitamin D levels and a number of bone-resorbing osteoclasts around graft particles suggesting that local bone remodelling was more pronounced when serum vitamin D levels were improved. They concluded by stating that vitamin D3 plus calcium supplements improve serum vitamin D levels and potentially impact local bone remodelling on a cellular level.

Gaber M, Saleh M, Fahmy M, Elba G (2015)[19]: this study aimed at evaluating the effect of cholecalciferol on the osseointegration of the dental implants. This study was conducted on fourteen adult male mongrel dogs which were equally divided into two groups namely the control group and the study group. These dogs received cholecalciferol for four weeks after extraction of mandibular right premolar and then the insertion of the immediate dental implant was done. Both the histological and radiological evaluations were carried out. They concluded by stating that the cholecalciferol i.e. Vitamin D3 has systemic effects in accelerating bone formation around titanium implants.

Oscar Salom_o-Coll, Federico Hern_andez-Alfaro,Jordi Gargallo-Albiol (2015)[20]The aim of this study was to evaluate the effect of topical application of vitamin D over implant surface which was placed immediately after the extraction with the throughout histological and histomorphometric analysis of peri-implant tissue. There were Six American foxhound dogs used for the study. Their mandibular premolar distal roots were extracted and 24 immediate implants were randomlyplaced on the distal site of the mandible. There were three groups in which Group CI- 12 titanium implants were placed alone. Test Group DI- 12 titanium implants were supplemented with vitamin D. Prior to implanting, test implants D were submerged in vitamin D. No treatment was done on the control implants CI. After a period of twelve weeks, the animals were sacrificed. Block sections were obtained and they were processed for mineralized ground sectioning. Bone-to-implant contact (Total BIC and BIC %), new bone formation (NBF), inter-thread bone (ITB), and histological linear measurements (HLM) were all analyzed. After a period of twelve weeks, all implants were clinically stable and they were also histologically osseointegrated. No statistically differences were seen regarding inter threads. Regarding peri-implant new bone formation also, no statistical differences could be found between the two groups. For linear measurements, the test group DI showed statistically significant less buccal crestal bone lossand vitamin D implants showed less lingual junctional epithelium. No differences were observed in the buccal mucosa. It was concluded that with the limitation of animal studies, topical application of vitamin D on dental implants could reduce crestal bone loss and increase 10% more bone-to-implant contact at a twelve- week follow-up period.

YashPaul Dev Sharma, Preetinder Singh,Raghav Yashbir, Kaur Manvir, Sharma Shivli,Wahi Ankur (2016)[21]: this study was done for the investigation of the effect of Vitamin D supplementation on osseointegration of implants in chronic kidney disease patients. 20 patients were taken out of which 10 were supplemented within vitamin D. Statistically significant results were seen in vitamin D supplemented groups in relation to the other groups without supplementation. They concluded that supplementation with 60,000 IU cholecalciferol for 12 weeks was an effective way of correcting vitamin D status in patients with CKD stage 3 and 4 and it also helped bone osseointegration. The study concluded that implants placed in CKD patients supplemented with vitamin D were more successfully osseointegrated and functional, and this was confirmed both clinically and radiographically.

Tobias Fretwurst, Sebastian Grunert, Johan P. Woelber, Katja Nelson and Wiebke Semper-Hogg (2016)[22]: in the literature an association between vitamin D deficiency and early dental implant failure has not been properly verified, but its role in osteoimmunology is highlighted. This study illustrated two case reports having vitamin D deficiency and showing early implant failure. In the procedure, prior to the implant placement, the first patient received crestal bone grafting with autologous material. Both the patients had received dental implants from different manufacturers in the molar regions of the mandible. In the first case with bone grafting, all the implants were placed following a two-stage procedure. All the implants had to be removed within fifteen days after implant placement. Vitamin D serum levels were measured for both the patients. Both showed a vitamin D deficiency of serum vitamin D level <20μg/l. They concluded by saying that though it was observed that after vitamin D supplementation, implant placement was successful in both the patients yet, more prospective and randomized trials have to be followed to affirm the relationship between vitamin D deficiency, osteoimmunology, and early implant failures.

Sachdeva A, Dhawan P, Madhukar P, Gupta S, Bhardawaj A.(2016)[23]: This study aimed to measure the stability and crestal bone level changes of indigenously developed implants in the fresh extraction sockets of the patients selected for the study. Forty implants were placed immediately in fresh extraction sockets of twenty seven patients in the age group belonging under 18–65 years. The clinical assessments of implant stability were made using resonance frequency

analysis (RFA) at the time of placement of implant and also at three, six, and twelve months postoperatively. Also radiographic crestal bone changes were evaluated using digital radiograph at the time of placement, three, six, and twelve months. The distance between the first visible bone-implant contact and implant shoulder was measured, and the crestal bone loss was calculated. The mean RFA values obtained were 48.08 implant stability quotient(ISQ) at the time of placement and reached 66.32 ISQ after a follow-up period of twelve months. The mean radiographic bone loss was seen to be 0.67 mm at the end of twelve months. The results highlighted that there was no significant bone loss. Out of forty dental implants, two had failed in the early phase. Thus, the survival rate of implants placed in fresh extraction sockets was seen to be 95% at the end of twelve months. It was concluded that immediately placed implants can attain an adequate level of primary stability. These stability levels were shown to improve with time, reaching similar values irrespective of the initial stability present. Also about 50% of the mean bone loss occurred during the first 6 months after implant placement suggesting several factors other than occlusal load affecting bone levels around implants. This study also found a negative correlation between the crestal bone loss and stability values in terms of ISQ at a statistically significant value.

Swami V, Vijayaraghavan V, and Swami V (2016)[24]: Implant stability plays a very crucial role for successful osseointegration of implants. The successful osseointegration of implant is a prerequisite for functional dental implants. Therefore continuous monitoring in an objective and qualitative manner is of utmost important to determine the status of implant stability. The implant stability is measured at two different stages which are primary and secondary. The primary stability comes from the mechanical engagement with the cortical bone. On the other hand, secondary stability is developed from regeneration and remodeling of the bone. It is also affected by the primary stability, bone formation and remodelling. The time of functional loading is also dependent upon the implant stability. In the past, the gold standard methods to evaluate implant stability were microscopic or histologic analysis and radiographs, but due to the invasiveness of these methods and related ethical issues various other methods have been proposed which are the cutting torque resistance, the reverse torque analysis and the model analysis, etc. Therefore, it is of the utmost

importance to be able to assess the stability of implant at various time points and to gain a long-term prognosis for successful therapy.

FrancescoMangano, Carmen Mortellaro,Natale Mangano, and CarloMangano (2016)[25]: they investigated the correlation between early dental implant failure and the low serum levels of vitamin D. In this study patients were treated with dental implants at a single centre following a period from year 2003–2015. The main outcome noted was early implant failure. They noted the influence of patient-related variables on implant survival which was calculated using the Chi-square test. Eight hundred twenty two patients were treated using one thousand six hundred twenty five implants selected for this study. There were twenty seven early failures recorded i.e. 3.2%. It was observed that there was no link between the parameters following gender, age, smoking, history of periodontitis, and an increased incidence of early failures. The statistical analysis reported nine early failures i.e. 2.2% in patients with serum levels of vitamin D > 30 ng/mL, sixteen early failures i.e. 3.9% in patients with levels between 10 and 30 ng/mL and two early failures i.e. 9.0% in patients with levels.

Fawad Javed, Hans Malmstrom,Sergio Varela Kellesarian,Abdulaziz A. Al-Kheraif, Fahim Vohra, and Georgios E. Romanos (2016)[26]: This study aimed to review the efficacy of vitamin D3 supplementation on the osseointegration of implants systematically. The addressed focused question that was highlighted was whether Vitamin D3 supplementation affects osseointegration around implants or not. The pattern of this systematic review was customized to primarily summarize the present data. The results of six experimental studies which were done on rodents and rabbits were included. The number of titanium implants placed ranged between twenty eight and hundred implants respectively. The results from the five studies showed that vitamin d3 supplementation accelerated the new bone formation and bone to implant contact around the implants. One study showed no significant difference in bone to implant contact and new bone formation around Vitamin D3 coated and uncoated implants. Another study reported that the insulin therapy with adjunct Vitamin D3 supplementation enhances new bone formation around implants in diabetic rats more than when insulin replacement therapy is used alone. It was concluded by stating that the efficacy of vitamin D3 supplementation on

osseointegration of implants remains controversial and further investigations are required in this subject.

Hassan H Koshak(2017)[27]: The search for a biological anomaly which has been labeled as a risk factor before dental implants is only limited to disease states such as diabetes, periodontitis, and smoking. It has been looked upon in recent years that the cholesterol and vitamin D levels should be more systematically investigated for such latent diseases. There also exists a very clear close relationship between cholesterol, and vitamin D. It is an interesting fact to be noted that both the cholesterol and the vitamin D have the same precursor, namely, 7-Dehydrocholesterol. There is good cholesterol called high-density lipoprotein [HDL] and a bad cholesterol called low-density lipoprotein [LDL]. Vitamin D , a fat soluble vitamin is one of the most important vitamins related to the bone growth. Also, vitamin D plays a vital role in reducing the effects of inflammation and thereby helps in improving the body's natural immune reactions. The assessment of the total serum cholesterol levels and vitamin D status, is therefore necessarily indicated for dental implants or bone grafts patient.

Engy M. Farid et al (2018)[28]: This study evaluated the effect of the combination of cholecalciferol and calcium on delayed dental implant healing in post-menopausal women. The clinical and radiographical study was done on fourteen post-menopausal women with age range between fourty to sixty years having missing maxillary anterior teeth. The study group received cholecalciferol and calcium for eight months and the control group didn't receive anything. The implants placed were evaluated clinically after 4 and 8 months respectively, also radiographically to evaluate the marginal bone loss. The study group showed an increase in the bone density. The difference in the bone density between the two groups was statistically significant. They concluded that calcium has systemic effects on accelerating bone formation around Ti implants.

Grzegorz TrybekF, Magda Aniko-Włodarczyk, Jakub Kwiatek, Olga Preuss, Andrzej Brodkiewicz, Andrzej Sinicyn, Anna Grzywacz (2018)[29] healthcare workers like doctors, dentists and implantologists have been seen to be increasingly interested in the effects of vitamin D on bone metabolism and the

immune system. It has been evidently seen that The correct concentration of the pro-hormone potentially correlates with implants 'success at each stage of osseointegration. A suitable level of vitamin D3 is crucial from the day of surgery and later on as required. It influences the modulation of the immune system and increases the production of cathelicidin and defensin proteins, and thus reduces the expression of pro-inflammatory cytokines. It also has a positive effect on the bone metabolism in osteo-suppression via the induction of osteoblasts and osteoclasts and it also affects the continuous bone remodeling around the implant after prosthetic restoration. This literature concluded that there is already a prevalence of low vitamin D levels in the European population and so a high deficit is not a factor directly responsible for failures in the process of osseointegration.

Anitua, Eduardo, Alkhraisat, Mohammad H. (2018)[30]: this study evaluated the survival and marginal bone loss around short dental implants and also assessed the influence of the anatomical location i.e. mandible and maxilla on these results for up to fifteen years. The marginal bone loss has been shown to be significantly higher in the maxilla than the mandible. The implant survival rate was observed to be 93.3%. Therefore it was concluded that short dental implants are a viable option to support fixed partial prosthesis in the mandible and the maxilla. They also stated that implant position may affect the marginal bone loss around the short dental implants.

Shikha Nandal, Pankaj Ghalaut, Himanshu Shekhawat (2018)[31] . Their study aimed at evaluation of the marginal bone level changes around dental implants based on the radiological examination and the relationship of various parameters. These parameters include patient's gender, implant length, implant diameter, implant location and also the amount of bone loss around dental implants. This study was undertaken to evaluate the crestal bone loss on the mesial and distal aspect of implants. It was done using standardized intra-oral periapical radiographs at the end of 6 months after placing the implants, but before loading it. The student's unpaired t-test was used as statistical analysis tool. Bone loss levels were measured and values were recorded immediately after implant placement and also after six months. It was observed as a result that bone loss on mesial and distal aspects of implants was found to be the same after six months. Bone loss was found to be the same in both thirteen mm and ten mm implants on the mesial aspect, whereas on the distal aspect, it was

more in ten mm implants. Also bone loss was found to be the same in both 3.5 mm and 4.3 mm diameter implants on both mesial and distal aspects of implants. Bone loss was also found to be the same in both maxilla and mandible on both mesial and distal aspects of implants. It was also observed that the bone loss was found to be more in females on both mesial as well as distal aspects of implants.

Adrien Naveau, Kouhei Shinmyouzu, Colman Moore, Limor Avivi-Arber, Jesse Jokerst , Sreenivas Koka (2019)[32]: New ways of appreciating CBL are blending traditional etiologies with novel mechanisms that better reconcile what was originally thought to be taking place during osseointegration with actual long-term clinical outcomes. Today, the ability to look back on osseointegration outcomes at the implant level, the prosthesis level, the patient level, and even the clinician level allow us to recognize that osseointegration likely represents a form of foreign body reaction and focuses our attention on elements that influence the immune response or the consequence of a patient's immune response. In this way, traditional etiologies such as inflammation from infection and overloading can be viewed as modulators of the immune response and the effect of the immune response through neuro-immunomodulation opens up new and exciting avenues for future research. Clinically, measuring crestal bone loss remains at the mercy of the constraints of radiographic imaging. although, new methodologies and digital technologies support the introduction of non-invasive methods that may be more sensitive and specific about the measurement of crestal bone position and changes in crestal bone position over time. Also, innovations in imaging will allow us to better assess the effect of new techniques, products, protocols, and materials.

MATERIALS AND METHODS:

- The study was conducted on the patients visiting to the clinical Department of Prosthodontics, Crown and Bridge Babu Banarasi Das College of Dental Sciences, Lucknow, Uttar Pradesh.
- Partially edentulous patients requiring dental implant restoration with different serum levels of vitamin D were undertaken for this study.
- Study sample and size:-
  - Study sample:- randomized
  - Sample size : 18 (6 in group A , 6 in group B and 6 in group C)
- **Eligibility criteria:-**
- **Inclusion criteria:-**

1) Patients who were conscious of their oral hygiene and were willing to undergo restoration treatments with dental implants.
2) Patients who possessed partially edentulate dentition.
3) Male and female patients who aged between 25 to 65 years.
4) Patients who possessed completely healed alveolar socket.
5) Healthy patients with no systemic diseases present so as to ensure uneventful healing and osseo-integration of implants following the treatment.
6) Patients who possessed good periodontal health status in the remaining dentition.

- **Exclusion criteria:-**

1) Patients who weren't willing to enrol in the study.
2) Patients with any known history of systemic diseases or conditions or taking any medications which could interfere with the wound healing or the surgical implant procedures.
3) Patients who were current smokers or consumed any other form of tobacco.
4) Patients who presented with allergy to any drug or any material used in the study.
5) Patients with a history of alcoholism or drug abuse within the past five years.
6) Patients who possessed severe wear of teeth with a presentation of bruxism and clenching habits.

7) Patients who were then undergoing chemotherapy or patient who had underwent radiation treatment to the head or neck region.
8) Patients who were unable to maintain adequate oral hygiene due to some dexterity or physical status.
9) Patients who were on the drug therapy such as bisphosphanates.

Study design:

In this study the patients who were enrolled were selected considering their medical and dental history, their current general and oral health statuses, and the above mentioned inclusion and exclusion criterion. An implant treatment case record sheet was formulated and utilized for all the cases. Patients were also provided with a mandatory consent form plus a patient information document (PID) regarding the nature of the treatment, the associated procedures and risks involved in the treatment.

Pre-operative and post-operative bone evaluation was done clinically and radiographically.

It included:

- Clinical photographs
- Study models
- Orthopantomogram
- CBCT
- Intra oral periapical X-ray

All patients were followed up for minimum of one year post operatively.

Armamentarium

Materials and instruments included:

- Instruments:
    - Implant kit (ADIN IMPLANT SYSTEM)
    - Physiodispenser (NSK)
    - Resonance frequency analyzer (ostell ISQ)
    - Miscellaneous instruments needed during the surgical and prosthetic procedures.

- Materials:
    - Lidocaine topical aerosol
    - 2% xylocaine with adrenaline (1: 80 ,000)
    - Povidine iodine solution (5w/v)
    - Saline (sodium chloride , I.P. 0.9% w/v)
    - Suture needle (ETHICON™)
    - Needle holder (API)
    - Suture thread (ETHICON™)
    - Suction tip
    - Chromatic alginate impression material.
    - Addition silicon rubber base impression material.
    - Clear auto-polymerizing polymethyl methacrylate resin
    - Model plaster
    - Dental stone (type IV)
    - Type I (luting) glass ionomer cement.
- Miscellaneous instruments needed during the surgical and prosthetic procedures.
    - Intra-oral periapical radiographic films (size 21x41 mm) (Kodak ® Ekta speed film.)
    - Periapical radiographic machine(Planmeca Prostyle intraoral X-ray machine)
    - Film positioning device
    - Panoramic dental film (size 15x30 cm) (Kodak T-MAT G/RA)
    - Panoramic and linear tomographic radiographic machine
    - Radiographic viewer
    - Intra oral peri-apical grid
    - 10ml single use syringe (Dispovan)
- Drugs: vitamin D oral supplements – (DV60K tablets; DV 60K contains 60000 IU of cholecalciferol-Vitamin D3) drug was prescribed only after proper consultation with general physician and taking all health assessment and evaluation and medical history into account. Drug was prescribed only to group c patients according to the deficiency range and requirement (one capsule per week).

METHODOLOGY

LAB INVESTIGATION:

It was mandatory for all the patients as it helps in developing the treatment plan for surgery and post operative care.

- Routine blood examination along with HBsAg, HIV, HbA1c.
- Fasting blood sugar
- Serum vitamin D test.

RADIOGRAPHIC EVALUATION:

It plays an important role in developing the patients treatment plan and objectives. All the patients were subjected to radiographic examination of the implant site using the following radiographs.

- Orthopantomograph
- Intraoral periapical radiograph using paralleling cone technique with positioning device.
- CBCT
- Panoramic radiographs: a screening procedure for pre implant alveolar bone dimensional assessment of the implant site and to decide the length of the implant to be used based on regional anatomy.
- Cone beam computed tomography (CBCT): used for pre-surgical diagnosis, preoperative planning, offering volumetric data on jaw bones and teeth.

Intra oral peri-apical radiographs:

- Pre-operative
- Immediately post –operative
- One-month after implant placement
- Two months after implant placement
- Three months after implant placement.

PROCEDURE:

Cases were divided under three groups.

GROUP A : 6 Implants were placed without vitamin D supplementation.	Group B: 6 Implants were placed without vitamin D supplementation)	Group C: 6 Implants were placed with vitamin D supplementation)
CONTROL GROUP	TEST GROUP 1	TEST GROUP 2
VIT D SUFFICIENCY : 30-60 ng/ml	VIT D INSUFFICIENCY : 20-30 ng/ml	VIT D INSUFFICIENCY: 20-30 ng/ml

Referred values of Vitamin D:

Serum 25-Hydroxyvitamin D [25(OH)D] Concentrations and Health [33]

nmol/L*	ng/mL*	Health status
<30	<12	Associated with vitamin D deficiency (rickets in infants and children and osteomalacia in adults).
30 to <50	12 to <20	Generally considered inadequate for bone and overall health in healthy individuals
≥50	≥20	Generally considered adequate for bone and overall health in healthy individuals
>125	>50	Linked to potential adverse effects, particularly at >150 nmol/L (>60 ng/mL)

*Serum concentrations of 25(OH) D in both nanomoles per liter (nmol/L) and nanograms per milliliter (ng/mL).

(1 nmol/L = 0.4 ng/mL, and 1 ng/mL = 2.5 nmol/L).

VITAMIN D STATUS[34]	**The serum level of vitamin D in ng/mL**
Deficiency	<20
Insufficiency	21-29
Sufficiency	>30
Toxicity	>150

Average daily recommended amounts are listed below in micrograms (mcg) and International Units[35:]

Life Stage	**Recommended Amount**
Birth to 12 months	10 mcg (400 IU)
Children 1–13 years	15 mcg (600 IU)
Teens 14–18 years	15 mcg (600 IU)
Adults 19–70 years	15 mcg (600 IU)
Adults 71 years and older	20 mcg (800 IU)
Pregnant and breastfeeding teens and women	15 mcg (600 IU)

Selected cases were first advised to undergo thorough oral prophylaxis. Impressions for both arches were taken and a surgical template was fabricated over the cast obtained. Mesio-distal width available for implant placement was measured. The selected implant diameter was to be 3mm narrower than this dimension. One hour before the surgical procedure patient was put on oral antibiotic prophylaxis. The oral cavity was then prepared with 5% povidine iodine solution.

STAGE I SURGERY:

After achieving anaesthesia, crestal incision was given. A periosteal elevator was used to make a full thickness soft tissue reflection and surgical site was exposed.

The implant osteotomy began with the punch cut of the pilot drill being made through the hole in the stent, to accurately reproduce the angulation. The stent was removed and the osteotomy was carried to the desired depth. The angulation was checked with the paralleling pin both clinically and radiographically, and any discrepancy found could be corrected subsequently. The osteotomy was then diametrically enlarged to desired width under constant irrigation. After completion of the osteotomy, implant was carried from the packaging to the site using the disposable carrier provided by the manufacturer. It was then screwed in or tightened using the hand ratchet and was made sure that a minimum torque of 35Nm - 45Nm is obtained while screwing the implant and followed by cover screw placement.

RFA MEASUREMENTS

Now the RFA measurements were to be performed, i.e. immediately following implant placement using a resonance frequency analyzer, an Osstell instrument. The transducer was attached to the implant perpendicular to the alveolar crest with a screw driver, using about 10 Ncm of torque. Care was taken to make sure that no tissue was trapped between the implant head and the transducer. The measurement was shown momentarily as a frequency/amplitude plot and an ISQ value was noted. If the plot indicated an erroneous measurement, the transducer was to be removed, the implant site was cleaned again , and a new measurement was made. A post-insertion periapical radiograph was made after attaching the cover screw. The soft tissue was then approximated and followed by suture.

All patients were kept on antibiotics and analgesics for next 5 days, along with chlorhexidine. 0.2% mouth rinse twice daily for 2 weeks. Patients were recalled after 7 days for suture removal. Suitable oral vitamin D supplements in the form of DV 60 K tablets were given to the participants of group C after assessment of physical status (was consulted with physician accordingly).

STAGE II SURGERY:

After healing period of 5 months, a second stage surgery was performed and healing abutments were placed. After 15 days of gingival collar placement, impression copings were placed and impressions were taken with closed tray impression technique. Impression were sent to the dental lab for prosthesis fabrication. Thereafter, following coping try-in, definitive restorations were cemented following the principles of implant protected occlusion.

INTRA ORAL RADIOGRAPHS:

For this study, intra oral periapical radiograph were taken at:

1) 0 month(at the time of placement)
2) 3rd month
3) 6th month

RFA readings were taken at:

1) Day 0(at the time of placement)
2) Day 90

All the patients were recalled for follow ups for minimum of 1 year post – operatively. The collected data was subjected to statistical analysis for the final result.

ANALYZING RADIOGRAPHS:

Using divider and scale, the measurements were taken from the grid IOPA. On the IOPA, the coronal surface of the implant fixture was taken as the reference line. Two perpendicular lines were dropped on from the mesial and distal margins of the implant reference line to the first bone-to-implant contact i.e. where the bone appeared to be in contact with the implant. The measurement was recorded by an mm scale. Values of each case in all the groups i.e. group I, group II and group III were determined from their pre-operative to post-operative period and IOPAs were compared to a period of 6 months of implant placement and averaged to yield mean crestal bone loss.

Figure 1- Physiodispenser with handpiece

Figure 2- Implant Fixtures

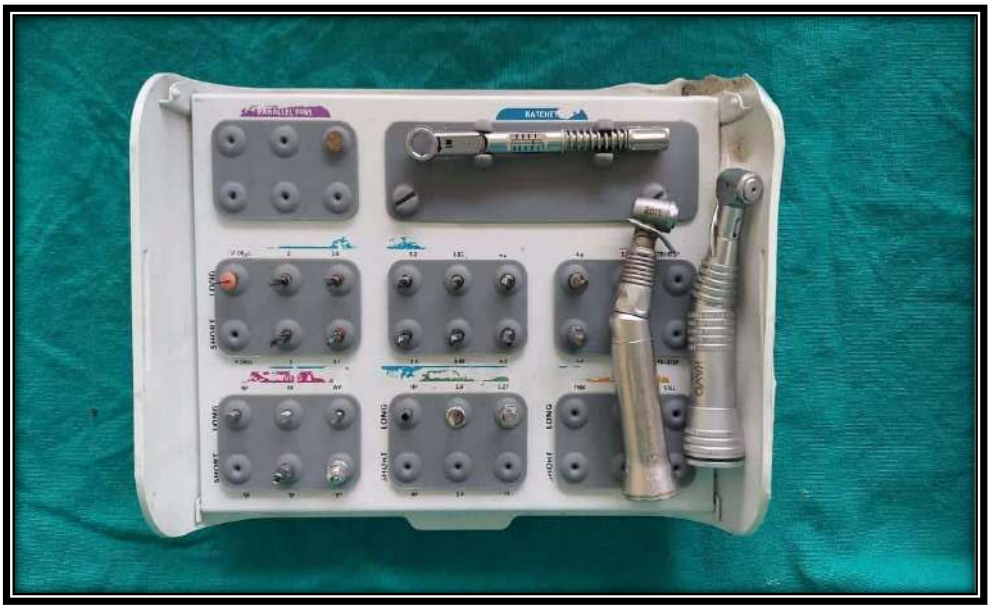
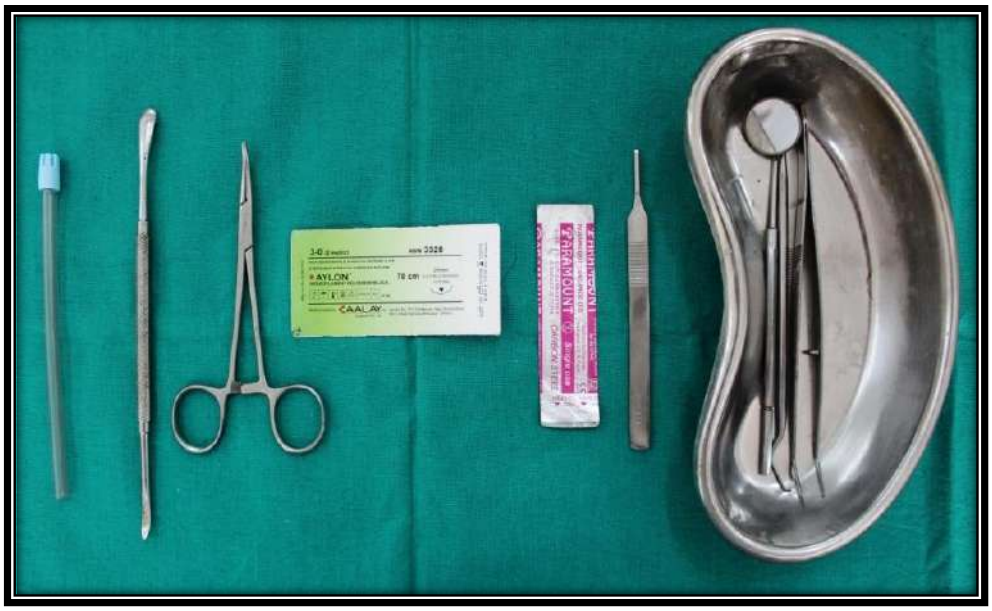


Figure 3 – Implant kit



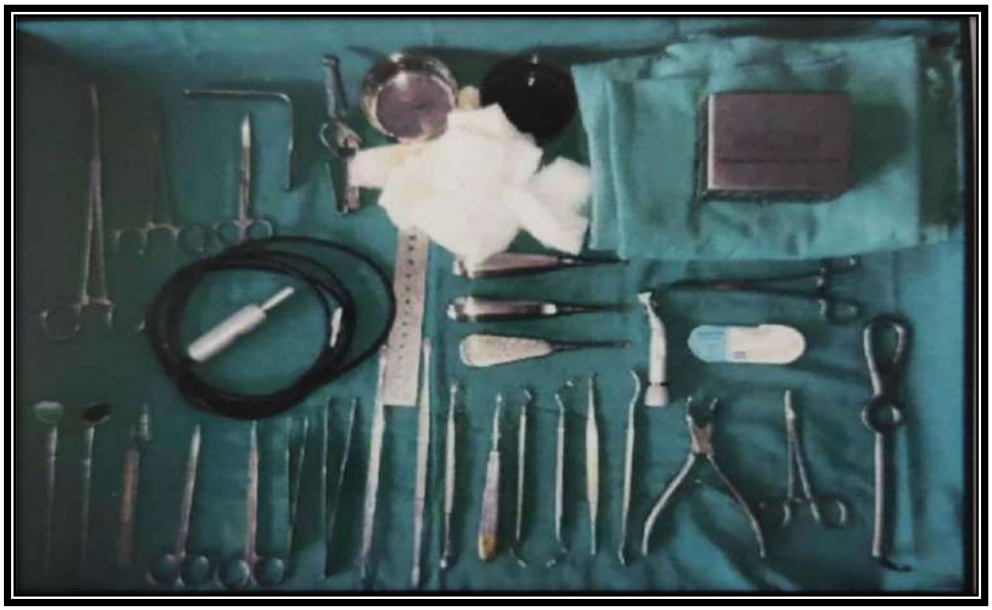


Figure 4 - Surgical Instruments

Figure 5- Materials

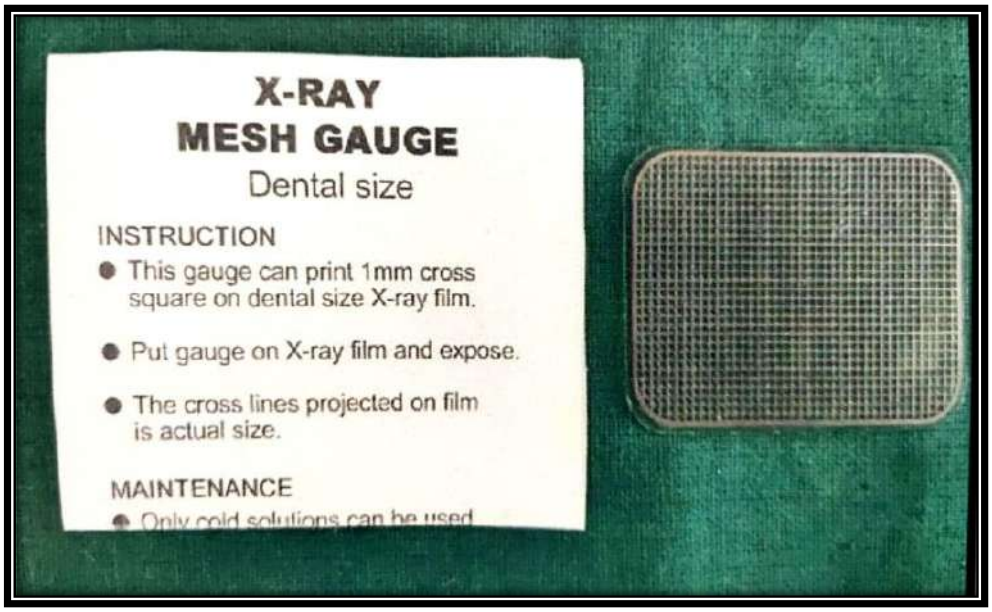


Figure 6- IOPA grid

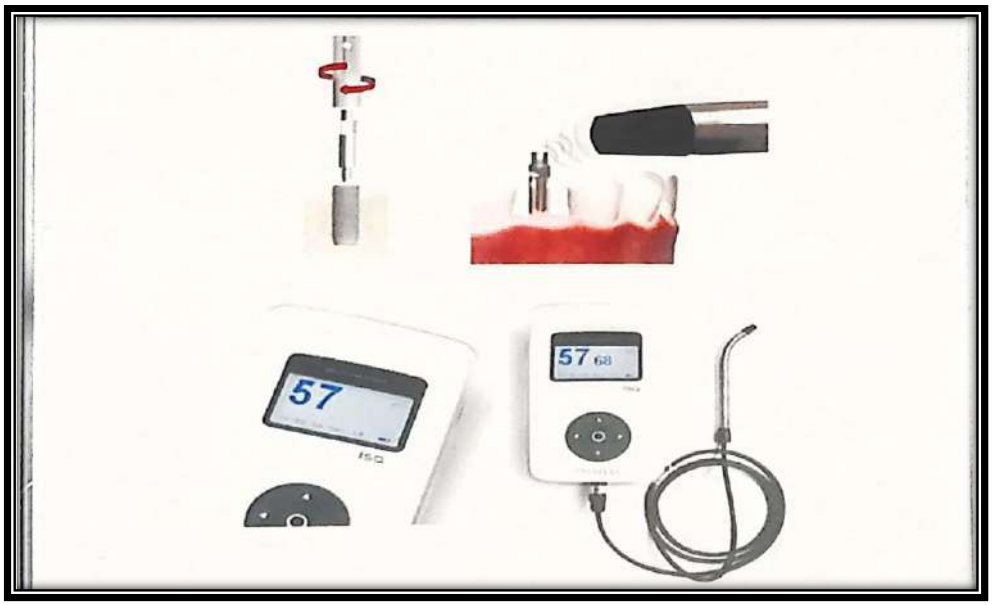


Figure 7- Resonance Frequency Analyzer

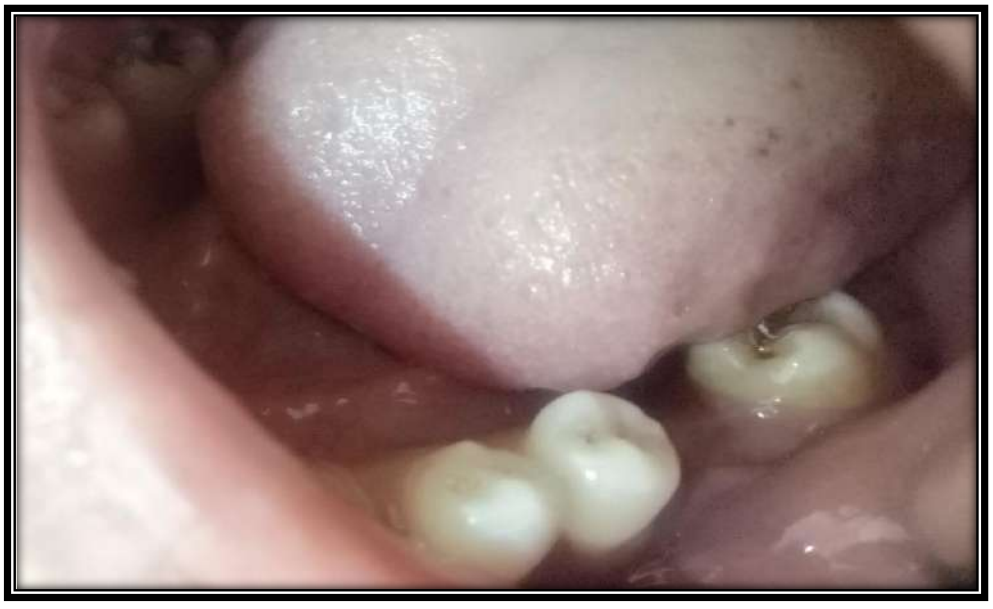


Figure 8- Pre-operative

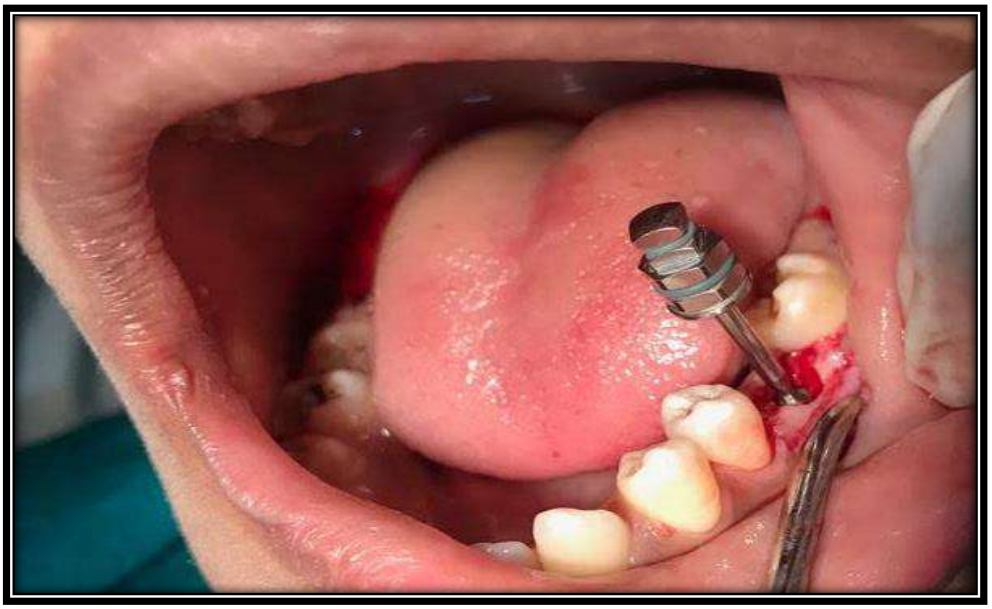


Figure 9- Cover screw tightened after subsequent implant

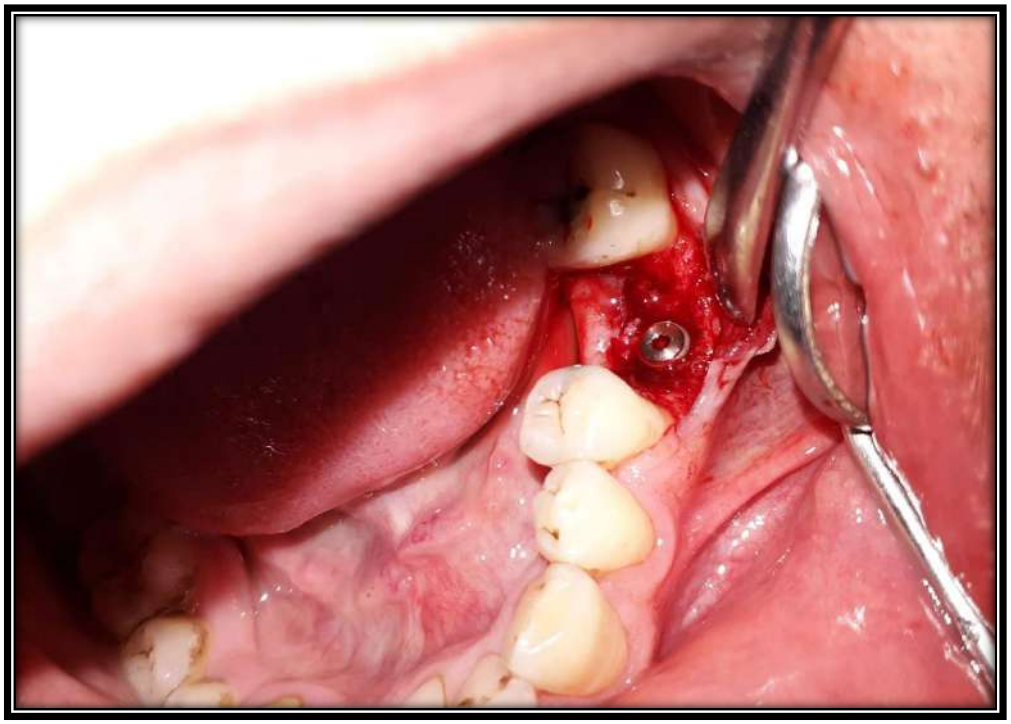


Figure 10- Implant with cover screw

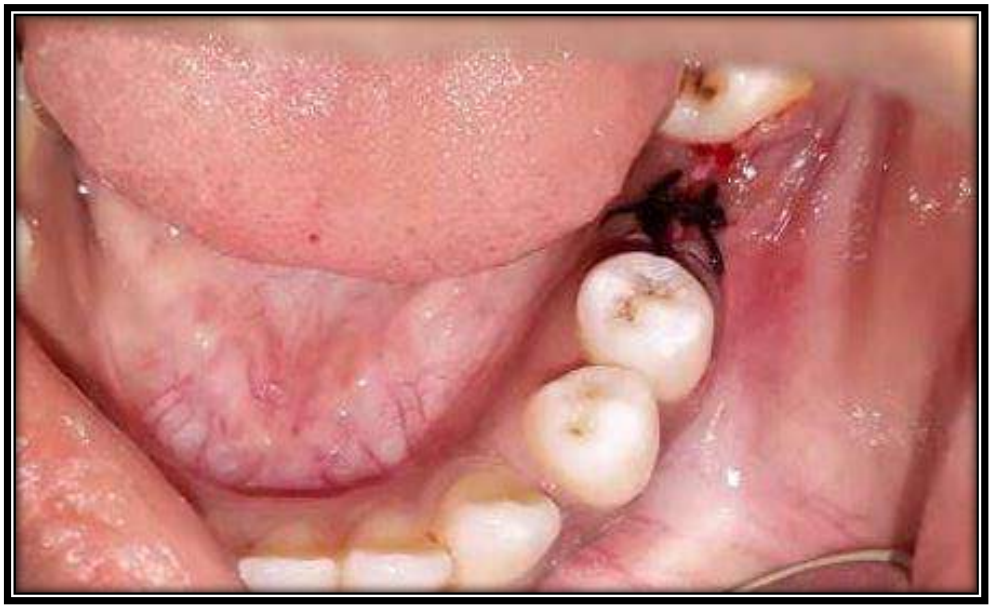


Figure 11- Flap Approximated And Sutured

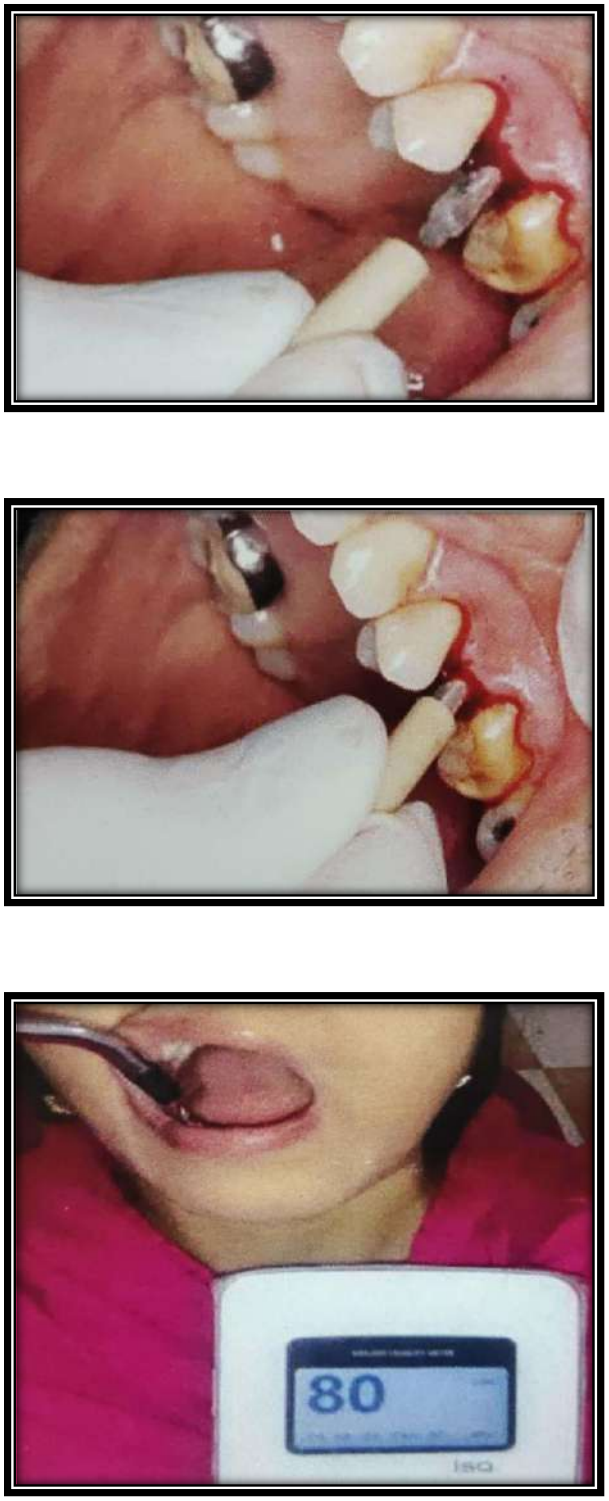
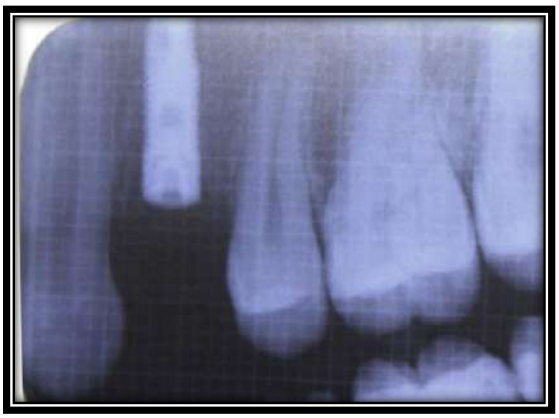
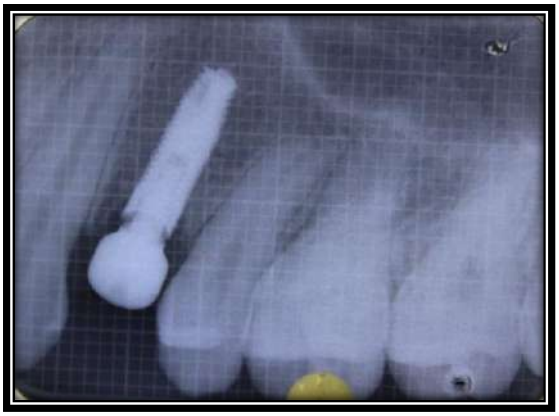


Figure 12- RFA readings by OSTELL radio frequency analyzer utilizing transducer known as Smart Peg.

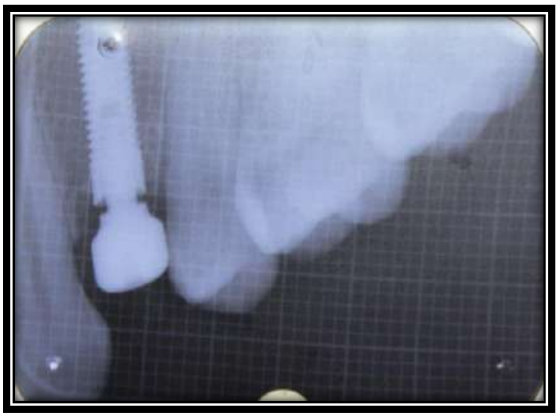
Figure 13- Cases



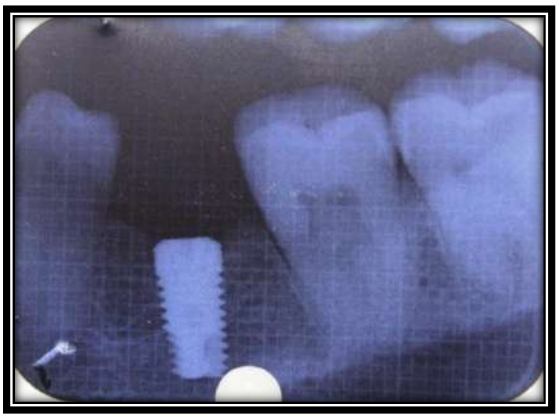
CASE 1 (a) I.O.P.A. Taken Immediately After Implant Placement



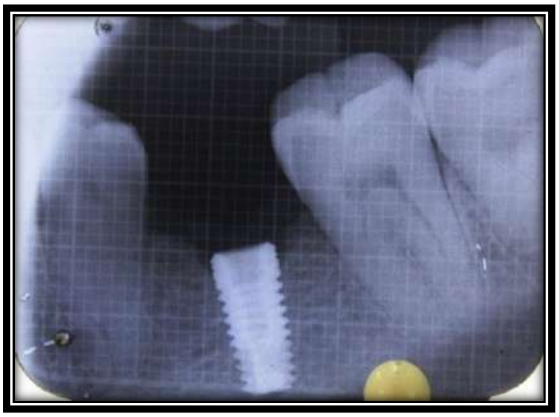
CASE 1 (b) I.O.PA. Taken after 3 months of implant Placement



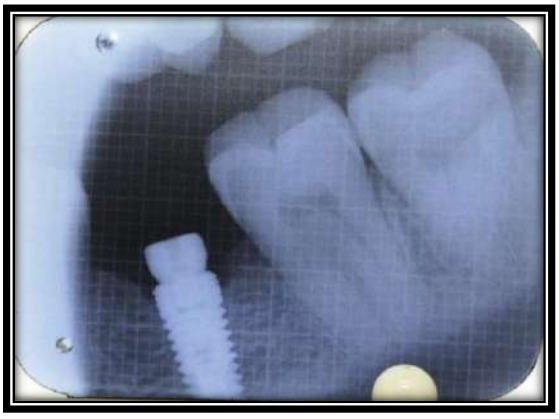
CASE 1 (c) I.O.P.A. Taken After 6 Months Of Implant Placement



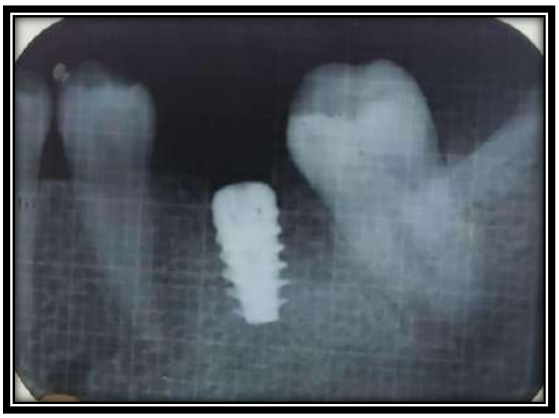
CASE 2 (a) I.O.P.A. Taken Immediately After Implant Placement



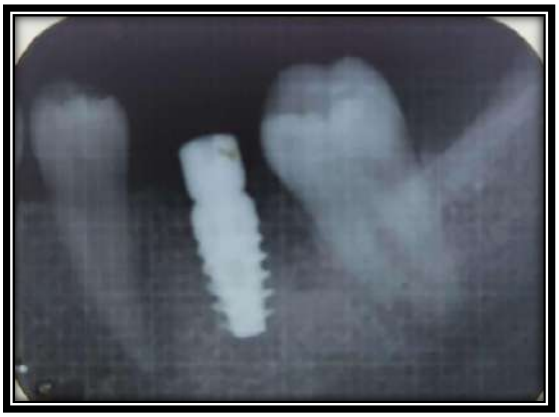
CASE 2 (b) I.O.PA Taken After 3 Months Of Implant Placement



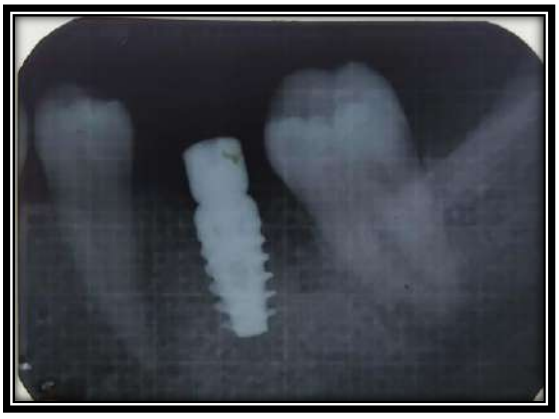
CASE 2 (c) I.O.P.A. Taken 6 Months After Implant Placement



CASE 3 (a) I.O.P.A. Taken Immediately After Implant Placement



CASE 3 (b) I.O.PA Taken After 3 Months Of Implant Placement



CASE 3 (c) I.O.P.A. Taken 6 Months After Implant Placement

Results

The data was entered in Microsoft excel format and was analysed using SPSS version 21(IBM SPSS Corp. Ltd. Armonk, N.Y).

Summarized data was presented using Tables and Graphs.

Descriptive data was reported for each variable.

Descriptive statistics such as mean and standard deviation for continuous variables was calculated.

Shapiro Wilk test was used to check the normality of the data.

As the data was found to be normally distributed bivariate analyses was performed using Paired t test and One way ANOVA followed by bonferroni correction for post hoc comparison.

To compare proportions of a categorical outcome chi square test was used. Level of statistical significance was set at p-value less than 0.05.

Table 1 shows Intragroup comparison of crestal bone loss in Group A on mesial side. On mesial side significant differences were seen in crestal bone loss from the time of placement to 3 and 6 months when compared using Paired t test as $p<0.05$ but from 3 months to 6 months no significant differences were seen .

Table 1: Intragroup comparison of crestal bone loss in Group A on mesial side

		Mean	N	Std. Deviation	Std. Error Mean	Mean difference	Std dev	P value
Mesial	At the time of placement	.033	6	.0516	.0211	-.20000	.08944	0.027
	At 3 months	.2333	6	.06831	.02789			
	At 3 months	.2333	6	.06831	.02789	-.05000	.04472	0.063
	At 6 months	.2833	6	.06055	.02472			
	At the time of placement	.033	6	.0516	.0211	-.25000	.07071	0.027
	At 6 months	.2833	6	.06055	.02472			

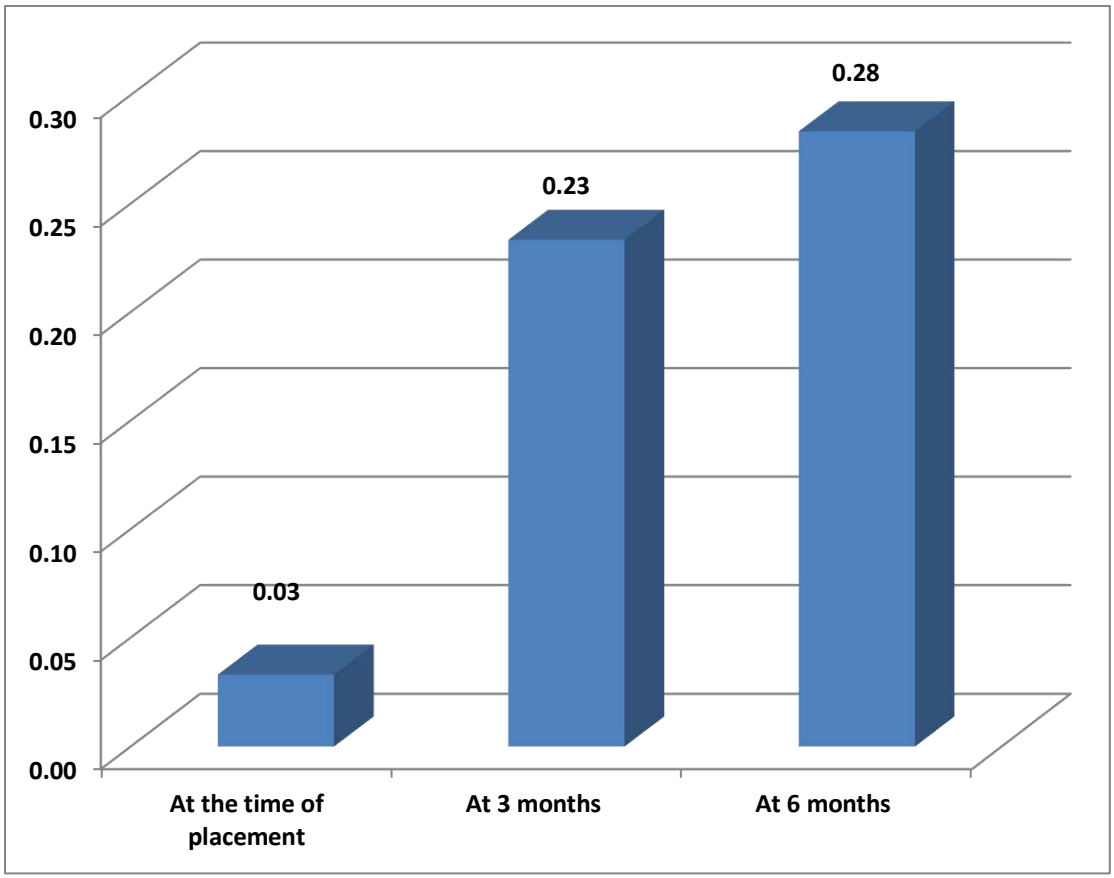

0.30
0.25
0.20
0.15
0.10
0.05
0.00
0.03
0.23
0.28
At the time of placement
At 3 months
At 6 months

Table 2 shows Intragroup comparison of crestal bone loss in Group B on mesial side. On mesial side no significant differences were seen in crestal bone loss from the time of placement to 3 or 6 months or from 3 to 6 months when compared using Paired t test as $p>0.05$

Table 2: Intragroup comparison of crestal bone loss in Group B on mesial side

		Mean	N	Std. Deviation	Std. Error Mean	Mean difference	Std dev	P value
Mesial	At the time of placement	.100	6	.2000	.0816	-.18333	.38687	0.336
	At 3 months	.2833	6	.24833	.10138			
	At 3 months	.2833	6	.24833	.10138	-.10000	.20000	0.180
	At 6 months	.3833	6	.20412	.08333			
	At the time of placement	.100	6	.2000	.0816	-.28333	.23166	0.066
	At 6 months	.3833	6	.20412	.08333			

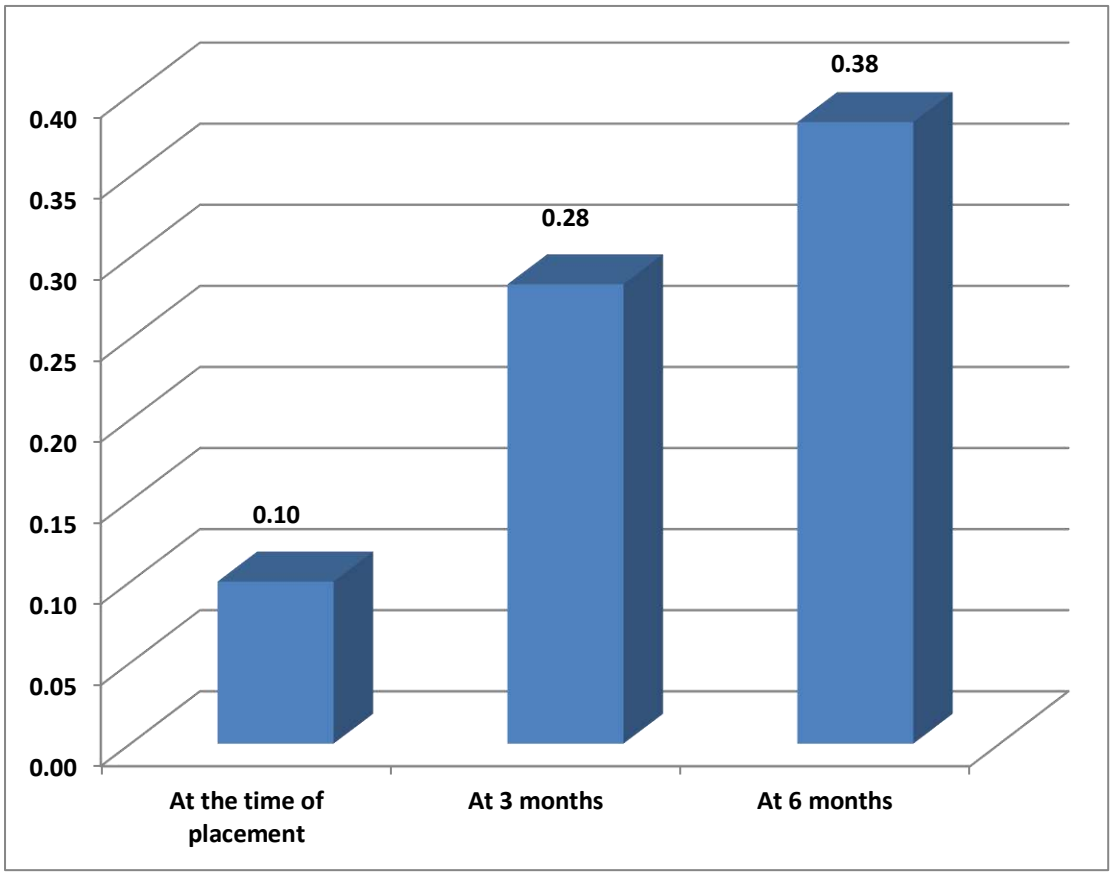

0.40
0.35
0.30
0.25
0.20
0.15
0.10
0.05
0.00
0.10
0.28
0.38
At the time of placement
At 3 months
At 6 months

Table 3 shows Intragroup comparison of crestal bone loss in Group C on mesial side. On mesial side no significant differences were seen in crestal bone loss from the time of placement to 3 or 6 months or from 3 to 6 months when compared using Paired t test as $p>0.05$.

Table 3: Intragroup comparison of crestal bone loss in Group C on mesial side

		Mean	N	Std. Deviation	Std. Error Mean	Mean difference	Std dev	P value
Mesial	At the time of placement	.017	6	.0408	.0167	-.27500	.26029	0.056
	At 3 months	.2917	6	.23327	.09523			
	At 3 months	.2917	6	.23327	.09523	.25000	.28107	0.098
	At 6 months	.0417	6	.06646	.02713			
	At the time of placement	.017	6	.0408	.0167	-.02500	.06124	0.317
	At 6 months	.0417	6	.06646	.02713			

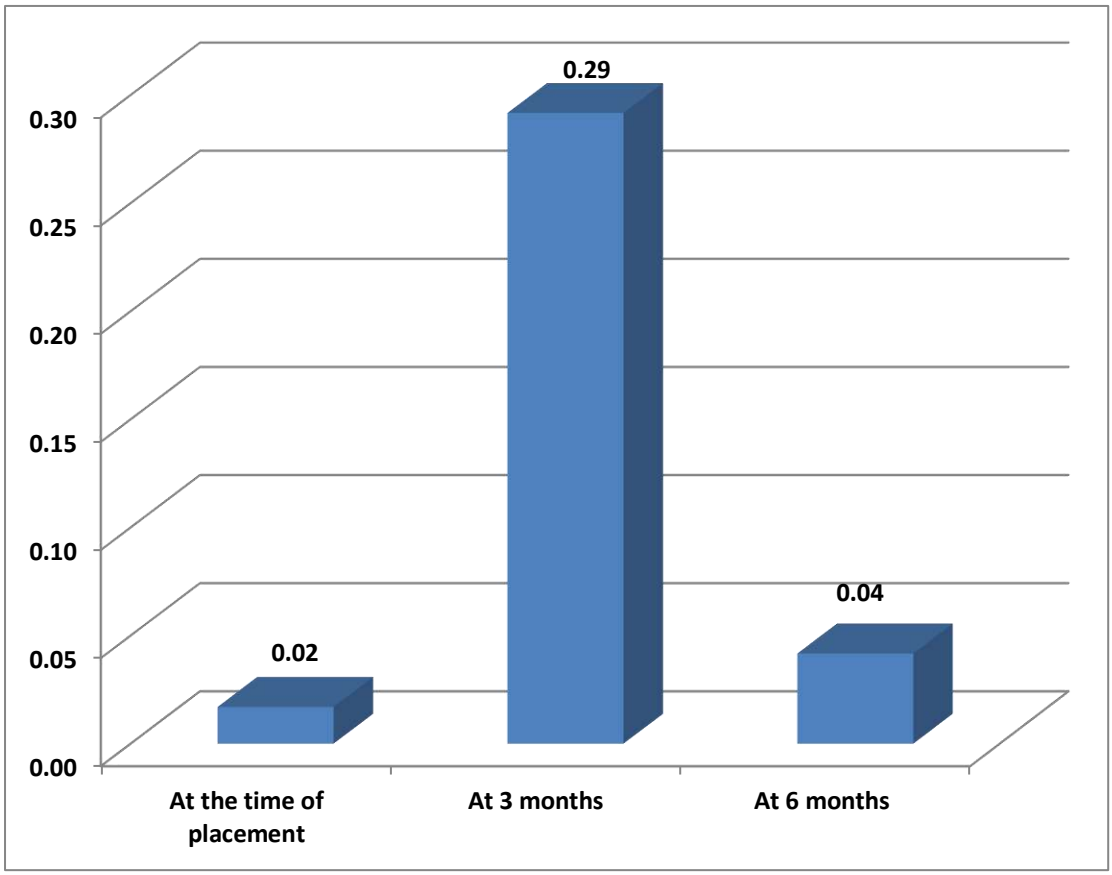

0.30
0.25
0.20
0.15
0.10
0.05
0.00
0.02
0.29
0.04
At the time of placement
At 3 months
At 6 months

Table 4 shows Intragroup comparison of crestal bone loss in Group A on distal side. Significant differences were seen in crestal bone loss from the time of placement to 3 or 6 months or from 3 to 6 months on distal side of Group A when compared using Paired t test as $p<0.05$.

Table 4: Intragroup comparison of crestal bone loss in Group A on distal side

		Mean	N	Std. Deviation	Std. Error Mean	Mean difference	Std dev	P value
Distal	At the time of placement	.0333	6	.05164	.02108	-.17500	.06124	0.001
	At 3 months	.2083	6	.02041	.00833			
	At 3 months	.2083	6	.02041	.00833	-.05833	.03764	0.013
	At 6 months	.2667	6	.04082	.01667			
	At the time of placement	.0333	6	.05164	.02108	-.23333	.04082	<0.0001
	At 6 months	.2667	6	.04082	.01667			

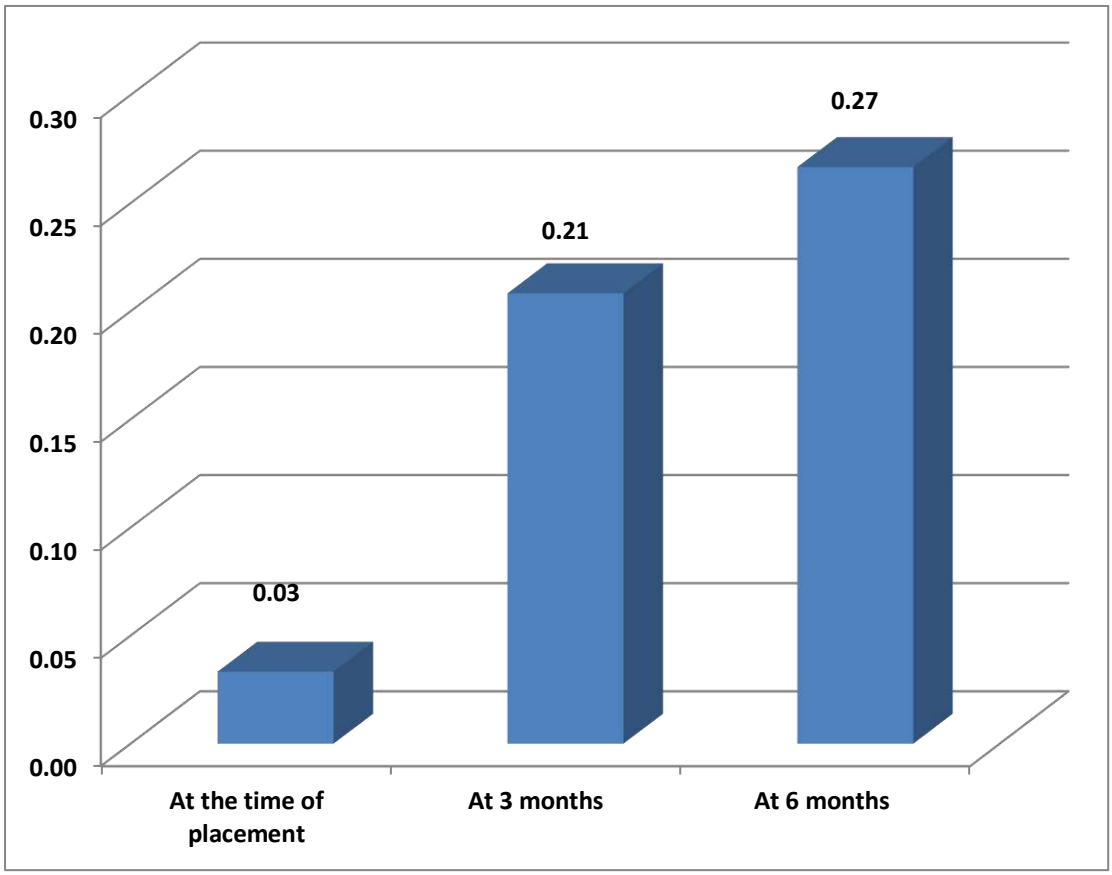

0.30
0.25
0.20
0.15
0.10
0.05
0.00
0.03
0.21
0.27
At the time of placement
At 3 months
At 6 months

Table 5 shows Intragroup comparison of crestal bone loss in Group B on distal side. Significant differences were seen in crestal bone loss from the time of placement to 6 months or from 3 to 6 months on distal side of Group B when compared using Paired t test as $p<0.05$. But no significant differences were seen in the crestal bone loss when compared from the time of placement to 3 months.

Table 5: Intragroup comparison of crestal bone loss in Group B on distal side

		Mean	N	Std. Deviation	Std. Error Mean	Mean difference	Std dev	P value
Distal	At the time of placement	.0417	6	.06646	.02713	-.15833	.29055	0.239
	At 3 months	.2000	6	.24495	.10000			
	At 3 months	.2000	6	.24495	.10000	-.25000	.20736	0.032
	At 6 months	.4500	6	.13784	.05627			
	At the time of placement	.0417	6	.06646	.02713	-.40833	.17440	0.002
	At 6 months	.4500	6	.13784	.05627			

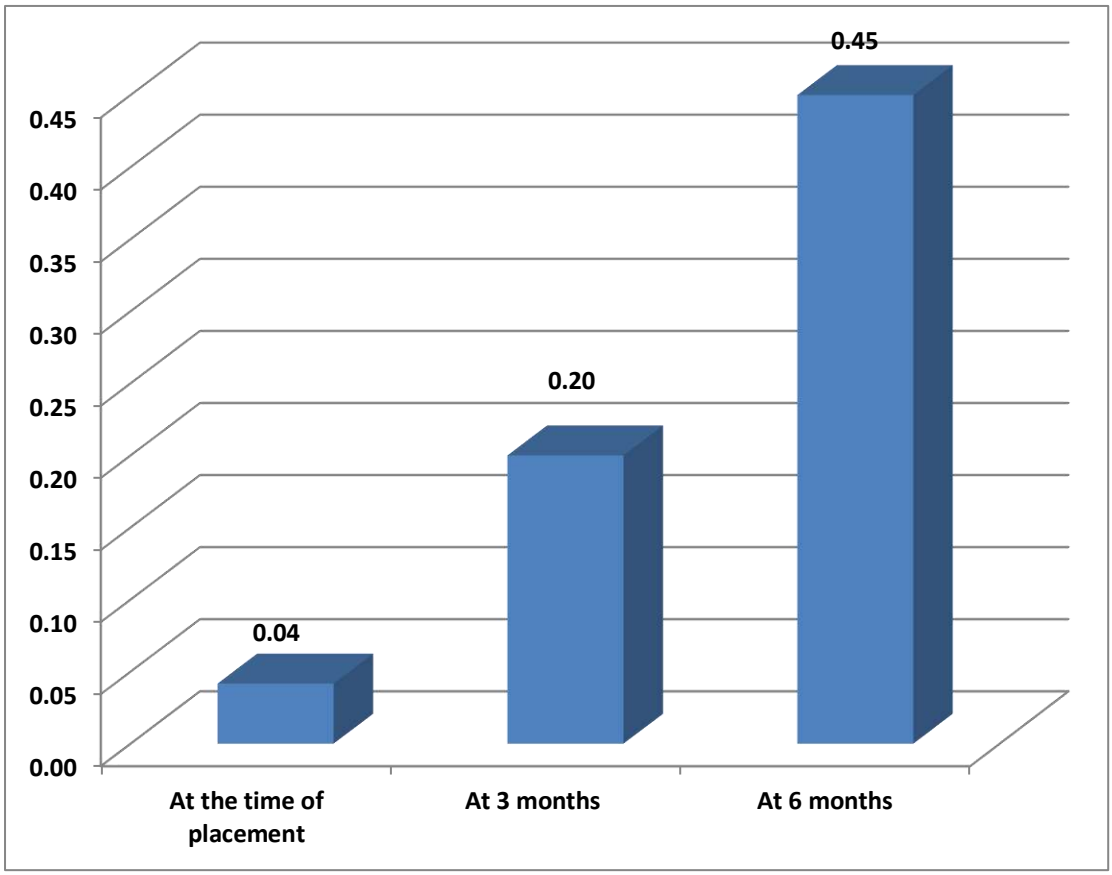

0.45
0.40
0.35
0.30
0.25
0.20
0.15
0.10
0.05
0.00
0.04
0.20
0.45
At the time of placement
At 3 months
At 6 months

Table 6 shows Intragroup comparison of crestal bone loss in Group C on distal side. No significant differences were seen in crestal bone loss from the time of placement to 3 or 6 months or from 3 to 6 months when compared using Paired t test as $p>0.05$ on distal side

Table 6: Intragroup comparison of crestal bone loss in Group C on distal side

		Mean	N	Std. Deviation	Std. Error Mean	Mean difference	Std dev	P value
Distal	At the time of placement	.0250	6	.06124	.02500	-.14167	.22004	0.176
	At 3 months	.1667	6	.18619	.07601			
	At 3 months	.1667	6	.18619	.07601	.16667	.18619	0.080
	At 6 months	.0000	6	.00000	.00000			
	At the time of placement	.0250	6	.06124	.02500	.02500	.06124	0.363
	At 6 months	.0000	6	.00000	.00000			

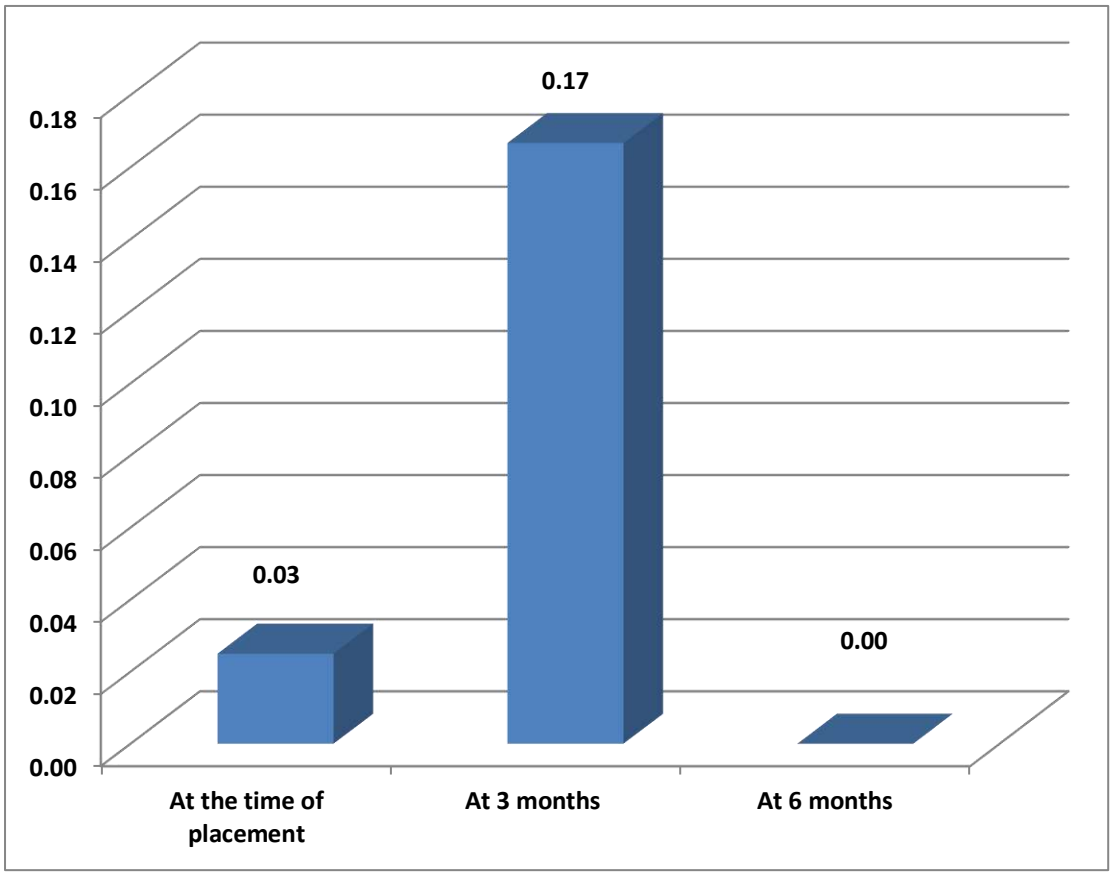

0.18
0.16
0.14
0.12
0.10
0.08
0.06
0.04
0.02
0.00
0.03
0.17
0.00
At the time of placement
At 3 months
At 6 months

Table 7 showed Intragroup comparison of overall crestal bone loss in Group A. Significant difference in overall crestal bone loss in Group A from the time of placement to 3 and 6 months as $p < 0.05$. No significant difference was seen from 3 to 6 months.

Table 7: Intragroup comparison of overall crestal bone loss in Group A

		Mean	N	Std. Deviation	Std. Error Mean	Mean difference	Std dev	P value
Overall	At the time of placement	.03333	6	.051640	.021082	-.208333	102062	0.004
	At 3 months	.2417	6	.06646	.02713			
	At 3 months	.2417	6	.06646	.02713	-.00333	.08641	0.928
	At 6 months	.2450	6	.05050	.02062			
	At the time of placement	.03333	6	.051640	.021082	-.211667	044907	0.0001
	At 6 months	.2450	6	.05050	.02062			

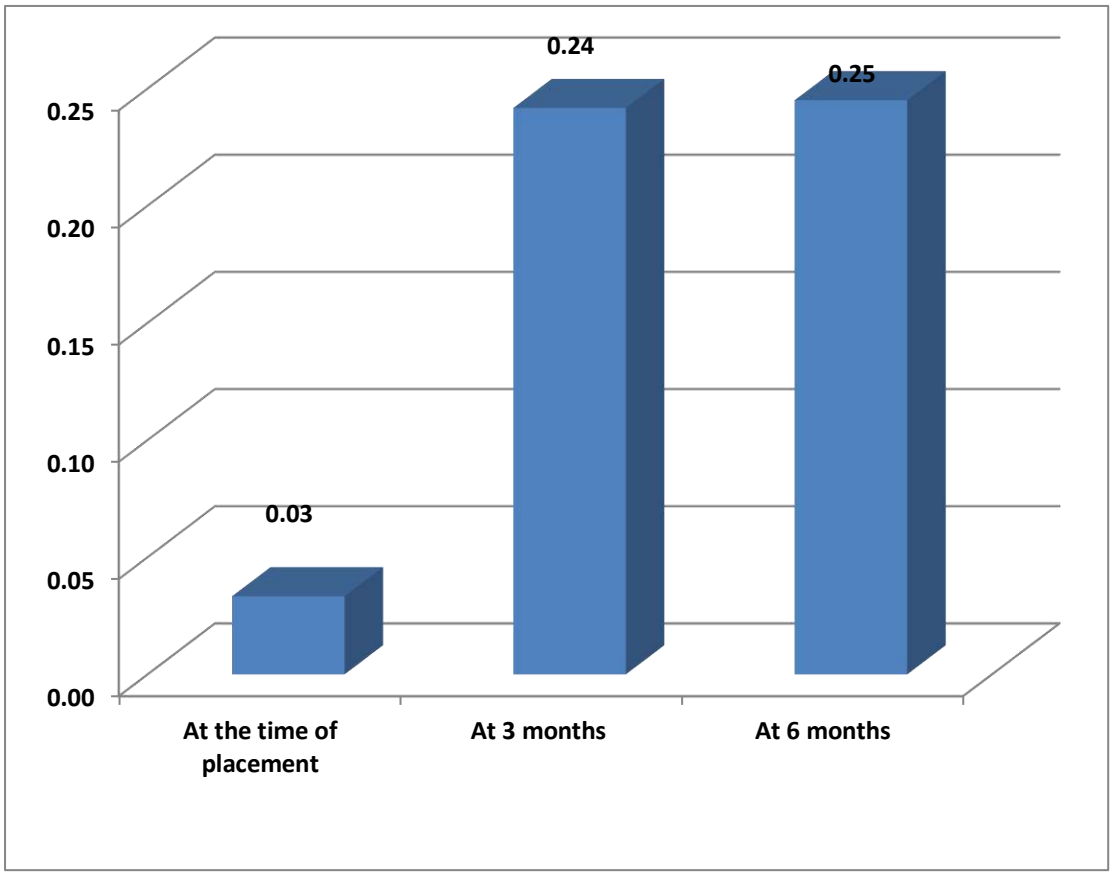
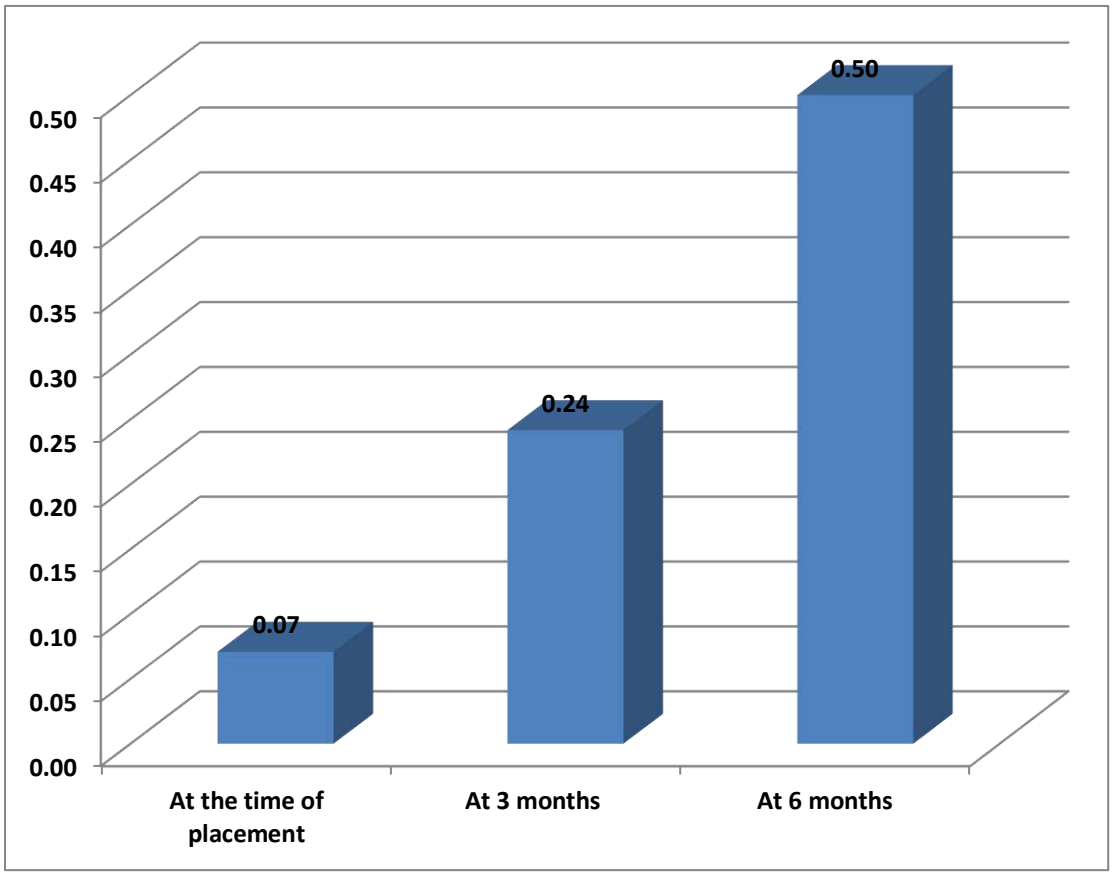

0.24
0.25
0.25
0.20
0.15
0.10
0.03
0.05
0.00
At the time of placement
At 3 months
At 6 months

Table 8 showed Intragroup comparison of overall crestal bone loss in Group B. Significant difference in overall crestal bone loss in Group B from the time of placement to 3 and from 3 to 6 months as $p < 0.05$. No significant difference was seen from the time of placement to 3 months.

Table 8: Intragroup comparison of overall crestal bone loss in Group B

		Mean	N	Std. Deviation	Std. Error Mean	Mean difference	Std dev	P value
Overall	At the time of placement	.07083	6	.116637	.047617	-.170833	.316392	0.243
	At 3 months	.2417	6	.22454	.09167			
	At 3 months	.2417	6	.22454	.09167	-.25833	.24782	0.050
	At 6 months	.5000	6	.14491	.05916			
	At the time of placement	.07083	6	.116637	.047617	-.429167	.134552	0.001
	At 6 months	.5000	6	.14491	.05916			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0.45
0.40
0.35
0.30
0.25
0.20
0.15
0.10
0.05
0.00
0.07
0.24
0.50
At the time of placement
At 3 months
At 6 months

Table 9 showed Intragroup comparison of overall crestal bone loss in Group C. Significant difference in overall crestal bone loss in Group c from the time of placement to 3 and from 3 to 6 months as $p < 0.05$. No significant difference was seen from 3 to 6 months.

Table 9: Intragroup comparison of overall crestal bone loss in Group C

		Mean	N	Std. Deviation	Std. Error Mean	Mean difference	Std dev	P value
Overall	At the time of placement	.00833	6	.020412	.008333	-.220000	.182209	0.032
	At 3 months	.2283	6	.16798	.06858			
	At 3 months	.2283	6	.16798	.06858	.20833	.18819	0.042
	At 6 months	.0200	6	.03162	.01291			
	At the time of placement	.00833	6	.020412	.008333	-.011667	.028577	0.363
	At 6 months	.0200	6	.03162	.01291			

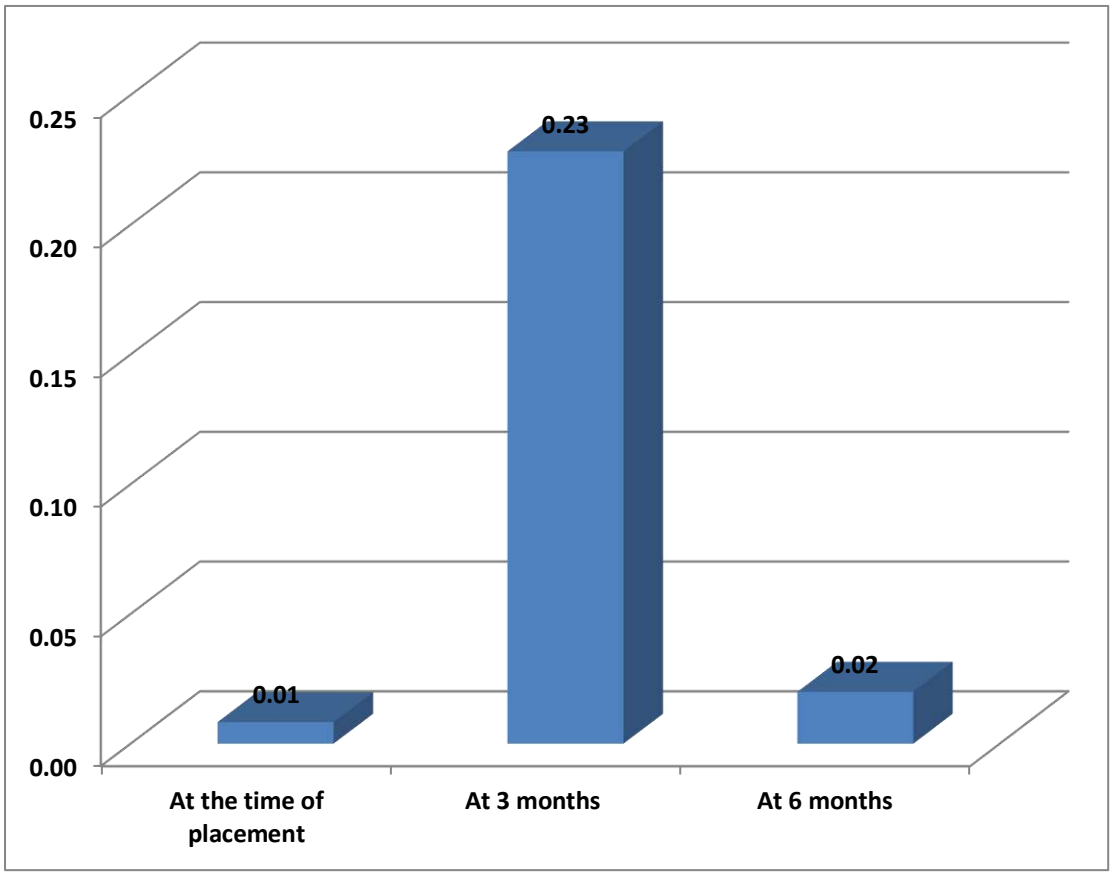
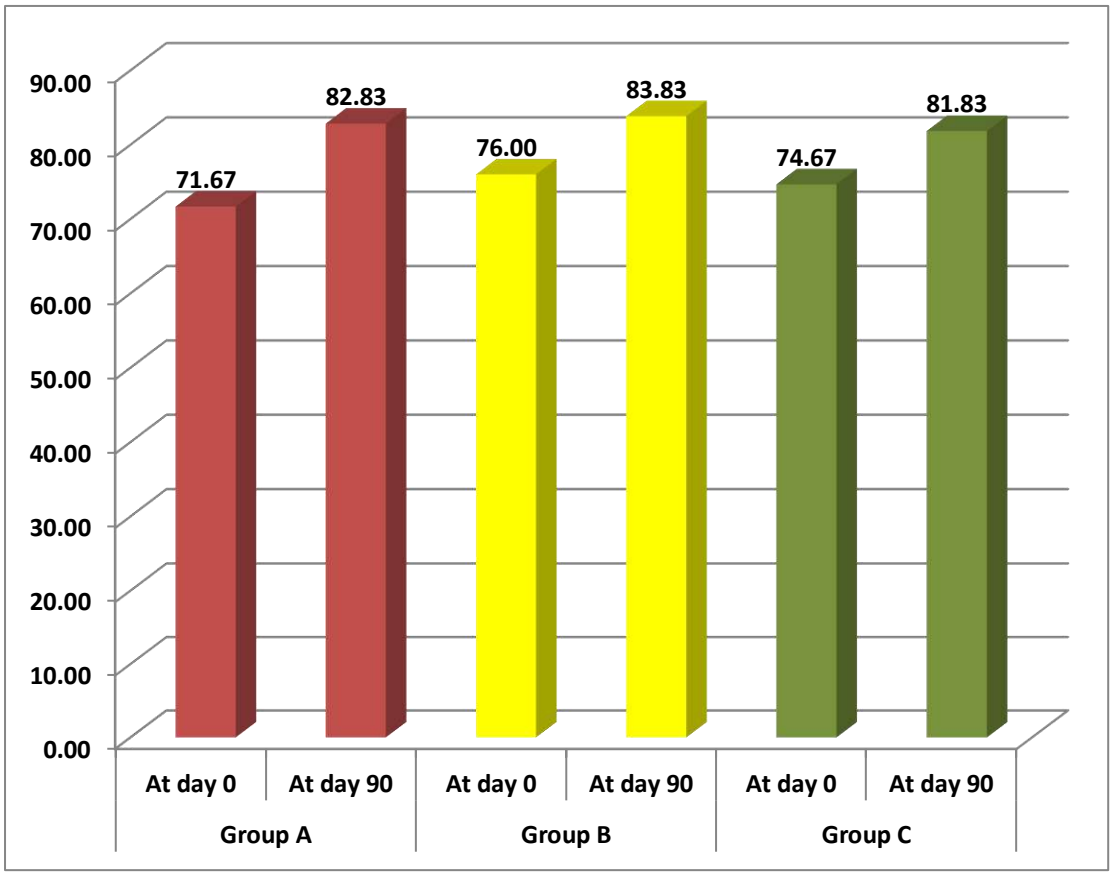

0.25
0.20
0.15
0.10
0.05
0.00
0.23
0.01
0.02
At the time of placement
At 3 months
At 6 months

Table 10 shows Intra group comparison of ISQ. Significant difference was seen in ISQ in Group A, B and C from day 0 to 90 days as $p<0.05$ when compared using Paired t test.

Table 10: Intra group comparison of ISQ

		Mean	N	Std. Deviation	Std. Error Mean	Mean Difference	Std. Deviation	P value
Group A	Atday0	71.667	6	7.2847	2.9740	-11.1667	4.3551	0.002
	Atday90	82.833	6	3.6560	1.4926			
Group B	Atday0	76.000	6	8.5088	3.4737	-7.8333	7.6790	0.055
	Atday90	83.833	6	2.6394	1.0775			
Group C	Atday0	74.667	6	6.5625	2.6791	-7.1667	4.4008	0.010
	Atday90	81.833	6	2.7142	1.1081			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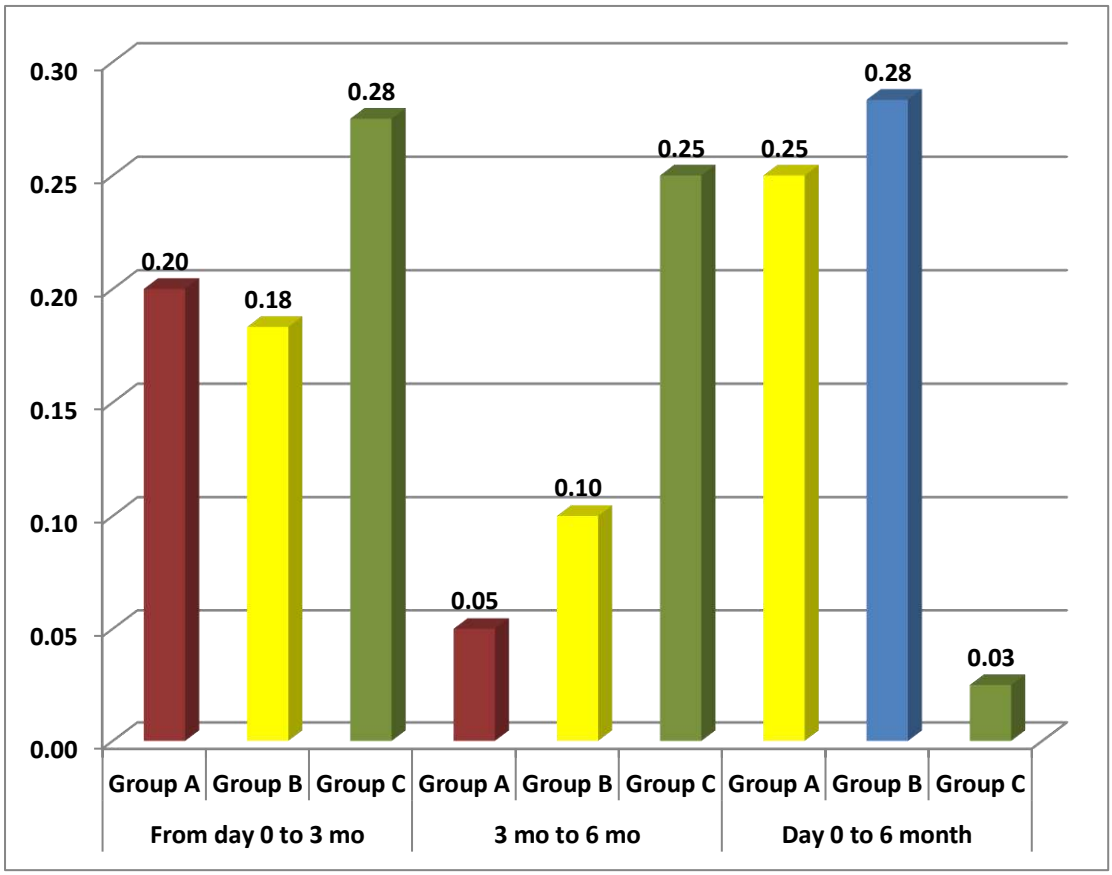
60.00
50.00
40.00
30.00
20.00
10.00
0.00
71.67
82.83
76.00
83.83
74.67
81.83
At day 0
At day 90
At day 0
At day 90
At day 0
At day 90
Group A
Group B
Group C

Table 11 shows Intergroup comparison of crestal bone loss on mesial side, no significant difference was seen in crestal bone loss on mesial side from 0 to 3 months. But from 3 to 6 or from day 0 to 6 months significant difference was seen.

Table 11: Intergroup comparison of crestal bone loss on mesial side

		Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum	P value	Post hoc
					Lower Bound	Upper Bound				
From day 0 to 3 mo	Group A	-.2000	.08944	.03651	-.2939	-.1061	-.35	-.10	0.829	
	Group B	-.1833	.38687	.15794	-.5893	.2227	-.50	.50		
	Group C	-.2750	.26029	.10626	-.5482	-.0018	-.50	.10		
3 mo to 6 mo	Group A	-.0500	.04472	.01826	-.0969	-.0031	-.10	.00	0.018	2-3
	Group B	-.1000	.20000	.08165	-.3099	.1099	-.50	.00		
	Group C	.2500	.28107	.11475	-.0450	.5450	-.10	.50		
Day 0 to 6 month	Group A	-.2500	.07071	.02887	-.3242	-.1758	-.35	-.15	0.014	1-3 2-3
	Group B	-.2833	.23166	.09458	-.5264	-.0402	-.50	.00		
	Group C	-.0250	.06124	.02500	-.0893	.0393	-.15	.00		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0.20
0.15
0.10
0.05
0.00
0.20
0.18
0.28
0.05
0.10
0.25
0.25
0.28
0.03
Group A
Group B
Group C
Group A
Group B
Group C
Group A
Group B
Group C
From day 0 to 3 mo
3 mo to 6 mo
Day 0 to 6 month

Table 12 shows Intergroup comparison of crestal bone loss on distal side. No significant difference was seen in crestal bone loss on distal side from day 0 to 3 months among 3 groups but from 3 to 6 or day 0 to 6 months significant difference was seen as $p<0.05$.

Table 12 : Intergroup comparison of crestal bone loss on distal side

		Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum	P value	Post hoc
					Lower Bound	Upper Bound				
From day 0 to 3 mo	Group A	-.1750	.06124	.02500	-.2393	-.1107	-.25	-.10	0.964	
	Group B	-.1583	.29055	.11861	-.4632	.1466	-.50	.15		
	Group C	-.1417	.22004	.08983	-.3726	.0892	-.50	.15		
3 mo to 6 mo	Group A	-.0583	.03764	.01537	-.0978	-.0188	-.10	.00	0.002	2-3
	Group B	-.2500	.20736	.08466	-.4676	-.0324	-.50	.00		
	Group C	.1667	.18619	.07601	-.0287	.3621	.00	.50		
Day 0 to 6 month	Group A	-.2333	.04082	.01667	-.2762	-.1905	-.30	-.20	<0.0001	1-2
	Group B	-.4083	.17440	.07120	-.5914	-.2253	-.60	-.10		2-3
	Group C	.0250	.06124	.02500	-.0393	.0893	.00	.15		1-3

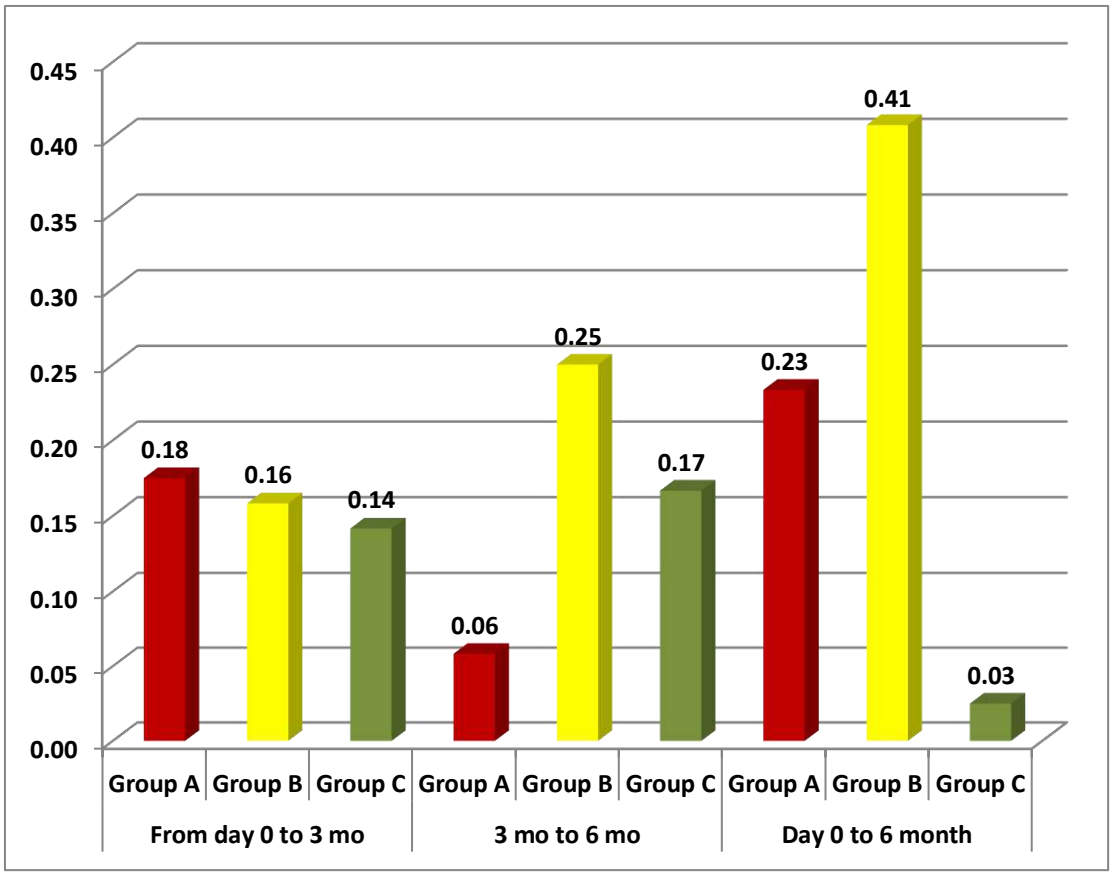
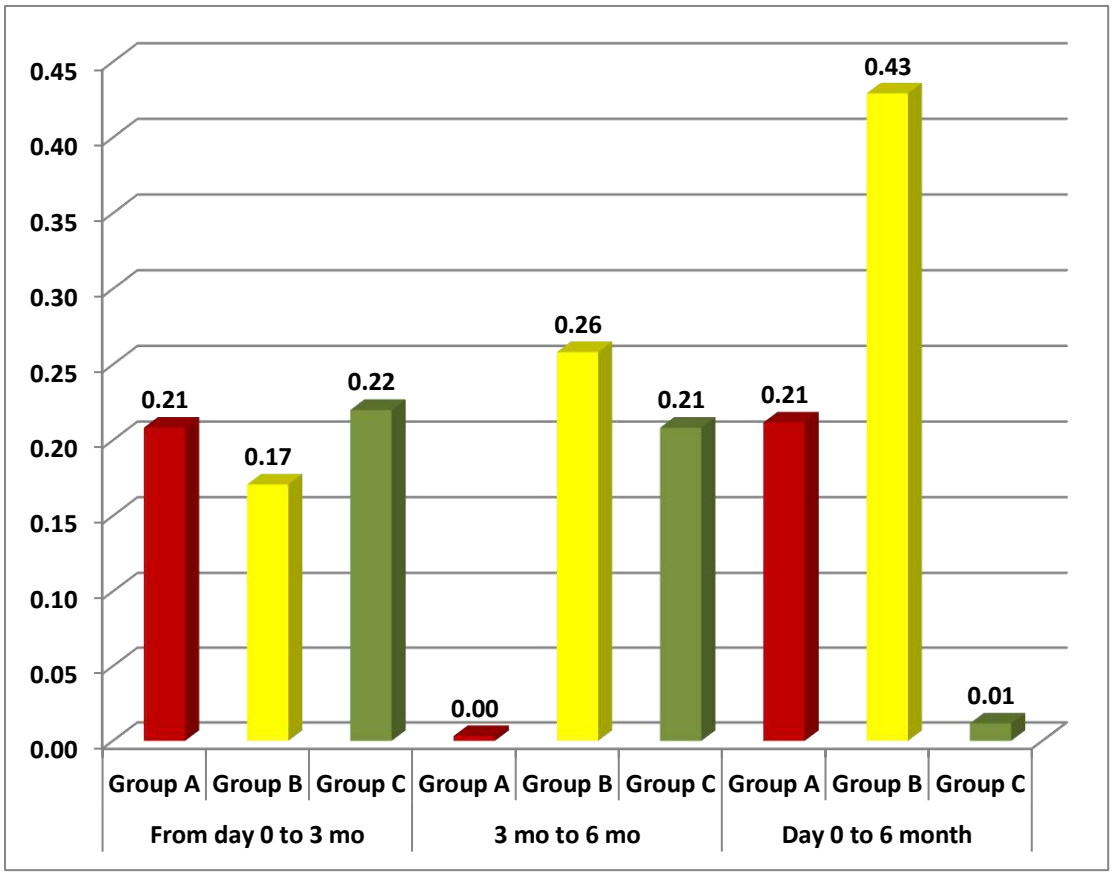

0.45
0.40
0.35
0.30
0.25
0.20
0.15
0.10
0.05
0.00
0.18
0.16
0.14
0.06
0.25
0.17
0.23
0.41
0.03
Group A
Group B
Group C
Group A
Group B
Group C
Group A
Group B
Group C
From day 0 to 3 mo
3 mo to 6 mo
Day 0 to 6 month

Table 13 showed Intergroup comparison of overall crestal bone loss. No significant difference was seen in overall crestal bone loss of three study group from day 0 to 3 months. From 3 months to 6 months significant difference was seen in three study group. Post hoc comparison showed bone loss was found to be more in Group B than Group C.

From 0 to 6 months, significantly lesser bone loss was seen in Group C followed by Group A and B.

Table 13: Intergroup comparison of overall crestal bone loss

		Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum	P value	Post hoc
					Lower Bound	Upper Bound				
From day 0 to 3 mo	Group A	-.2083	.10206	.04167	-.3154	-.1012	-.35	-.10	0.921	
	Group B	-.1708	.31639	.12917	-.5029	.1612	-.50	.30		
	Group C	-.2200	.18221	.07439	-.4112	-.0288	-.50	.05		
3 mo to 6 mo	Group A	-.0033	.08641	.03528	-.0940	.0873	-.10	.15	0.002	2-3
	Group B	-.2583	.24782	.10117	-.5184	.0017	-.70	.00		
	Group C	.2083	.18819	.07683	.0108	.4058	-.05	.50		
Day 0 to 6 month	Group A	-.2117	.04491	.01833	-.2588	-.1645	-.30	-.17	<0.0001	1-2 2-3 1-3
	Group B	-.4292	.13455	.05493	-.5704	-.2880	-.55	-.18		
	Group C	-.0117	.02858	.01167	-.0417	.0183	-.07	.00		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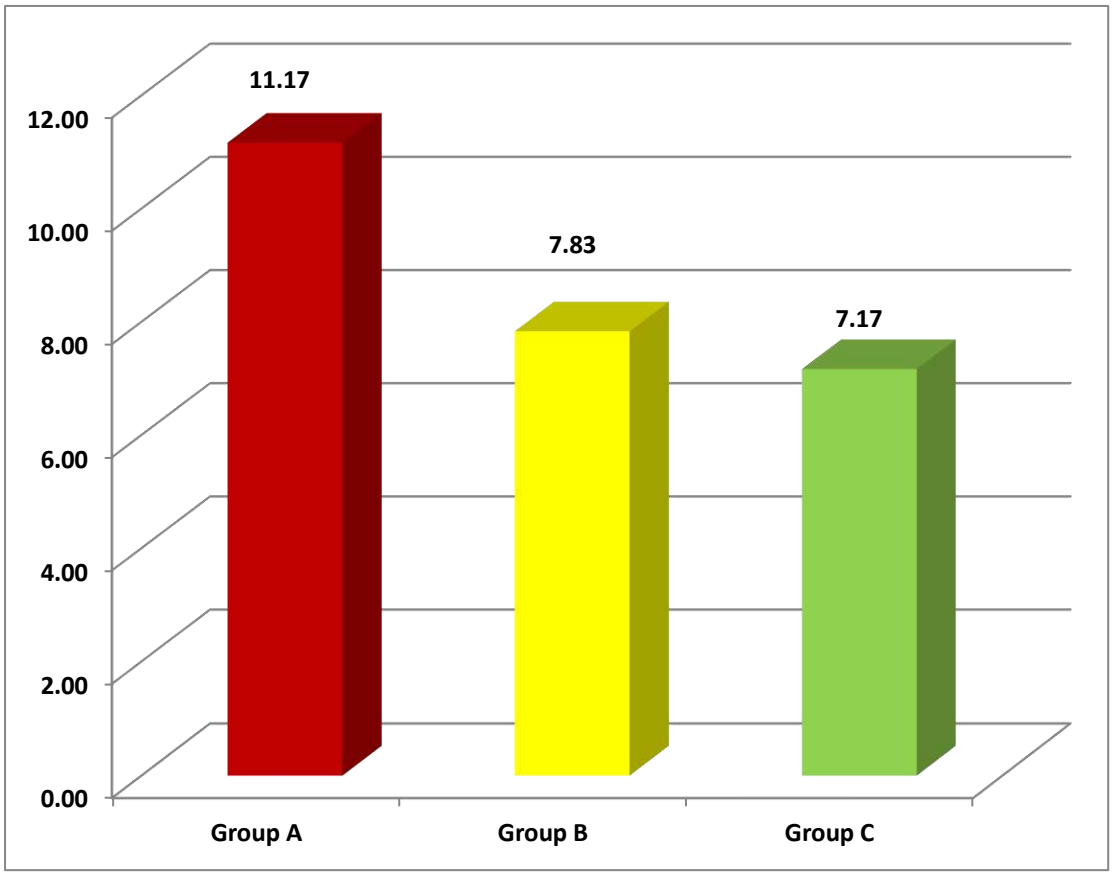
0.40
0.35
0.30
0.25
0.20
0.15
0.10
0.05
0.00
0.21
0.17
0.22
0.00
0.26
0.21
0.21
0.43
0.01
Group A
Group B
Group C
Group A
Group B
Group C
Group A
Group B
Group C
From day 0 to 3 mo
3 mo to 6 mo
Day 0 to 6 month

Table 14 showed Intergroup comparison of difference in ISQ from day 0 to day 90, no significant difference was in ISQ of three groups from day 0 to day 90 when compared using One way Anova test as p >0.05.

Table 14: Intergroup comparison of difference in ISQ from day 0 to day 90

	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
				Lower Bound	Upper Bound		
Group A	-11.1667	4.35507	1.77795	-15.7370	-6.5963	-17.00	-6.00
Group B	-7.8333	7.67898	3.13493	-15.8919	.2253	-23.00	-2.00
Group C	-7.1667	4.40076	1.79660	-11.7850	-2.5484	-14.00	-2.00
P value	0.447						


11.17
7.83
7.17
12.00
10.00
8.00
6.00
4.00
2.00
0.00
Group A
Group B
Group C

In today's era endosseous implants form a major part of dentistry. Research has validated the success of osseointegrated implants as a viable replacement for partial and complete edentulous individuals. Implant's success depends on the course of osseointegration. Osseointegration is a functional and a direct structural connection between the surface of the implant carrying functional loads and the structured live bone[36]. The most commonly used implants are the titanium intraosseous ones which have a biocompatible surface, it allows a persistent connection between the implant and the bone tissue. Following the implant surgery there is a formation of a post-operative wound within the soft and the hard tissues. The relationship which the implant and the surrounding tissue share between them is a dynamic and a continuous process[37, 38.] Vitamin D has seen to play a role in implant dentistry as it affects various stages of osseointegration of intraosseous implants. It has become a vital part of dental surgery due to its role played in the metabolism of the bone tissues and the immune system of the body. Vitamin D functionally influences the osseointegration of implants, which can be observed at three phases during the changes that occur in the tissues following the implant surgery:

• Firstly, there is a wound healing period which is up to a week after the implantation,
• Secondly, there is a period of implant integration with the bone tissue, it lasts from one to three months after implantation,
• Lastly there is a period of stabilization followed by the functional loading of the implant with the prosthesis which is about three to six months.

At each and every phase, the activity of vitamin D holds an extreme importance. The main goal in the 1st phase is to heal the wound. The influence of vitamin D in this phase holds utmost importance as it has an active part to play through a number of processes in the immune system, which is proven by various studies conducted over the last twenty years. Calcitriol, which is the active form of vitamin D is seen to be playing an immunomodulatory role, by stimulating the innate and the acquired immune responses of the body. It alters the innate immunity by amplifying the function of the macrophage cells. It also boosts up the chemotaxis and phagocytosis processes by increasing the production of cathelicidins and defensins peptides. These peptides have their production regulated by vitamin D at the genomic level. This results in an enhanced antibacterial, antifungal and antiviral activity. The immune proteins which are induced by vitamin D can be found in different immune cells like the mast cells, the monocytes, the B lymphocytes, and also the intestinal

enterocytes [39,30,41,42]. In documented studies on the tuberculosis infection, it was proven that at low serum concentrations of 25-hydroxy vit D (<20 ng/ml), the macrophages and the monocytes aren't able to initiate an innate immune response in the body[43]. On the other hand one of the immune-modulatory role of vitamin D also consists of stimulating the acquired response. The enzyme 1-alpha-hydroxylase which is present in the immune cells among the macrophages, also performs local synthesis of calcitriol. This in turn helps in stimulating the action of interferon and also helps in promoting the antimicrobial function of those cells [44].

Schauber J &Gallo R L in their study mentioned the role of calcitriol in transforming T lymphocytes which are altered from the Th1 phenotype to Th2. They also mentioned its role in inducing a decrease production of interleukin 2 (IL-2) which significantly results in an increased production of interleukin 4 (IL-4)[45]. Rutkowski et al., in their study mentioned the role of calcitriol in reducing allergic reactions [24]. Following the implant surgery in the 1st phase vitamin D induces anti-inflammatory cytokines and also reduces the levels of pro-inflammatory cytokines, which helps in minimising the body's response to the surgery. An indication of an important role of vitamin D in the body's immune function clinically is the clear evidence of fact that in a patient with chronic kidney disease there is a dip in concentration of 25-hydroxy vitamin D which leads to immuno-compromised state with more vulnerability to bacterial and viral infections[47]. Following the 1st phase after surgery there is an intensive increase in resorption and osteogenesis for few months, and during this period of osseointegration adequate levels of vitamin D have to be maintained.

Vitamin D influences the body bone tissue by regulating the calcium and phosphate balance in the body. For the proper functioning of bone and tooth mineralization there needs to be a balance in the levels of calcium and phosphates in the bone tissues and the extracellular fluid. Its main function is to magnify the active absorption of these ions which occurs in a bifunctional way. On one hand it modifies the phospholipid membrane structure of the enterocyte cells which increases its permeability to calcium ions [48] and on the other hand, its indirect function is to activate the genes which are responsible for the production of calcium binding proteins. [49]. We know that the reduced blood calcium and hypocalcaemia, stimulates the production of the parathyroid hormone. It results in increased calcium resorption from the bones which results in systematic conditions of osteomalacia or

osteoporosis[48]. Therefore vitamin D holds importance in the calcium metabolism too. Vitamin D has also been seen to be essential for functioning of bone cells by its action on differenciation and maturation of osteoblasts and osteoclasts.

Walika M et al 2012 mentioned the role of the vitamin in increasing osteoid mineralization[50]. This is of utmost importance during the phase of stabilization of the implant, where loading protocol is undertaken with a restorative prosthesis. The function of vitamin D is of utmost importance in reducing inflammation around the implants[51]. It is of an utmost importance to note the function of vitamin D in reducing inflammation around the implant and local induction of immune cells by the production of 1-alpha-hydroxylase by monocytes[51].

Based on all the literature available, it has been a proven fact that there is a strong correlation between vitamin D levels and the dental implants' osseointegration process and its role in regulating all the phases following the implant surgery. These studies have been confirmed so far on the animal models only and theres still a need to conduct more such studies including human studies as well.

Though various techniques and materials have been developed which are capable of high degree of clinical success, yet the ultimate success of implants in the long run depends solely on the efforts of implantologist and dentist together in maintaining the peri-implant tissue health. There are different parameters which have an impact on the integration of implant, most importantly being the initial loss of bone and the bone lost after the integration process. Various Albrektsson T et al in 1986 gave criterion for the implant's success[52]. The most important of all of them is peri–implant bone levels. Hence bone loss both at the initial level and after the implant placement is very important for the evaluation. Similarly implant stability which is an indirect indication of osseointegration is measured utilizing RFA. There are two different stages namely the primary and the secondary stability respectively where the implant stabilities are achieved [53.] The primary stability is the one which is achieved at the time of implant placement and is believed to be related to the level of primary bone contact and mostly comes from mechanical engagement with the cortical bone, while secondary stability is the result of the formation of woven bone, followed by its maturation into lamellar bone which may be reflected in terms of increased ISQ values. It dictates the time of functional loading[53,54,55].

There are various factors which influence implant stability[53].Factors affecting primary stability are bone quantity and quality, surgical technique, implant geometry, length, diameter and surface characteristics. The factors which affect the secondary stability include the primary stability, the remodelling process and the implant's surface characteristics. The RFA can assess implant stability, which is a function of strength of implant bone interface. It may provide a possibility to individualize implant treatment with regards to the healing periods, detecting failing implants, type of prosthetic construction, and if one or two staged procedures should be followed[55, 56, 57, 58]. It can also establish prognostic criteria for long term implant success[53].

The outcome measures of this study were to see the effect of Vitamin D on crestal bone height both mesially and distally around implants placed and their implant stability quotient (ISQ). The crestal bone level was assessed at pre treatment or baseline (day 0), 3rd month and day 6th month treatment and measured in mm. The ISQ was assessed at pre treatment and 90 days post treatment.

A delayed loading protocol was followed and all the implants were loaded after three months from their placement[59, 60]. This was done because early loading could result in fibrous encapsulation of the implant and lack of osseointegration. Also the overheated bone tissue, which undergoes necrosis from the osteotomy preparation, is rapidly remodeled and during that period, the strength of the bone to implant contact is compromised. Lastly, 3 to 6 months healing period is essentially required in order to remodel the bone adjacent to implant bone interface[60].Conventional loading protocol has also been supported by Smukler-Moncler et al. 2002. The required healing time was clinically established as 3 months for mandible and 6 months for maxilla[60].

There are different methods and equipments available and many are being discovered to predict implant stability at the time of placement and at different time periods. Some methods are surgeon's perception, insertion torque, seating torque, percussion testing, reverse torque testing, radiographs, periotest, resonance frequency analysis. Several studies have been conducted to check their authenticity and usefulness. Among them some are based on clinical criteria like clinicians perception as in insertion torque test , reverse torque test, percussion torque test, push out/pull out test, histomorphic data which needs experience of clinician and utilizes more

objective and quantifiable criteria, and are invasive as well, thereof can be used for experimental studies only. So far, only radiographic analysis, periotest and radio frequency analysis (RFA)are the non-invasive methods available. It is impractical for a clinician to detect changes in radiographic bone loss at 0.1 mm resolution and crestal bone changes can be reliably measured without distortion when the central ray of the x ray source is perfectly parallel with the structures of interest so it reduces its reliability. Periotest and RFA both are among the most useful non-invasive methods to predict implant stability although there is indirect evaluation of implant stability and osseointegration. Periotest was originally used for measurement of natural tooth mobility. Major difference between implants and teeth is the presence of pdl fibres in natural conditions, which puts great impact on reliability of periotest. It is not capable of evaluating the mesiodistal stability.

Meredith and co-workers first described the RFA method in 1996. The first generations of RFA utilized, a transducer fabricated from stainless steel or titanium and comprised of an offset cantilever beam with peizo-ceramic elements. The frequency ranged provided was from five to fifteen kHz, which was then received and processed by a frequency resonance analyzer. The other peizo-ceramic element was used to measure the beam ray response. A charged amplifier was then used to amplify the signal which was received. Thereafter an increase in amplification was observed. The resonance frequency at which the peak showed was used to explain the stability of the implant in Hertz (Hz) [61, 62].

Currently two RFA machines are in clinical use: Ostell (Integration Diagnostics) and Implomates (Bio Tech One). The Ostell system has combined the transducer, the computerized analysis and the excitation source into one machine which closely resembles the model used by Meredith. In the early studies, the Hertz was used as the measurement unit. Later, Ostell created the implant stability quotient as a measurement unit in place of hertz. In this system the values which range from three thousand to eight thousand Hertz are translated into the stability quotients ranging from zero to hundred. Higher the value, higher is the stability, lower the value greater is the instability. A successful implant typically has an ISQ value greater than 65. An ISQ <50 may indicate potential failure or increased rate of failure [6, 63, 64.]

In magnetic Ostell (Ostell Mentor TM) the RF between 3500Hz -8500Hz formed from the magnetic fields is converted into ISQ value. The transducer of OSTELL MENTOR TM has a magnetic peg on the top and is fixed to the implant fixture or abutment by a screw below. When magnetic resonance frequency is released from the probe, the magnetic peg is activated. The activated peg starts to vibrate and the magnet induces electric volt into the probe coil and the electric volt is sampled by the magnetic resonance frequency analyzer. The values are expressed as numbers between 1-100 ISQ[64].

Studies show that the predictive value of technique increases when used to monitor implant stability in long term period. Repetitive measurements with the Ostell device real time comparisons of implant stability as implants undergo the osseointegration process and it leads to transformation from mechanical to biological stability. There are numerous studies that have revealed a harmonious relationship between implant stability and osseointegration process [8]. Throughout the osseointegration process, a shift towards higher ISQ value is recorded while high ISQ scores generally characterize successfully osseointegrated implants. Accordingly, implants demonstrating a failure in the osseointegration have shown low ISQ value or a shift towards low values[65].

Based on several studies, it is found that an implant and the surrounding bone functions as a single unit; thus a change in stiffness is considered to represent the change of osseointegration of an implant. Study says that resonance frequencies measured with the Ostell device, are directly proportional to the stiffness of the implant bone interface, and therefore an increase bone implant contact is supposed to result in higher structure stiffness, thus increasing interfacial strength. Going by the studies the 'stiffness' of an implant is a function of its geometric and material composition which includes length, diameter, overall shape and the stiffness of the implant tissue interface depends on the bond made between the surface of the implant and the surrounding bone. Lastly, the stiffness of the surrounding tissue is determined by the ratio of cancellous to cortical bone and the density of the bone with which an implant engages. Stiffness found at the bone implant interface changes over time. As the mechanical properties of implant and bone are generally constant, the factors affecting stiffness remain relatively stable. The only factor that could significantly

influence the stiffness and resonance frequency of the implant would be the exposed implant length, as shown in several studies[9, 62, 66, 67].

Considering this point, it isn't surprising why several authors advocated that increasing bone to implant contact during the healing phase and osseointegration may be reflected in increasing ISQ values over time. However, the correlation between the obtained ISQ scores after the healing period expressing secondary stability and the degree of osseointegration is still under debate with some authors advocating that what the ISQ values really represent is not the real bone to implant contact, but the stiffness of the bone to implant complex[7].

For the morphological evaluation of the implant bone interface is histomorphometric analysis. However recent histomorphometric studies did not find authentic evidence on a possible correlation between ISQ values and level of bone implant contact (BIC). Recent animal studies failed to identify correlation between histomorphometrical parameter of osseointegration and ISQ values[9,68]. Cadaver studies also show no correlation between RFA values and bone density or bone implant contact at the time of implant placement, but these findings might be biased by the fact, that a bone implant interface after placement, does probably respond in a vital, perfused environment than in a bloodless cadaver[69]. Contrary to these views there are studies which support direct correlation between ISQ values and BIC. Hsu et al (2013) used micro CT to investigate how BIC actually influenced the initial implant stability and its correlation with ISQ value and there result demonstrated even stronger correlation. Some other studies also reported in the support of above result. Taking all these studies into account the correlation between the quality of osseointegration or BIC and RFA remains unclear.

Tozum TF et al in 2008 assessed the implant stability by resonance frequency analyzer and the marginal bone loss and revealed that a significant negative correlation existed between implant stability (RFA scores) and marginal bone level[70]. Intra oral peri-apical radiograph (IOPAR), orthopantomogram (OPG), cone beam computerized tomography (CBCT) are the most commonly suggested techniques for implant assessment. Though CBCT has been the gold standard for many years due to the nature of information it provides which is 3-dimensional and most accurate, IOPA with OPG has also been shown to be reasonably accurate for the measurement of

mesio-distal dimension of the edentulous span, proximity of roots of adjacent teeth or implants and distance between the crest of the ridge and the superior border of inferior alveolar canal for the placement of implants. Also CBCT evaluations are expensive and the software isn't readily available and delivers a relatively higher dose of radiation to the individual[71]. Therefore CBCT was limited to the initial screening of the patient for the volumetric bone analysis.

To enable an accurate measurement on a radiograph, radiographic grids were introduced and IOPA with grid in millimeters (mms) was used for further steps in the study. Schwarz and Baird proposed techniques for the incorporation of the grids in the radiographs[72]. Larheim et al reported a high degree of reproducibility using the long cone paralleling technique with a grid overlay for assessing radiographic bone levels around implants[73]. In the grid system, a pre measured grid with a $1mm^2$ framework is placed along with the radiographic film, and the film is exposed. The image obtained has anatomic structures with a grid overlying over it. Even if the image is foreshortened or elongated, the grid lines help in accurately measuring the radiographic length as the distance between the two grids lines on the radiographs is 1 mm.

In the present study correlation of the effect of vitamin D supplementation on radiographic crestal bone level and implant stability was measured the IOPAR grid and by resonance frequency analysis. The study included three groups A, B and C, which comprised of healthy partially edentulous patients, selected amongst the outdoor patients of clinical Department of Prosthodontics & Crown and Bridge at Babu Banarsi Das College of Dental Sciences, Lucknow, Uttar Pradesh.

- GROUP A had 6 patients and was the control group without vitamin D supplementations. (VIT D SUFFICIENCY :30-60 ng/ml)
- Group B had 6 patients which was test group I and without vitamin D supplementation. (VIT D INSUFFICIENCY :20-30 ng/ml)
- Group C had 6 patients and was test group II with vitamin D supplementation. (VIT D INSUFFICIENCY: 20-30 ng/ml)

A standardized protocol for each individual was followed. It included proper case selection, evaluation of the implant site and overall health evaluation, diagnosis and treatment planning, pre-operative protocols, treatment protocol and post-operative procedure and care. Comprehensive medical and medical history was obtained. The patients were properly educated and guided about the treatment. After a thorough patient education regarding the procedure, an informed written consent was taken for the study. The study protocol was approved by the institutional ethical committee of Babu Banarsi Das College of Dental Sciences.

Subjects with one or more missing teeth(partially edentulous) with adequate bone volume, suitable bone quality and sufficient inter-arch apace to accommodate the required restorative component as well as stable dental and periodontal status were included in the study[74,75]. Subjects with history of any systemic diseases, conditions or medications which may otherwise interfere with the results of study as well as patients with any known allergy to any drugs or materials used in the study were excluded. Similarly current smokers, subjects with para-functional habits, completely edentulous patients, or sites with infection were also not included [74, 76, 77] .

Patients were asked mandatorily to follow the oral hygiene and care protocol for phase I therapy. Only those patients were selected who had their plaque and gingival indices lesser than twenty percents[78]. Implants were subsequently placed and the outcome measures of this study were to see the effect of Vitamin D on crestal bone height both mesially and distally around implants placed and their implant stability quotient (ISQ). The crestal bone level was assessed at pre-treatment or baseline (day 0), 3rd month and day 6th month treatment and measured in mm. The ISQ was assessed at pre-treatment and 90 days post treatment. The objective of the study was to observe the crestal bone height and implant stability among the borderline and the optimum level groups with one test group supplemented with vitamin D and compare the outcome measures of the period.

A delayed loading protocol was followed and all the implants were loaded after three months from their placement.

The crestal bone loss(mm) at mesial over the periods for GROUP A, B , and C is summarized in Table 1,2 and 3 respectively and also depicted in the graphs following the table.

The crestal bone loss(mm) at distal over the periods for GROUP A, B , and C is summarized in Table 4,5 and 6 respectively and also depicted in the graphs following the table.

The overall crestal bone loss in Group A is shown in Table 7. Significant difference was seen in overall crestal bone loss in Group A from the time of placement to 3 and 6 months as $p < 0.05$. No significant difference was seen from 3 to 6 months.

The overall crestal bone loss in Group B is summarized in table 8. Significant difference in overall crestal bone loss in Group B from the time of placement to 3 and from 3 to 6 months is seen as $p < 0.05$. No significant difference was seen from the time of placement to 3 months.

The overall crestal bone loss in Group C is summarized in table 9. Significant difference in overall crestal bone loss in Group C from the time of placement to 3 and from 3 to 6 months is seen as $p < 0.05$. No significant difference was seen from 3 to 6 months.

Intra group comparison of ISQ is summarised in Table 10. Significant difference was seen in ISQ in Group A, B and C from day 0 to 90 days as $p<0.05$ when compared using Paired t test.

Intergroup comparison of crestal bone loss on mesial side is summerised in Table 11. No significant difference was seen in crestal bone loss on mesial side from 0 to 3 months but from 3 to 6 or from day 0 to 6 months significant difference was seen.

Intergroup comparison of crestal bone loss on distal side is summarized in Table 12. No significant difference was seen in crestal bone loss on distal side from day 0 to 3 months among the three groups but from 3 to 6 or day 0 to 6 months significant difference was seen as $p<0.05$.

Intergroup comparison of overall crestal bone loss is summarized in table 13. No significant difference was seen in overall crestal bone loss of three study group from day 0 to 3 months. But from 3 months to 6 months significant difference was seen in three study group.

Post hoc comparison showed bone loss was found to be more in Group B than Group C.

From 0 to 6 months, significantly lesser bone loss was seen in Group C followed by Group A and B.

Intergroup comparison of difference in ISQ from day 0 today 90is summarized in Table 14. No significant difference was in ISQ of three groups from day 0 to day 90 when compared using One way Anova test as $p > 0.05$.

The present in-vivo study assessed comparative evaluation of vitamin D levels on crestal bone height and implant stability. Evaluations were carried out at baseline i.e., at the day of implant placement, 3rd month and 6th month respectively. Following conclusions were drawn:

- No significant difference was seen in overall crestal bone loss of three study group from day 0 to 3 months. From 3 months to 6 months significant difference was seen in three study groups, bone loss was found to be more in Group B than Group C. From 0 to 6 months, significantly lesser bone loss was seen in Group C followed by Group A and B.
- No significant difference was seen in Implant Stability Quotient (ISQ) scores of three groups from day 0 to day 90.

Within the limitations of this study, it can be concluded that there is statistically significant positive association of vitamin D level on crestal bone height but there is no such association between vitamin D levels and implant stability.

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

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"Comparative Evaluation of Vitamin D Levels on Crestal Bone Height and Implant Stability."** submitted by **Dr Aakanksha Pandey** Post graduate student from the **Department of Prosthodontics and Crown & Bridge** as part of MDS Curriculum for the academic year 2018-2021 with the accompanying proforma was reviewed by the Institutional Research Committee present on **26th November 2018** at BBDCODS.

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

Prof. Vandana A Pant
Co-Chairperson

Prof. B. Rajkumar
Chairperson

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

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

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

IEC Code: 37 **BBDCODS/01/2019**

Title of the Project: Comparative Evaluation of Vitamin D Levels on Crestal Bone Height and Implant Stability.

Principal Investigator: Dr. Aakanksha Pandey **Department:** Prosthodontics, Crown & Bridge

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

Type of Submission: New, MDS Project Protocol

Dear Dr. Aakanksha Pandey,

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

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

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

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

Forwarded by:

Lakshmi Bala
21/01/19

(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

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

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow-227105, INDIA

PARTICIPANT INFORMATION DOCUMENT (PID)

1. Study Title

COMPARATIVE EVALUATION OF VITAMIN D LEVELS ON CRESTAL BONE HEIGHT AND IMPLANT STABILITY

2. Invitation Paragraph

You are being invited to take part in a research 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 in the study.

3. What is the purpose of the study?

The aim of this study is to observe the effect of vitamin D supplementation on crestal bone height changes and its effect on implant stability.

The purpose of this study is:

- To compare crestal bone height among participants with optimal levels of vitamin D, not supplemented with vitamin D,
- In participants with borderline levels of vitamin D, not supplemented with vitamin D,
- In participants with borderline levels of vitamin D, supplemented with vitamin D,
- And to compare the implant stability among the three groups.

4. Why have I been chosen?

You have been chosen because you are fulfilling one of the criteria's for the study.

5. Do I have to take part?

The participation in the research is entirely voluntary. If you decide to take part you will be given this information sheet to keep and be asked to withdraw anytime and without giving a reason.

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

Implants will be placed in the area of missing teeth, x-rays, blood test and vitamin D test will be conducted and you will be required to follow up at intervals of 3 months and 6 months respectively.

7. What do I have to do?

There will be no lifestyle restrictions and there are no dietary restrictions for you. You can drive, drink (not at the time of study) and can take part in sports. You can consume all sorts of food products and beverages. However you should refrain from consuming alcohol and tobacco. Consumption of alcohol and tobacco can be a risk factor for your health and the implant treatment and be a negative factor for the study.

8. What is the procedure that is being tested?

-The procedure evaluates the effect of vitamin D level on the crestal bone height and implant stability .The procedure comprises of placing an implant and additionally supplementation of vitamin D in the borderline levels participants.

9. What are the interventions for the study?

There are no interventions to this study.

10. What are the side effects of taking part?

They are no side effects as such. Post operative pain and swelling may occur associated with implant placement which will eventually subside with proper medications. Patient should stick to the drug dosage prescribed to him after medical consultation. There will be a regular monitoring of the vitamin D levels. As vitamin D

supplementation is being given to the borderline levels there are no chances of toxicity or side effects.

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

There will be no potential disadvantages and risks of taking part in the study.

12. What are the possible benefits of taking part?

The quality of life of the patient will be improved by rehabilitation with the implant prosthesis.

13. What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the research being studied. If this happens, the patient will be informed about it and it will be discussed with the participant whether you want to continue in the study. If you decide to withdraw, your researcher/investigator will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

14. What happens when the research study stops?

If the study finishes/stops before the stipulated time, it will be explained to the participant.

15. What if something goes wrong?

Nothing is meant to go wrong intentionally/unintentionally as the procedure of implant will be done under the strict guidance of staff mentors and the seniors at the workplace and the procedure will be performed after medical consultation. If incase it goes wrong we can remove the implant and graft with suitable prosthesis.

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

All the information collected about you for the study will be kept strictly confidential.

If you consent to take part in the research any of your medical records may be inspected by the doctors and the staff concerned and for purposes of analyzing the

results. They may also be looked at by people from regulatory authorities/IEC to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the laboratory/centre.

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

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

The results of the study maybe needed for reports or reputed publications for the use of general practitioners but the patient's identity will be kept confidential.

18. Who is organizing the research?

The research study is being conducted by Dr. Aakanksha Pandey (junior resident) at the Prosthodontics department of Babu Banarsi Das College of Dental Sciences under the guidance of Dr. Manoj Upadhyay (Guide) and Dr. Amrit Tandan (HOD).

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

If you wish to go through the results of the study it will be available to you.

20. Who has reviewed the study?

The study has been reviewed by the head of the department, IRC and IEC respectively.

21. Contact for further information:

DR. AAKANKSHA PANDEY
JUNIOR RESIDENT
DEPT. OF PROSTHODONTICS,
BBDCODS, LUCKNOW
Email: akki2809@gmail.com
Phone: 8299395927

DR.LAKSHMI BALA
MEMBER SECRETARY,
ETHICS COMMITTEE OF THE INSTITUTION
BBDCODS, LUCKNOW
Email: bbdcods.iec@gmail.com

Thank you for taking part in the study.

Signature of PI -

Name-

Date-

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES

(बाबू बनारसी दास विश्वविद्यालय)

बीबीडी सिटी, फैजाबाद रोड, लखनऊ -227105 , INDIA

प्रतिभागी जानकारी दस्तावेज़ (पीआईडी)

1. अध्ययन शीर्षक

विटामिन डी के स्तर पर (CRESTAL) हड्डी ऊंचाई और इम्प्लांट स्थिरता की तुलनात्मक मूल्यांकन

2. निमंत्रण अनुच्छेद

आपको एक शोध 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 अध्ययन में भाग लेना चाहते हैं या नहीं ।

3. अध्ययन का उद्देश्य क्या है?

इस अध्ययन का उद्देश्य क्रस्टल की हड्डी की ऊंचाई में परिवर्तन पर विटामिन डी पूरकता के प्रभाव और प्रत्यारोपण स्थिरता पर इसके प्रभाव का निरीक्षण करना है।

इस अध्ययन का उद्देश्य है:

- विटामिन डी के इष्टतम स्तरों के साथ प्रतिभागियों के बीच क्रस्टल हड्डी की ऊंचाई की तुलना करने के लिए, विटामिन डी के साथ पूरक नहीं है,

- विटामिन डी के पूरक नहीं, विटामिन डी के बॉर्डरलाइन स्तर वाले प्रतिभागियों में,

- विटामिन डी के पूरक विटामिन डी के बॉर्डरलाइन स्तर वाले प्रतिभागियों में,- और तीन समूहों के बीच प्रत्यारोपण स्थिरता की तुलना करने के लिए।

4. मुझे क्यों चुना गया है?
आपको इसलिए चुना गया है क्योंकि आप किसी एक को पूरा कर रहे हैं अध्ययन के लिए मानदंड ।

5. क्या मुझे भाग लेना है?
अनुसंधान में भागीदारी पूरी तरह से स्वैच्छिक है। यदि आप भाग लेने का निर्णय लेते हैं तो आपको यह सूचना पत्र रखने के लिए दिया जाएगा और बिना कारण बताए किसी भी समय वापस लेने के लिए कहा जाएगा ।

6. भाग लेने पर मेरा क्या होगा ?
प्रत्यारोपण लापता दांत, एक्स रे, रक्त परीक्षण और विटामिन डी परीक्षण के क्षेत्र में रखा जाएगा आयोजित किया जाएगा और आप क्रमश: 3 महीने और 6 महीने के अंतराल पर अनुवर्ती कार्रवाई करने के लिए आवश्यक हो जाएगा।

7. मुझे क्या करना है?
कोई जीवन शैली प्रतिबंध नहीं होगा और यहां आपके लिए कोई आहार प्रतिबंध नहीं हैं। आप ड्राइव कर सकते हैं, पी सकते हैं (अध्ययन के समय नहीं) और खेल में भाग ले सकते हैं। आप सभी प्रकार के खाद्य उत्पादों और पेय पदार्थों का सेवन कर सकते हैं। हालांकि आपको शराब और तंबाकू का सेवन करने से बचना चाहिए। शराब और तंबाकू का सेवन आपके स्वास्थ्य और प्रत्यारोपण उपचार के लिए जोखिम कारक हो सकता है और अध्ययन के लिए नकारात्मक कारक हो सकता है।

8. वह प्रक्रिया क्या है जिसका परीक्षण किया जा रहा है?
-प्रक्रिया क्रस्टल की हड्डी की ऊंचाई और प्रत्यारोपण स्थिरता पर विटामिन डी के स्तर के प्रभाव का मूल्यांकन करती है। प्रक्रिया इम्प्लांट और साथ ही सीमा रेखा के स्तर भागीदार रों में विटामिन डी की पूरकता रखने शामिल हैं।

9. अध्ययन के लिए हस्तक्षेप क्या हैं?
इस अध्ययन में सर्जिकल प्रत्यारोपण हस्तक्षेप है ।

10. भाग लेने के दुष्प्रभाव क्या हैं?
वे इस तरह के कोई दुष्प्रभाव नहीं हैं। पोस्ट ऑपरेटिव दर्द और सूजन प्रत्यारोपण प्लेसमेंट से जुड़ी हो सकती है जो अंततः उचित दवाओं के साथ कम हो जाएगी। रोगी को चिकित्सकीय परामर्श के बाद उसके द्वारा निर्धारित दवा की खुराक से चिपके रहना चाहिए। विटामिन डी के स्तर का एक नियमित निगरानी होगी। विटामिन डी के रूप में सीमावर्ती स्तरों पर पूरकता दी जा रही है जिससे विषाक्तता या दुष्प्रभाव होने की कोई संभावना नहीं है।

11. भाग लेने के संभावित नुकसान और जोखिम क्या हैं?
S t u d y में भाग लेने का कोई संभावित नुकसान और जोखिम नहीं होगा ।

12. भाग लेने के संभावित लाभ क्या हैं?
रोगी के जीवन की गु ई गुणवत्ता प्रत्यारोपण कृत्रिम अंग के साथ पुनर्वास द्वारा सुधार किया जा जाएगा।

13. यदि नई जानकारी उपलब्ध हो जाए तो क्या होगा?

कभी-कभी एक शोध परियोजना के दौरान, अध्ययन किए जा रहे शोध के बारे में नई जानकारी उपलब्ध हो जाती है। यदि ऐसा होता है, तो रोगी को इसके बारे में सूचित किया जाएगा और यह प्रतिभागी के साथ एड पर चर्चाकरेगा कि क्या आप अध्ययन जारी रखना चाहते हैं। यदि आप वापस लेने का निर्णय लेते हैं, तो आपके शोधकर्ता / अन्वेषक आपकी निकासी की व्यवस्था करेंगे। यदि आप अध्ययन जारी रखने का निर्णय लेते हैं, तो आपको एक अद्यतन सहमति पत्र पर हस्ताक्षर करने के लिए कहा जा सकता है।

14. जब शोध अध्ययन रुक जाता है तो क्या होता है?

यदि अध्ययन निर्धारित समय से पहले समाप्त / बंद हो जाता है, तो उसे प्रतिभागी को समझाया जाएगा।

15. अगर कुछ गलत हो जाए तो क्या होगा?

जानबूझकर / अनजाने में कुछ भी गलत करने का मतलब नहीं है क्योंकि प्रत्यारोपण की प्रक्रिया कर्मचारियों के संरक्षक और कार्यस्थल पर सेन iors के सख्त मार्गदर्शन में की जाएगी और चिकित्सा परामर्श के बाद प्रक्रिया का प्रदर्शन किया जाएगा। अगर यह गलत हो जाता है तो हम प्रत्यारोपण और ग्राफ्ट को उपयुक्त कृत्रिम अंग के साथ हटा सकते हैं।

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

आल थे अध्ययन के लिए आपके बारे में एकत्र की गई जानकारी को कड़ाई से गोपनीय रखा जाएगा।

यदि आप अनुसंधान में भाग लेने के लिए सहमति देते हैं, तो आपके किसी भी मेडिकल रिकॉर्ड का निरीक्षण डो सेक्टर्स और संबंधित कर्मचारी द्वारा किया जा सकता है और परिणामों के विश्लेषण के प्रयोजनों के लिए। वे यह भी देख सकते हैं कि नियामक अधिकारियों / IEC के लोगों ने यह जांचने के लिए कि अध्ययन सही ढंग से किया जा रहा है। हालाँकि, आपके नाम का खुलासा प्रयोगशाला / केंद्र के बाहर नहीं किया जाएगा।

अनुसंधान के दौरान आपके बारे में एकत्र की गई सभी जानकारी को कड़ाई से गोपनीय रखा जाएगा। कोई भी जानकारी जो प्रयोगशाला को छोड़ देती है, आपका नाम और पता हटा दिया जाएगा ताकि आपको उससे पहचाना नहीं जा सके।

17. शोध अध्ययन के परिणामों का क्या होगा?

सामान्य चिकित्सकों के उपयोग के लिए रिपोर्ट या प्रतिष्ठित प्रकाशनों के लिए आवश्यक अध्ययन के परिणाम लेकिन मरीज की पहचान को गोपनीय रखा जाएगा।

18. अनुसंधान का आयोजन कौन कर रहा है?

शोध अध्ययन डॉ। आकांक्षा द्वारा किया जा रहा है पी Andey (जूनियर निवासी) बाबू के पी rosthodontics विभाग में डॉ। मनोज के मार्गदर्शन में बनारसी दास कॉलेज ऑफ डेंटल साइंसेज उपाध्याय (गाइड) और डॉ। अमृत टंडन(HOD & Co-guide) ।

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

यदि आप अध्ययन के परिणामों से गुजरना चाहते हैं तो यह आपके लिए उपलब्ध होगा।

20. अध्ययन की समीक्षा किसने की?
अध्ययन की समीक्षा विभाग के प्रमुख , आईआरसी और आईईसी द्वारा क्रमशः की गई है।

21. अधिक जानकारी के लिए संपर्क करें:
डॉ। आकांक्षा पांडे
जूनियर रेजिडेंट
विभाग। PROSTHODONTICS की,
BBDCODS, LUCKNOW
ईमेल: akki2809@gmail.com
फोन: 8299395927

DR.LAKSHMI बाला
सदस्य सेक्रेटरी,
इंस्टीट्यूट ऑफ इंश्योरेंस
BBDCODS, LUCKNOW
ईमेल: bbdcods.iec@gmail.com

धन्यवाद आप वें ई अध्ययन में भाग लेने के लिए ।

पीआई का हस्ताक्षर -

नाम-

दिनांक-

Consent Form (English)

Title of the Study .....

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

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

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 Acceptable representative Date.....

सहमति पत्र

अध्ययन शीर्षक.....

अध्ययन संख्या.....

प्रतिभागी के पूर्ण नाम.....

जन्म तिथि / आयु.....

प्रतिभागी का पता .....

फोन नं. और ई-मेल पता .....

योग्यता .....

व्यवसाय: छात्र / स्व कार्यरत / सेवा / ग्रहिणी .....

अन्य (उचित रुप मे टिक करें) .....

प्रतिभागी की वार्षिक आय .....

प्रत्याशीयो के नाम और प्रतिभागी से संबंध...(परीक्षण से संबंधित मौत के मामले मे मुआवजे के प्रयोजन के लिए)

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

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

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

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

5. भविष्य के अनुसंधानें के लिए भंडारित नमूना (ऊतक/रक्त) पर अध्ययन के लिए अपनी सहमति देता हुँ।

हॉ [ ] नही [ ] अनउपयुक्त [ ]

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

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

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

अध्ययन अन्वेषक का नाम .....

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

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

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

Case History Sheet

Name: Tel:

Age: Sex: Email:

Address:

Chief complaint:

History of present illness:

Past Medical History

Please tick Yes or No box	Yes	No
Diabetes		
Hypertension		
Anemia		
Ischemic heart disease		
Myocardial infarction		
Congenital heart disease		
Respiratory diseases		
GIT disorders		
Renal disorders		
Hepatic disorders		
Epilepsy		
Any other medical disorders		

Drug allergies:

Current medications:

Previous surgeries or hospital admissions if any:

Personal history:

Occupation:

Habits: (Smoking, Alcohol, Pan chewing, Tobacco chewing, Drugs)

General examination:

Intra oral examination:

Teeth present:

3 7 6 5 4 3 2 1	1 2 3 4 5 6 7 8
3 7 6 5 4 3 2 1	1 2 3 4 5 6 7 8

Tooth absent:

3 7 6 5 4 3 2 1	1 2 3 4 5 6 7 8
3 7 6 5 4 3 2 1	1 2 3 4 5 6 7 8

Periodontal status:

Any Existing prosthesis:

Interarch space:

Existing vertical dimension of occlusion:

Maxillomandibular arch relations:

Temporomandibular joint status:

Arch form:

Lip line:

At rest:

During speech:

Soft tissue support:

Evaluation of existing natural dentition:

1. Crown root ratio:
2. Periodontal condition:
3. Alignment:
4. Restorative needs:

Interarch relationships:

a. Occlusion:

b. Jaw relation:

c. Temporomandibular joint function:

Evaluation of edentulous ridge:

1. Amount of resorption
2. soft and hard tissue anatomy
3. Deficiencies:
4. Limitations:

Relationship to anatomical structures:

Inferior alveolar canal:

Mental foramen:

Maxillary sinus:

Nasal cavity:

Radiographic evaluation:

Intra oral periapical radiograph:

Orthopantomogram:

Blood Tests

CBC

BT, CT, PT

RBS

Type of stent prepared:

Radiographic Surgical Dual Purpose

Bone mapping:

Mucosal thickness-

1. Crestal:
2. Buccal:
3. Lingual:

Evaluation of available bone:

1. Length:
2. Height:
3. Width:
4. Density:

Diagnosis:

Treatment Planning:

Hard and soft tissue modifications:

Grafts

Implant selection rationale with diagram:

1. Type
2. Number
3. Placement position (s)

MASTER CHART READINGS TABLES

GROUP A											
S No.	Crestal Bone Level /loss (mm)									Implant Stability Quotient (ISQ) (Score)	
	Mesial			Distal			Overall (Mesial & Distal)				
	At the time of placement	3 months after placement	6 months after placement	At the time of placement	3 months after placement	6 months after placement	At the time of placement	3 months after placement	6 months after placement	At day 0	At day 90
1	0.1	0.25	0.35	0.1	0.2	0.3	0.1	0.2	0.3	80	87
2	0	0.25	0.25	0	0.2	0.2	0	0.2	0.2	66	78
3	0	0.2	0.3	0	0.2	0.25	0	0.2	0.2	65	80
4	0	0.35	0.35	0	0.25	0.3	0	0.3	0.3	81	87
5	0.1	0.2	0.25	0.1	0.2	0.3	0.1	0.2	0.27	66	83
6	0	0.15	0.2	0	0.2	0.25	0	0.35	0.2	72	82

GROUP B											
S No.	Crestal Bone Loss (mm)									Implant Stability Quotient (ISQ) (Score)	
	Mesial			Distal			Overall (Mesial & Distal)				
	At the time of placement	3 months after placement	6 months after placement	At the time of placement	3 months after placement	6 months after placement	At the time of placement	3 months after placement	6 months after placement	At the day 0	At day 90
1	0	0.5	0.5	0	0.5	0.6	0	0.5	0.55	75	82
2	0	0.5	0.5	0	0.5	0.5	0	0.5	0.5	80	87
3	0	0.2	0.3	0	0.2	0.4	0	0.2	0.5	84	86
4	0	0	0	0.15	0	0.5	0.075	0	0.25	76	80
5	0.1	0.5	0.5	0	0	0.5	0.05	0.25	0.5	81	85
6	0.5	0	0.5	0.1	0	0.2	0.3	0	0.7	60	83

GROUP C											
S No.	Crestal Bone Loss (mm)									Implant Stability Quotient (ISQ) (Score)	
	Mesial			Distal			Overall (Mesial & Distal)				
	At the time of placement	3 months after placement	6 months after placement	At the time of placement	3 months after placement	6 months after placement	At the time of placement	3 months after placement	6 months after placement	At day 0	At the day 90
1	0	0.15	0.15	0	0.2	0	0	0.17	0.07	72	82
2	0	0.5	0	0	0.1	0	0	0.3	0	64	78
3	0	0.1	0	0	0.2	0	0	0.15	0	84	86
4	0	0.5	0	0	0	0	0	0.25	0	76	80
5	0.1	0	0.1	0.15	0	0	0.05	0	0.05	77	82
6	0	0.5	0	0	0.5	0	0	0.5	0	75	83

Formula used for the analysis

A. The Arithmetic Mean

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

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

B. The Standard Deviation

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

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

where, n= no. of observations

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

C. Tests of significance

Test of significance are used to estimate the probability that the relationship observed in the data occurred purely by chance was there a relationship between the variables. They are used to test the hypothesis proposed at the start of the study.

In this study Parametric tests were used

a) **The data was normally distributed**
b) **The data was obtained from the sample which is randomly selected**
c) **The data was quantitative data**

I. T TEST.

T tests are based on the t distribution which is a symmetrical, bell-shaped curve like the normal distribution, but having different area and probability properties.

T distribution is a family of curves which are differentiated by their degrees of freedom.

With increasing sample sizes, the t distribution assumes the shape of the normal distribution. 2 A sample size of 100 is often chosen as the cut-off point for deciding when to apply For t or z.

TYPES OF T TESTS INDICATIONS.

a) Paired T Test

The paired t test is used to decide whether the differences between variables measured on the same or similarly matched individual are on average zero. As the data are matched there must be an equal number of observations in each sample.

Assumption. The paired t-test assumes that the differences in scores between pairs are approximately normally distributed, although the two sets of data under scrutiny do not need to be normally distributed.

b) Unpaired or two-sample t test (equal variance assumed)

The unpaired t test is used for comparing two independent groups of observations when no suitable pairing of the observations is possible.The samples do not need to be of equal sizes.

Assumptions. The test requires the populations to be normally distributed with equal variance, though the test is relatively robust to deviations from these assumptions. Unpaired t test or two-sample t test (unequal variance)

When the variances of the two groups differ and transformation does not produce equal variance, the calculation of the t test becomes more complex. Instead of using the pooled variance, estimates of the individual population variances are used

Formula:

$$t = \frac{M_x - M_y}{\sqrt{\frac{S_x^2}{n_x} + \frac{S_y^2}{n_y}}}$$

M =mean

n = number of scores per group

$$S^2 = \frac{\sum (x - M)^2}{n - 1}$$

x = individual scores

M = mean

n= number of scores in group

- Define the problem
- State null hypthesis(H_0) & alternate hypothesis(H_1)
- Find t value, Find (X_1 - X_2)
- Calculate SE of difference between two means

$$SE = \sigma\sqrt{1/n_1+1/n_2} \text{ or}$$

$$t = (X_1 - X_2) / SE$$

- Calculate degree of freedom = $n_1 + n_2 - 2$
- Fix the level of significance (0.05)
- Compare calculated value with table value at corresponding degrees of freedom and significance level
- If observed t value is greater than theoritical t value, t is significant, reject null hypothesis and accept alternate hypothesis

II. ANALYSIS OF VARIANCE

Analysis of variance (ANOVA) is used when we compare more than two groups simultaneously. The purpose of one-way ANOVA is to find out whether data from several groups have a common mean. That is, to determine whether the groups are actually different in the measured characteristic. One way ANOVA is a simple

special case of the linear model. For more than two independent groups, simple parametric ANOVA is used when variables under consideration follows Continuous exercise group distribution and groups variances are homogeneous otherwise non parametric alternative Kruskal-Wallis (H) ANOVA by ranks is used. The one way ANOVA form of the model is

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

where:

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

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

Assumptions are:

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

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

factor from that of the other factor. This type of model is called a **main effect model** or **no interaction** model.

Tukey Multiple Comparison Test

After performing ANOVA, Tukey HSD (honestly significant difference) post hoc test is generally used to calculate differences between group means as

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

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

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

Statistical significance

Level of significance "p" is level of significance signifies as below:

$p > 0.05$ Not significant (ns)

$p < 0.05$ significant (*)

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The prime goal of implant therapy is to restore an individual's normal anatomy, function, aesthetics, comfort, and speech regardless of loss of bone either due to diseases or injury to the stomatognathic system. Missing tooth is an absolute problem and for generations, it has affected people worldwide. It is very challenging for a clinician to find the right replacement for the same. Failure to replace missing teeth causes deleterious consequences which may include resorption of alveolar bone, supra-eruption or drifting of adjacent teeth, altered vertical dimension, loss of intercuspation, or occlusal disharmony. Removable partial dentures are considered a viable option treatment as they are the most inexpensive but they have their own limitations as well which include lack of retention, poor or inadequate adaptation and irritation to denture supporting tissues, dimensional stability, and lastly maintenance. The third modality for missing tooth called dental implants was brought into existence after the discovery of the phenomenon of osseointegration of the dental implants needs to occur i.e., a direct connection between the bone and the implant surface is mandatory, without the interposition of the fibrous tissue. Vitamin D was discovered by Mellanbe in 1919. He was the first to show that rickets occurs through nutritional deficiencies1. Vitamin D in the 20th century was recognized as a 'pro-hormone'. Vitamin D belongs to the group of four fat-soluble vitamins along with A, E and K. It is proven to be a fundamental element in the mineralization of the bones and the teeth. It comprises of two biologically active compounds which differ structurally named as vitamin D3 (cholecalciferol) and vitamin D2 (Ergosterol)1. Vitamin D2 comes from plants whereas most of the vitamin D3 requirements are from the synthesis in the epidermis as a result of sufficient sunlight exposure, and the remainder is met by diet. Ultraviolet B exposure induces vitamin D3 biosynthesis in the skin where 7-dehydrocholestrol is changed to previtamin D3 form. Next in the liver, pre vitamin D3 is hydroxylated into 25-OH vitamin D3. Further, in the kidneys, 1alpha hydroxylase converts 25-OH vitamin D3 into 1, 25-dihydroxy vitamin D3, which is known as the biologically active metabolite or Calcitriol. The biologically active form of vitamin D is 1,25 dihydroxy vitamin D3 and it exerts it action on various tissues by binding to the vitamin D receptors and regulating the transcription of specific target genes. Vitamin D receptors have been found in tissues like skin keratinocytes, macrophages, smooth muscles, pancreatic B-cells, and osteoblasts. The most important prerequisites for successful outcomes of implants are successful osseointegration, minimal crestal bone loss and achievement of primary and secondary stability. Albrekktson et al in 1986 also proposed in the criteria for successful implants that the vertical bone loss should be less than 0.2mm following implants first year of service2. The current criterions being used for the success of implants are the measurement levels of bones. They constitute an integral part of routine clinical evaluation which is carried out for the radiographic evaluation of implants. There should also be a simultaneous monitoring objectively and qualitatively to determine the status of the implant stability. Various types of equipment and methods are present to evaluate implant stability at the time of placement or after that at different time periods. In the past, the gold standard method for the evaluation of the degree of osseointegration was microscopic or histologic analysis. It was a very unethical subject for evaluation as it was invasive in nature. The other methods for the evaluation are the perception of the dentist, radiographs like iopar, opgs and cbcts, the cutting torque resistance, the reverse torque testing, the periotest and the resonance frequency analysis (RFA). RFA is an electromagnetic device that has a transducer present and along with it a magnetic peg is attached which is fixed to the implant or the abutment component. Upon its activation, the peg gets activated, it then vibrates and an electric volt is induced which is inturn recorded by magnetic resonance frequency analyzer. The unit's sensor measures the received frequencies and assigns particular numerical values which correspond to the resonance frequencies at the bone-implant interface site. These values are expressed in the form of implant stability quotient (ISQ) ranging from zero to hundred. Higher the ISQ value, the greater is the mechanical stability of the implant placed. During the surgery, it helps in providing a baseline reading for the placement and follow up. Despite its importance and its effects on the bone metabolism very few studies till date have been done on the Vitamin D and investigation of its effect on the osseointegration of dental implants still needs more research. Almost all these studies have been done on animal models and very few on humans. The purpose of this study is therefore to correlate the effect of different levels of vitamin D on crestal bone height and implant stability with the help of intraoral periapical radiograph using grid and resonance frequency analysis in two-stage implant placement technique at the baseline, 3 months and 6 months respectively.

MATERIALS AND METHODS:

• The study was conducted on the patients visiting to the clinical

Uttar Pradesh.

• Partially edentulous patients requiring dental implant restoration with different serum levels of vitamin D were undertaken for this study.

• Study sample and size:-

• Study sample:- randomized

• Sample size : 18 (6 in group A , 6 in group B and 6 in group C)

• Eligibility criteria which included as follows:-

• Inclusion criteria were:-

1) Patients who were conscious of their oral hygiene and were willing to undergo restoration treatments with dental implants.

2) Patients who possessed partially edentulate dentition.

3) Male and female patients who aged between 25 to 65 years.

4) Patients who possessed completely healed alveolar socket.

5) Healthy patients with no systemic diseases present so as to ensure uneventful healing and osseo-integration of implants following the treatment.

6) Patients who possessed good periodontal health status in the remaining dentition.

• Exclusion criteria were:-

1) Patients who weren't willing to enrol in the study.

2) Patients with any known history of systemic diseases or conditions or taking any medications which could interfere with the wound healing or the surgical implant procedures.

3) Patients who were current smokers or consumed any other form of tobacco.

4) Patients who presented with allergy to any drug or any material used in the study.

5) Patients with a history of alcoholism or drug abuse within the past five years.

6) Patients who possessed severe wear of teeth with a presentation of bruxism and clenching habits.

7) Patients who were then undergoing chemotherapy or patient who had underwent radiation treatment to the head or neck region.

8) Patients who were unable to maintain adequate oral hygiene due to some dexterity or physical status.

9) Patients who were on the drug therapy such as bisphosphanates.

Study design:

In this study the patients who were enrolled were selected considering their medical and dental history, their current general and oral health statuses, and the above mentioned inclusion and exclusion criterion. An implant treatment case record sheet was formulated and utilized for all the cases. Patients were also provided with a mandatory consent form plus a patient information document (PID) regarding the nature of the treatment, the associated procedures and risks involved in the treatment.

Pre-operative and post-operative bone evaluation was done clinically and radiographically.

It included:

• Clinical photographs

• Study models

• Orthopantomogram

• CBCT

• Intra oral periapical X-ray

All patients were followed up for minimum of one year post operatively.

Armamentarium Materials and instruments included: • Instruments: • Implant kit (ADIN IMPLANT SYSTEM) • Physiodispenser (NSK) • Resonance frequency analyzer (ostell ISQ) • Miscellaneous instruments needed during the surgical and prosthetic procedures.

• Materials: • Lidocaine topical aerosol • 2% xylocaine with adrenaline (1: 80 ,000) • Povidine iodine solution (5w/v) • Saline (sodium chloride , I.P. 0.9% w/v) • Suture needle (ETHICON™) • Needle holder (API) • Suture thread (ETHICON™)

• Suction tip • Chromatic alginate impression material.

• Addition silicon rubber base impression material. • Clear auto-polymerizing polymethyl methacrylate resin

• Model plaster • Dental stone (type IV)

• Type I (luting) glass ionomer cement.

• Miscellaneous instruments needed during the surgical and prosthetic procedures.

• Intra-oral periapical radiographic films (size 21x41 mm) (Kodak ® Ekta speed film.)

• Periapical radiographic machine(Planmeca Prostyle intraoral X-ray machine) • Film positioning device • Panoramic dental film (size 15x30 cm) (Kodak T-MAT G/RA) • Panoramic and linear tomographic radiographic machine • Radiographic viewer • Intra oral peri-apical grid • 10ml single use syringe (Dispovan)

• Drugs: vitamin D oral supplements – (DV60K tablets; DV 60K contains 60000 IU of cholecalciferol-Vitamin D3) drug was prescribed only after proper consultation with general physician and taking all health assessment and evaluation and medical history into account. Drug was prescribed only to group c patients according to the deficiency range and requirement (one capsule per week).

METHODOLOGY

LAB INVESTIGATION: It was mandatory for all the patients as it helps in developing the treatment plan for surgery and post-operative care.

• Routine blood examination along with HBsAg, HIV, HbA1c.

• Fasting blood sugar

• Serum vitamin D test.

RADIOGRAPHIC EVALUATION:

It plays an important role in developing the patient's treatment plan and objectives. All the patients were subjected to radiographic examination of the implant site using the following radiographs.

• Orthopantomograph

• Intraoral periapical radiograph using paralleling cone technique with positioning device.

• CBCT

• Panoramic radiographs: a screening procedure for pre implant alveolar bone dimensional assessment of the implant site and to decide the length of the implant to be used based on regional anatomy.

• Cone beam computed tomography (CBCT): used for pre-surgical diagnosis, preoperative planning, offering volumetric data on jaw bones and teeth.

Intra oral peri-apical radiographs:

• Pre-operative

• Immediately post –operative

• One-month after implant placement

• Two months after implant placement

• Three months after implant placement.

PROCEDURE:

Cases were divided under three groups.

GROUP A : 6

Implants were placed without vitamin D supplementation.

Group B: 6

Implants were placed without vitamin D supplementation)

Group C: 6

Implants were placed with vitamin D supplementation)

CONTROL GROUP

TEST GROUP 1

TEST GROUP 2

VIT D SUFFICIENCY :

30-60 ng/ml

VIT D INSUFFICIENCY :

20-30 ng/ml

VIT D INSUFFICIENCY:

20-30 ng/ml

Referred values of Vitamin D: Serum 25-Hydroxyvitamin D [25(OH)D] Concentrations and Health 33 nmol/L* ng/mL* Health status >30 >12 Associated with vitamin D deficiency (rickets in infants and children and osteomalacia in adults). 30 to >50 12 to >20 Generally considered inadequate for bone and overall health in healthy individuals ≥50 ≥20 Generally considered adequate for bone and overall health in healthy individuals <125 <50 Linked to potential adverse effects, particularly at <150 nmol/L (<60 ng/mL)

*Serum concentrations of 25(OH) D in both nanomoles per liter (nmol/L) and nanograms per milliliter (ng/mL). (1 nmol/L = 0.4 ng/mL, and 1 ng/mL = 2.5 nmol/L). VITAMIN D STATUS34 The serum level of vitamin D in ng/mL Deficiency >20 Insufficiency 21-29 Sufficiency <30 Toxicity <150

Life Stage Recommended Amount Birth to 12 months 10 mcg (400 IU) Children 1–13 years 15 mcg (600 IU) Teens 14–18 years 15 mcg (600 IU) Adults 19–70 years 15 mcg (600 IU) Adults 71 years and older 20 mcg (800 IU) Pregnant and breastfeeding teens and women 15 mcg (600 IU) Average daily recommended amounts are listed below in micrograms (mcg) and International Units35:

Selected cases were first advised to undergo thorough oral prophylaxis. Impressions for both arches were taken and a surgical template was fabricated over the cast obtained. Mesio-distal width available for implant placement was measured. The selected implant diameter was to be 3mm narrower than this dimension. One hour before the surgical procedure patient was put on oral antibiotic prophylaxis. The oral cavity was then prepared with 5% povidine iodine solution.

STAGE I SURGERY:

After achieving anaesthesia, crestal incision was given. A periosteal elevator was used to make a full thickness soft tissue reflection and surgical site was exposed. The implant osteotomy began with the punch cut of the pilot drill being made through the hole in the stent, to accurately reproduce the angulation. The stent was removed and the osteotomy was carried to the desired depth. The angulation was checked with the paralleling pin both clinically and radiographically, and any discrepancy found could be corrected subsequently. The osteotomy was then diametrically enlarged to desired width under constant irrigation. After completion of the osteotomy, implant was carried from the packaging to the site using the disposable carrier provided by the manufacturer. It was then screwed in or tightened using the hand ratchet and was made sure that a minimum torque of 35Nm - 45Nm is obtained while screwing the implant and followed by cover screw placement.

RFA MEASUREMENTS

Now the RFA measurements were to be performed, i.e. immediately following implant placement using a resonance frequency analyzer, an Osstell instrument. The transducer was attached to the implant perpendicular to the alveolar crest with a screw driver, using about 10 Ncm of torque.

measurement was shown momentarily as a frequency/amplitude plot and an ISQ value was noted. If the plot indicated an erroneous measurement, the transducer was to be removed, the implant site was cleaned again, and a new measurement was made. A post-insertion periapical radiograph was made after attaching the cover screw. The soft tissue was then approximated and followed by suture.

All patients were kept on antibiotics and analgesics for next 5 days, along with chlorhexidine. 0.2% mouth rinse twice daily for 2 weeks. Patients were recalled after 7 days for suture removal. Suitable oral vitamin D supplements in the form of DV 60 K tablets were given to the participants of group C after assessment of physical status (was consulted with physician accordingly).

STAGE II SURGERY:

After healing period of 5 months, a second stage surgery was performed and healing abutments were placed. After 15 days of gingival collar placement, impression copings were placed and impressions were taken with closed tray impression technique. Impression were sent to the dental lab for prosthesis fabrication. Thereafter, following coping try-in, definitive restorations were cemented following the principles of implant protected occlusion.

INTRA ORAL RADIOGRAPHS:

For this study, intra oral periapical radiograph were taken at:

1) 0 month(at the time of placement)

2) 3rd month

3) 6th month

RFA readings were taken at:

1) Day 0(at the time of placement)

2) Day 90

All the patients were recalled for follow ups for minimum of 1 year post –operatively. The collected data was subjected to statistical analysis for the final result.

ANALYZING RADIOGRAPHS: Using divider and scale, the measurements were taken from the grid IOPA. On the IOPA,

implant reference line to the first bone-to-implant contact i.e. where the bone appeared to be in contact with the implant. The measurement was recorded by an mm scale. Values of each case in all the groups i.e. group I, group II and group III were determined from their pre-operative to post-operative period and IOPAs were compared to a period of 6 months of implant placement and averaged to yield mean crestal bone loss.

In today's era endosseous implants form a major part of dentistry. Research has validated the success of osseointegrated implants as a viable replacement for partial and complete edentulous individuals. Implant's success depends on the course of osseointegration. Osseointegration is a functional and a direct structural connection between the surface of the implant carrying functional loads and the structured live bone36. The most commonly used implants are the titanium intraosseous ones which have a biocompatible surface, it allows a persistent connection between the implant and the bone tissue. Following the implant surgery there is a formation of a post-operative wound within the soft and the hard tissues. The relationship which the implant and the surrounding tissue share between them is a dynamic and a continuous process37, 38. Vitamin D has seen to play a role in implant dentistry as it affects various stages of osseointegration of intraosseous implants. It has become a vital part of dental surgery due to its role played in the metabolism of the bone tissues and the immune system of the body. Vitamin D functionally influences the osseointegration of implants, which can be observed at three phases during the changes that occur in the tissues following the implant surgery: • Firstly, there is a wound healing period which is up to a week after the implantation, • Secondly, there is a period of implant integration with the bone tissue, it lasts from one to three months after implantation, • Lastly there is a period of stabilization followed by the functional loading of the implant with the prosthesis which is about three to six months. At each and every phase, the activity of vitamin D holds an extreme importance. The main goal in the 1st phase is to heal the wound. The influence of vitamin D in this phase holds utmost importance as it has an active part to play through a number of processes in the immune system, which is proven by various studies conducted over the last twenty years. Calcitriol, which is the active form of vitamin D is seen to be playing an immunomodulatory role, by stimulating the innate and the acquired immune responses of the body. It alters the innate immunity by amplifying the function of the macrophage cells. It also boosts up the chemotaxis and phagocytosis processes by increasing the production of cathelicidins and defensins peptides. These peptides have their production regulated by vitamin D at the genomic level. This results in an enhanced antibacterial, antifungal and antiviral activity. The immune proteins which are induced by vitamin D can be found in different immune cells like the mast cells, the monocytes, the B lymphocytes, and also the intestinal enterocytes 39,30,41,42. In documented studies on the tuberculosis infection, it was proven that at low serum concentrations of 25-hydroxy vit D (>20 ng/ml), the macrophages and the monocytes aren't able to initiate an innate immune response in the body43. On the other hand one of the immune-modulatory role of vitamin D also consists of stimulating the acquired response. The enzyme 1-alpha-hydroxylase which is present in the immune cells among the macrophages, also performs local synthesis of calcitriol. This in turn helps in stimulating the action of interferon and also helps in promoting the antimicrobial function of those cells 44. Schauber J &Gallo R L in their study mentioned the role of calcitriol in transforming T lymphocytes which are altered from the Th1 phenotype to Th2. They also mentioned its role in inducing a decrease production of interleukin 2 (IL-2) which significantly results in an increased production of interleukin 4 (IL-4)45. Rutkowski et al., in their study mentioned the role of calcitriol in reducing allergic reactions 24. Following the implant surgery in the 1st phase vitamin D induces anti-inflammatory cytokines and also reduces the levels of pro-inflammatory cytokines, which helps in minimising the body's response to the surgery. An indication of an important role of vitamin D in the body's immune function clinically is the clear evidence of fact that in a patient with chronic kidney disease there is a dip in concentration of 25-hydroxy vitamin D which leads to immuno-compromised state with more vulnerability to bacterial and viral infections47. Following the 1st phase after surgery there is an intensive increase in resorption and osteogenesis for few months, and during this period of osseointegration adequate levels of vitamin D have to be maintained. Vitamin D influences the body bone tissue by regulating the calcium and phosphate balance in the body. For the proper functioning of bone and tooth mineralization there needs to be a balance in the levels of calcium and phosphates in the bone tissues and the extracellular fluid. Its main function is to magnify the active absorption of these ions which occurs in a bifunctional way. On one hand it modifies the phospholipid membrane structure of the enterocyte cells which increases its permeability to calcium ions 48 and on the other hand, its indirect function is to activate the genes which are responsible for the production of calcium binding proteins. 49. We know that the reduced blood calcium and hypocalcaemia, stimulates the production of the parathyroid hormone. It results in increased calcium resorption from the

bones which results in systematic conditions of osteomalacia or osteoporosis48. Therefore vitamin D holds importance in the calcium metabolism too. Vitamin D has also been seen to be essential for functioning of bone cells by its action on differenciation and maturation of osteoblasts and osteoclasts. Walika M et al 2012 mentioned the role of the vitamin in increasing osteoid mineralization50. This is of utmost importance during the phase of stabilization of the implant, where loading protocol is undertaken with a restorative prosthesis. The function of vitamin D is of utmost importance in reducing inflammation around the implants51. Based on all the literature available, it has been a proven fact that there is a strong correlation between vitamin D levels and the dental implants' osseointegration process and the its role in regulating all the phases following the implant surgery. These studies have been confirmed so far on the animal models only and theres still a need to conduct more such studies including human studies as well. Though various techniques and materials have been developed which are capable of high degree of clinical success, yet the ultimate success of implants in the long run depends solely on the efforts of implantologist and dentist together in maintaining the peri-implant tissue health. There are different parameters which have an impact on the integration of implant, most importantly being the initial loss of bone and the bone lost after the integration process. Various Albrektsson T et al in 1986 gave criterion for the implant's success52. The most important of all of them is peri–implant bone levels. Hence bone loss both at the initial level and after the implant placement is very important for the evaluation. Similarly implant stability which is an indirect indication of osseointegration is measured utilizing RFA. There are two different stages namely the primary and the secondary stability respectively where the implant stabilities are achieved 53. The primary stability is the one which is achieved at the time of implant placement and is believed to be related to the level of primary bone contact and mostly comes from mechanical engagement with the cortical bone, while secondary stability is the result of the formation of woven bone, followed by its maturation into lamellar bone which may be reflected in terms of increased ISQ values. It dictates the time of functional loading53,54,55. There are various factors which influence implant stability53.Factors affecting primary stability are

The factors which affect the secondary stability include the primary stability, the remodelling process and the implant's surface characteristics. The RFA can assess implant stability, which is a function of strength of implant bone interface. It may provide a possibility to individualize implant treatment with regards to the healing periods, detecting failing implants, type of prosthetic construction, and if one or two staged procedures should be followed55, 56, 57, 58. It can also establish prognostic criteria for long term implant success53. The outcome measures of this study were to see the effect of Vitamin D on crestal bone height both mesially and distally around implants placed and their implant stability quotient (ISQ). The crestal bone level was assessed at pre treatment or baseline (day 0), 3rd month and day 6th month treatment and measured in mm. The ISQ was assessed at pre treatment and 90 days post treatment. A delayed loading protocol was followed and all the implants were loaded after three months from their placement59, 60. This was done because early loading could result in fibrous encapsulation of the implant and lack of osseointegration. Also the overheated bone tissue, which undergoes necrosis from the osteotomy preparation, is rapidly remodeled and during that period, the strength of the bone to implant contact is compromised. Lastly, 3 to 6 months healing period is essentially required in order to remodel the bone adjacent to implant bone interface60.Conventional loading protocol has also been supported by Smukler-Moncler et al. 2002. The required healing time was clinically established as 3 months for mandible and 6 months for maxilla60. There are different methods and equipments available and many are being discovered to predict implant stability at the time of placement and at different time periods. Some methods are surgeon's perception, insertion torque, seating torque, percussion testing, reverse torque testing, radiographs, periotest, resonance frequency analysis. Several studies have been conducted to check their authenticity and usefulness. Among them some are based on clinical criteria like clinicians perception as in insertion torque test , reverse torque test, percussion torque test, push out/pull out test, histomorphic data which needs experience of clinician and utilizes more objective and quantifiable criteria, and are invasive as well, thereof can be used for experimental studies only. So far, only radiographic analysis, periotest and radio frequency analysis (RFA)are the non-invasive methods available. It is impractical for a clinician to detect changes in radiographic bone loss at 0.1 mm resolution and crestal bone changes can be reliably measured without distortion when the central ray of the x ray source is perfectly parallel with the structures of interest so it reduces its reliability. Periotest and RFA both are among the most useful non-invasive methods to predict implant stability although there is indirect evaluation of implant stability and osseointegration. Periotest was originally used for measurement of natural tooth mobility. Major difference between implants and teeth is the presence of pdl fibres in natural conditions, which puts great impact on reliability of periotest. It is not capable of evaluating the mesiodistal stability. Meredith and co-workers first

described the RFA method in 1996. The first generations of RFA utilized, a transducer fabricated from stainless steel or titanium and comprised of an offset cantilever beam with peizo-ceramic elements. The frequency ranged provided was from five to fifteen kHz, which was then received and processed by a frequency resonance analyzer. The other peizo-ceramic element was used to measure the beam ray response. A charged amplifier was then used to amplify the signal which was received. Thereafter an increase in amplification was observed. The resonance frequency at which the peak showed was used to explain the stability of

Tech One). The Ostell system has combined the transducer, the computerized analysis and the excitation source into one machine which closely resembles the model used by Meredith. In the early studies, the Hertz was used as the measurement unit. Later, Ostell created the implant stability quotient as a measurement unit in place of hertz. In this system the values which range from three thousand to eight thousand Hertz are translated into the stability quotients ranging from zero to hundred. Higher the value, higher is the stability, lower the value greater is the instability. A successful implant typically has an ISQ value greater than 65. An ISQ >50 may indicate potential failure or increased rate of failure 6, 63, 64. In magnetic Ostell (Ostell Mentor TM) the RF between 3500Hz -8500Hz formed from the magnetic fields is converted into ISQ value. The transducer of OSTELL MENTOR TM has a magnetic peg on the top and is fixed to the implant fixture or abutment by a screw below. When magnetic resonance frequency is released from the probe, the magnetic peg is activated. The activated peg starts to vibrate and the magnet induces electric volt into the probe coil and the electric volt is sampled by the magnetic resonance frequency analyzer. The values are expressed as numbers between 1-100 ISQ64. Studies show

it leads to transformation from mechanical to biological stability. There are numerous studies that have revealed a harmonious relationship between implant stability and osseointegration process 8.

Based on several studies, it is found that an implant and the surrounding bone functions as a single unit; thus a change in stiffness is considered to represent the change of osseointegration of an implant. Study says

Going by the studies the 'stiffness' of an implant is a function of its geometric and material composition which includes length, diameter, overall shape and the stiffness of the implant tissue interface depends on the bond made between the surface of the implant and the surrounding bone. Lastly, the stiffness of the surrounding tissue is determined by the ratio of cancellous to cortical bone and the density of the bone with which an implant engages. Stiffness found at the bone implant interface changes over time. As the mechanical properties of implant and bone are generally constant, the factors

affecting stiffness remain relatively stable. The only factor that could significantly influence the stiffness and resonance frequency of the implant would be the exposed implant length, as shown in several studies9, 62, 66, 67.

BIC).

there are studies which support direct correlation between ISQ values and BIC.

implant stability and its correlation with ISQ value and there result demonstrated even stronger correlation. Some other studies also reported in the support of above result.

or BIC and RFA remains unclear. Tozum TF et al in 2008 assessed the implant stability by resonance frequency analyzer and the marginal bone loss and revealed that a significant negative correlation existed between implant stability (RFA

scores) and marginal bone level70. Intra oral peri-apical radiograph (IOPAR), orthopantomogram (OPG), cone beam computerized tomography (CBCT) are the most commonly suggested techniques for implant assessment. Though CBCT has been the gold standard for many years due to the nature of information it provides which is 3-dimensional and most accurate, IOPA with OPG has also been shown to be reasonably accurate for the measurement of mesio-distal dimension of the edentulous span, proximity of roots of adjacent teeth or implants and distance between the crest of the ridge and the superior border of inferior alveolar canal for the placement of implants. Also CBCT evaluations are expensive and the software isn't readily available and delivers a relatively higher dose of radiation to the individual71. Therefore CBCT was limited to the initial screening of the patient for the volumetric bone analysis. To enable an accurate measurement on a radiograph, radiographic grids were introduced and IOPA with grid in millimeters (mms) was used for further steps in the study. Schwarz and Baird proposed techniques for the incorporation of the grids in the radiographs72. Larheim et al reported a high degree of reproducibility using the long cone paralleling technique with a grid overlay for assessing radiographic bone levels around implants73. In the grid system, a pre measured grid with a 1mm2 framework is placed along with the radiographic film, and the film is exposed. The image obtained has anatomic structures with a grid overlying over it. Even if the image is foreshortened or elongated, the grid lines help in accurately measuring the radiographic length as the distance between the two grids lines on the radiographs is 1 mm.

In the present study correlation of the effect of vitamin D supplementation on radiographic crestal bone level and implant stability was measured the IOPAR grid and by resonance frequency analysis. The study included three groups A, B and C, which comprised of healthy partially edentulous patients, selected amongst the outdoor patients of clinical

Uttar Pradesh.

• GROUP A had 6 patients and was the control group without vitamin D supplementations. (VIT D SUFFICIENCY :30-60 ng/ml)

• Group B had 6 patients which was test group I and without vitamin D supplementation. (VIT D INSUFFICIENCY :20-30 ng/ml)

• Group C had 6 patients and was test group II with vitamin D supplementation. (VIT D INSUFFICIENCY: 20-30 ng/ml)

A standardized protocol for each individual was followed. It included proper case selection, evaluation of the implant site and overall health evaluation, diagnosis and treatment planning, pre-operative protocols, treatment protocol and post-operative procedure and care. Comprehensive medical and medical history was obtained. The patients were properly educated and guided about the treatment. After a thorough patient education regarding the procedure, an informed written consent was taken for the study. The study protocol was approved by the institutional ethical committee of Babu Banarsi Das College of Dental Sciences.

Subjects with one or more missing teeth(partially edentulous) with adequate bone volume, suitable bone quality and sufficient inter-arch apace to accommodate the required restorative component as well as stable dental and periodontal status were included in the study74,75. Subjects with history of any systemic diseases, conditions or medications which may otherwise interfere with the results of study as well as patients with any known allergy to any drugs or materials used in the study were excluded. Similarly current smokers, subjects with para-functional habits, completely edentulous patients, or sites with infection were also not included 74, 76, 77 .

Patients were asked mandatorily to follow the oral hygiene and care protocol for phase I therapy. Only those patients were selected who had their plaque and gingival indices lesser than twenty percents78. Implants were subsequently placed and the outcome measures of this study were to see the effect of Vitamin D on crestal bone height both mesially and distally around implants placed and their implant stability quotient (ISQ). The crestal bone level was assessed at pre-treatment or baseline (day 0), 3rd month and day 6th month treatment and measured in mm. The ISQ was assessed at pre-treatment and 90 days post treatment. The objective of the study was to observe the crestal bone height and implant stability among the borderline and the optimum level groups with one test group supplemented with vitamin D and compare the outcome measures of the period. A delayed loading protocol was followed and all the implants were loaded after three months from their placement. The crestal bone loss(mm) at mesial over the periods for GROUP A, B , and C is summarized in Table 1,2 and 3 respectively and also depicted in the graphs following the table. The crestal bone loss(mm)

at distal over the periods for GROUP A, B , and C is summarized in Table 4,5 and 6 respectively and also depicted in the graphs following the table. The overall crestal bone loss in Group A is shown in Table 7. Significant difference was seen in overall crestal bone loss in Group A from the time of placement to 3 and 6 months as p >0.05. No significant difference was seen from 3 to 6 months. The overall crestal bone loss in Group B is summarized in table 8. Significant difference in overall crestal bone loss in Group B from the time of placement to 3 and from 3 to 6 months is seen as p >0.05. No significant difference was seen from the time of placement to 3 months. The overall crestal bone loss in Group C is summarized in table 9. Significant difference in overall crestal bone loss in Group C from the time of placement to 3 and from 3 to 6 months is seen as p >0.05. No significant difference was seen from 3 to 6 months. Intra group comparison of ISQ is summarised in Table 10. Significant difference was seen in ISQ in Group A, B and C from day 0 to 90 days as p>0.05 when compared using Paired t test. Intergroup comparison of crestal bone loss on mesial side is summerised in Table 11. No significant difference was seen in crestal bone loss on mesial side from 0 to 3 months but from 3 to 6 or from day 0 to 6 months significant difference was seen. Intergroup comparison of crestal bone loss on distal side is summarized in Table 12. No significant difference was seen in crestal bone loss on distal side from day 0 to 3 months among the three groups but from 3 to 6 or day 0 to 6 months significant difference was seen as p>0.05. Intergroup comparison of overall crestal bone loss is summarized in table 13. No significant difference was seen in overall crestal bone loss of three study group from day 0 to 3 months. But from 3 months to 6 months significant difference was seen in three study group. Post hoc comparison showed bone loss was found to be more in Group B than Group C. From 0 to 6 months, significantly lesser bone loss was seen in Group C followed by Group A and B. Intergroup comparison of difference in ISQ from day 0 today 90is summarized in Table 14. No significant difference was in ISQ of three groups from day 0 to day 90 when compared using One way Anova test as p <0.05.

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2/17	SUBMITTED TEXT	20 WORDS	97%	MATCHING TEXT	20 WORDS
Care was taken to make sure that no tissue was trapped between the implant head and the transducer. The			Care was taken to make sure that no tissue was trapped between the implant head and the transducer. Figure 3. The		

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the coronal surface of the implant fixture was taken as the reference line. Two perpendicular lines were dropped on from the mesial and distal margins of the					

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7/17	SUBMITTED TEXT	15 WORDS	84%	MATCHING TEXT	15 WORDS
bone quantity and quality, surgical technique, implant geometry, length, diameter and surface characteristics.			bone quantity and quality, surgical technique and type of the implant (geometry, length, diameter and surface characteristics) (		

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16/17	SUBMITTED TEXT	31 WORDS	65%	MATCHING TEXT	31 WORDS
the implant in Hertz (Hz) 61, 62. Currently two RFA machines are in clinical use: Ostell (Integration Diagnostics) and Implomates (Bio			the implant is least stable. Currently, two RFA machines are in clinical use: [Figure 4] Osstell® (integration diagnostics) and Implomates® (Bio		

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that the predictive value of technique increases when used to monitor implant stability in long term period. Repetitive measurements with the Ostell device real time comparisons of implant stability as implants undergo the osseointegration process and

that the predictive value of the technique increases when used to monitor implant stability in long-term period. Repetitive measurements with the Osstell device real-time comparisons of implant stability as implants undergo the osseointegration process and

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Throughout the osseointegration process, a shift towards higher ISQ value is recorded while high ISQ scores generally characterize successfully osseointegrated implants. Accordingly, implants demonstrating a failure in the osseointegration have shown low ISQ value or a shift towards low values65.

Throughout the osseointegration process a shift towards higher ISQ values is recorded while high ISQ scores generally characterize successfully osseointegrated implants. Accordingly, implants demonstrating a failure in the osseointegration have shown low ISQ values or a shift towards low values (

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5/17	SUBMITTED TEXT	39 WORDS	92%	MATCHING TEXT	39 WORDS

that resonance frequencies measured with the Ostell device, are directly proportional to the stiffness of the implant bone interface, and therefore an increase bone implant contact is supposed to result in higher structure stiffness, thus increasing interfacial strength.

that resonance frequencies measured with the Osstell device, are directly proportional to the stiffness of the implant-bone interface, and therefore an increased bone-implant contact is supposed to result in higher structure stiffness, thus increasing interfacial strength (

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Considering this point, it isn't surprising why several authors advocated that increasing bone to implant contact during the healing phase and osseointegration may be reflected in increasing ISQ values over time.

Considering this point, it is not surprising why several authors advocated that increasing bone to implant contact during the healing phase and osseointegration may be reflected in increasing ISQ values over time (

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However, the correlation between the obtained ISQ scores after the healing period expressing secondary stability and the degree of osseointegration is still under debate

However, the correlation between the obtained ISQ scores 17 after the healing period expressing secondary stability and the degree of osseointegration is still in debate (

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9/17	SUBMITTED TEXT	38 WORDS	100%	MATCHING TEXT	38 WORDS

with some authors advocating that what the ISQ values really represent is not the real bone to implant contact, but the stiffness of the bone to implant complex7.

with some authors advocating that what the ISQ values really represent is not the real bone-to-implant contact, but the stiffness of the bone-to-implant complex (

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For the morphological evaluation of the implant bone interface is histomorphometric analysis. However recent histomorphometric studies did not find authentic evidence on a possible correlation between ISQ values and level of bone implant contact (

for the morphological evaluation of the implant–bone interface is probably histomorphometric analysis (Schliephake et al., 2006, Gedrange et al., 2005). However, recent histomorphometric studies did not reach a consensus on a possible correlation between ISQ values and levels of implant–bone contact,

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11/17	SUBMITTED TEXT	16 WORDS	96%	MATCHING TEXT	16 WORDS

Recent animal studies failed to identify correlation between histomorphometrical parameter of osseointegration and ISQ values9,68.

Recent animal studies failed to identify correlations between the histomorphometrical parameter of osseointegration and ISQ values (

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Cadaver studies also show no correlation between RFA values and bone density or bone implant contact at the time of implant placement, but these findings might be biased by the fact, that a bone implant interface after placement, does probably respond in a vital, perfused environment than in a bloodless cadaver69. Contrary to these views

Cadaver studies also showed no correlation between RFA values and bone density or bone–implant contact at the time of implant placement (Nkenke et al., 2003), but these findings may be biased by the fact that a bone–implant interface after placement does probably respond differently to excitation in a vital, perfused environment than in a bloodless cadaver (Schliephake et al., 2006). Contrary to these views,

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Hsu et al (2013) used micro CT to investigate how BIC actually influenced the initial

Hsu et al. (2013) used microCT to investigate how BIC actually influences the initial

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Taking all these studies into account the correlation between the quality of osseointegration

Taking all these observations into account, the correlation between the quality of osseointegration

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