EVALUATION OF PERI-IMPLANT BONE LOSS AROUND PLATFORM SWITCHING AND NON PLATFORM SWITCHING IMPLANTS – A RANDOMIZED CONTROLLED TRIAL

Dissertation submitted to

THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY

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BRANCH II

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CERTIFICATE - I

This is to certify that **Dr. C. SUGIRTHA,** Post Graduate student in the Department of Periodontics, J.K.K. Nattraja Dental College and Hospitals, Komarapalayam has done this dissertation titled **"EVALUATION OF PERI-IMPLANT BONE LOSS AROUND PLATFORM SWITCHING AND NON PLATFORM SWITCHING IMPLANTS – A RANDOMIZED CONTROLLED TRIAL"** under my direct guidance during her post graduate study period 2017 - 2020.

This dissertation is submitted to **THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY** in partial fulfillment of the degree of **MASTER OF DENTAL SURGREY, BRANCH II – PERIODONTICS.**

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<u>CERTIFICATE - II</u>

This is to certify that this dissertation work titled **“EVALUATION OF PERI-IMPLANT BONE LOSS AROUND PLATFORM SWITCHING AND NON PLATFORM SWITCHING IMPLANTS – A RANDOMIZED CONTROLLED TRIAL”** of the candidate **Dr. C. SUGIRTHA** with the registration number **241713102** for the award of **MASTER OF DENTAL SURGERY** in the **Branch II - PERIODONTICS**. I personally verified the urkund.com website for the purpose of plagiarism check. I found that the upload thesis file contains from introduction to conclusion pages and results shows 5 percentage of plagiarism in the dissertation.

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Dentistry is now focused mainly on the fixed replacement of lost teeth with priority given to aesthetic and function. Implants have been used for various purposes such as single, multiple or full arch restoration. It could be a single or two piece implant system. Single implant system eliminates the junction between implant platform and abutment. Also have limitations of positioning, integration and aesthetics.[1] Traditional two stage implants have enjoyed a long history of clinical success and have offered surgical and prosthetic versatility. They have been used in various situations with better emergence profile as well as bone integration at the implant abutment interface which gives rise to a new concept called Platform Switching.[1]

For two piece implant system, there exists two potential pathways for bacterial penetration resulting in crestal bone loss. One route is through the inside of the abutment, along the screw threads eventually at the implant abutment interface or micro gap. Another route through which bacterial penetration happens is along the outer surface of the abutment.[2]

There exist two important entities in the implant crestal region i.e. plaque associated inflammatory cell infiltrate and implant associated inflammatory cell infiltrate. The apical border of an inflammatory cell infiltrate is the aetiological factor for crestal bone loss which was always separated from the bone crest at 1 mm of healthy connective tissue. However, early crestal bone loss has been commonly observed in both the entities. [2]

Biologic width is a natural seal that develops around any object protruding from the bone and through the tissue into the oral environment. This seal isolates the bone from the oral environment. Biological width forms within the first 2-4 weeks after the implant abutment junction has been exposed to the oral cavity. When implants are initially placed within bone and then covered with an adequate layer of soft tissue (first stage surgery), there is typically little or no crestal bone resorption.[3]

When the implant is uncovered (in second stage surgery) and connected to an abutment, the body then reacts for the process of creating the biologic width, the crestal bone may resorb. In two stage implant systems, after abutment is connected, a microgap exists between the implant and the abutment at or below the alveolar crest. This microgap between the implant/abutment has a direct effect on crestal bone loss, independent of surgical approaches. Crestal bone loss is observed 2 mm below the microgap due to the epithelial proliferation to establish biological width. [4]

Heat generated during drilling, elevation of the periosteal flap and excessive pressure at the crestal region during implant placement may contribute to implant bone loss during the healing period. Thus, surgical trauma is unlikely to cause early crestal bone loss. Cortical bone is least resistant to shear force, which is significantly increased in bending overload. Excessive stress on the immature implant bone interface in the early stage of prosthesis in function is likely to cause crestal bone loss. Crestal bone preservation should be thought during the treatment planning stage itself. There are various approaches described in the literature, among which platform switching concept is used to prevent crestal bone loss. [4]

Platform switching is the use of prosthetic components having a less abutment diameter when compared to the diameter of the implant platform. In this way, the prosthetic connection is displaced horizontally inwards from the perimeter of the implant platform, creating an angle or step between the abutment and implant; improving the distribution of forces.[5]

There appear to be two results of the horizontal inward repositioning of the implant-abutment interface. First, with the increased surface area created by the exposed implant seating surface, there is a reduction in the amount of crestal bone resorption necessary to expose a minimum amount of implant surface to which the soft tissue can attach. Second, and perhaps more important, by repositioning the IAJ (Implant Abutment Junction) inward and away from the outer edge of the implant and adjacent bone, the overall effect of the abutment ICT (Inflammatory Cell Infiltrate) on the surrounding tissue may be reduced, thus decreasing the resorptive effect of the abutment ICT on crestal bone.[6]

Platform switching repositions the abutment ICT further away from crestal bone and locates the inflammatory infiltrate within an approximate ≤ 90 degree confined area of exposure instead of a ≤ 180 degree area of direct exposure to the surrounding hard and soft tissues. Platform switching increases implant longevity, improves esthetics as crestal bone preservation helps preserve papilla and the effect of inter-implant distance is minimized.[7] The choice to use a platform switched or matched implant design is currently not guided by evidence based protocols and is mainly influenced by manufacturers recommendations.[8] Hence the aim of this study is to clinically and radiographically evaluate the peri-implant bone loss around platform and non platform switching implants.

1. To assess if any significant correlations exists between the width of keratinized mucosa, thickness of the peri-implant mucosa, papilla index, soft tissue index, probing pocket depth around platform and non platform switching implants.

2. To evaluate and compare peri-implant bone loss around platform and non platform switching implants.

Dental implants history returns to hundreds of years prior and individuals have endeavored to supplant the missing teeth with various approaches to recapture full, agreeable masticatory capacity and facial feel. In 1991, *3i* implant innovations aimed to construct wide-diameter implants with the larger diameter restorative platforms than standard implants. But, for some time, corresponding prosthetic components were unavailable; hence, standard prosthetic abutments (4.1 mm diameter) were used instead of abutments that matched the 5 and 6 mm implant diameters. The consequence of this form of treatment was an unintentional "change of platform", which became known as platform switching (PLS). This concept was introduced in the literature by Lazzara, Porter, and Gardner (2006).[5]

HUMAN STUDIES:

Tarnow DP et al., (2000)[9] evaluated the lateral dimension of the bone loss at the implant-abutment interface and determined if the lateral dimension has an effect on the height of the crest of bone between adjacent implants separated by different distances. The study concluded that selective utilization of implants with a smaller diameter at the implant-abutment interface may be beneficial when multiple implants are to be placed in the esthetic zone so that a minimum of 3 mm of bone can be retained between them at the implant-abutment level. Implants involving an expanded platform integrated in their macrostructure, ensured bone crest preservation seen to be 57% greater than with a traditional restoration design.

Hermann J et al., (2001)[10] reviewed platform switching implant design in cervical region, nano roughness, biological width, fine threads, abutment designs and avoidance of micro lesions in the peri-implant soft tissue. The results concluded that these factors determine the aesthetic outcomes of implant restorations.

Gardner DM et al., (2005)[11] presented a case study using platform switching implants that dealts with the changes that occur when an implant was placed in bone. The result concluded that the main advantage of platform switching was that it is an effective way to control circumferential bone loss around dental implants.

Baumgarten H et al., (2005)[12] described the usefulness of platform switching technique in situations where shorter implants must be used, in aesthetic zones and conditions where a larger implant is desirable but prosthetic space is limited. They concluded that sufficient tissue depth of approximately 3mm or more was necessary to accommodate an adequate biologic width. The platform switching helps to prevent the anticipated bone loss and also preserves crestal bone.

Lazzara RJ et al., (2006)[5] observed histologically and radiographically the biologic dimension of hard and soft tissue around implants restored conventionally with prosthetic components and suggested that when the outer edge of the implant-abutment interface is horizontally repositioned inwardly and away from the outer edge of the implant platform the loss of crestal bone height gets altered.

Vela Nebot X et al., (2006)[13] assessed interproximal bone resorption on the mesial and distal aspect of each implant using digital radiography at 1, 4, and 6 months after abutment attachment. Platform modification has been proposed to reduce the biologic and mechanical aggressions on the biologic width. The resulting peri-implant bone preservation leads to better aesthetics results.

Hurzeler M et al., (2007)[14] studied that crestal bone height around dental implants using a platform switch protocol. They concluded that the concept of platform switching appears to limit crestal resorption and seems to preserve peri-implant bone levels.

Canullo L et al., (2007)[15] evaluated the soft and hard tissue response to immediately placed implants. In addition, assessment was conducted for the soft tissue response to a transmucosal abutment which was narrower than the implant platform. This proof of concept study suggested that immediate loading with platform switching can provide peri-implant hard tissue stability with soft tissue and papilla preservation.

Degidi M et al., (2008)[16] conducted a study in which he used three morse cone connection implants inserted in the right posterior mandible in partially edentulous patient. The platform of the implant was inserted 2 mm below the level of the alveolar crest. The results confirmed that abutments smaller than the diameter of the implant body (platform switching) in combination with an absence of micromovement and microgap may protect the peri-implant soft and mineralized tissues, and resulted in the absence of bone resorption. Immediate loading did not interfere with bone formation and did not have adverse effects on osseointegration.

Qian Li et al., (2008)[17] evaluated the clinical results of dental implant treatment with platform switching technique in esthetic zone and investigated its technical characteristics. He concluded that platform switching was a simple and reliable technique for dental implant treatment, that helps to control marginal bone loss and ensured esthetic results in the esthetic zone.

Cappiello M et al., (2008)[18] in the prospective study evaluated clinically and radiographically the bone loss around two-piece implants that were restored according to the platform switching protocol. The results showed a vertical bone loss between 0.6 mm and 1.2 mm in platform switched implants comparatively lesser than regular two piece implants.

Canullo L et al., (2009)[19] evaluated bone level response around single, immediately placed and provisionalized platform switching implants. The average bone resorption level in the platform switching group was smaller than that in the non-platform switching group. This preliminary study suggested that immediate single implant restorations in specific maxillary sites with subsequent platform switching may provide peri-implant alveolar bone level stability.

Crespi *R* et al., (2009)[20] assessed the marginal bone around two different types of implant-abutment junctions a so called platform switched assembly and a conventional external hexagon connection. The results of this study indicated that implants placed immediately in fresh extraction sockets and loaded immediately represent a predictable procedure, with no differences in bone level changes between "platform-switched" and conventional external hexagon implants after 24 months.

Lopez Mari L et al., (2009)[21] reviewed published articles dealing with platform switched implants and concluded that platform switching helps to prevent crestal bone loss after implant placement and helps to obtain satisfactory aesthetic results.

Prosper L et al., (2009)[22] evaluated the effectiveness of the platform switching technique to prevent crestal bone loss following the restoration of dental implants. The findings of the current trial indicated that the use of implants with an enlarged platform can result in better preservation of crestal bone as compared with conventional cylindric implants when a reduced abutment is mounted.

Trammell K et al., (2009)[23] in a case control study, measured the radiographic crestal bone loss and biologic width around conventional and platform switched implants. Implants were randomly assigned into conventional or switched categories within the same prosthesis. The findings suggested that less crestal bone loss occurs around a platform switched dental implant versus a conventional implant.

Wagenberg B et al., (2010)[24] evaluated implant survival and crestal bone levels around implants that used the platform switching concept. All implants had been placed at the crestal level at the time of surgery. 84% of the mesial surfaces and 88% of the distal surfaces had 0.8 mm or less of bone loss. This is the longest follow up to a prospective investigation of platform switched implants and confirmed the concept for preservation of crestal bone levels.

Annibali S et al., (2010)[25] systematically reviewed the literature to compare implant survival and marginal bone loss around platform switched versus conventionally used platform matching dental implants and concluded that the platform switching technique appeared to be useful in limiting bone resorption.

Cocchetto et al., (2010)[26] examined whether shifting the microgap further inward by increasing the discrepancy between the implant platform and abutment diameter would result in a decrease in crestal bone loss. The implants were connected to 4.1mm healing abutments in a single stage protocol. Increasing the discrepancy between the diameter of the implant platform and the restorative abutment may lead to a decrease in the amount of subsequent coronal bone loss.

Bilhan H et al., (2010)[27] compared bone around platform switched and regular platform implants that support removable prostheses and reported the clinical outcomes after a loading period of 36 months. The study concluded that platform switching caused statistically significant lower bone loss at the 36th months on the mesial as well as distal sides.

ANIMAL STUDIES:

Becker J et al., (2007)[28] investigated the influence of platform switching on crestal bone level changes at non submerged titanium implants. In his histomorphometric study in dogs, the study concluded crestal bone level changes happened but they found no significant differences between them.

Sarment DP et al., (2008)[29] elucidated the influence of implant dimensions on crestal bone morphology. The results concluded that craterization after placement of healing abutments and a healing period was observed around all implants. Width and height of the cuff varied significantly with implant diameter and platform design, but the angle formed with the implant did not vary significantly.

Weiner S et al., (2008)[30] examined the crestal bone, connective tissue, and epithelial cell response to a laser microtextured collar compared with a machined collar, in the dog model.Initially the experimental implants showed greater bone attachment along the collar. With time the bone heights along the control and experimental collars were equivalent. However, the controls had more soft tissue downgrowth, greater osteoclastic activity, and increased saucerization compared with sites adjacent to experimental implants. There was closer adaptation of the bone to the laser microtextured collars. They concluded that the use of tissue engineered collars with microgrooving seems to promote bone and soft tissue attachment along the collar and facilitate development of a biological width.

HISTOLOGICAL STUDIES:

Ericsson I et al., (1995)[31] found histological evidence that an inflammatory cell infiltrate was located 1 to 1.5 mm adjacent to the IAJ. Considering the fact that bone is always encircled by approximately 1 mm of healthy connective tissue, it was assumed that crestal bone remodeling may take place establish space between the bone and the microbial contaminated tissue of the IAJ to create a biologic seal.

Luongo R et al., (2008)[32] studied biopsy specimen to find out the biologic process occurring around the platform switched implant. They found that an inflammatory connective tissue infiltrate was localized over the entire surface of the implant platform and approximately 0.35 mm coronal to the IAJ but did not reach the crestal bone, which may be the reason for crestal bone preservation by platform switching.

Degidi M et al., (2008)[33] evaluated the histology and histomorphology of three morse cone connection implants in a real case report and concluded that when there is zero microgaps and no micro movement, platform switching shows no resorption and this method provides better aesthetic results.

Cochran DL et al., (2009)[34] histologically evaluated the alveolar bone change around a bone level, non matching implant abutment diameter configuration that incorporated a horizontal offset and a morse taper internal connection. The results revealed that minimal histologic bone loss occurred when dental implants with non matching implant abutment diameters were placed at the bone crest. The bone loss was significantly less (five to six fold) than that reported for bonelevel implants with matching implant abutment diameters (butt joint connections).

FINITE ELEMENT ANALYSIS STUDIES:

Maeda Y et al., (2007)[35] showed that the stress level in the cervical bone area at the implant was greatly reduced when the narrow diameter abutment was connected and compared with the regular sized one. They suggested that the platform switching configuration has the biomechanical advantage of shifting the stress concentration area away from the cervical bone implant interface.

Schrotenboer et al.,(2008)[36] investigated the effects of implant microthreads on crestal bone stress compared to a standard smooth implant collar and analyzed different abutment diameters that influenced the crestal bone stress level. They concluded that microthreads increased crestal stress upon loading. Reduced abutment diameter resulted in less stress translated to the crestal bone in the microthread and smooth neck groups.

Hsu JT et al., (2009)[37] analyzed the behaviour of reduced platform restorations in a 3 D FEA. Their results showed a 10% decrease in all the prosthetic loading forces transmitted to the bone implant interface.

Rodriguez-Ciurana X et al., (2009)[38] in a two-dimensional biomechanical study involving platform switching integrated into the implant design, failed to obtain peri-implant bone force attenuation values as high as those reported in earlier studies, when comparing platform expansion with a traditional restoration model. In addition, the authors concluded that force dissipation in the platform switching restoration was slightly more favourable in an internal than in an external junction, since it improves distribution of the loads applied to the occlusal surface of the prosthesis along the axis of the implant. On the other hand, this concentration of forces along the axis of the implant, transmitted through the retention screw, increases the possibility of abutment fracture, and thus may lead to failure of the restoration.

Canay S et al., (2009)[39]in a three dimensional finite elements analysis involving different implant free expanded platform dimensions and a range of abutment designs, claimed that the effect of platform expansion is not attributable to the distribution of loads to the peri-implant bone but rather simply to redistribution of the new biological space. The most appropriate reduced platform abutment design for securing lesser implant abutment material fatigue was represented by conical emergence abutments with a variable height of 1.5-2 mm, freeing extension of the implant platform between 0.5-0.75 mm.

Tabata LF et al., (2010)[40] evaluated the biomechanical concept of platform switching with relation to stress distribution using two-dimensional finite element analysis. The result of this study showed that the platform switching presented better biomechanical behavior in relation to stress distribution on the implant especially in the bone tissue (80% less). However, in the crown and retention screw, an increase in stress concentration was observed.

This study was designed and conducted by the Department of Periodontics, JKKN Dental College and Hospital, Komarapalayam, to evaluate clinically and radiographically the peri-implant bone loss around platform switching and non platform switching implants.

STUDY DESIGN

This study was designed as a randomized controlled split-mouth trial. Ten patients with bilaterally missing mandibular posteriors to be restored with implant supported single crowns, were consecutively enrolled. The ethical clearance was obtained from the Institutional Review Board (IRB) prior to the start of the study. A coin toss was utilized to randomize the implant placed in the patient. A total of 20 implants were placed. The test implants were integrated with a concept of platform switching and control implants with non platform switching design. Peri-implant crestal bone levels were standardized by radiovisiography prior to surgery. Implants were purchased from Norris implant (Norris Medical Ltd. Headquarters and R&D center, Israel) and the trade name for platform switching is Tuff TT implants and non-platform switching is Tuff implants as shown in (Fig: 2&3). Patients were selected according to the following inclusion and exclusion criteria.

INCLUSION CRITERIA

- Patients with bilateral missing mandibular posteriors.
- Patients with age limit ≥18 years of bothgender.
- Residual bone height ≥ 10 mm and bone width ≥ 4mm with stable interocclusal contacts.
- Bone density of D1 and D2.

EXCLUSION CRITERIA

- History of periodontitis.
- Reported uncontrolled diabetes and or alcoholism.
- Known Drug allergy.
- Smokers.
- Pregnancy and lactating women.
- Lack of occluding dentition and bruxism.
- Immunosuppression.

STUDY DESIGN:

1st month → 1st Stage surgery (Implant placement)

3rd – 4th month → 2nd Stage surgery (Healing abutment)

Final abutment placement with prosthetic procedure

4th – 5th month → Final restoration with baseline

9th month → Second Follow -Up

12th month → Third Follow - Up

The nature and design of the clinical trial was explained to the patients and consent was obtained for their participation. All the patients were subjected for scaling and oral hygiene instructions were given (Appendix-1).

Criteria for grouping

The single tooth implant sites bilaterally were selected in the posterior region of the lower jaw. The selected sites were categorized into two groups.

Group A: Edentulous area placed with Non Platform switching implants (Control site).

Group B: Edentulous area placed with Platform switching implants (Test site).

Pre – Surgical procedure

Panoramic radiographs were taken for the preoperative evaluation of the bone quality, implant position and orientation. The diagnostic template was made which has 5 mm ball bearing, incorporated around the curvature of the dental arch and worn by the patient during the radiographic examination, which enabled the operator to determine the amount of magnification in the radiograph as shown in (Fig: 6). Ridge mapping was done with an endodontic stopper penetrated through the soft tissue in the area under evaluation for implants. The soft tissue thickness at the ridge crest, at two points vertically down on the buccal and the lingual areas, was measured. The edentulous area of the diagnostic cast was sectioned perpendicular to the ridge. The tissue thickness was then mapped out on the sectioned diagnostic cast using a pencil. Based on this analysis, the appropriate implant diameter and platform size was selected to best fit the single tooth edentulous area. After a preoperative work-up, a diagnostic wax-up of the planned restoration and fabrication of a surgical stent was done before the implant surgery. This stent was made for proper positioning of implant shoulder and provide an ideal emergence profile with long term peri-implant hard and soft tissue support.

Surgical procedure

All the patients were surgically prepared with routine blood investigation and radiographic assessment. Antimicrobial prophylaxis (Amoxicillin 500mg) was given one hour before surgery and continued thrice daily for 7 days. Post-surgical analgesics (Paracetamol 325mg + Aceclofenac 100 mg + Serratiopeptidase 15 mg) were prescribed twice daily for one week and oral hygiene instructions were given (Appendix-1).

A total of 20 implants were inserted in 10 patients requiring oral rehabilitation with bilaterally missing mandibular posteriors. Local anesthesia was induced by using lignocaine (2%) and adrenaline (1:80,000) for both the groups.

Two types of cylindric titanium implants (Norris) were used in this study. Both had a three thread zones, Tuff implants have been uniquely designed according to the anatomy of the bone structure. The lower V-shape thread zone is for self-tapping. The middle zone has a square thread design, used especially for compressing cancellous bone, and help achieving maximum bone implant contact (BIC). The microthread design on the upper zone adds stability and reduces crestal bone loss. The difference in the structure of Tuff TT implants compared to Tuff implants is their converging coronal shape that allows platform switch technology to reduce crestal bone loss. The control implants were Norris Tuff implants with an internal hex. The test implants were Norris Tuff TT implants with an internal hex.

A minimally invasive flap was designed with an intrasulcular and crestal incision, without releasing incision. Drills were used to prepare the implant site according to bone density and the manufacturer’s instructions. Implants were placed with an insertion torque between >35 and <45 Ncm. Implant diameter used in this study were 3.75mm, 4.2mm and 5mm and lengths ranging from 8 mm, 10 mm, 11.5 mm. The mesio-distal and bucco-lingual implant position was partially determined by the morphology of alveolus. Then the implant was placed using pilot, intermediate, and final drill in such a way that cover screw was corresponding to the level of the adjacent bone. The primary closure of the wound was achieved by stabilization of the flap with simple interrupted suture 3-0 silk thread. The suture was removed one week after the implant surgery.

After 3 months of implant placement, the patients were subjected to a second surgical procedure. Healing abutments were mounted on to the implants in order to condition the peri-implant soft tissues for 4-6 weeks.[41] This healing abutment connection was done by a simple midcrestal incision. Later, final abutment was selected and placed at 35Ncm by using torque wrench. The Tuff TT implants (Test site) received a lesser diameter healing abutments than the implant platform diameter. The Tuff implants (Control site) received identical abutments matching the implant platform diameters. The prosthetic crown was prepared, cemented with type I GIC cement and baseline data were recorded as shown in (Fig: 7&8). Then the patients were recalled for further follow up at 9th and 12th month corresponding to a functional loading time of 4 months and 1 year respectively.

Clinical parameters:

Assessment of soft tissues at the implant site was performed after crown cementation at baseline, 9 months & 12 months by single examiner. At the follow up visits, the following parameters were assessed as shown in (Fig: 9).

1. Width of keratinized mucosa (Bouri A et al., 2008)[42]
2. Thickness of peri-implant mucosa (Austria M et al., 1992)[43]
3. Papilla Index (Jemt T et al., 1997)[44]
4. Soft tissue Index (Bengaziet al., 1996)[45]
5. Probing Pocket Depth (Schroppet al., 2005)[46]

1) Width of keratinized Mucosa - (Bouri A et al., 2008)

The width of the keratinized mucosa was measured at the mid-facial aspect of each implant using UNC 15 (equinox) ® probe. Each measurement was made from the gingival margin to the mucogingival junction. The mucogingival junction was identified by the rolling technique, where in the mucosa was rolled until the non movable portion of the attached keratinized tissue was identified.

2) Thickness of peri-implant Mucosa - (Austria M et al., 1992)

The thickness of the gingiva around dental implant was measured approximately 2 mm apical to the gingival margin on the facial aspect of the implant. After topical anesthetic application, the thickness was measured gently inserting a sterile endo reamer with a rubber stopper, until contact of the underlying bone structure. The gingival biotype was considered thin if the measurement was less than 1.0 mm and thick if it measured greater than 1.0 mm.

3) Papilla Index - (Jemt T et al., 1997)

Clinical photographs were taken with single examiner using the same magnification and illumination. These photographs were digitalized at a resolution of 1000 dpi. Papilla was scored using a modified scale previously described by Jemt.

The index was defined briefly as,

Score 1: No papilla was present.

Score 2: Less than 50% filling with minimal papilla present.

Score 3: Papilla that did not fill the space completely and had over 50% of the space filled.

Score 4: The papilla fills up the entire interdental space and had comparable filling to adjacent, non-implant restored papilla.

4) Soft Tissue Index - (Bengazi et al., 1996)

Indices used to access marginal mucosal conditions around oral implants are followed,

Score 0: No color or texture alterations

Score 1: Slight change in color and texture

Score 2: Marked change in color or texture and bleeding following superficial probing.

5) Probing Pocket Depth - (Schropp et al., 2005)

Probing pocket depth was measured (distance between the gingival margin and the most apically probeable portion, in millimeters) at the buccal, mesial, distal and lingual aspects of the single tooth implant by plastic probe (Hu-friedy)®.

RADIOGRAPHIC ASSESSMENT

RadioVisioGraphs (RVG) of the implants were obtained after 2nd stage surgery during cementation of the crown. The CCD (Charge Coupled Device) of RVG was kept in precise orientation with bisecting angle technique and data was recorded. The assessment was carried out at baseline, 9th and 12th month follow up visits as shown in (Fig. 10). Radiographs were digitalized and analysed for peri-implant bone loss using Sopro imaging software.

Measurements - (Tomas Linkevicius, 2015)

Bone loss in millimeters was calculated by comparing the baseline radiographs with radiographs obtained during recall visits.

The edge of the implant and the first radiographic bone-implant contact were selected as the reference points for bone loss calculation. The mean of the mesial and distal measurement was recorded for the implant as shown in (Fig: 11).[47]

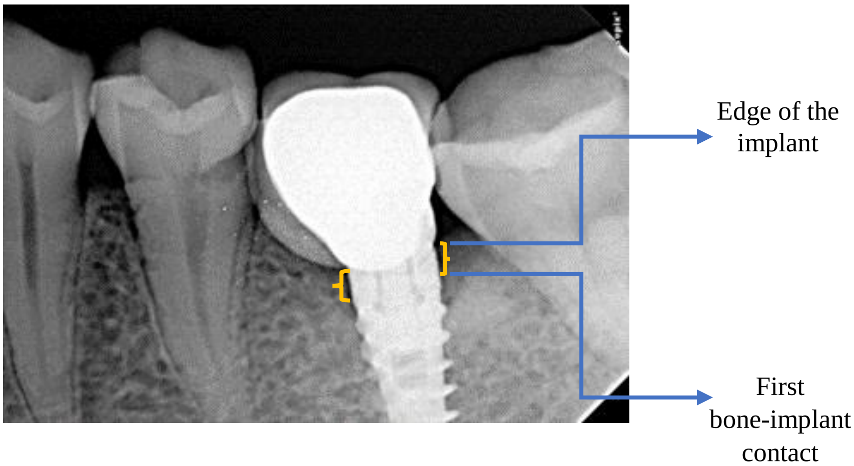


FIGURE: 11

APPENDIX -1

Instructions to the Patient

1. Advised to follow the prescribed medication.
2. To perform regular oral hygiene habits by appropriate brushing technique using tooth brush and tooth paste.
3. 0.2% chlorhexidine gluconate rinse twice daily for 2 weeks after surgery.
4. In case of discomfort, patients were advised to report immediately.
5. Patients were instructed to maintain a soft diet for 4 weeks.
6. The patients were dispersed and instructed to report at regular intervals.

APPENDIX -2

ARMAMENTARIUM

MATERIALS AND INSTRUMENTS USED FOR IMPLANT SURGERY

- Surgical Gloves
- Mouth mask
- Patient apron
- Chair apron
- Head cap
- Sterile gauze
- Saline
- Betadine
- Kidney tray
- Lignocaine
- Syringe
- Mouth mirror
- Straight probe
- Explorer
- William's graduated periodontal probe
- Hu-Friedy plastic probe
- UNC 15 probe
- Ridge caliber

- Metal scale
- Bard Parker blade no 11, 15
- Periosteal elevator
- Tweezer, Tissue holding forceps
- Metal suction tube
- Physio dispenser
- Implant kit
- Needle holder
- 3-0 suture material
- Cutting scissors

APPENDIX -3

PROFORMA

Op No:	Date:
Name:	Age:
Sex:	Ph no:

Occupation:

Address:

Chief complaint:

Platform switching Implant: ☐ Non Platform switching Implant: ☐

Pre-surgical medical history:

Pre-surgical dental history:

Oral hygiene habits:

Materials used to clean the teeth:

If brush:

1) Type of brush

2) Paste powder others

3) Frequency of Brushing

4) Method of brushing

Pre-surgical Oral examination:

Extra-Oral examination:

Intra oral examination:

Information on bone quality: (Misch 1988)

D 1 ☐

D 2 ☐

D 3 ☐

D 4 ☐

Type of placement:

Implant region:

Implant tooth site:

Adjacent Tooth:

Duration:

(Partial edentulous period)

Implant size: Diameter: Length:

CLINICAL PARAMETERS

Width of the keratinized gingiva:

(Facial side)

Control Site:

	At midline of the crown (mm)
Baseline	
9th month	
12th month	

Test site:

	At midline of the crown (mm)
Baseline	
9th month	
12th month	

Thickness of peri-implant mucosa:

(2 mm below the gingival margin at the midline of the crown)

Control Site:

	At midline of the crown (mm)
Baseline	
9th month	
12th month	

Test Site:

	At midline of the crown (mm)
Baseline	
9th month	
12th month	

Papilla Index score:

Control Site:

	Mesial	**Distal**
Baseline		
9th month		
12th month		

Test Site:

	Mesial	**Distal**
Baseline		
9th month		
12th month		

Soft tissue Index score:

Control Site:

	SCORE LEVEL
Baseline	
9th month	
12th month	

Test Site:

	SCORE LEVEL
Baseline	
9th month	
12th month	

Probing Pocket Depth: (mm)

Control site:

	Mesial	Distal	Buccal	Lingual
Baseline				
9th month				
12th month				

Test site:

	Mesial	Distal	Buccal	Lingual
Baseline				
9th month				
12th month				

Radiological assessment:

Peri-implant Bone loss:

Control site:

	Mesial	Distal	Average
Baseline			
9^{th} month			
12^{th} month			

Test site:

	Mesial	Distal	Average
Baseline			
9^{th} month			
12^{th} month			

J.K.K NATTRAJA DENTAL COLLEGE, KOMARAPALAYAM

DEPARTMENT OF PERIODONTICS

INFORMED CONSENT OBTAINED FROM THE PATIENT

Patient Name:

I have been explained about the nature and purpose of the study in which, I have been asked to participate. I understand that I am free to withdraw my consent and discontinue at any time without prejudice to me or effect on my treatment.

I have been given the opportunity to question about the material and study, I have also given the consent for photographs to be taken at the beginning, during and at the end of the study. I have fully agreed to participate in this study.

I hereby give the consent to be included in “EVALUATION OF PERI-IMPLANT BONE LOSS AROUND PLATFORM SWITCHING AND NON PLATFORM SWITCHING IMPLANTS” – A Randomized controlled trial.

Place:

Date: **Signature of the patient:**

ARMAMENTARIUM

FIGURE 1: SURGICAL INSTRUMENTS WITH PHYSIODISPENSER

FIGURE 2: NORRIS IMPLANT KIT

FIGURE 3: NON PLATFORM AND PLATFORM SWITCHING IMPLANTS

PRE-OPERATIVE EVALUATION

FIGURE 4: PRE-OPERATIVE

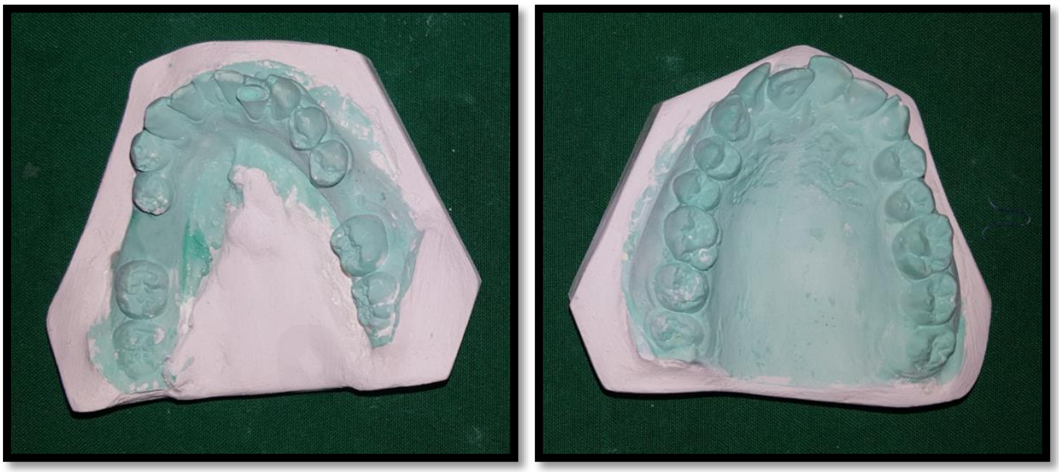


FIGURE 5: DIAGNOSTIC CAST

FIGURE 6: ORTHOPANTAMOGRAPHY (OPG)

FIGURE 7: CLINICAL CASES

CONTROL SITE

PRE-OPERATIVE

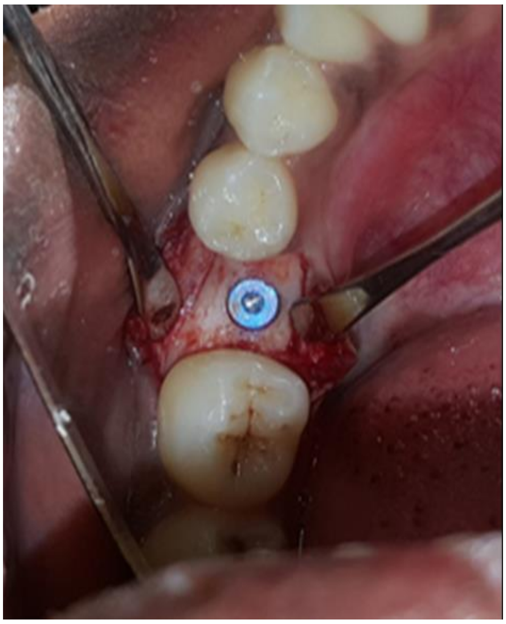
CRESTAL INCISION GIVEN

MUCOPERIOSTEAL

FLAP ELEVATED

OSTEOTOMY SITE

PREPARED USING DRILLS

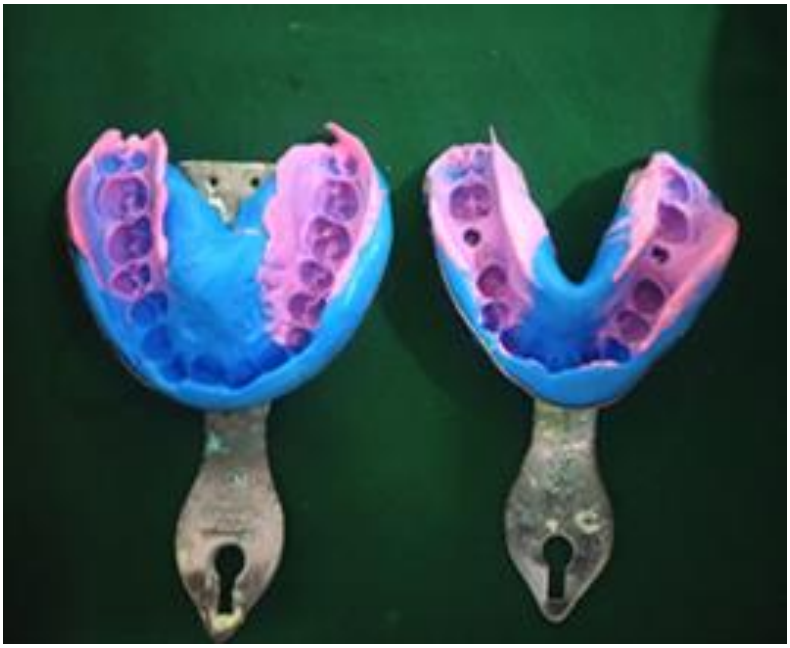


IMPLANT PLACED INTO OSTEOTOMY SITE

SIMPLE INTERRUPTED SUTURE GIVEN

HEALING ABUTMENT PLACED

FINAL ABUTMENT PLACED



IMPRESSION MADE

CROWN PLACED IN 36

FIGURE 8: CLINICAL CASES

TEST SITE

PRE-OPERATIVE

CRESTAL INCISION GIVEN

MUCOPERIOSTEAL FLAP ELEVATED

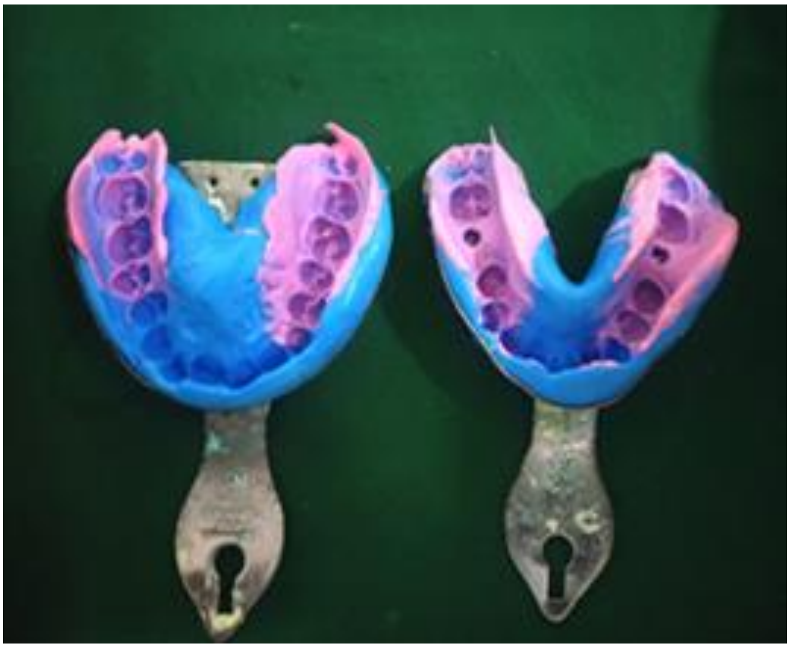
OSTEOTOMY SITE PREPARED USING DRILLS

IMPLANT PLACED INTO OSTEOTOMY SITE

SIMPLE INTERRUPTED SUTURE GIVEN

HEALING ABUTMENT PLACED

FINAL ABUTMENT PLACED



IMPRESSION MADE

CROWN PLACED IN 46

FIGURE 9: CLINICAL PARAMETERS

CONTROL SITE | **TEST SITE**

WIDTH OF KERATINIZED GINGIVA

WIDTH OF KERATINIZED GINGIVA

THICKNESS OF PERI IMPLANT MUCOSA

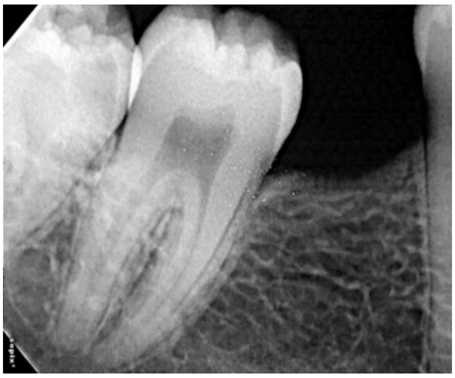
THICKNESS OF PERI IMPLANT MUCOSA

PROBING POCKET DEPTH

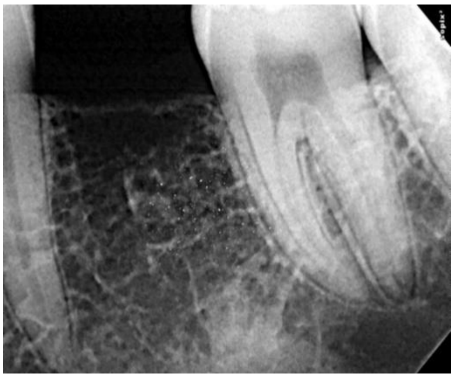
PROBING POCKET DEPTH

FIGURE 10: RADIOGRAPHIC VIEW

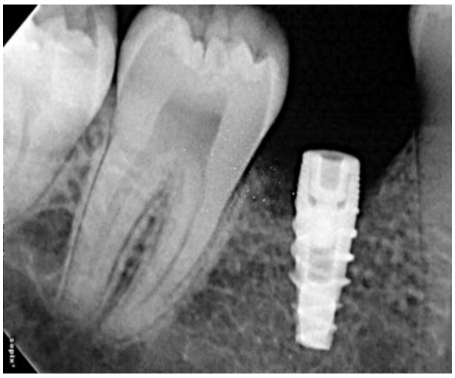
CONTROL SITE | **TEST SITE**



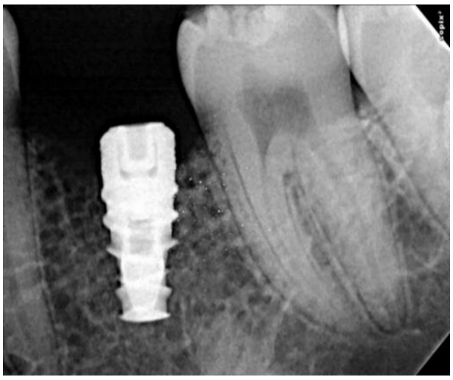
PRE-OPERATIVE



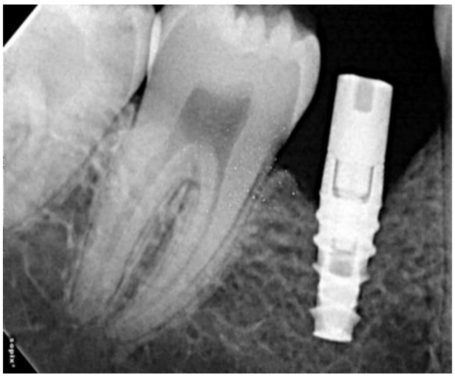
PRE-OPERATIVE



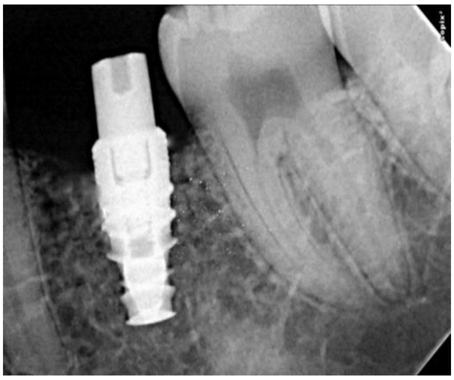
IMPLANT PLACED



IMPLANT PLACED



HEALING ABUTMENT PLACED

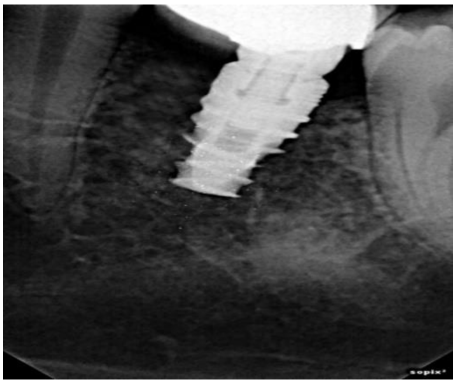


HEALING ABUTMENT PLACED

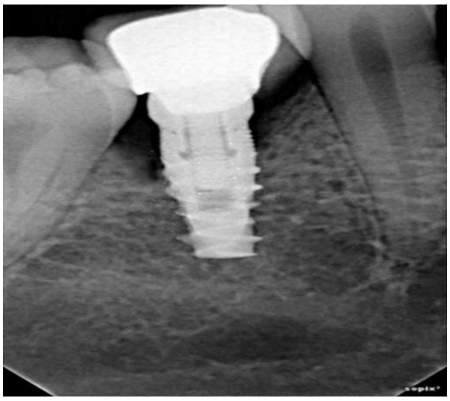
FINAL ABUTMENT PLACED

FINAL ABUTMENT PLACED

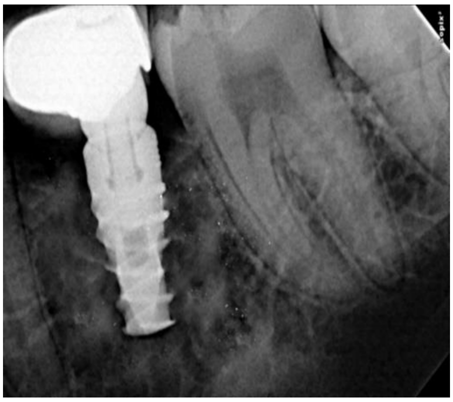
POST OPERATIVE



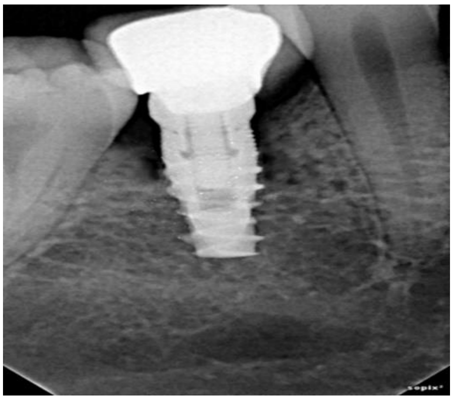
POST OPERATIVE



POST OPERATIVE 9 MONTHS



POST OPERATIVE 9 MONTHS



POST OPERATIVE 12 MONTHS

POST OPERATIVE 12 MONTHS

STATISTICAL ANALYSIS:

The data collected were compiled using MS-office excel and was subjected to statistical analysis using IBM corp. SPSS (Statistical package for social sciences) Statistics for windows, version 20.0 (Armonk,NY). Descriptive and Inferential statistics were used to analyse the data. Normality of the data was assessed. Paired 't' test was used for within group comparison and Independent't' test was used for between group comparisons. p-value ≤ 0.05 was denoted as the statistically significant value.

RESULTS

A total of 20 subjects were selected for the study and were divided in a split mouth design. Group A subjects were placed with non platform switching implants, whereas Group B subjects were placed with platform switching implants.

Width of keratinized gingiva: (mm)

In Group A, the mean width of keratinized gingival at baseline was 2.8 ± 0.51 mm and after 9 months the value was 2.19 ± 0.39 mm and at 12 months the value was 1.8 ± 0.44 mm. In Group B, the mean width of keratinized gingiva at baseline was 2.89 ± 0.54 mm and after 9 months the value was 2.69 ± 0.50 mm and at 12 months the value was 2.4 ± 0.48 mm as shown in Table and Graph - 1. Statistically significant difference was found in Group B when compared to Group A at 9 and 12 months ($p<0.05$).

Thickness of peri-implant mucosa: (mm)

In Group A, the thickness of peri-implant mucosa at baseline was 2.3 ± 0.48 mm and after 9 months the value was 1.9 ± 0.31 mm and at 12 months the value was 1.8 ± 0.37mm. In Group B, the thickness of peri-implant mucosa at baseline was 2.28 ± 0.55 mm and after 9 months the value was 1.97 ± 0.71mm and at 12 months the value was 1.90 ± 0.68 mm as shown in Table and Graph - 2. No statistically significant difference was found between the two groups. ($p>0.05$).

Papilla Index:

In Group A, the papilla index score at 9 months showed a complete filling up of the entire interdental space in 70% of the patients and 50% of the space filled in 30% of the patients and at 12 months showed a complete filling up of the entire interdental space in 60% of the patients and 50% of the space filled in 40% of the patients. Whereas in Group B, the papilla index score at 9 months showed a complete filling up of the entire interdental space in 100% of the patients and at 12 months showed a complete filling up of the entire interdental space in 90% of the patients and 50% of the space filled in 10% of the patients as shown in Table and Graph - 3&4. No statistically significant difference was found between the two groups ($p>0.05$).

Soft Tissue Index:

In Group A, the soft tissue index score at 9 and 12 months showed no color or texture alterations in 10% of the patient and slight change in color or texture alterations in 90% of patients. Whereas, in Group B the soft tissue index score at 9 and 12 months showed no color or texture alterations in 50% of the patient and slight change in color or texture alterations in 50% of patients as shown in Table and Graph - 5&6. Statistically significant difference was found in Group B when compared to Group A ($p<0.05$).

Probing Pocket Depth: (mm)

In Group A, the mean Probing Pocket Depth at baseline was 2.6 ± 0.69 mm and after 9 months the value was 2.7 ± 0.48 mm and at 12 months the value was 3.8 ± 0.91 mm. In Group B, the mean Probing Pocket Depth at baseline was 2.3 ± 0.48 mm and after 9 months the value was 2.4 ± 0.51 mm and at 12 months the value was 3.2 ± 0.63 mm as shown in Table and Graph - 7. A clinically significant difference was found in Group B when compared to Group A but no statistically significant difference was found between the groups ($p>0.05$).

Crestal bone loss: (mm)

In Group A, the mean crestal bone loss at 9 months was 2.67 ± 0.22 mm and after 12 months the value was 2.8 ± 0.23 mm. In Group B, the mean crestal bone loss at 9 months was 1.4 ± 0.07 mm and after 12 months the value was 1.35 ± 0.09 mm as shown in Table and Graph - 8. Statistically significant difference was found in Group B when compared to Group A ($p<0.05$).

TABLE 1: Comparison of the Width of keratinized gingiva in Group A and B at baseline, 9 months and 12 months.

Time	Group A Mean ± SD	Group B Mean ± SD	p - value
Baseline	2.8 ± 0.51	2.89 ± 0.54	> 0.05
9 months	2.19 ± 0.39	2.69 ± 0.50	< 0.05*
12 months	1.88 ± 0.44	2.43 ± 0.48	< 0.05*

p –value < 0.05* denotes statistically significant at 5% level.

p – value > 0.05 denotes statistically insignificant at 5% level.

TABLE 2: Comparison of Thickness of peri-implant mucosa in Group A and B at baseline, 9 months and 12 months.

Time	Group A Mean ± SD	Group B Mean ± SD	p - value
Baseline	2.3 ± 0.48	2.28 ± 0.55	> 0.05
9 months	1.93 ± 0.31	1.97 ± 0.71	> 0.05
12 months	1.8 ± 0.37	1.90 ± 0.68	> 0.05

p –value > 0.05 denotes statistically insignificant at 5% level.

TABLE 3: Comparison of Papilla Index in Group A and B at 9 months and 12 months.

Time	Score	9 Months		12 Months	
		Frequency	Percent	Frequency	Percent
Group A	**0**	0	0	0	0
	1	0	0	0	0
	2	0	0	0	0
	3	3	30.0	4	40.0
	4	7	70.0	6	60.0
Group B	**0**	0	0	0	0
	1	0	0	0	0
	2	0	0	0	0
	3	0	0	1	10.0
	4	10	100.0	9	90.0

TABLE 4: Intergroup comparison of Papilla Index between Group A and B using Independent 't' Test.

Time	t	df	p - value	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
						Lower	Upper
9 months	1.964	18	> 0.05	0.3000	0.1528	-0.0209	0.6209
12 months	1.567	18	> 0.05	0.3000	0.1915	-0.1023	0.7023

p –value > 0.05 denotes statistically insignificant at 5% level.

TABLE 5: Comparison of Soft tissue Index in Group A and B at 9 months and 12 months.

Time	Score	9 Months		12 Months	
		Frequency	Percent	Frequency	Percent
Group A	**0**	1	10.0	1	10.0
	1	9	90.0	9	90.0
	2	0	0	0	0
	3	0	0	0	0
	4	0	0	0	0
Group B	**0**	5	50.0	5	50.0
	1	5	50.0	5	50.0
	2	0	0	0	0
	3	0	0	0	0
	4	0	0	0	0

TABLE 6: Intergroup comparison of Soft tissue Index between Group A and B using Independent 't' Test.

Time	t	df	p - value	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
						Lower	Upper
9 months	-2.058	18	< 0.05*	-0.4000	0.1944	-0.8083	0.0083
12 months	-2.058	18	< 0.05*	-0.4000	0.1944	-0.8083	0.0083

p –value < 0.05* denotes statistically significant at 5% level.

TABLE 7: Comparison of Probing Pocket Depth in Group A and B at baseline, 9 months and 12 months.

Time	Group A Mean ± SD	Group B Mean ± SD	p - value
Baseline	2.6 ± 0.69	2.3 ± 0.48	> 0.05
9 months	2.7 ± 0.48	2.4 ± 0.51	> 0.05
12 months	3.8 ± 0.91	3.2 ± 0.63	> 0.05

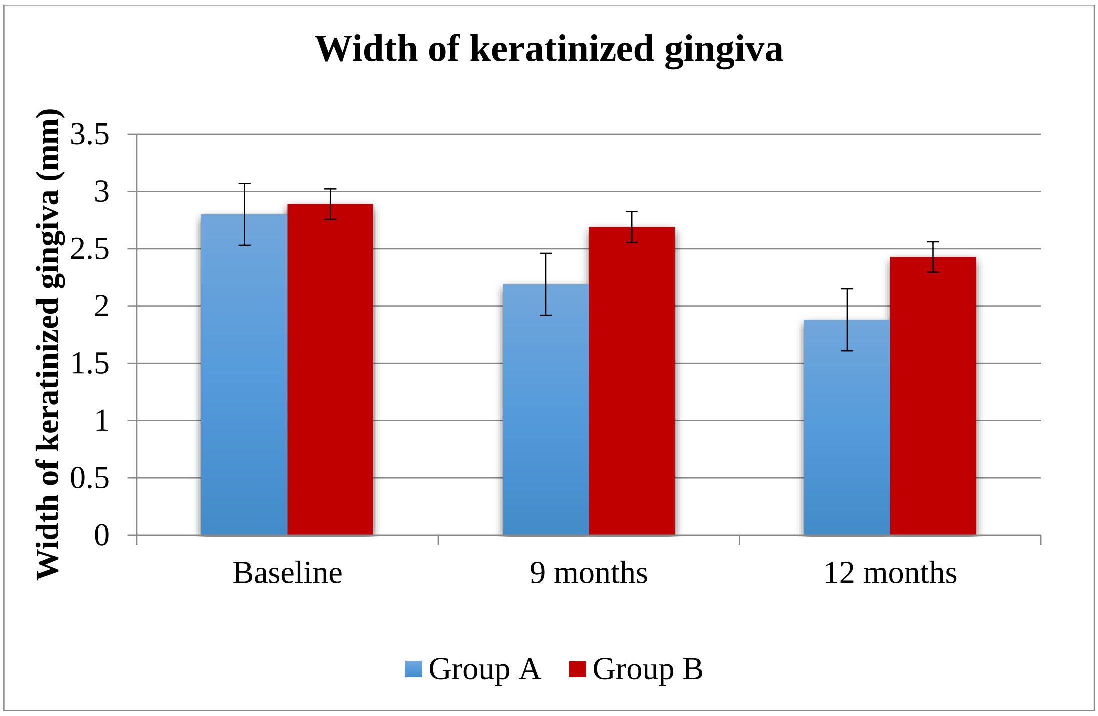
p –value > 0.05 denotes statistically insignificant at 5% level.

TABLE 8: Comparison of Crestal bone loss in Group A and B at 9 months and 12 months.

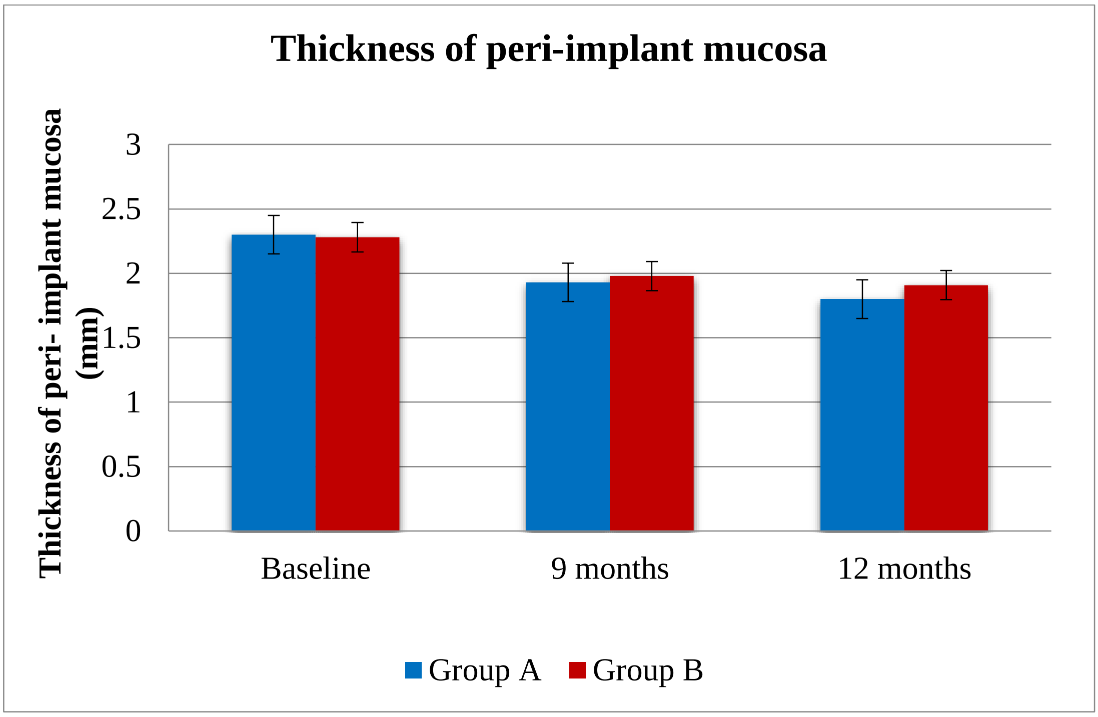
Time	Group A Mean ± SD	Group B Mean ± SD	p - value
9 months	2.6 ± 0.22	1.40 ± 0.07	< 0.05*
12 months	2.8 ± 0.22	1.35 ± 0.09	< 0.05*

p –value < 0.05* denotes statistically significant at 5% level.

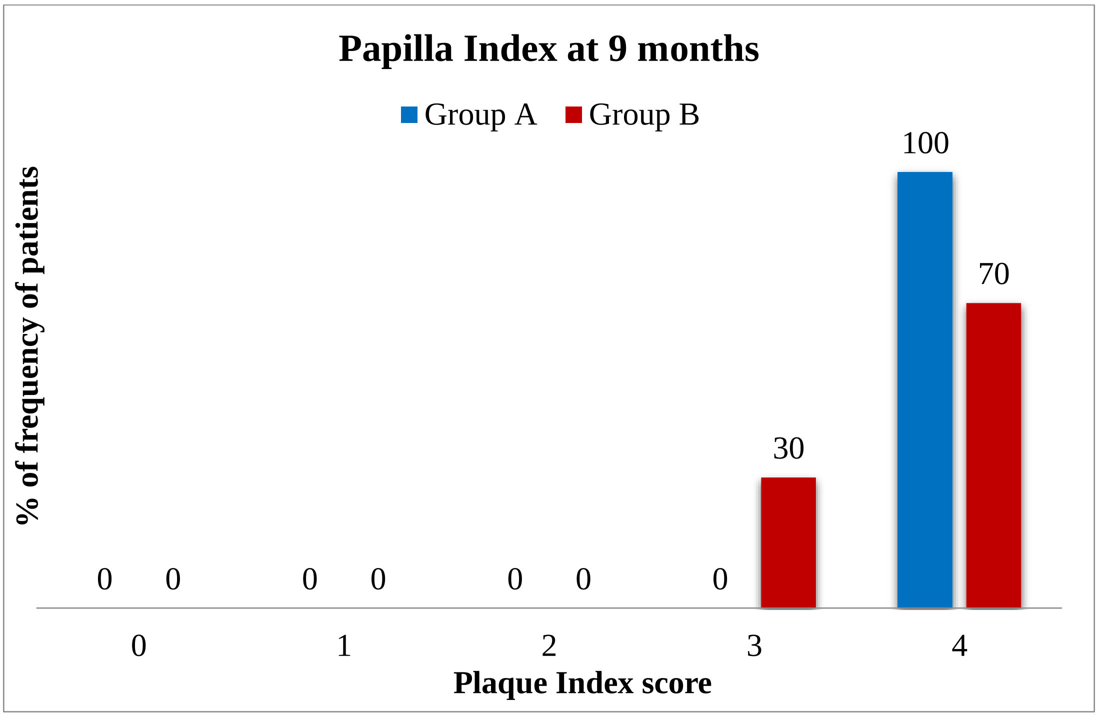
GRAPH 1: Comparison of the Width of keratinized gingiva in Group A and B at baseline, 9 months and 12 months.



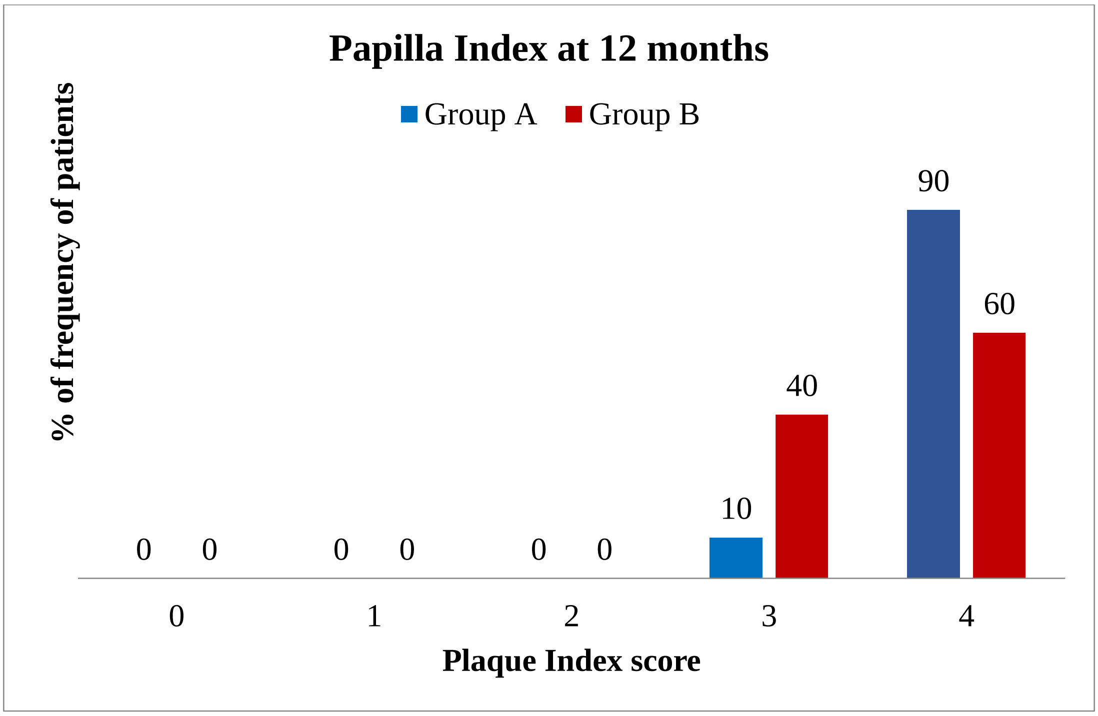
GRAPH 2: Comparison of Thickness of peri-implant mucosa in Group A and B at baseline, 9 months and 12 months.



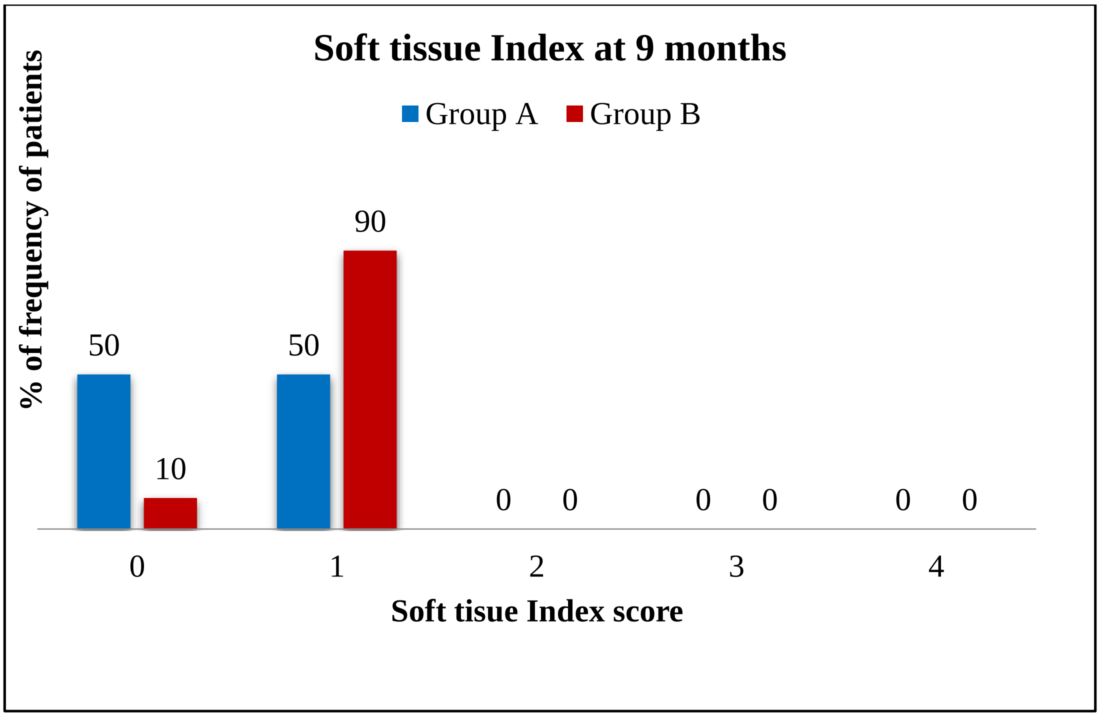
GRAPH 3: Distribution based on Papilla Index in Group A and B at 9 months.



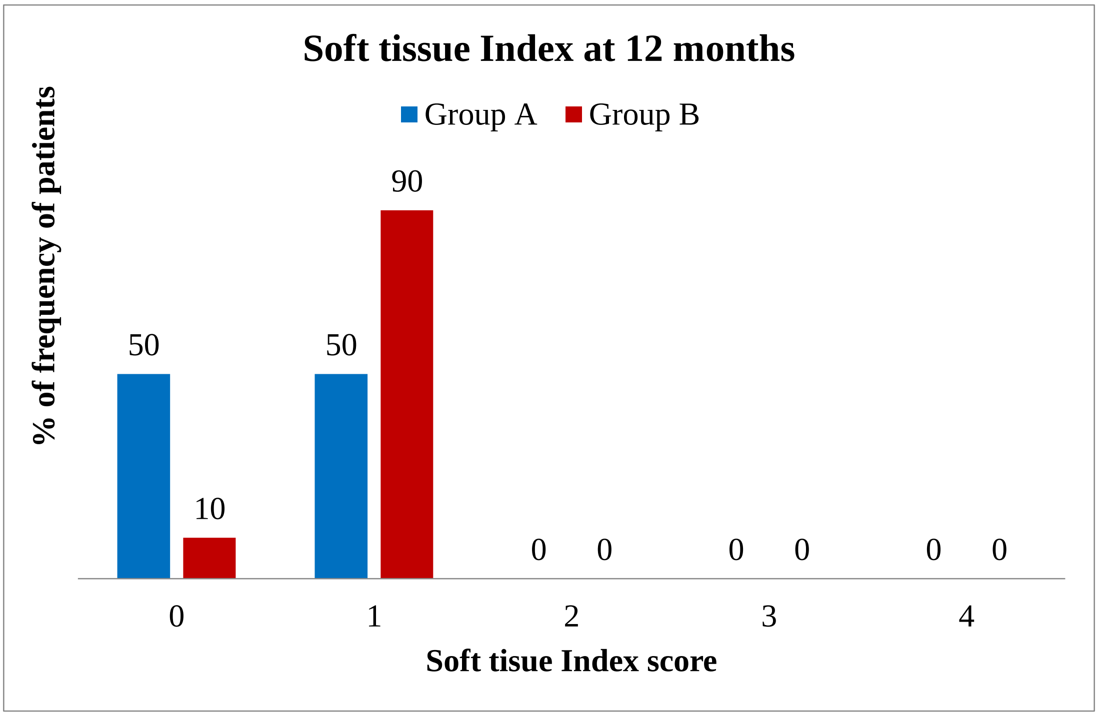
GRAPH 4: Distribution based on Papilla Index in Group A and B at 12 months.



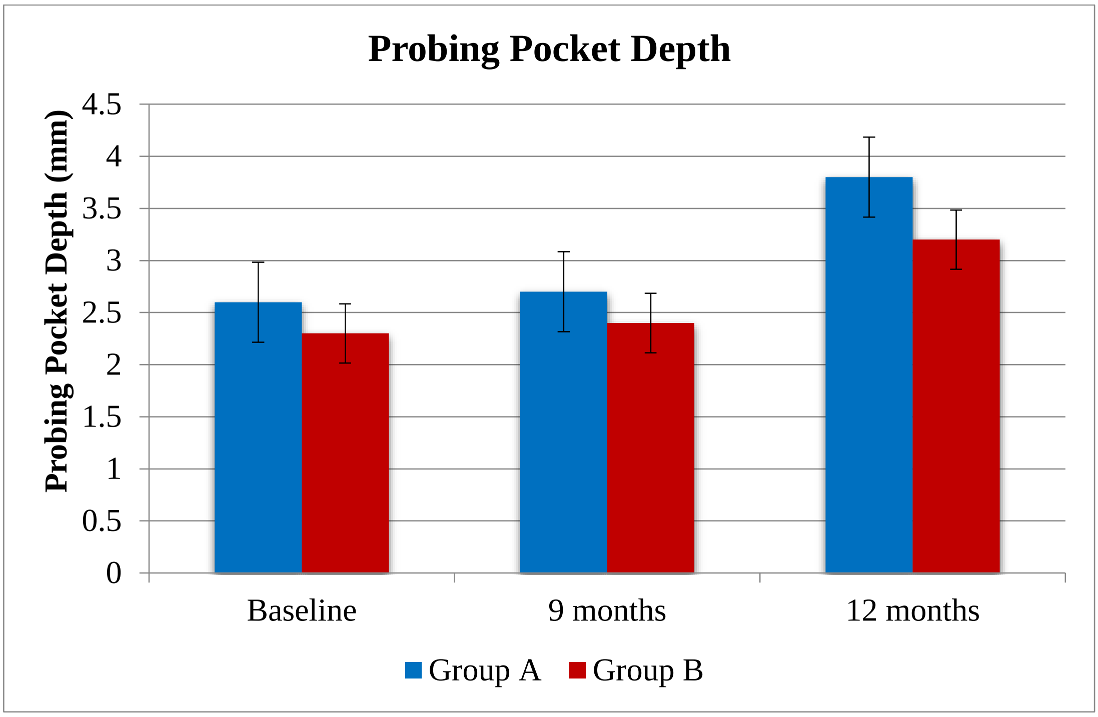
GRAPH 5: Distribution based on Soft tissue Indexin Group A and B at 9 months.



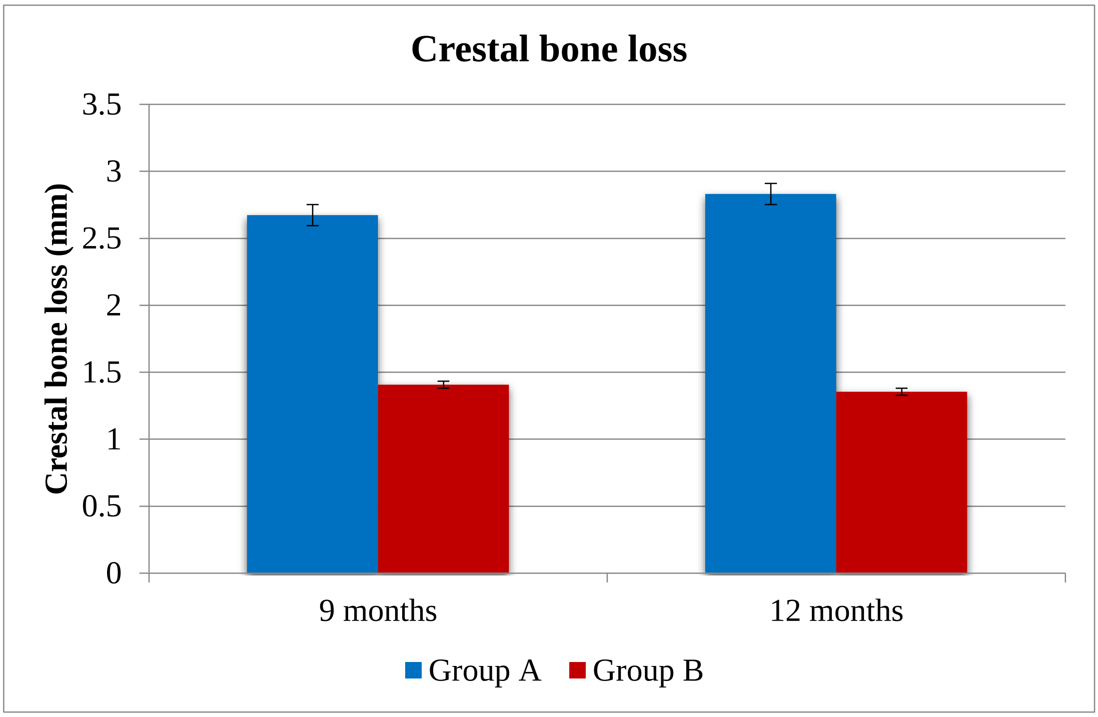
GRAPH 6: Distribution based on Soft tissue Indexin Group A and B at 12 months.



GRAPH 7: Comparison of Probing Pocket Depth in Group A and B at baseline, 9 months and 12 months.



GRAPH 8: Comparison of Crestal bone loss in Group A and B at 9 months and 12 months.



The success of dental implant is dependent upon the integration between the implant and the intraoral hard/soft tissue. Crestal bone loss is one of the factors that affect the long term prognosis of a dental implant. Platform switching is a concept recently introduced to reduce the crestal bone loss that is commonly found around implants exposed to the oral environment.

The aim of this study was to evaluate the peri-implant bone loss around platform switching and non platform switching implants observed over a period of 9 and 12 months. The width of keratinized gingiva, thickness of peri-implant mucosa, soft tissue index, papilla index and probing depth were also consistently examined. In this study, a two stage implant system was used in conjunction with platform switching to improve and maintain both osseous and soft tissue levels.

In the present study, at baseline, the mean width of keratinized gingiva for Group A was 2.80 ± 0.51 mm, at 9 months the value was 2.19 ± 0.40 mm and at 12 months the value was 1.88 ± 0.44 mm. In Group B the mean width of keratinized gingiva at baseline was 2.89 ± 0.54 mm, and the value at 9 months was found to be 2.69 ± 0.50 mm and at 12 months the value was 2.43 ± 0.49 mm as shown in (Table and Graph 1). Statistically significant difference was found between the two groups.

The mean thickness of peri-implant mucosa at baseline for Group A was 2.30 ± 0.48 mm, at 9 months the value was 1.93 ± 0.31 mm and at 12 months the value was 1.80 ± 0.37 mm. In Group B the mean thickness of peri-implant mucosa at baseline was 2.28 ± 0.55 mm, and the value at 9 months was found to be 1.98 ± 0.72mm and at 12 months the value was 1.90 ± 0.68 mm as shown in (Table and Graph 2). This was in accordance with the study done by Clavijo et al., 2012[48] who proposed that platform switching implants may perform alterations on adjacent soft tissues, associated to the correct surgical and prosthetic planning ensuring excellent esthetics and function.

In the present study, the soft tissue index for Group A at 9 and 12 months showed no color or texture alterations in 10% of the patient and slight change in color or texture alterations in 90% of patients. The soft tissue index for Group B at 9 and 12 months showed no color or texture alterations in 50% of the patient and slight change in color or texture alterations in 50% of patients (Table and Graph 3 & 4). This was in accordance with the study done by Baumgarten et al., 2005[12] who observed that the preservation of the residual bone height via platform switching was used for the rehabilitation of two central incisors and concluded that platform switching helped to preserve crestal bone and ensure more predictable long-term soft tissue levels.

In Group A, the papilla index score at 9 months showed a complete filling up of the entire interdental space in 70% of the patients and 50% of the space filled in 30% of the patients and at 12 months showed a complete filling up of the entire interdental space in 60% of the patients and 50% of the space filled in 40% of the patients. Whereas in Group B, the papilla index score at 9 months showed a complete filling up of the entire interdental space in 100% of the patients and at 12 months showed a complete filling up of the entire interdental space in 90% of the patients and 50% of the space filled in 10% of the patients as shown in (Table and Graph 5 & 6). This was supported by a study done by Tarnow et al., (2003)[49] who reported that platform switching reduces the physiological resorption, moving the microgap away from the bone that supports the papilla. This helps to avoid cosmetic deformities, phonetic problems and lateral food impaction.

In Group A, the mean Probing Pocket Depth at baseline was 2.6 ± 0.69 mm and at 9 months the value was 2.7 ± 0.48 mm and at 12 months the value was 3.8 ± 0.91. In Group B, at baseline the mean probing depth was 2.3 ± 0.48 mm, and at 9 months the value was 2.4 ± 0.51 mm and at 12 months the value was 3.2 ± 0.63 mm. A clinically significant difference was found in Group B when compared to Group A but no statistically significant difference was found between the groups as shown in (Table and Graph 7). According to Salimi et al., 2011[50], the initial shallower probing depth in the platform switching group may be a result of higher resistance to mechanical peri-implant probing because of the inward shift of the implant-abutment junction and possible soft tissue folding around the abutment.

In the present study, the crestal bone loss in Group A was found to be 2.6 ± 0.22 mm at 9 months and 2.8 ± 0.22 mm at 12 months. In Group B the crestal bone loss was found to be 1.4 ± 0.07 mm at 9 months and 1.3 ± 0.09 mm at 12 months as shown in (Table and Graph 8). This was in accordance with the study done by Lazarra et al.,(2006)[5], who observed that when smaller diameter components were placed on wider diameter implant platforms, no vertical loss was seen in the crestal bone height. This could be due to the increased surface area created by the exposed implant seating surface, there is a reduction in the amount of implant surface to which the soft tissue can attach. Second, and perhaps the more important by repositioning the IAJ inward and away from the outer edge of the implant and adjacent bone, the overall effect of the abutment ICT on the surrounding tissue may be reduced, thus decreasing the resorptive effect of the abutment ICT on crestal bone.

This was also supported by another study done by Vela nebot et al., (2006)[13] who proposed that, platform switching reduced the biologic and mechanical aggressions on the biologic width, thus resulting in peri-implant bone preservation with better aesthetics results. A study by Bilhan et al., (2010)[27] concluded that the marginal bone loss around implants that support removable prostheses was significantly lower in platform switching situations, owing to the fact that the platform switching repositions the abutment ICT on crestal bone and locates the inflammatory infiltrate within an approximate 90 degree confined area of exposure instead of 180 degree are of direct exposure to the surrounding hard and soft tissues. As a consequence, the reduced exposure and confinement of the platform switched abutment ICT may result in a reduced inflammatory effect within the surrounding soft tissue and crestal bone.

Based on the results obtained from the present study, there was a minute refinement in clinical parameters, with a marked reduction in the peri-implant bone loss when platform switching implants were placed compared to the traditional non platform switching implants.

However, the limitations of the study includes a small sample size and a short term follow up. In order to evaluate the long term effect of platform switching, a long term study with a larger sample size is required.

This study was conducted to evaluate the peri-implant bone loss around platform switching and non platform switching implants.

The study was designed as a randomized controlled split mouth clinical trial for a period of 12 months. The study population comprised of 10 subjects and 20 sites. Group A consists of 10 sites, in which non platform switching implants was placed (Control sites) and Group B consists of 10 sites, in which platform switching implants was placed (Test sites).

Clinical parameters such as width of keratinized gingiva, thickness of the peri-implant mucosa, papilla index, soft tissue index, probing pocket depth were evaluated. Radiographic evaluation of peri-implant bone loss was also analyzed.

Within the framework of this study, the following conclusions have been elucidated,

- Platform switching seems to reduce peri-implant crestal bone resorption and increase the long-term predictability of implant therapy.
- The width of keratinized gingiva and Soft tissue index in Group B showed statistically significant difference when compared to Group A.
- The thickness of peri-implant mucosa and Papilla index showed no statistically significant difference between the groups.
- The probing pocket depth showed a clinically significant difference in Group B when compared to Group A but no statistically significant difference was found between the groups.

- Crestal bone loss showed a statistically significant difference in Group B when compared to Group A

In summary, a promising method to reduce crestal bone loss is "The concept of platform switching". Platform switching showed a positive impact in maintenance or even enhancement of crestal bone levels when compared with platform matching abutments of the same implant system, allowing clinicians to a better understanding of two different techniques at 12 months post-loading.

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