A COMPARATIVE STUDY OF SOCKET PRESERVATION TECHNIQUE WITH AND WITHOUT DEMINERALIZED FREEZE DRIED BONE ALLOGRAFT AND CHORION MEMBRANE- A CLINICAL STUDY

DISSERTATION

Submitted to

BABUBANARASI DASUNIVERSITY, LUCKNOW. UTTAR PRADESH

In the partial fulfilment of the requirement of the degree of

MASTER OF DENTAL SURGERY

IN

PERIODONTOLOGY

By

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Under the guidance of

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BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

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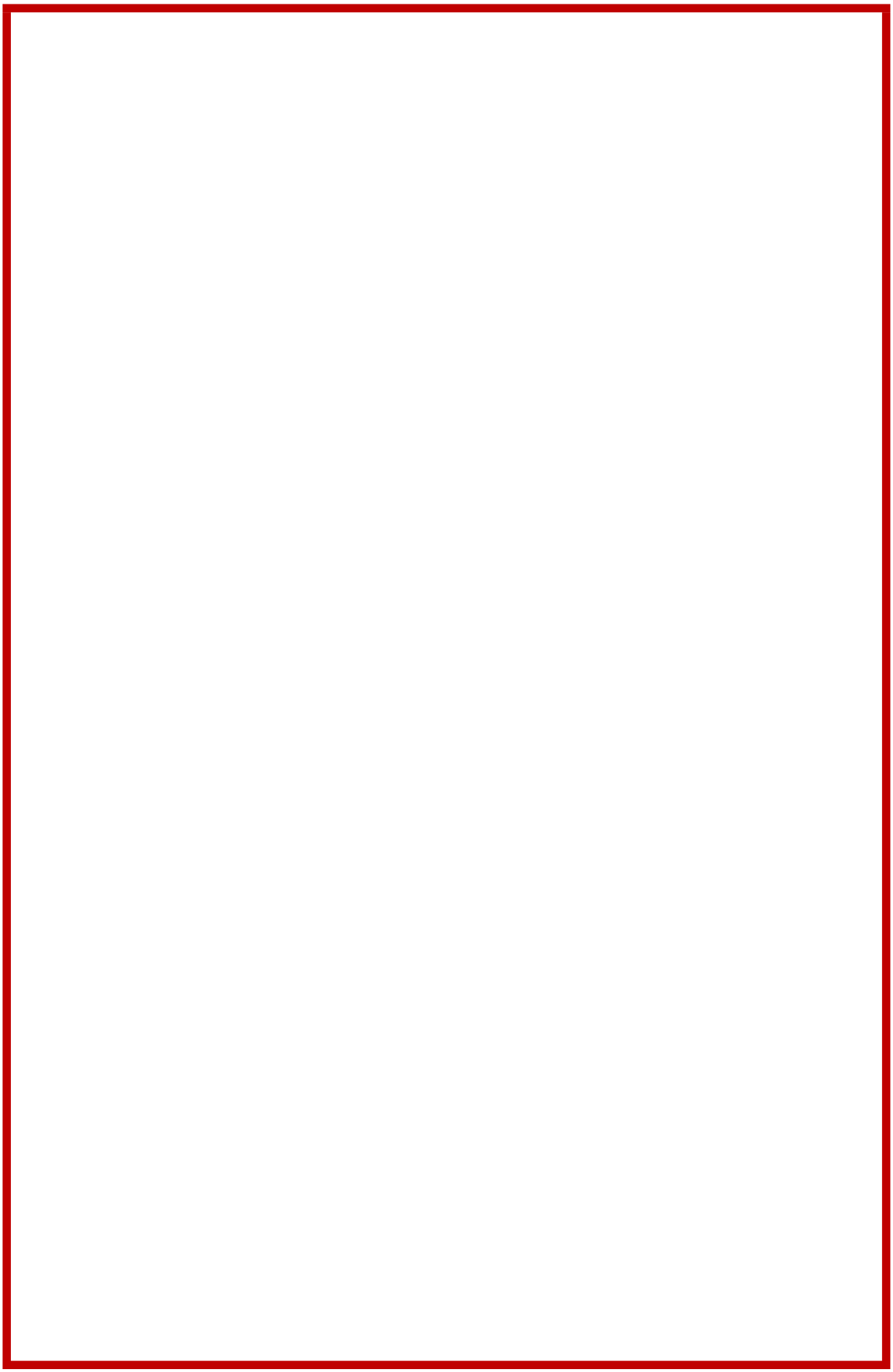

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REGARDS,

Dr. Hiya Datta

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LIST OF ABBREVIATIONS

DFDBA	Demineralized Freeze Dried Bone Allograft
d-HCM	Decellularized Human Chorion Membrane
ARP	Alveolar Ridge Preservation

ABSTRACT

INTRODUCTION: - The alveolar process is a tooth-dependent tissue that is developed in conjunction with tooth eruption. Subsequent to tooth extraction, the alveolar ridge undergoes resorption and atrophy resulting in loss of vital soft and hard tissues. The range of this dimensional change varies greatly among individuals. Approximately 5–7 mm of buccolingual or horizontal ridge reduction occurs over a 6–12-month period, with the majority of this change occurring during the first 4 months of healing. Alveolar ridge preservation (ARP) after extraction has been shown to be effective and predictable in reducing the postoperative buccolingual and vertical bone loss. Ridge preservation is any procedure undertaken at the time of or following an extraction that is designed to minimize external resorption of the ridge and maximize bone formation within the socket. Many grafting materials have been used and these include autogenous bone, demineralized freeze-dried bone allografts (DFDBA), xenografts, bioactive glass, hydroxyapatite and calcium sulphate. Barrier membranes are used as occlusive barriers in order to prevent the soft tissue from proliferating into the defect. Hence, the aim of the study is to preserve the extraction socket with allograft and barrier membrane and asses the bone gain 3 months post operatively.

MATERIAL AND MEDTHODOLOGY :- A 3 month longitudinal prospective study was conducted with 2 groups- Test and control groups which had 10 patients in each group. The concerned tooth was extracted and the socket was grafted with bone graft and membrane in the test group and in the control group the socket was allowed to heal on its own.

RESULT :- Socket preservation with DFDBA and dHCM aided in bone gain in post extraction socket when compared to non grafted extraction socket

CONCLUSION :- Due to the osteoconductive and osteoinductive property of DFDBA along with the low immunogenicity, anti-inflammatory, wound-protecting, and scar-reducing properties of the dHCM net bone gain was seen in the post extraction socket after 3 months

The alveolar process develops with tooth eruption. Following tooth extraction, the alveolar ridge experiences atrophy and resorption, which causes the loss of important hard and soft tissues. Individual differences in this dimension change's range are significant. The shape, condition, and surrounding soft and hard tissues of the tooth determine how much resorption occured. Compared to the thicker, less scalloped patient phenotype, thinner, more heavily scalloped hard and soft tissues are more likely to show signs of hard and soft tissue recession. Resorption of bone after extraction could provide serious complications for implants [12]

Over the course of six to twelve months, there is a reduction in the buccolingual or horizontal ridge of around 5-7 mm; the majority of this change happens in the first four months of healing [1]. It is seen that a reduction in buccolingual width by 50% takes place over a 12 month period following extractions with two thirds occurring in the first 3 months. These changes are more pronounced in molars as compared to other teeth. There is a apico coronal reduction in ridge height of approximately 0.8mm at 3 months [2] The term socket preservation was first coined by Cohen in 1988

It has been demonstrated that alveolar ridge preservation (ARP) during extraction is a reliable and efficient method of minimizing buccolingual and vertical bone loss following surgery. Any operation done during or after an extraction with the goal of minimizing ridge external resorption and maximizing bone growth within the socket is known as ridge preservation.

If an implant is to be placed more than six to eight weeks after tooth extrtaction, ridge preservation should be taken into consideration. When an implant placement is not planned in near future, ridge preservation should still be considered to retain the possibility of an implant option for the patient in the future if needed. Ridge preservation should also be considered for conventional fixed prosthesis for esthetic concern [3]

Many grafting materials like autogenous bone, demineralized freeze-dried bone allografts (DFDBA), xenografts, bioactive glass, hydroxyapatite and calcium sulphate. have been used for ridge preservation purposes. Although autogenous bone is considered as the ‘‘gold standard’’.

The beneficial property of an allograft bone graft is the ability to obtain essential amounts of graft material. These grafts can be categorized as demineralized frozen or freeze-dried bone (DFDBA) or mineralized frozen or freeze-dried bone (FDBA).[4] DFDBA has both osteo inductive and osteoconductive properties and it additionally releases bone morphogenetic proteins (BMPs). [5,6] which give the allograft the added benefit of osteo inductive property. The available BMPs in DFDBA stimulate host osteoprogenitor cells to differentiate into osteoblasts and begin the process of osteogenesis.

Placement of the graft not only aids in bone formation but may also provide bulk which may prevent tissue collapse.[4]

Barrier membranes are used as barriers in order to prevent the proliferation of unwanted soft tissue into the defect. Ideal membrane properties include biocompatibility, non-toxicity to the surrounding tissue, tissue tolerance, adequate structural integrity etc [7]

Collagen membranes are natural, resorbable membranes made from porcine or bovine sources. Type I collagen is abundant in the periodontal connective tissue and, thus, has been widely used to develop commercial collagen membranes. The effective properties of collagen membranes include biocompatibility, hemostatic and chemotactic support and wound-healing enhancement through clot stabilization. The capability of collagen membranes to prevent epithelial downgrowth and weak immunogenicity has made them suitable for periodontal regeneration.[8]

PURION processed (MiMedx, mimedx.com) dehydrated de-epithelialized Human Amnion/Chorion provides for accelerated healing, antimicrobial action, and anti-inflammatory components.[9] Although dHACM contains cellular material such as cell membrane-associated proteins and intracellular proteins. Due to presence of the intra- and extracellular proteins in the membrane there is down regulatation of the inflammatory response in the applied area and serve as chemotactic source for hematopoetic and mesenchymal stem cells. [10] Due to the reduced immune response, patients treated with these tissues generally experience less postoperative pain. [11]

Hence, the following study was carried out to assess the combined effect of DFDBA and chorion membrane over self healing extraction socket

AIM :-

This study was taken up with the aim to assess the amount of bone gain using DFDBA and Chorion Membrane in the extracted socket.

OBJECTIVES :-

1. To assess the amount of bone gain in the grafted extraction sockets
2. To assess the amount of bone gain in the naturally healing/ non grafted site.
3. To compare and analyse the amount of bone gain in the grafted and non-grafted sites.

Brugnami F, Peter R, Moroi H and Cataldo W. Leone (1996)[12] Conducted a study which evaluated new bone formation in human extraction sockets treated with demineralized freeze-dried bone allografts (DFDBA) and cell occlusive membranes. Human decalcified freeze-dried bone allografts (DFDBA) are used in periodontal regeneration and in the maintenance and repair of alveolar ridges to provide sufficient quantity of bone for the placement of endosseous implants. DFDBA is also believed to act as a space maintaining and bone-growth promoting agent.

Iasella J et al (2003)[13] in his study stated that the normal post extraction healing of an extraction socket is resorptive. The greatest amount of bone loss occurs in the horizontal aspect and the facial aspect of the ridge. Ridge preservation with an intraosseous graft and membrane should preserve the original ridge dimensions and contours thereby facilitating proper implant placement.

Zubillaga G, Hagen S V, Simon B I, Deasy M I (2003)[14] stated that extraction sockets treated with extended polytetrafluoroethylene membranes retained significantly greater dimensions of alveolar ridge when compared to sites not treated with membranes. Bioabsorbable membranes is shown to have successful results in guided bone regeneration around natural teeth, implants. He studied the bone preservation with bone grafts and membranes. The result showed more internal socket fill, less alveolar ridge height loss and less horizontal bone loss. A variety of graft materials are used to augment sockets. Most of the bone grafts have a osteoconductive property along with bone morphogenic proteins

Darby I, Chen S, Poi De R (2008)[15] in his study stated that prerequisites for successful implant therapy are integration of the implant, ideal implant position and appropriate hard and soft tissue contours. These require sufficient alveolar bone volume and favourable ridge architecture coupled with an appropriate surgical technique. Ridge preservation is any procedure undertaken at the time of or following an extraction that is designed to minimize external resorption of the ridge and maximize bone formation within the socket Many procedures have been suggested including minimally traumatic tooth extraction, soft and hard tissue grafting, concomitant use of barrier membranes and immediate implant placement.

Niknejad H et al (2008)[16] stated that an important component of tissue engineering (TE) is the supporting matrix upon which cells and tissues grow, also known as the scaffold The amniotic membrane (AM) is considered an important potential source scaffold The amniotic membrane (AM) is considered an important potential source for scaffolding material. The AM represents the innermost layer of the placenta and is composed of a single epithelial layer, a thick basement membrane and an avascular stroma. the AM has other biological properties important for TE, including anti-inflammatory, anti-microbial, anti-fibrosis, anti-scarring, as well as reasonable mechanical property and low immunogenicity.

Giorgio Pagni, Pellegrini G,William V, Rasperini G (2012)[17] conducted that post extraction alveolar ridge resorption is an inevitable process. Molar ridges present higher degrees of resorption than premolar areas do. Socket grafting techniques have been readily adopted to treat alveolar bone resorption. osteoconductive-mineralized grafts does not accel-erate bone healing, but may allow for a better preservation of the ridge volume that is highly desirable for both esthetic and function of the future implant restoration

Thomas J Koob et al (2013)[18] stated that dHACM is a multifaceted tissue graft that has the potential to positively affect at least four distinct physiological processes, including cell proliferation, inflammation, metalloproteinase activity and recruitment of stem cells, all of which are intimately involved in regenerative wound healing and soft tissue repair. In socket augmentation dHACM is used as a barrier membrane.

Elizabeth M Tomlin, Shelby J Nelson, and Jeffrey A Rossmann (2014)[19] stated that healing of the extraction socket after tooth removal involves retention of the blood clot followed by a sequence of events that lead to changes in the alveolar process in a three dimensional fashion. This normal healing event results in a minimal loss of vertical height (around 1mm), but a substantial loss of width in the buccal-lingual plane (4-6 mm). Several techniques have been employed as ridge preservation procedures involving the use of bone grafts, barrier membranes and biologics to provide a better restorative outcome

Mardas N, Trullenque-Eriksson A, MacBeth N, Donos N (2015)[20] in his study stated that the success of implant-supported restorations depends on the interaction between a number of anatomical, technical, surgical and prosthetic factors. Amongst them, restorative-driven implant placement allows the optimal support of the surrounding soft and hard tissues and a satisfactory emergence profile of the final prosthesis. When permanent teeth are lost, the alveolar process undergoes significant dimensional changes complicating implant placement in the ideal prosthetic position. When extensive ridge resorption has occurred, ridge augmentation procedures, prior or simultaneously with implant placement, are required to allow a prosthetically driven implant placement

Whetman J (2016)[21] conducted that the effect of healing time on new bone formation following ridge preservation with DFDBA, on an average is 9 weeks and 19 weeks after tooth extraction. DFDBA was used in the study due to the osteoconductive property. The demineralization process of DFDBA additionally releases bone morphogenetic proteins (BMPs). The released BMPs give the allograft the added benefit of osteoinductivity

Mohamed A. Maksoud and Kevin A. Guze (2017)[22] stated that the human chorion membrane produces various growth factors including basic fibroblast growth factor, hepatocyte growth factor, and transforming growth factor which helps in promoting expedited healing with rapid cell migration and so preserving the bone mass in the extraction socket. It also possesses anti-inflammatory, wound-protecting, and scar reducing properties. Because of the adhesion of the dehydrated human amnion/chorion membrane and rapid wound regeneration, it demonstrates a superior wound closure to other comparable membranes widely used.

Troiano G et al (2017)[23] In his study stated that alveolar ridge preservation (ARP) techniques are aimed to reduce the resorption after tooth extraction. Alveolar bone dimensional changes of post-extraction sockets in humans showed that resorption of the alveolar ridges was 3.87 mm in width and 1.67 mm in height on the buccal side. The combination of a graft material covered with a resorbable membrane represent one of the most common strategies performed in the clinical practice. Cortical

mineralized freeze dried bone allograft (FDBA) and cortical demineralized freeze-dried bone allograft, (DFDBA) alloplastic bone grafts, xenografts, consisting of porcine or bovine bone have been used for socket filling either alone or covered by barrier membranes.

Pamungkas S Nardiatmo S, Mapangara S, Irawati Jais A (2019)[24] stated that natural healing of alveolar remodeling following tooth extraction include three dimensional bone remodeling and ridge atrophy after tooth extraction, bundle bone lining, the extraction socket is resorbed. Tooth extraction can induce significant changes to the residual alveolar ridge. These dimensional changes can significantly affect the alveolar ridge in both width and height. Extraction without ridge preservation can result in a mean height loss of 1.24 mm and mean width reduction of 3.79 mm. There were significant ridge dimensional changes between preserved and non preserved socket after extraction using DFDBA or FDBA materials, but there were no significant ridge dimensional change compere both materials. There were significant new vital bone formation when using DFDBA compere to FDBA as a bone substitution materials for socket preservation procedure.

Olivier JPJ, Marnewick J, Postma TC (2021)[25] stated that dental implant treatment aims to restore form and function of the dentally compromised patient when used to support over-structures. Sufficient volume and quality of bone is necessary for anchoring the implant. While the goal of DFDBA placement in extraction sockets is to preserve the volume of bone available for implant placement it is important to determine the quality of bone achieved through this grafting procedure Based on this premise, this study therefore aimed to histologically compare dental extraction sites grafted with DFDBA with non-grafted sites before implant placement.

Dhamija R, Shetty V , Vineeth K , Nagaraju R, Roopa S(2021)[26] conducted a study stating that edentulism is a debilitating condition leading to both ridge height and widthloss. Implant-supported fixed prosthesis ensures improved esthetic and functional restoration of missing teeth in terms of keratinized mucosa width, gingival recession, and papilla fill, improving chewing efficiency and enhancing psychological benefit for the patient. Thus, placement of dental implants and ridge preservation

through graft materials can successfully rehabilitate an edentulous site in bone formation in human sockets. In this study the authors used demineralized freeze-dried bone allograft (DFDBA) and platelet-rich fibrin (PRF) for ridge augmentation and determining the bone–implant contact (BIC) ratio with cone-beam computed tomography (CBCT), at 3 months after implant placement and 3 months after loading.

Alauddin MS , Hayei A , Sabarudin A, Baharin M (2022)[27] stated that Guided bone and tissue regeneration remains an integral treatment modality to regenerate bone surrounding teeth and dental implants. Barrier membranes have been developed and produced commercially to allow space for bone regeneration and prevent the migration of unwanted cells. Ideal membrane properties, including biocompatibility, sufficient structural integrity and suitable shelf life with easy clinical application are important to ensure good clinical regenerative outcomes.

Shah R , Thomas R , Mehta D S(2022)[28] stated that that a loss of 2.6–4.6 mm in width and 0.4–3.9 mm in height is possible when an extraction socket is left to heal unaided. DFDBA has both osteo inductive and osteoconductive properties. Placement of the graft not only aids in bone formation but may also physically provide bulk which may prevent tissue collapse. Fetal allograft membranes such as amnion and chorion have been used for several extra- oral procedures. Chorion membrane is a resorbable fetal derived allograft. It contains collagen Type I, III, IV, V, VI, and several proteoglycans. It also contains several cell adhesion bioactive factors such as fibronectin and laminin. These allografts also have very low immunogenicity. It has also been demonstrated to enhance gingival biotype.

Tanuja B, Kondareddy KM , Ramesh A , Rajesh N , Siva Rami Reddy, Prakash R (2022)[29] stated that the success of implant therapy depends on the prosthetic-driven position of the implant, bone to implant contact, an adequate number of ridge contours, and proper surgical procedure. Tooth extraction and subsequent healing usually result in bony deformities, including reduced alveolar ridge height and reduced width with unfavorable ridge architecture for dental implant placement. Ridge preservation is a surgical procedure carried out after extraction to prevent the collapse of the ridge and to preserve the ridge dimension, as usual, for implant site

development . For this purpose, allografts, alloplasts, and xenograft materials, along with autogenous bone can be utilized. The addition of platelet-rich fibrin (PRF) to the graft materials enhances wound healing and hemostasis, bone growth and maturation, and bone density, which impart better handling properties to the graft materials . The chorion membrane acts as a barrier for scaffolds in tissue regeneration.

Sheikh Z, Hamdan N, Glogauer M (2023)[30] stated that in order for implant therapy to be successful there is a need for the dental implant to be adequately integrated into host bone in the proper position in three dimensions. For this to be achieved, adequate height and volume of alveolar bone is required. However, the alveolar ridge is prone to resorption following extraction of teeth which results in inadequate bone volume and unfavourable alveolar ridge architecture which ultimately limits the successful placement of dental implants. Many bone replacement grafting materials have been investigated and used for extraction socket preservation and these include autologous bone, allografts (mineralized and demineralized freeze-dried bone allografts, FDBA and DFDBA), xenografts, bioactive glass, and synthetic hydroxyapatite. Barrier membranes are used as occlusive barriers in order to prevent the soft tissue from proliferating into the defect. The most commonly used non-resorbable barrier membrane to maintain the alveolar ridge after tooth extraction is dens polytetrafluoroethylene (dPTFE).

Cullum D, Lucas M (2023)[31] stated that post-extraction site preservation grafting is often indicated to ensure adequate alveolar bone dimensions at pontic sites and effective delayed implant placement to prevent significant loss of ridge volume over time. Numerous graft materials and barrier membranes have been cited for use in such procedures. Autologous bone and adjuncts, including platelet-rich plasma, plasma rich in growth factors, and platelet-rich fibrin preparations, have been investigated for use in site preservation procedures to provide signaling molecules capable of accelerated wound healing.

The following randomized prospective clinical study was carried out in the Department of Periodontology, Babu Banarasi Das College of Dental Sciences, Lucknow (BBDCODS) to assess the amount of bone gain using DFDBA and Chorion Membrane in the extracted socket. For radiographic analysis, a IOPAR was taken along with the grid .

A total of 20 patients irrespective of gender, based upon the following inclusive and exclusive criteria were selected from the OPD of the department. An appropriate clearance from the Institutional Ethics Committee (Annexure no 1) was taken for the study. The patients were clearly explained about the study protocol and procedure. A duly signed consent form was taken from them. At the time of screening, medical and dental history was obtained.

INCLUSION CRITERIA

- Patients within age group- 25 to 50 years
- Patients with grade III tooth mobility (Miller's Classification 1985)
- Patients with carious tooth that needs extraction
- Adequate space for Implant prostheses
- Systemically healthy patients

EXCLUSION CRITERIA

- Patients allergic towards local anaesthesia
- Patients with uncontrolled systemic diseases
- Patients having poor oral hygiene
- Patients under active immunosuppressive agents
- Pregnant and lactating mothers
- Patients with mental disabilities

It is an experimental and a longitudinal study. Each individual was subjected to a detail case history record , signed consent form, intra oral periapical radiographs along with a grid for assessing the alveolar ridge dimensions and routine blood investigations.

The patients underwent phase I therapy which included oral hygiene instructions, full mouth supra and sub gingival scaling and root planing. Oral prophylaxis was done using ultrasonic devices. Adjunctive chemical plaque control measures were

instructed. Use of chlorhexidine 0.2 % mouthwash twice daily and the patient were reevaluated after 7 days.

At Baseline Clinical and Radiographic parameters were recorded and the subjects were randomly divided into 2 groups.

Clinical Parameters-

- Horizontal ridge width at the alveolar crest level
- Horizontal ridge width at the mid crest level

Radiological parameters-

- Intraoral periapical radiograph along with a grid

Group I (10) - Patients undergoing extraction followed by placement of Demineralized Freeze Dried Bone Allograft (DFDBA) and Dehydrated Human chorion membrane, dHACM

Group II (10) – Patients undergoing extraction with no graft or membrane

ARMAMENTARIUM

- Mouth mirror
- Tweezer
- UNC 15 Probe
- Explorer
- Cheek retractor
- Ultrasonic scaler
- Periotome
- Extraction forceps
- Elevators
- Local anesthetic agent 2% lignocaine
- Sterilized cotton, gauze
- Povidine iodine solution 5%
- Normal saline
- Syringe 3ml and 5ml
- 15C Surgical blade
- 2 Bard-Parker handle

- B.P. blade nos 11,12, 15
- Vernier calliper
- Demineralized Freeze Dried Bone Allograft (Tata Memorial Hospital, Tissue Bank, Mumbai)
- Chorion Membrane (Tata Memorial Hospital, Tissue Bank, Mumbai)
- Cumin scaler and condenser
- A set of surgical curettes (Gracey's Hu-Friedy)
- Periosteal elevator (Hu-Friedy)
- Castroviejo scissors, needle holder
- Sutures (3-0)
- Coe-pack for dressing

SURGICAL PROCEDURE

GROUP I

Routine preparation of the patient using 5% povidine iodine solution was carried out. Following administration of local anaesthesia, sulcular incisions along with vertical releasing incisions on either side of the tooth to be extracted upto the mucogingival junction were given. Full thickness mucoperiosteal flap was reflected buccally to obtain complete access of the crestal bone. Periotome was used to break the periodontal attachment and tooth was extracted as atraumatically as possible. After extraction, proper debridement of the granulation tissue was done with a surgical curette and irrigated with normal saline. The socket was measured buccolingually and mesiodistally at the alveolar crest and mid crest levels using a vernier caliper. Intra oral peri apical radiograph(IOPAR) of the tooth extraction site was taken with grid in the paralleling technique. DFDBA was mixed with saline and condensed inside the extraction site, chorion membrane was placed over the grafted site. The flaps were coronally advanced for close approximation then sutured with 4-0 silk sutures. The surgical area was covered by periodontal dressing (Coe pack). The patients were kept on antimicrobial therapy, and chlorhexidine 0.2% mouthwash was prescribed daily for 2 weeks. Post surgical instruction were given in writing and the patient was recalled after 10 days for evaluation and for sutures and coe pack removal

GROUP II

The tooth was extracted as atraumatically as possible. IOPAR along with the grid was taken. Patient was given oral hygiene instructions and was recalled after 7 days for suture and coe pack removal.

After 3 months the patients from both group I and group II were recalled for follow up. The extraction site was anaesthetised and with a vernier calliper, the clinical and radiological parameters were recorded. Clinically, the horizontal ridge width was taken at the alveolar crest and at the mid crest by substracting 1mm from each side along with the soft tissue thickness at the buccal and lingual aspect. Radiologically, IOPAR was taken along with the grid.

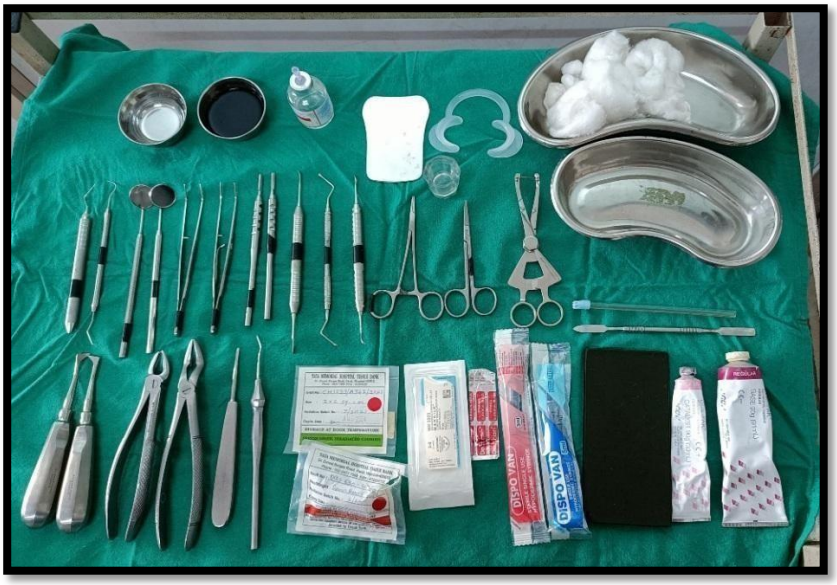


FIG 1 Armamentarium for socket preservation surgery

FIG 2 Demineralized freeze dried bone allograft and human chorion membrane

PLATE NO 1

FIG 3 Xray sensor with grid

TEST GROUP

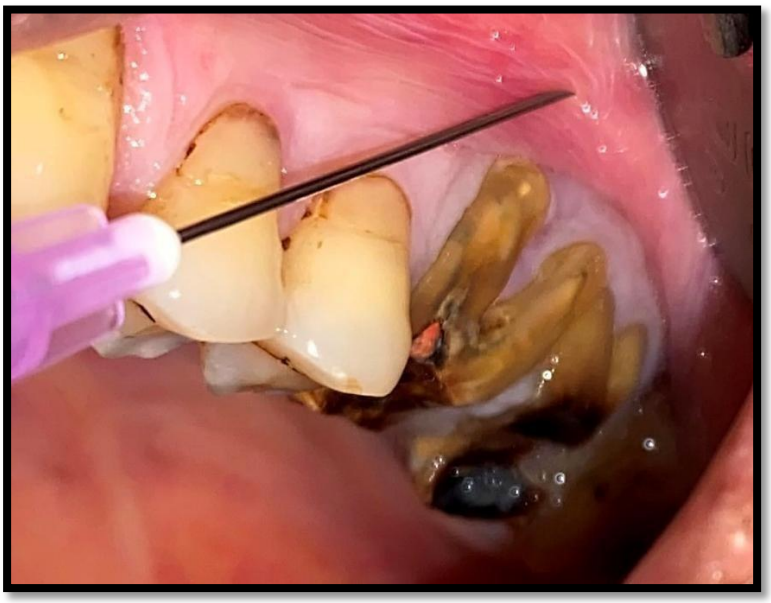


FIG 4 (i) Pre operative view of the tooth to be extracted

PLATE NO 2

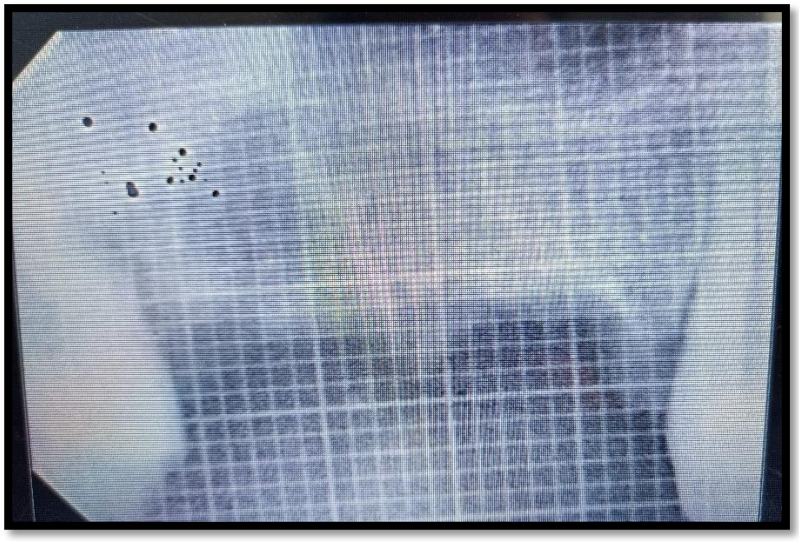


FIG NO 4 (ii) Pre operative radiograph with grid

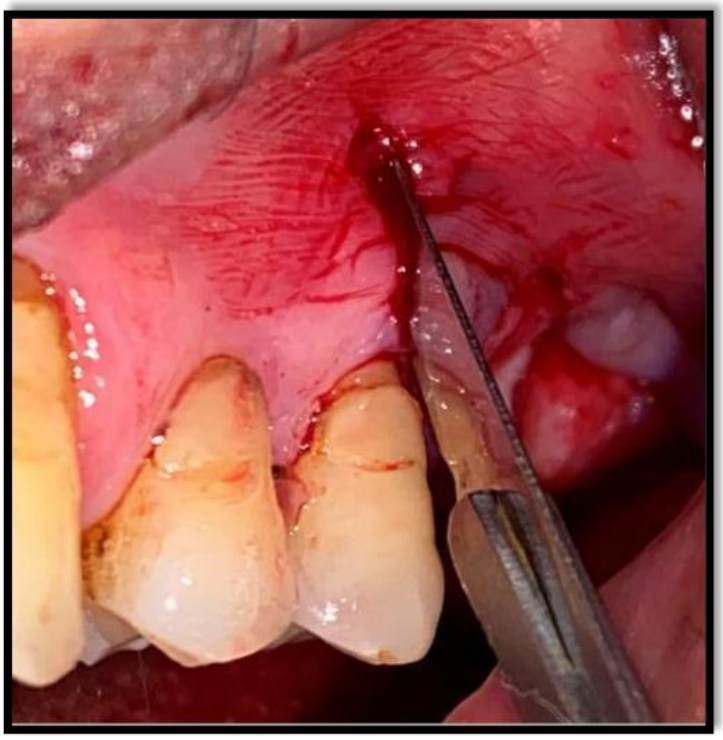


FIG 4 (iii) Vertical incision given

PLATE NO 3

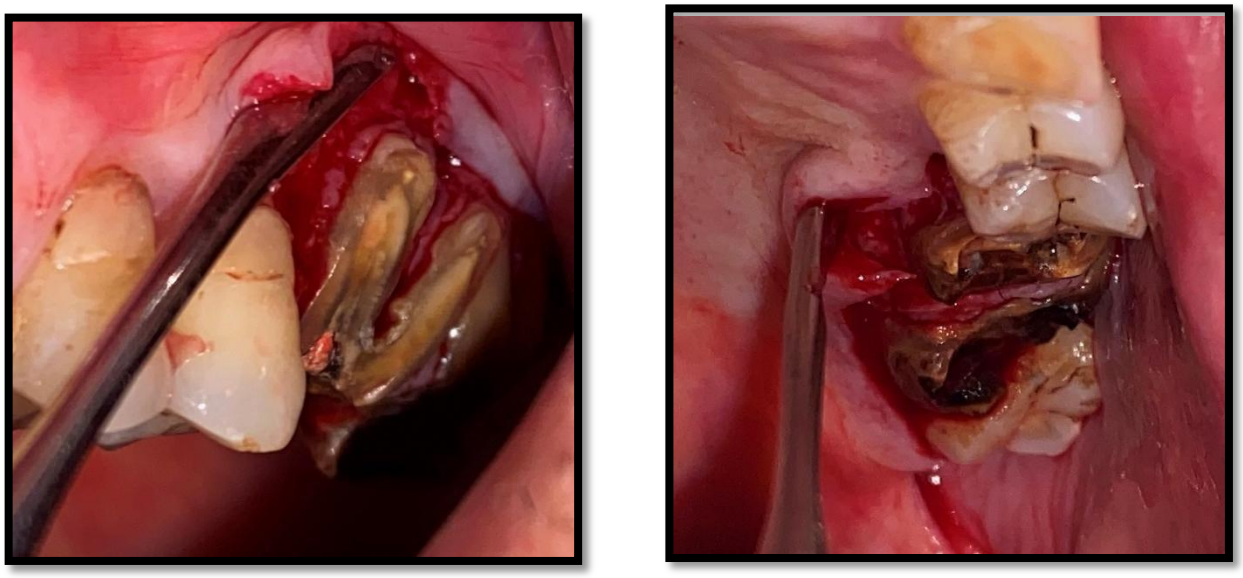


FIG NO 4 (iv) Reflection of mucoperiosteal flap in buccal and palatal direction

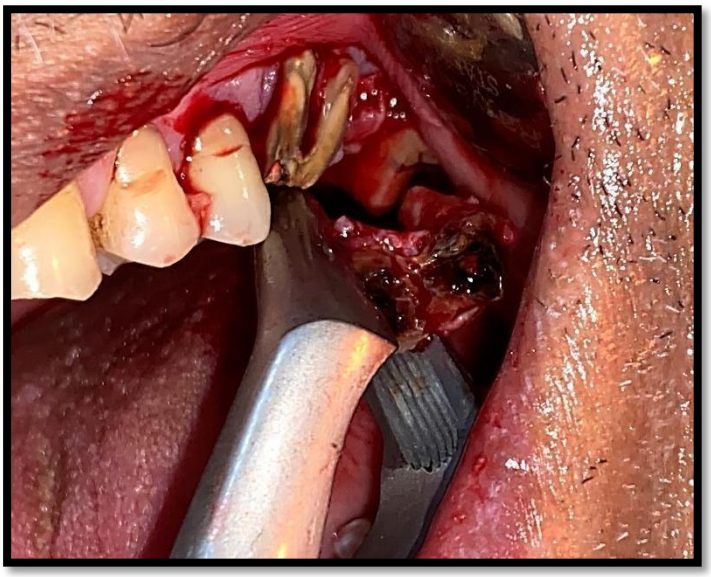


FIG NO 4 (v) Tooth extracted atraumatically

PLATE NO 4

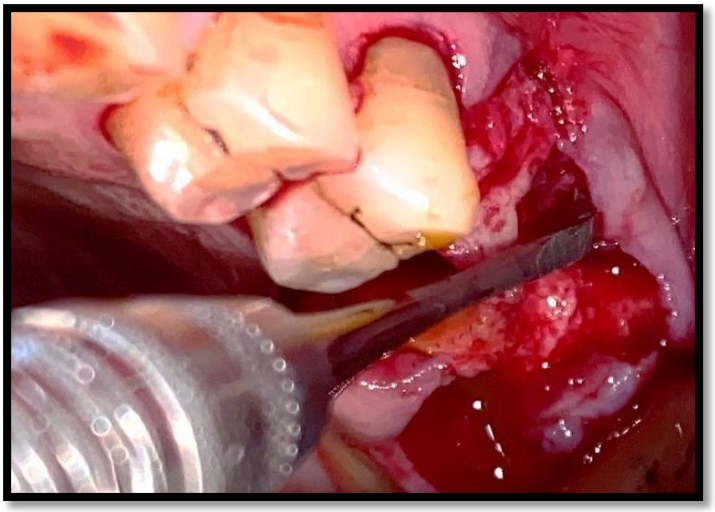


FIG NO 4 (vi) Debridement of the extraction socket

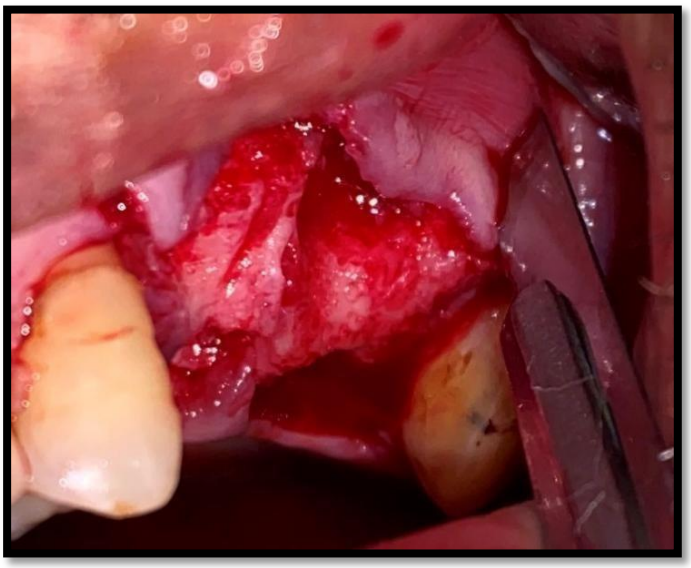


FIG NO 4 (vii) Split thickness flap reflected

PLATE NO 5

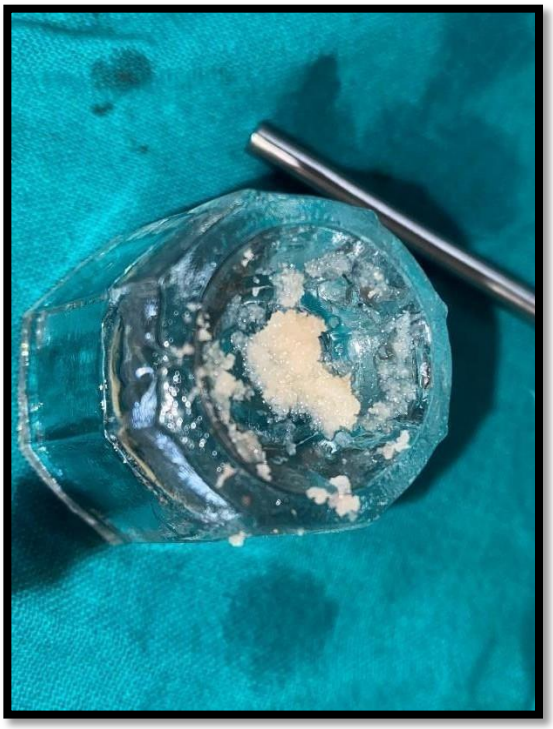
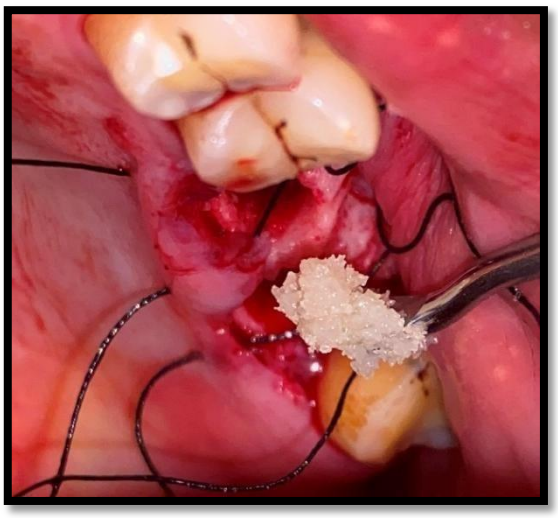


FIG NO 4 (viii) Bone graft mixed with normal saline



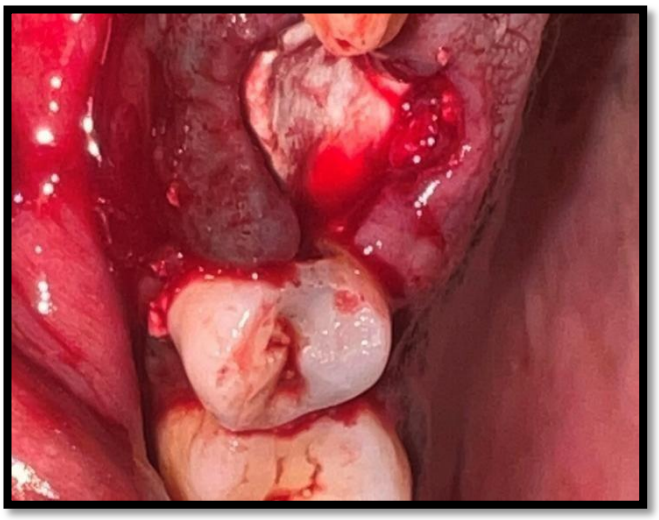


FIG NO 4 (ix) Bone graft and membrane placement

PLATE NO 6

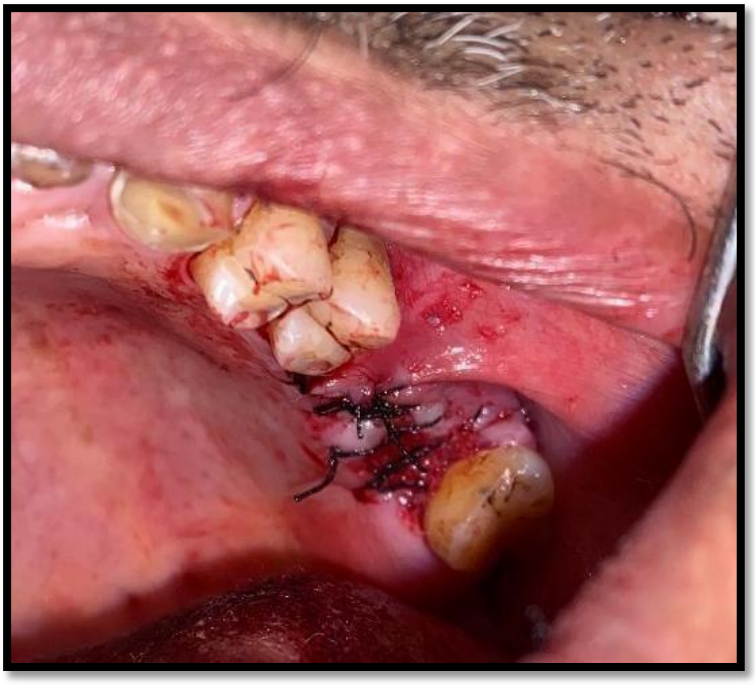


FIG NO 4 (x) Flap approximated with sutures

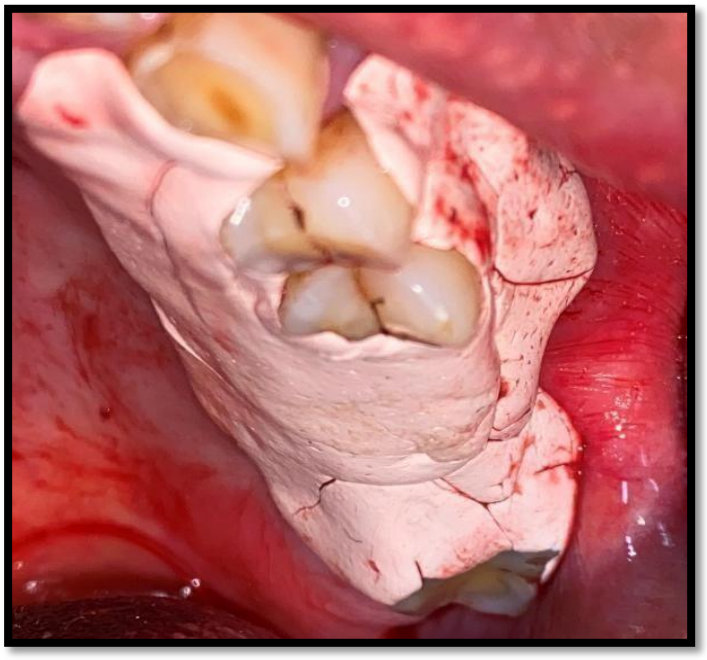


FIG NO 4 (xi) Periodontal dressing placed

PLATE NO 7

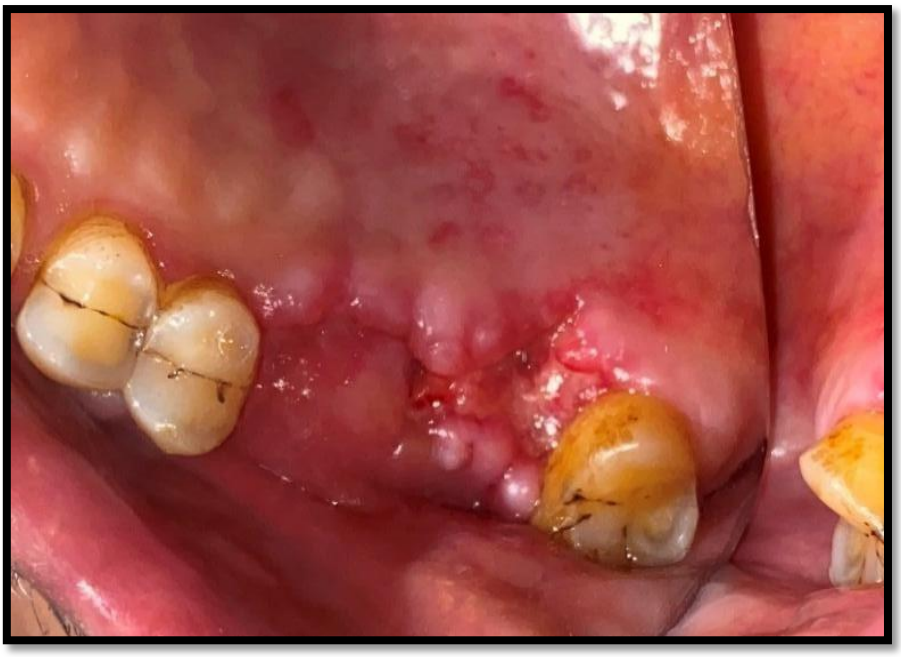


FIG NO 4 (xii) Post operative view after 7 days

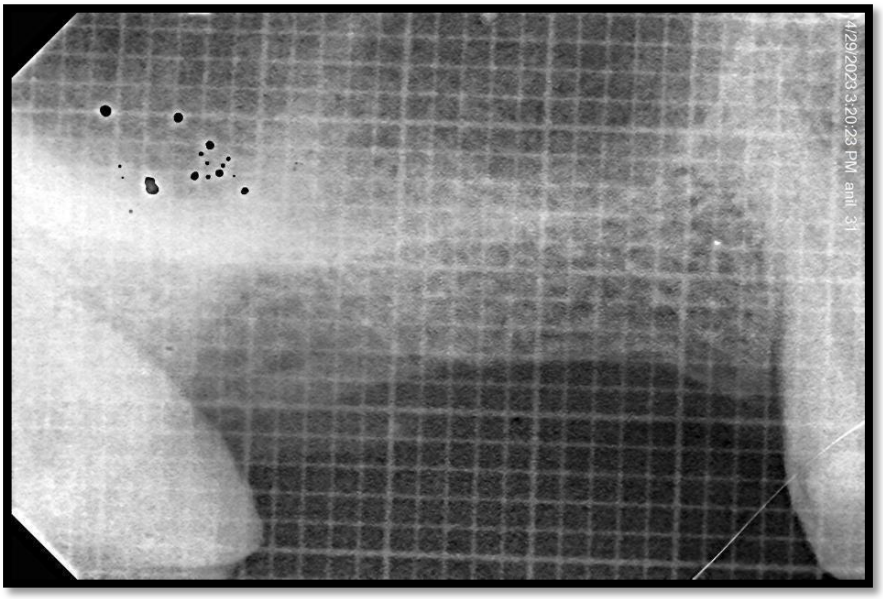


FIG NO 4 (xiii) Radiograph taken after 3 months

PLATE NO 8

CONTROL GROUP

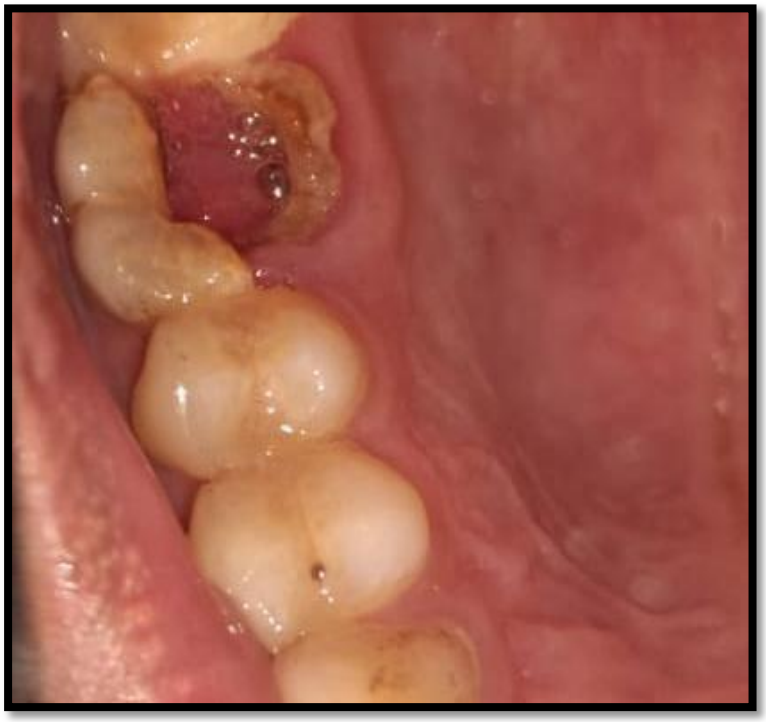


FIG NO 5 (i) Preoperative view of the tooth to be extracted

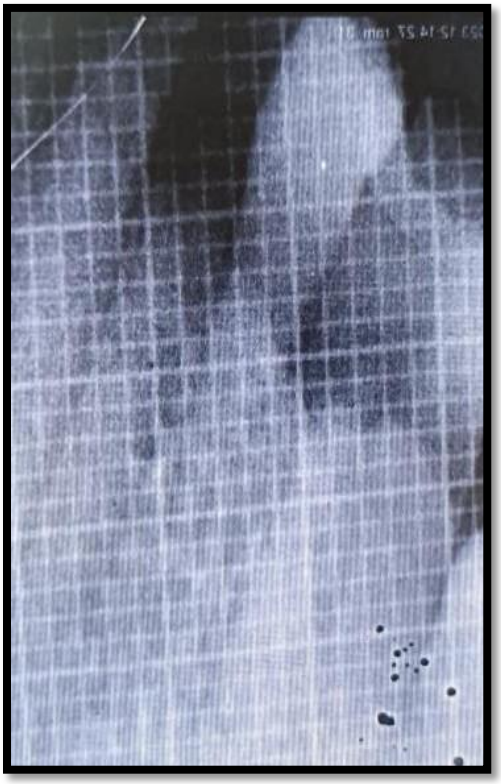


FIG NO 5 (ii) Pre operative radiograph

PLATE NO 9

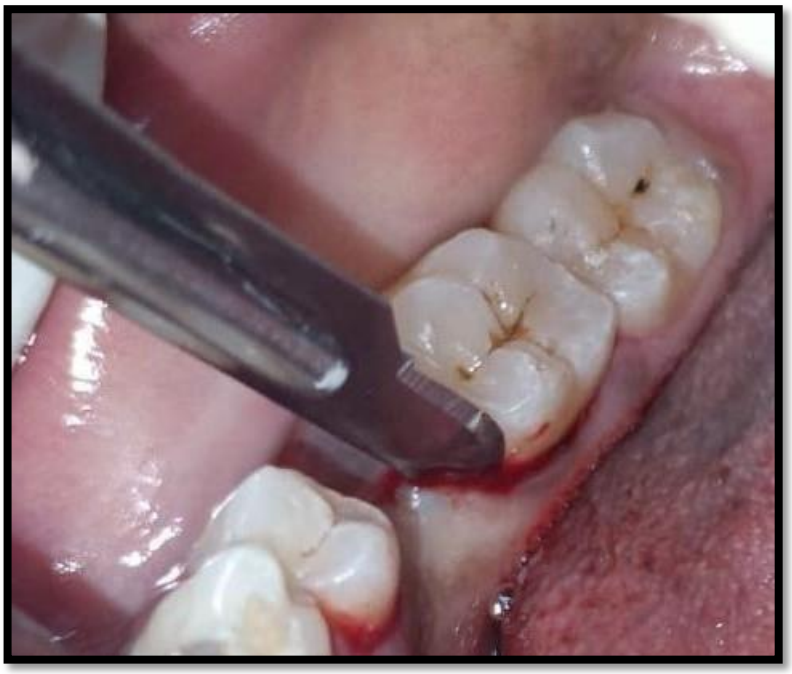


FIG NO 5 (iii) Incisions given

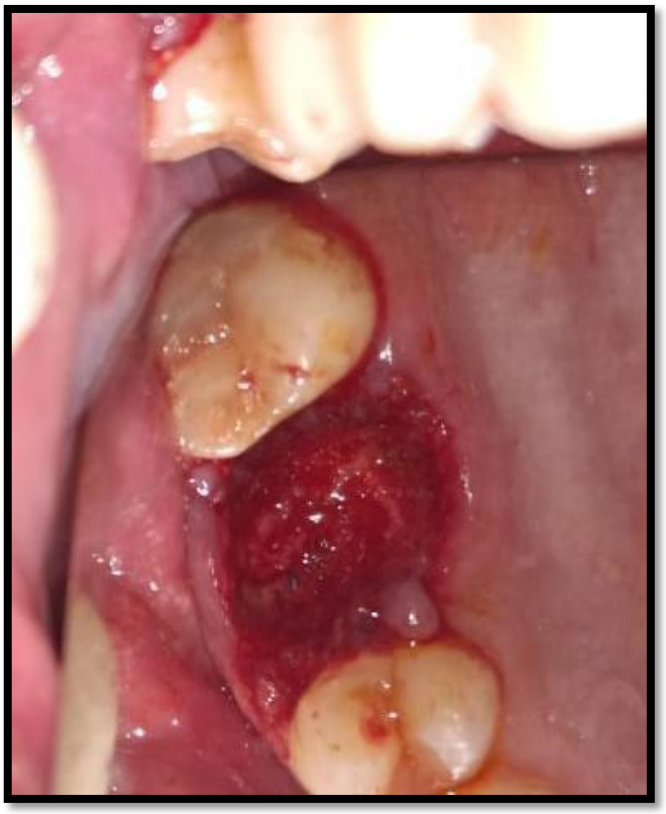


FIG NO 5 (iv) Tooth extracted

PLATE NO 10

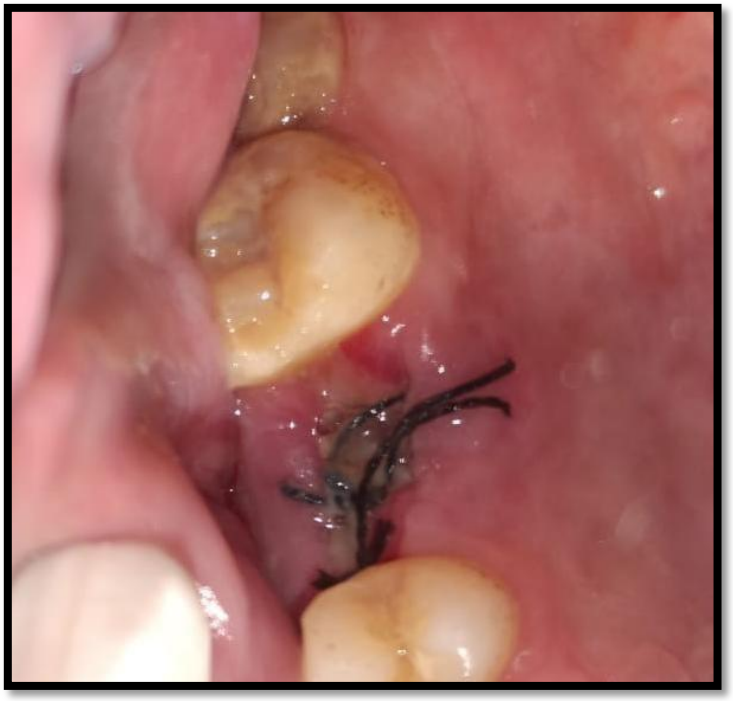


FIG NO 5 (v) Suture removal after 7 days

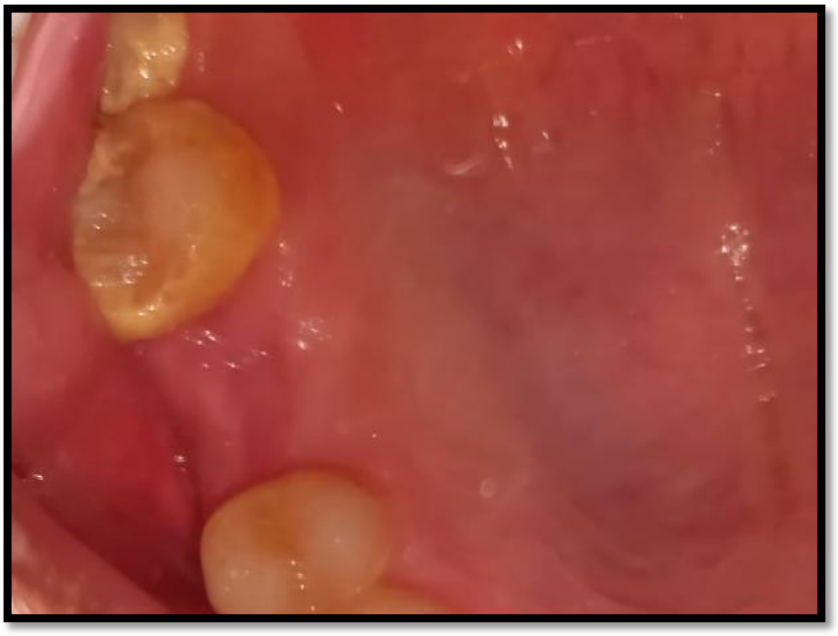


FIG NO 5 (vi) 3 months post operative view

PLATE NO 11

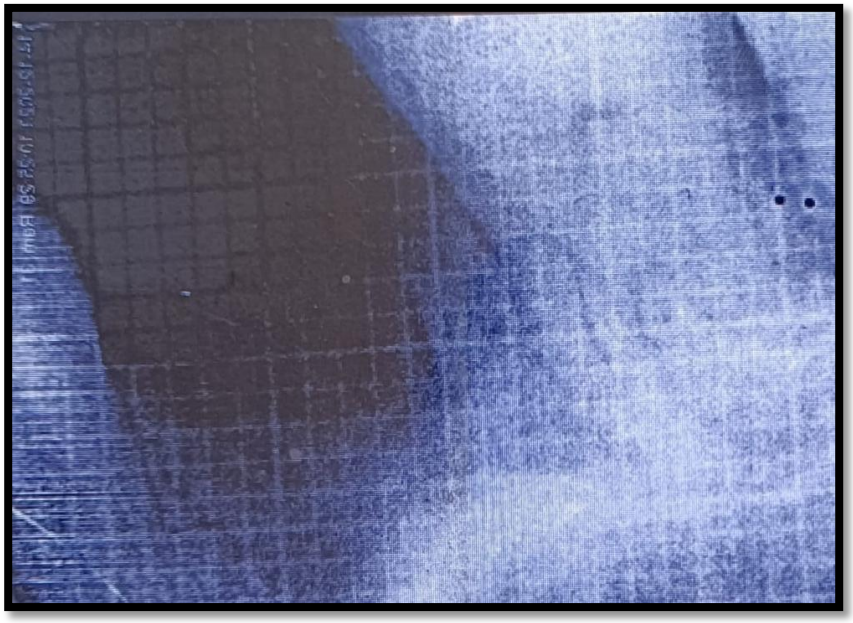


FIG NO (vii) 3 months post operative radiograph

PLATE NO 12

INTERGROUP COMPARISON OF CHANGE IN ALVEOLAR CREST WIDTH BETWEEN CONTROL GROUP AND TEST GROUP (TABLE 1 AND GRAPH 1)

In the control group, the mean horizontal R.W at alveolar crest was 11.62 at baseline and 11.14 at 3months time interval . The mean bone loss was 0.48 in the control group .

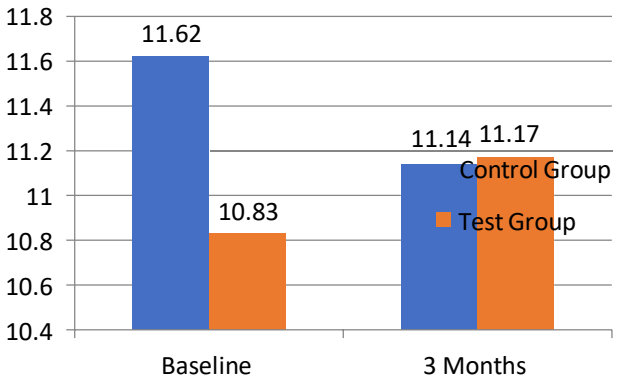
In the test group, the mean horizontal R.W at alveolar crest was 10.83 at baseline and 11.17 at 3months time interval . The mean increase in the bone level was 0.34 in the test group.

The intergroup comparison of mean change n alveolar bone width at alveolar crest was statistically significant between the groups when analysed using Independent t test

	Baseline		At 3 Months		Mean Change		P value
	Mean	SD	Mean	SD	Mean	SD	
Control Group	11.62	0.439	11.14	0.445	-0.48	0.113	0.001 (Sig)
Test group	10.83	0.596	11.17	0.724	0.34	0.171	

P value < 0.05

TABLE 1 - Intergroup comparison of change in alveolar crest width between control group and test group



GRAPH 1- Intergroup comparison of change in alveolar crest width between control group and test group

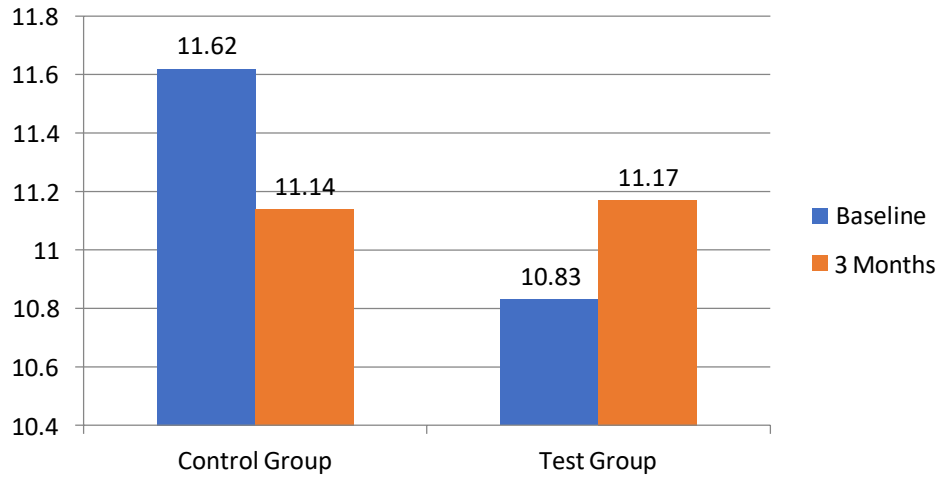
INTRAGROUP COMPARISON OF CHANGE IN ALVEOLAR CREST WIDTH BETWEEN BASELINE AND 3 MONTHS IN CONTROL AND TEST GROUP (TABLE 2 AND GRAPH 2)

The intragroup change n alveolar bone width at alveolar crest from baseline to 3 months was statistically significant in both the groups when analyzed using Paired t test

However, in it was seen that there was significant bone gain in the Test group (11.17mm) as compared to Control group (11.14mm), P value < 0.05

	Baseline		At 3 Months			
	Mean	SD	Mean	SD	P value	Significance
Control Group	11.62	0.439	11.14	0.445	0.001	Significant
Test Group	10.83	0.596	11.17	0.724	0.001	Significant

TABLE 2 - Intragroup comparison of change in alveolar crest width between baseline and 3 months in control and test group



GRAPH NO 2 - Intragroup comparison of change in alveolar crest width between baseline and 3 months in control and test group

INTERGROUP COMPARISON OF CHANGE IN MID CREST WIDTH BETWEEN CONTROL GROUP AND TEST GROUP (TABLE 3 AND GRAPH 3)

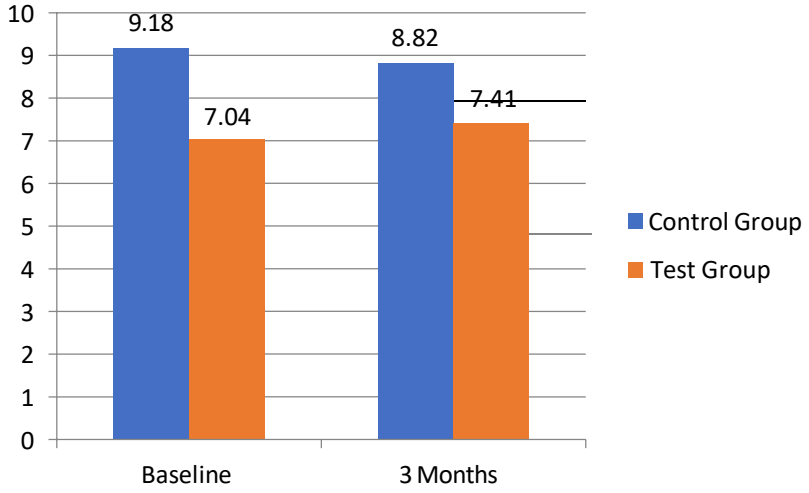
In the Control group. the mean horizontal R.W at mid crest was 9.18 at baseline and 8.82 at 3 months time interval . The mean decrease in the RW at mid crestal level was 0.360 .

In the test group, the mean horizontal R.W at mid crest was 7.04 at baseline and 7.41 at 3months time interval . The mean increase in the RW was 0.370 in the test group.

The intergroup comparison of mean change and alveolar bone width at mid crest was statistically significant between the two groups groups using independent t test

	Baseline		At 3 Months		Mean Change		P value
	Mean	SD	Mean	SD	Mean	SD	
Control Group	9.18	0.859	8.820	0.854	-0.360	0.189	0.001 (Sig)
Test Group	7.04	1.380	7.410	1.451	0.370	0.133	

TABLE NO 3- Intergroup comparison of change in mid crest width between control group and test group



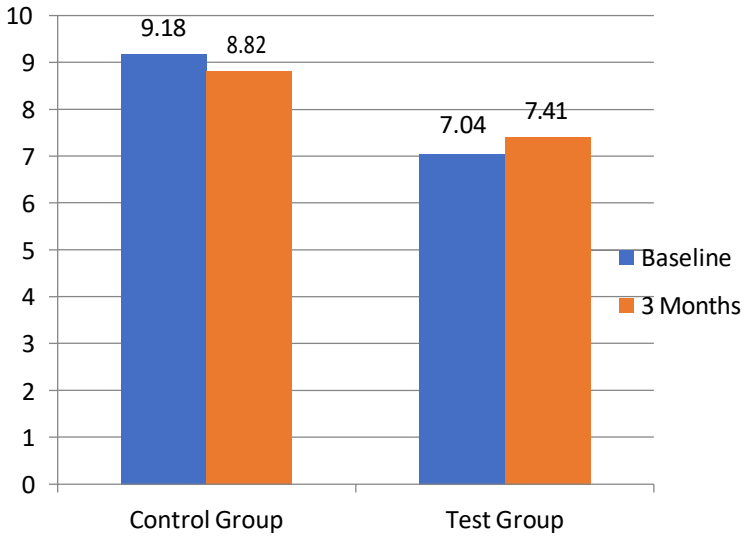
GRAPH NO 3 - Intergroup comparison of change in mid crest width between control group and test group

INTRAGROUP COMPARISON OF CHANGE IN MID CREST WIDTH BETWEEN BASELINE AND 3 MONTHS IN CONTROL AND TEST GROUP (TABLE 4 AND GRAPH 4)

The intragroup change in alveolar bone width at mid crest from baseline to 3 months was statistically significant in both the groups when analyzed using Paired t test

	Baseline		At 3 Months			
	Mean	SD	Mean	SD	P value	Significance
Control Group	9.18	0.859	8.820	0.854	0.001	Significant
Test Group	7.04	1.380	7.410	1.451	0.001	Significant

TABLE NO 4- Intragroup Comparison Of Change In Mid Crest Width Between Baseline And 3 Months In Control And Test Group



GRAPH NO 4 -Intragroup Comparison Of Change In Mid Crest Width Between Baseline And 3 Months In Control And Test Group

INTERGROUP COMPARISON OF CHANGE IN SOFT TISSUE (BUCCAL) BETWEEN CONTROL GROUP AND TEST GROUP (TABLE 5 AND GRAPH 5)

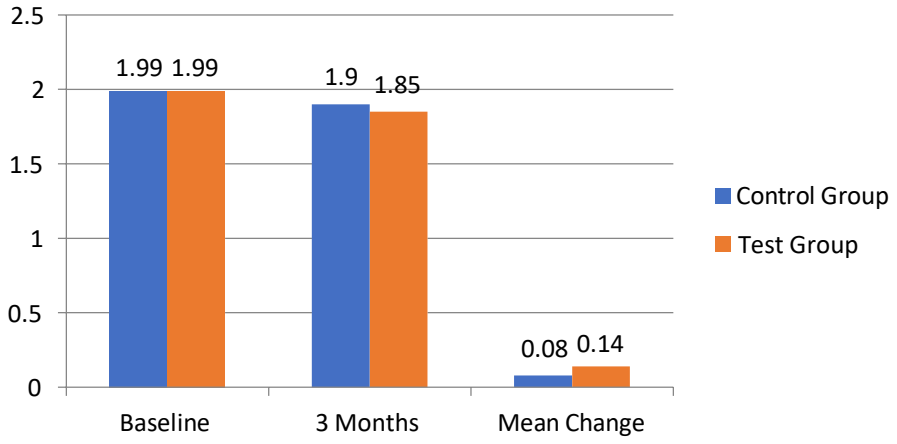
In the Control group, the mean soft tissue thickness (buccal) was 1.99mm at baseline and 1.90mm at 3months time interval . The mean decrease in the soft tissue thickness (buccal)was 0.08mm

In the test group, mean soft tissue thickness (buccal) was 1.99mm at baseline and 1.85mm at 3months time interval . The mean decrease soft tissue thickness (buccal) was 0.14 mm

The intergroup comparison of mean soft tissue thickness (buccal) was statistically non-significant between the groups when analyzed using Independent t test

	Baseline		At 3 Months		Mean Change		P value
	Mean	SD	Mean	SD	Mean	SD	
Control Group	1.99	0.260	1.90	0.312	0.08	0.077	0.284(Non-Sig)
Test Group	1.99	0.226	1.85	0.340	0.14	0.133	

TABLE NO 5- Intergroup Comparison Of Change In Soft Tissue (Buccal) Between Control Group And Test Group



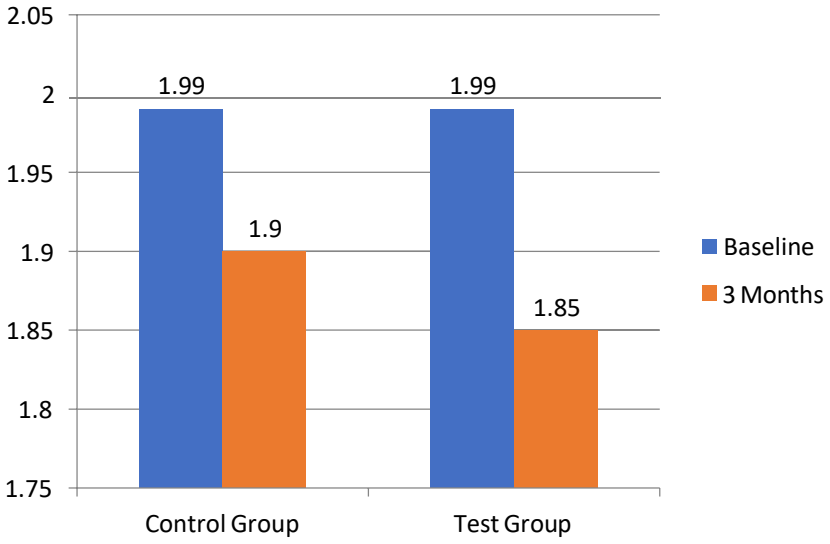
GRAPH NO 5-Intergroup Comparison Of Change In Soft Tissue (Buccal) Between Control Group And Test Group

INTRAGROUP COMPARISON OF CHANGE IN SOFT TISSUE (BUCCAL) BETWEEN BASELINE AND 3 MONTHS IN CONTROL AND TEST GROUP (TABLE 6 AND GRAPH 6)

The intragroup change in soft tissue thickness from baseline to 3 months was statistically significant in both the groups when analyzed using Paired t test

	Baseline		At 3 Months			
	Mean	SD	Mean	SD	P value	Significance
Control Group	1.99	0.260	1.90	0.312	0.001	Significant
Test Group	1.99	0.226	1.85	0.340	0.001	Significant

TABLE NO 6-Intragroup Comparison Of Change In Soft Tissue (Buccal) Between Baseline And 3 Months In Control And Test Group



GRAPH NO 6- Intragroup Comparison Of Change In Soft Tissue (Buccal) Between Baseline And 3 Months In Control And Test Group

INTERGROUP COMPARISON OF CHANGE IN SOFT TISSUE (LINGUAL) BETWEEN CONTROL GROUP AND TEST GROUP (TABLE 7 AND GRAPH 7)

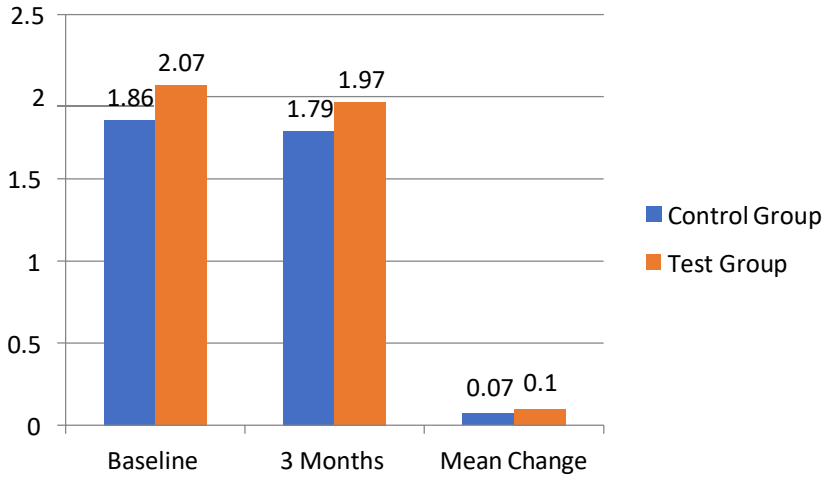
In the Control group, the mean soft tissue thickness (Lingual) was 1.86mm at baseline and 1.79mm at 3months time interval . The mean decrease in the soft tissue thickness (buccal)was 0.07mm

In the test group, mean soft tissue thickness (buccal) was 2.07mm at baseline and 1.97mm at 3months time interval . The mean decrease in soft tissue thickness (Lingual) was 0.10 in the test group.

The intergroup comparison of mean soft tissue thickness (Lingual) was statistically non-significant between the groups when analyzed using Independent t test

	Baseline		At 3 Months		Mean Change		P value
	Mean	SD	Mean	SD	Mean	SD	
Control Group	1.86	0.367	1.79	0.347	0.07	0.068	0.217 (Non-Sig)
Test Group	2.07	0.110	1.97	0.097	0.10	0.020	

TABLE NO 7-Intergroup Comparison Of Change In Soft Tissue (Lingual) Between Control Group And Test Group



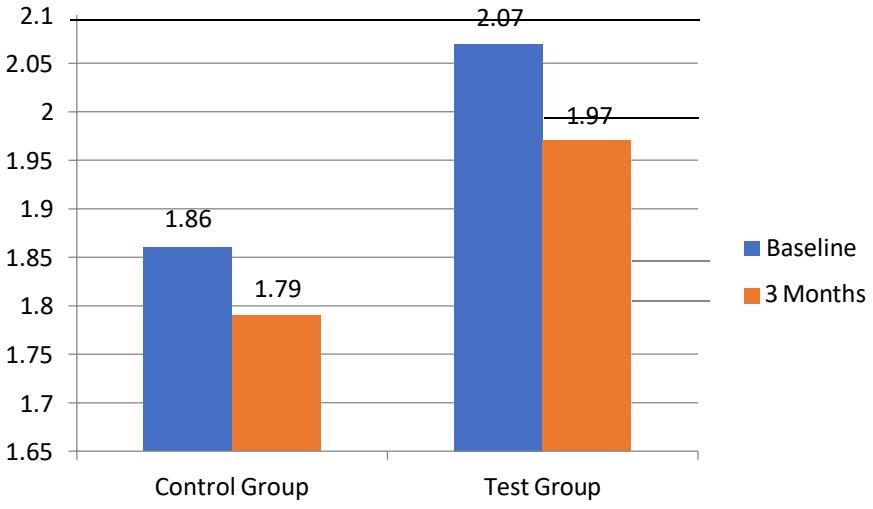
GRAPH NO 7- Intergroup Comparison Of Change In Soft Tissue (Lingual) Between Control Group And Test Group

INTRAGROUP COMPARISON OF CHANGE IN SOFT TISSUE (LINGUAL) BETWEEN BASELINE AND 3 MONTHS IN CONTROL AND TEST GROUP (TABLE 8 AND GRAPH 8)

The intragroup change in soft tissue thickness from baseline to 3 months was statistically significant in both the groups when analyzed using Paired t test

	Baseline		At 3 Months			
	Mean	SD	Mean	SD	P value	Significance
Control Group	1.86	0.367	1.79	0.347	0.001	Significant
Test Group	2.07	0.110	1.97	0.097	0.001	Significant

TABLE NO 8- Intragroup Comparison Of Change In Soft Tissue (Lingual) Between Baseline And 3 Months In Control And Test Group



GRAPH NO 8-Intragroup Comparison Of Change In Soft Tissue (Lingual) Between Baseline And 3 Months In Control And Test Group

Following tooth extraction the following changes are observed :-

Internal changes following tooth extraction are characterized by:

Hemorrhage occurs during tooth extraction leading to the formation of a blood clot inside the socket. Followed by the formation of granulation tissue that stimulates the proliferation of inflammatory and immune cells. The blood clot begins to breakdown within 48 to 72 hours as granulation tissue infiltrates the clot

The periphery of the socket is infiltrated by epithelium and immature connective tissue within 96 hours. There is complete formation of granulation tissue by the end of 7 days and osteoid formation takes place at the base of the socket as unmineralized bone spicules. The osteoid then begins and continues to mineralize for the next two to three weeks. At around 100 days post-extraction. [32,33,34] there is further bone fill which is seen as radiographic density

External changes following tooth extraction are characterized by:

Significant dimensional changes occur within the initial 8 weeks after tooth extraction, primarily driven by pronounced osteoclastic activity. This activity leads to the resorption of the crestal region in both the buccal (outer) and lingual (inner) bone walls of the extraction site. The reduction in wall height is more noticeable on the buccal side compared to the lingual side of the extraction socket. This decrease in height is coupled with a horizontal bone loss, a result of osteoclasts located in lacunae on the surfaces of both the buccal and lingual bone walls. The rate of resorption is four times greater in the mandible than in maxilla because the mandible experiences more mechanical stress and functional activities like mastication, speech [35,36,37]

A number of local biological events occur within the socket mainly in the first 3 months and continue upto 1 year following tooth extraction1 . These changes results in reduction of height and width of the residual ridge. [38] Over the course of six to twelve months, there is a reduction in the buccolingual or horizontal ridge of around 5-7 mm; the majority of this change happens in the first four months of healing[1] There is an apico coronal reduction in ridge height of approximately 0.8mm at 3 months. [2]

Misch and colleagues1 stated that the loss of crestal bone height and labial plate may be attributed to the constriction of the blood clot within the alveolus (the socket where

the tooth was extracted) and the remodeling of thin labial cortical plates. This remodeling or resorption is believed to occur in response to inadequate blood supply following the tooth extraction. [39]

Mecall and Rosenfeld (2015) established that the resorption of the residual ridge, primarily from the labial direction, can result in a compromise in the positioning of the implant fixture. [40] Indeed, Spray and colleagues (2016) have validated the necessity for sufficient facial bone thickness post dental implant placement to reduce the loss of facial bone height. Through a comprehensive examination of 3061 implants in 32 Veteran Affairs Medical Centers, they aimed to identify a "critical thickness" of facial bone where no change or bone gain occurred following implant placement. They determined this critical thickness to be 2 mm. Instances where the remaining facial plate was less than 2 mm after implant placement experienced more frequent vertical bone loss. Implants with over 3 mm of vertical bone loss exhibited a mean facial bone thickness of 1.3 mm at insertion. Consequently, various techniques have been proposed to preserve the sufficient width and height of the alveolar ridge post-extraction. The objective of ridge preservation procedures is to avert the atrophy of the jawbone and uphold the necessary height and width of bone to facilitate the successful placement of implants.[41]

These procedures are particularly recommended in situations where natural healing of the alveolar socket is expected to yield unfavorable ridge morphology, especially when aesthetics or bone volume are crucial. In such cases, it becomes necessary to augment the extraction socket with new bone to establish a stable vascular foundation. This foundation then allows for the subsequent placement of secondary soft tissue grafts and/or implant fixtures if necessary. Also we need to preserve socket otherwise sinus pnuematization and resorption close to the mental nerve occurs. [42]

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FIG NO 24 Depicts the healing of the extraction socket with (below arrows) and without socket grafting(above arrows) When the socket is not grafted, a large amount of alveolar ridge resorption takes place, The bundle bone is completely resorbed causing a reduction in the vertical ridge. In a second phase, the woven bone gets resorbed causing horizontal and vertical ridge reduction. When socket is grafted vertical bone reduction still occur, however, the horizontal contraction are reduced.

Nicholas Caplanis, Jaime L. Lozada and Joseph Y.K. Kan (2005) have devised a classification system for extraction defects characterizes the status of hard and soft tissues immediately after tooth extraction. It aims to anticipate the wound healing response and offers fundamental treatment guidelines to ensure reliable implant integration and achieve optimal esthetics, making it easy for the clinicians to administer correct treatment protocols. [43, 44]

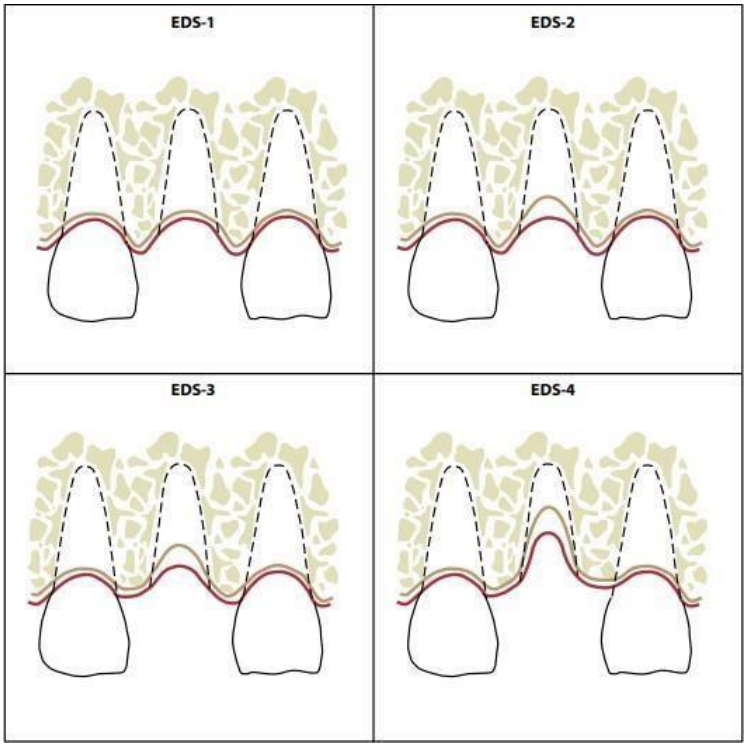

FIG NO 25- Illustration of Extraction socket defect by Nicholas Caplanis, Jaime L. Lozada and Joseph Y.K. Kan (2005)

The Extraction Defect Sounding Classification

Defect Type	General Assessment	#Socket Walls Affected	Biotype	Hard Tissue	Distance to Reference	Ideal Soft Tissue	Treatment Recommendations
EDS-1	Pristine	0	Thick	0 mm	0-3 mm	Predictable	Immediate implant (one-stage)
EDS-2	Pristine to slight damage	0-1	Thin or thick	0-2 mm	3-5 mm	Achievable but not predictable	Site preservation or immediate implant (one- or two-stage)
EDS-3	Moderate damage	1-2	Thin or thick	3-5 mm	6-8 mm	Slight compromise	Site preservation then implant placement (two-stage)
EDS-4	Severe damage	2-3	Thin or thick	≥6 mm	≥9 mm	Compromised	Site preservation then site development then implant placement (three-stage)

According to Nicholas Caplanis, Jaime L. Lozada, and Joseph Y.K. Kan (2005) the extraction socket defect can be classified into 4 groups- (**TABLE NO 9)**

Thus, the ideal situations that require socket preservation are:

When the thickness of buccal plate is less than 1.5–2 mm or when there has been any damage or loss of one or more of the socket walls.

Sites where maintaining the bone volume is important to minimize the risk of involving maxillary sinus or inferior alveolar nerve if further bone is lost.
In cases where multiple teeth are to be extracted simultaneously and preservation of the bone is important for further restoration. Post-extraction socket grafting may minimize ridge resorption and allow the placement of a prosthesis that maintains the aesthetic and functional criteria. [30]

In this study, DFDBA and dHCM were used in socket preservation technique to assess the bone gain at baseline and 3 months post extraction. 20 samples were randomly divided into the Test group and Control group. In the test group, tooth was atraumatically extracted and the socket was grafted with bone graft and membrane and in the control group, the extracted socket was allowed to heal on its own. 3 months post extraction a significant bone gain was seen in the test group and bone resorption occurred in the control group.

The success of bone grafting stems from the inherent capability of bone tissue to undergo complete regeneration. Ideally, the grafting material enhances the natural process of osteogenesis.

Osteoconduction refers to the mechanism in which bone graft material functions as a framework, aiding in the development of new bone by supporting the host bone. The bone graft material acts as a scaffold, facilitating the spread of osteoblasts from the periphery of the grafting site and the generation of fresh bone.

Osteoinduction entails triggering osteoprogenitor cells to undergo differentiation into osteoblasts, ultimately resulting in the formation of new bone. Marshall and R Urist in 1965 in his study stated that Bone Morphogenetic Protein (BMP), a growth factor bonded to cell surface receptors stimulates mesenchymal cells to differentiate into osteoblasts. *45, 46+

Bone morphogenetic proteins (BMPs) constitute a distinctive family within the transforming growth factor beta (TGF-β) superfamily of proteins, playing a crucial role in the regulation of bone formation and repair. Although BMPs are commonly referred to as growth factors, they are currently recognized as differentiation factors due to their involvement in morphogenesis and organogenesis. More than 20 BMP-related proteins have been identified. BMPs play a role in inducing the differentiation

of mesenchymal progenitor cells into various cell types, including chondroblasts and osteoblasts. This indicates that BMPs have the potential to influence both direct and indirect mechanisms of bone formation.[46]

Bone morphogenetic proteins (BMPs) play a vital role in the regeneration of periodontal tissues, aiding in the restoration of cementum, periodontal ligament, and alveolar bone.[47] In a study involving beagle dogs, the use of recombinant human BMP-2 (rhBMP-2) in a prepared periodontal defect demonstrated significant regeneration of the periodontal tissues.[48]

There are different types of grafting material like autograft, allograft, xenograft and alloplastic material that are used in socket preservation purposes. Autografts possess osteoconductive, osteoinductive and osteogenic properties. However, there are certain limitations involving autogenous bone grafting - such as the need for second surgery for harvesting the graft from the donor site. [49]

Allograft pertains to tissue grafts sourced from donors of the same species but with genetic differences. A typical illustration of this is Demineralised Freeze-Dried Bone Allograft (DFDBA), which possesses both osteoconductive and osteoinductive characteristics. Consequently, DFDBA can act as a scaffold for existing osteoblasts while also triggering the generation of new osteoblasts, fostering a quicker integration of the graft. [50]

Intergroup comparison of change in alveolar crest width between control group and test group :-

In the control group, the mean horizontal R.W at alveolar crest was 11.62 at baseline and 11.14 at 3months time interval . The mean bone loss was 0.48 in the control group .

In the test group, the mean horizontal R.W at alveolar crest was 10.83 at baseline and 11.17 at 3months time interval . The mean increase in the bone level was 0.34 in the test group.

Intergroup comparison of change in mid crest width between control group and test group :-

In the Control group. the mean horizontal R.W at mid crest was 9.18 at baseline and 8.82 at 3 months time interval . The mean decrease in the RW at mid crestal level was 0.360 .

In the test group, the mean horizontal R.W at mid crest was 7.04 at baseline and 7.41 at 3months time interval . The mean increase in the RW was 0.370 in the test group.

So, there was significant bone gain in the Test group as compared to the Control group as seen in Table no 1 and 3

Our results are in corelation with the studies done by the following authors

Wood and Mealey in the year 2021, undertook a histological investigation involving the division of 40 extraction sockets into two groups. Either DFDBA or FDBA was randomly chosen and grafted into the extraction sockets. No significant differences were observed in the changes in alveolar ridge dimensions between the two groups. However, DFDBA exhibited a significantly higher percentage of vital bone at 38.42%, compared to FDBA at 24.63%. [51]

Borg and Mealey in the year 2015, conducted a comparison between ridge preservation using an allograft composed of 100% mineralized FDBA and a combination allograft with a ratio of 30% DFDBA/70% FDBA at 19 weeks of healing and the mean new vital bone formation in the combination allograft group was 36.16%. This represented a significantly higher level of new bone formation compared to the group treated with FDBA alone (24.7%). [50]

In the present investigation, Jeremiah Whetman and Brian L. Mealey (2016) observed a notably higher formation of new vital bone following tooth extraction and ridge preservation with DFDBA. The study suggests that waiting for 19 weeks before dental implant placement yields significantly greater outcomes compared to a waiting period of only 9 weeks. [21]

Brugnami et al in 1996 human extraction sockets were treated with demineralized freeze-dried bone allografts (DFDBA) and cell occlusive membranes. Notably, there was minimal fibrous encapsulation of the allograft, and limited osteoclasis was

observed. These findings highlight the potential of commercially available DFDBA to serve as a physical stimulus for the growth of new bone in alveolar sockets post-tooth extraction.[12]

In 2017, Troiano et al. demonstrated that employing a bone substitute to fill the extraction socket, followed by the application of a resorbable membrane, can effectively decrease bone resorption in comparison to natural healing. The meta-analysis conducted after tooth extraction indicated a diminished resorption of 2.19 mm in width and 1.72 mm in height of the alveolar ridge. [23]

In 2022, Tanuja B and colleagues concluded that the combination of bone graft material, platelet-rich fibrin (PRF), and the chorion membrane proves to be an effective approach for ridge preservation procedures. Individuals undergoing this treatment exhibited a favorable ridge form, making it conducive for the placement of both fixed and removable prostheses, and even implant placement if deemed necessary. [29]

Evaluating the soft tissue thickness in buccal and lingual aspect there was a decrease in soft tissue thickness in control group compared to the test group evaluated in Table no 5-8 because of the tissue shrinkage that occurred over the 3 months time period because the extraction socket was not grafted. This result had positive corellation with the below mentioned studies by other authors.

Luigi C and colleagues in 2022 asserted that crosslinked collagen membranes and autogenous soft tissue grafts are efficient in preserving soft tissue dimensions after extraction. The study's results confirmed that utilizing crosslinked collagen membranes and autogenous soft tissue grafts, with a minimum follow-up of six weeks, emerged as the most optimal biomaterial options for socket sealing during alveolar ridge preservation (ARP), effectively minimizing post-extraction soft tissue dimensional shrinkage.[52]

In 2022, Paolo De Angelis, in his research, unveiled substantially greater vertical and horizontal bone reduction, along with larger volumetric shrinkage in the spontaneous healing group, in contrast to the ARP group. [53]

Barrier membranes find widespread use in dentistry, serving as valuable adjuncts in bone augmentation for implant therapy and periodontal regenerative dentistry. Guided

bone regeneration (GBR) and guided tissue regeneration (GTR) have been thoroughly investigated and widely embraced as fundamental procedures for the regeneration of lost periodontal tissue. Typically, a barrier membrane is applied to a regenerative site that has experienced volumetric tissue loss. This application aims to inhibit the migration of undesirable cells from the gingival epithelium and connective tissue. [54]

Buser et al. were among the pioneering clinicians to document successful ridge augmentation through guided bone regeneration (GBR) in humans, employing an e-PTFE membrane and tenting pins. Their study involved twelve patients undergoing alveolar ridge augmentation before dental implant placement. After a healing period of six to ten months, the authors observed a substantial increase in bone volume, enabling the placement of dental implants in nine out of the twelve sites. The newly formed bone ranged from 1.5 to 5.5 mm [55]

The amnion, situated as the innermost layer of the placenta, is composed of five layers: the epithelium, basement membrane, compact layer, fibroblast layer, and intermediate layer. The epithelial layer of the amnion is in close proximity to the developing fetus, while the spongy layer is connected to the chorion, which is three to four times thicker than the amnion. The amnion's suitability for allografting is attributed to its low immunogenicity. Additionally, it possesses anti-inflammatory, wound-protecting, and scar-reducing properties. The adhesion of the dehydrated human amnion/chorion membrane (dHACM) and its rapid wound regeneration contribute to superior wound closure compared to other widely used membranes. These combined characteristics make the amniotic membrane valuable for promoting epithelial healing. Another noteworthy attribute is its lack of immunogenicity, as the tissue does not express typical major histocompatibility antigens, thereby avoiding the induction of immune responses.[56]

The dHCM membrane generates diverse growth factors such as basic fibroblast growth factor, hepatocyte growth factor, and transforming growth factor.

In our study, we used dHCM as a barrier material for socket preservation technique. There was a gain in bone level 3 months post operatively.

In a recent systematic review by Gulameabasse et al in the year 2021, which encompassed 21 studies involving 375 human patients, the use of CM and

amnion/chorion membrane (ACM) was evaluated. The findings revealed that CM and ACM serve as effective alternatives to existing techniques for addressing diverse oral soft-tissue defects, including gingival recession, intrabony and furcation defects, and alveolar ridge preservation. [57]

According to Ten Heggeler et al. in the year 2011 stated that, if an extraction socket is allowed to heal without intervention, there is a potential loss of 2.6–4.6 mm in width and 0.4–3.9 mm in height Additionally, with the use of a foetal membrane, they have been shown to improve gingival biotype with the use of a foetal membrane. [58]

In our study, we found that there was significant bone gain and soft tissue gain in the test group (Grafted sites) as compared to the Control sites (non grafted)

Thus, it can be concluded that implementing socket preservation procedures during tooth extraction enhances the outlook for maintaining the width and height of the remaining bone. Grafting at the time of extraction capitalizes on the regional acceleratory phenomenon triggered by the extraction trauma, resulting in a shortened healing time. Recent research suggests that socket preservation can provide more available bone for better rehabilitation, better esthetics and performing oral hygiene measures thereby contributing to overall success.

The alveolar bone, a structural component, typically diminishes after tooth extraction. According to Tan et al.'s systematic review, there is an average decrease of 29 to 63% in horizontal bone and 11 to 22% in vertical bone at 6 months post-extraction. Failure to address a compromised extraction socket results in more pronounced loss of bone volume throughout the socket compared to intact extraction sites. This underscores the importance of alveolar bone reconstruction before implant placement.

Dental implants have gained widespread acceptance as a reliable treatment option for replacing missing teeth. Adequate bone width at the implant site is a crucial requirement for ensuring a predictable and long-term success in implant dentistry. When evaluating the extent of dimensional changes in both hard and soft tissues of the alveolar ridge following tooth extraction in humans, the use of ARP (alveolar ridge preservation) in extraction sockets proves beneficial by mitigating dimensional changes compared to non-grafted control sites.

In this study, socket preservation procedure was done by using DFDBA and Chorion Membrane in the extraction socket. 3 months post extraction new vital bone gain was observed.

Decalcified freeze-dried bone allografts (DFDBA) derived from human sources find applications in periodontal regeneration as well as in the maintenance and restoration of alveolar ridge due to its osteoinductive and osteoconductive properties.

Dehydrated human amnion/chorion membrane (dHACM) functions as a barrier in scaffolds used for tissue regeneration due to its antibacterial, antimicrobial, and anti-inflammatory properties, with very low immunogenicity it enhances gingival biotype.

Clinicians should be mindful that achieving ideal functional and esthetic prosthetic reconstruction following implant therapy requires sufficient alveolar bone volume and a favorable architecture of the alveolar ridge. Future studies should focus on a large number of patients with long-term follow-up

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ANNEXURE 1

INSTITUTIONAL ETHICAL COMMITTEE

BABU BANARASI DAS UNIVERSITY
BBD COLLEGE OF DENTAL SCIENCES, LUCKNOW

BBDCODS/IEC/09/2022 **Dated: 16th September, 2022**

Communication of the Decision of the Xth Institutional Ethics Sub-Committee Meeting

IEC Code: 29

Title of the Project: A Comparative Study Of Socket Preservation Technique With And Without Demineralized Freeze Dried Bone Allograft And Chorion Membrane- A Clinical Study.

Principal Investigator: Dr Hiya Datta **Department:** Periodontology

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

Type of Submission: New, MDS Project Protocol

Dear Dr Hiya Datta,

The Institutional Ethics Sub-Committee meeting comprising following members was held on 15th September, 2022.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry
2.	Dr. Praveen Singh Samant Member	Prof. & Head, Department of Conservative Dentistry & Endodontics
3.	Dr. Jiji George Member	Prof. & Head, Department of Oral Pathology & Microbilogy
4.	Dr. Amrit Tandan Member	Professor, Department of Prosthodontics and Crown & Bridge
5.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics & Dentofacial Orthopaedics

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:

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

Lakshmi Bala 16/09/22

Dr. Lakshmi Bala
Member-Secretary
Institutional Ethics Sub-Committee (IEC)
BBD College of Dental Sciences
BBD University, Lucknow
Member-Secretary
Institutional Ethic Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

ANNEXURE 2

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL CERTIFICATE

BABU BANARASI DAS UNIVERSITY

BBD COLLEGE OF DENTAL SCIENCES, LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"A Comparative Study Of Socket Preservation Technique With And Without Demineralized Freeze Dried Bone Allograft And Chorion Membrane- A Clinical Study"** submitted by **Dr Hiya Datta** Postgraduate student in the **Department of Periodontology** for the Thesis Dissertation as part of MDS Curriculum for the academic year 2021-2024 with the accompanying proforma was reviewed by the Institutional Research Committee in its meeting held on **14th September, 2022** 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. Dr. Puneet Ahuja
Chairperson

Dr. Mona Sharma
Co-Chairperson

ANNEXURE-3

Consent form

Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Consent Form (English)

Title of the Study ……..

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

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

Acceptable representative

ANNEXURE-4
PID FORM

Babu Banarasi Das College of Dental Sciences (Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Participant Information Document (PID)

1. StudyTitle

A comparative study of A Comparitive Study Of Socket Preservation Technique With And Without Demineralized Freeze Dried Bone Allograft And Chorion Membrane- A Clinical Study

2. InvitationParagraph

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

3. What is the purpose of the study?

The aim of the present study is to asses the amount of bone gain using DFDBA and Chorion membrane in the extracted sockets

4 .Why have I been chosen?

You have been chosen for the study as you are fulfilling the required criteria for the study.

5. Do I have to take part?

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

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

You will have to come four to five times, with complete scaling and route planning done on the first visit. At the next visit, the affected tooth will be extracted under local anesthesia, after which the tooth socket will be measured buccolingually and mesiodistally and intra-oral peri-apical radiographs will be taken along with the grid. The socket will be packed with the graft and the membrane and flaps will be approximated and sutures will be placed. You will be called back after 10 days for suture removal and again after 3 months to see the benefits of the surgery. As a volunteer, your responsibility will be to arrive on time

7. What do I have to do?

You do not have to change your regular lifestyles for the investigation of the study**.**

8. What is the procedure that is being tested?

The extracted socket in group I will be grafted with demineralized freeze dried allograft (DFDBA) with Chorion membrane. The flap will be sutured to the adjacent incision. In Group II the sockets will be allowed to heal themselves without any grafting material. Further recall for clinical and radiographic re-evaluation will be scheduled in 3 months. On each visit, hygeine control measures will be put in place and Supra Gingival scaling will be carried out if necessary

9. What are the interventions for the study? ;

Pre-surgical- IOPAR and complete blood test will be done. The affected tooth will be removed under local anesthesia. Before extraction, sulcular incisions will be made with vertical releasing incisions. The flap will be retracted and the teeth will be removed. The bone graft will be packed inside the extracted socket and the chorion membrane will be adapted over it and the flap will be sutured. The benefits will be measured after 3 months. After surgery, medicines will be prescribed such as antibiotics and NSAIDs.

10. What are the side effects of taking part?

There are no side effects on patients of this study.

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

- Patients allergic towards local anaesthesia
- Patients with uncontrolled systemic diseases
- Patients having poor oral hygiene
- Patients under active immunosuppressive agents
- Pregnant and lactating mothers
- Patients with mental disabilities

12. What are the possible benefits of taking part?

Participating in this study will give you better treatment options for your discomfort. These types of grafts will produce good results because they contain growth factors.

13. What if new information becomes available?

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

14. What happens when the research study stops?

If the study finishes/stops before the stipulated time, this should be explained to the patient/volunteer.

15. What if something goes wrong?

If any severe adverse event occurs, or something goes wrong during the study, the complaints will be handled by the doctors expertising in the field at BBDCODS opd.

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

Yes, it will be kept confidential. Your name, address or any other personal information will not be shared outside the BBDCODS.

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

The identity of the participants will not be disclosed in any results, reports or publications.

18. Who is organizing the research?

This research study is organized by the academic institute (BBDCODS)

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

Yes. If the patient wishes, the result of the study will be made available to him/her.

20. Who has reviewed the study?

The study has been reviewed and approved by the Head of the Department, IEC/IRC of the institution.

21. Contact for further information

Dr. Hiya Datta

Department of Periodontology and Implantology

Babu Banarasi Das College of Dental Sciences.
Lucknow – 226028

Mob: 9007651108

Dr. Laxmi Bala, Member Secretary,
Babu Banarasi Das College of Dental Sciences.

Lucknow – 226028 bbdcods.iec@gmail.com

Signature of PI……

Name……..

Date……..

ANNEXURE-5

Babu Banarasi Das College of DentalSciences

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

Guidelines for Devising a Participant / Legally Acceptable Representative InformationDocument (PID) in Hindi

1. अध्ममन शीषषक

डडमभनयराइज्ड फ्रीज़ ड्राइड फोन एरोग्राफ्ट औय कोरयमोन भेम्ब्रेनके साथ औय बफना सॉकेट संयक्षण तकनीक का तुरनात्भक अध्ममन का एक तुरनात्भक अध्ममन- एक नैदाननक अध्ममन

2. ननभंत्रण नैयाग्राप

आनको एक शोध/नयीक्षण अध्ममन मरए आभंबत्रत ककमा जा यहा है। भें बाग रेने के

ननणम रेने से नहरे आनको मह सभझना भहत्वनूणष है कक शोध/अध्ममन को ककमा जा यहा है और इसभें क्मा शामभर होगा। कृनमा

ननम्न मरखखत जानकायी मरए सभम ननकारें औय मदद चाहें तो ध्मान से नढ़ें

आन चाहें तो दोस्तों, रयश्तेदायों औयअन्म रोगों से इस ऩय चचाष कयें

चचककत्सक/नारयवारयक डॉक्टय के साथ इस नय चचाष कयें। हभसे

ऩूछें कक कोई फात स्नष्ट नहीं है मा ऐसा कुछ है जो आन अचधक जानकायी चाहते हैं। मह तम कयने कक मरए सभम रें कक आन बाग रेना चाहते हैं मा नहीं।

3. अध्ममन का उद्देश्म क्मा है?

वतभान अध्ममन का उद्देश्म ननकारे गए सॉंके ट भेद डीएपडीफीए औय कोरयमोन झल्ीका उन्नमोग कयके हEाीकेराब की भात्रा का आकरन कयना है।

4 .भॉंझॉंके कोचनॉंा गमा हॉं

आन्नकॉॉो अध्ममन ंंTॉॉंंTा गमा हॉॉंंै कोॉॉो कक आन्न कौौंंे मरए अध्ममन कौौंंे मरए आवश्मक चनभानदॉॉडोो को न या कय यहे हैं।

5. का भ् झे बाग रेना होगा?

शोध भाग लेने से जुड़े जोखिम: ऐसी कोई संभावित जोखिम नहीं है। मदद आन ऐसा कयता हैं, तो आनको कोई ऩैसा नहीं मिलेगा।

मह स नों नत्रक ययानी के मरए ददमा जाएगा और एक सहभनत ऩत्र नय हस्ताक्षर कयना मरए कहा जाएगा। अध्ममनके दौयान आन अबी बी ककसी बी सभम बफना कोई कायण फताए अऩना नाभ वानस रेने के मरए स्वतंत्र हैं।

6. मदद भैं इस अध्ममन भें बाग रेने के लिए सहभत हूँ तो भुझे क्मा कयना होगा?

नहरे भात्र आऩ की सहभनत रे ना, और उसके साथ आनको चाय से नांच फाय भुराकात कयनी होगी। अगय आऩ भरेरयमा से ऩीड़ित हैं, तो ऩरयवतत दवाओं को साथ रे भानक प्रोटोकॉर के अनुसाय ननकारा जाएगा, जिसके फाद टेस्ट की टेस्ट कयने के लिए भरेरयमा की जांच की जाएगी।

जाएगा और जिसके साथ इंटय-ओयर नेयी-एवनकर येडमोग्राफ मरमा जाएगा। सारे टेक्नोग्राफ कैसे रगेंगे और झरयी और फ्रोयाइड का भी अनुभान रगामा जाएगा और दांतों के रगाए जाएंगे।

मसवनी हटानक मरए

आऩको 10 ददनोंक फाद

वॉनस फॉरॉमा जॉएगॉा औय सजयॉी काँे यॉाब दाँने
ॉॉे
काँे मरए 3

भहीनॉे काँे फाद कपय से

फॉरॉमा जॉएगॉा। एक सॉवमॉसॉे वक काँे यॉ ऩ
भॉे ॉाँॉे आऩकॉी

चॉॉजम ॉॉे दॉायॉी सभम ऩय ऩहॉ ॉॉॉचनॉॉे
ॉॉ कॉॉीहोगी
ॉभ

7. भुझे का कयना होगा?

अध्ममन की जॉॉॉोचकेमरए आऩको अऩनी नन्ममभत जीवनशैरी भें
फदराव कयने की ज़रॉॉ यत नहाँ हॉॉै ।

8. वह कौन सी प्रक्रिया है जिसका नियंत्रण करना जरूरी है ?

सभॉह I भॉे ाँाे ा ननकॉारॉे गए सॉकॉे ट कॉो कॉोरयमोन झल् ाॉरॉी काँाे साथ

डडमभनयराइ फ़रीजॉं. उाम एरोग्राफ़्ट (DFDBA)केसाथ ग्राफ्ट ककमा जाएगा।र जॉडीये नय न को आसन्न

मसर

ददमा जॉाएगॉा। सम्हाII भॉे ाँाे सॉकॉे टॉस कककसॉी ग्रॉाचॉफ्ट सॉाभग्रॉी काँाे

य ाॉाॉॉॉद

कॉो ठाँीक

कयनॉे कॉी अनॉुभनत दॉी जॉाएगॉी। चॉक्र मॉाॉॉोकन काँाे मरए ननकर औय यॉे डडमॉोग्रॉाकपक न्यूनभॉल् ाॉॉ

आगॉॉाे कॉॉी वानसी 3 भहीनॉॉाे भॉॉाे ाॉाेा ननधॉॉाषरयत कॉॉी जाएगी। प्रत्मॉॉाे क दॉॉौयॉॉा नय, सॉॉवछछताॉा ननमॉॉॉत्रण

उनॉॉाम ककए जॉॉाएॉॉॉगॉॉाे औय मदद आवश्मक ॉॉॉ वर सॉॉकॉॉा हॉॉो तॉॉो सॉॉ प्रॉॉा चॉॉभरग कॉॉ जॉॉाएगॉॉ ॉचॉ ॉज

9. अध्ममनकेमरए का हसाे ाॉॉाे न हैं? ;

प्रॉॉ-सचजकर- IOPAR औय सॉॉॉनॉॉ णष यकृत नयॉॉीाे ण ककमा जॉॉाएगॉॉा। प्रबॉॉावत दॉॉाॉॉत को

सॉॉथॉॉानीम ॉॉीमसमॉॉा कॉॉाे तहत हटा ददमा षण सॉॉाे एनॉॉाे जाएगा। ननषॉॉक नहरॉॉाे, सॉॉथ ऊध्वाषधय

रयरीच्जॉॉग साथ गोराकाय चीये रगाए जाएँगे।फ्र न को वानस रे मरमा जाएगा चीयो के

औय दाॉॉॉत हटा ददए जाएॉगे। हEाके ग्राफ्ट का ननकारे गए सॉके टके अदय

नैक ककमॉॉा जॉॉाएगा औय कोरयमॉॉोन झलाॉॉा रॉॉी कॉॉो इसकॉॉाे ऊनय अनॉॉकॉॉ मरत ककमा जॉॉाएगॉॉ औय फॉॉरैन कॉॉो मसर ददमा जाएगा। राब 3 भहीनॉॉाे कॉॉाे फाद भानॉॉा जॉॉाएगा। सजयॉॉी कॉॉाे फाद, एॉॉटॉॉीफामोदटक्स औय एनएसएआईडी जैसॉॉ दवाएँ ननधॉॉाषरयत कॉॉ जाएँगी।

10. बॉॉाग रॉॉाे नॉॉाे कॉॉाे दषाॉॉ प्रबॉॉाव का हॉॉाै ाॉॉाेा?

इस अध्ममन कॉॉा भयॉॉीजॉॉोॉॉो नय कॉॉोई दषाॉॉ प्रबॉॉाव नहॉॉीॉॉॉ हॉॉाे।

11. बाग रॉॉाे नॉॉाे कॉॉाे सॉॉॉबॉॉावत नॉॉकसॉॉान औय जॉॉोखिभ का हॉॉाै ाॉॉाेा?

- भयीजोो को रोकर एनेस्थीमसमा से एरजी है
- अननमॉॉॉबत्रत प्रणारीगत योगॉॉोॉॉॉ वारॉॉाे योगॉॉी
- याायॉॉाफ भौखि ॉॉक सॉॉवछछतॉॉा वारॉॉाे

भयीज़

- सक्कॅम प्रनतयंॅादभनकायॅी एजॅे ाॉॉॅTोTटॅोॅो काँे तहत योगॅी
- गबवती औय स्नान कयाने वारी भाताएँ
- भानमसक ववकरााँगता वारे भयीज़

12. बाग रे नेकेसौंबावत रूाब क्या है?

इस अध्ममन भेंे बाग रेने से आन्नकाे अन्ननी न्यशानीकेमरएफेहतय उन्नचायकेववककल्न

मभरेंे गे। इस एकायके ग्राफ्ट अछछे न्नरयणाभ क उनभें ववकास

देंे गे कोोकायकहोते हैं।

13. मदद नई जानकायी उन्नरब्ध हो जाए तो का होगा?

कबी-कबी ककसी शोध न्नरयमोजनके दौयान अध्ममन ककए जा यहे शोधके फाये भेंे

नई जानकायी उन्नरबॉध हो जातॉी हॉै । मदद ऐसा होतॉा हॉै , तॉो आन्नका

शोधकतॉाष आन्नकाे इसकॉे फायॉे भॉे

ाॉै ाे फतॉाएगा औय आन्नसे

चचॉाष कयॉे ाे गॉा कक कॉा आन्न अध्ममन जॉायी यॉन्ना

चॉाहतॉे ाे हॉै ाे। मदद आन्न वान्नस रॉे ाे नके कॉा ननणम रॉे ाे तॉे ाे हॉै ाे, तॉो आन्नका शोधकतॉाष/अन्वेषक

आन्नकी वान्नसी वस ॉा कयॉे ाे गा। मदद आन्न अध्ममन जायॉी कॉी वॉम ॉथ ययॉोॉनके कॉा ननणम रॉे ाे त

हैंं, तो आन्नसे एक अद्यतन सहभनत प्रन्न न्नय हसाा ाें य कयनक मरए कहा जा सकता है।

14. जफ शोध अध्ममन फौद हो जाता है तो का होता है?

मदद अध्ममन ननधाषरयत सभम से न्नहरे सभाप्त/फॉद हो जाता हैै, तो यागी/स्वमॉसेवक को मह सभझामा जाना चादहए।

15. अगय क ु छ गरत हो गमा तो का होगा?

मदद कॉोई गॉाॉोबॉीय प्रनतकॉ र घटनॉा घटतॉी हॉै , मा अध्ममन काॉे

दॉीय

ॉान कॉ ु छ गरत हॉोतॉा हॉै , तॉो मशकॉामतॉोॉो कॉो फीफॉीसीओडीएस ओन्नीडी

भॉॉ◌ॉ◌े ◌ॉॉँ◌ॉ◌ेा ◌ॉं ◌ाॉॉॉ◌ॉ◌े ।भॉॉ◌ॉ◌े ◌ॉॉँ◌ॉ◌ेा ववशषा डॉॉक टयोो दॉॉवायाा ननमॉॉबत्रत ककमा जाएगा।

16. का इस अध्ममन भें भेयी बागीदायी को गोऩनीम माया जाएगा?

हाॉॉॉॉ, इसे गोऩनीम माया जामेगा। आऩका नाभ, ऩता मा कोई अन्म व्मक्तगत जानकायी फीफीडीसीओडीएसकेफाहय साझा नहीॉॉॉो की जाएगी।

17. शोध अध्ममनके नरयणाभोंका क्मा होगा?

ककसी बी नरयणाभ, रयनोटष मा प्रकाशन भें ◌ा◌ा◌ा◌ा सा नहीं ◌ाैं◌ा◌ा प्रनतबाचगमोंकी नहचान कयना
म◌ा◌ा रककमा जाएगा।

18. अनुसंधान का आमोजन कौन कय यहा है?

मह शोध अध्ममन अकादमभक संस्थान (फीफीडीसीओडीएस) द्वाया
आमोजजत ककमा जाता है।

19. क्मा अध्ममनके नरयणाभ अध्ममन सभाप्त होनक फाद उऩरब्ध कयाए

जाएंगे?हाँ। मदद योगी चाहे तो अध्ममन का नरयणाभ उसे उऩरब्ध कयामा

जाएगा।

20. अध्ममन की सभी ◌ा◌ा◌ा◌ा ककसने की है?

अध्ममन की सभी ◌ा◌ा◌ा◌ा औय अनुभोदन संस्थान के ववबागाध्मक्ष,
आईईसी/आईआयसी दवाया ककमा गमा है।

21. अचधक जानकायी

कें मरए संऩकष कयें डॉ.

दहमा दत्ता

नेरयमो ◌ोरजी औय ◌ा◌ाटरांजी
डोट इमुबपर

ववबाग फाफ फनायसी दास कॉरेज ऑप डेंटर

साइंसेज।

ररनऊ-226028

भोफाइर: 9007651108

डॉ. रुभी फारा, सदस्म सचचव,

फाफ फनायसी दास कॉरेज ऑप डेंटर

साइंसेज। ररनऊ - 226028

bbdcods.iec@gmail.comनीआई ` क

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नाभ……..

तायीयाॉॉं……..

ANNEXURE-6

PATIENT PROFORMA

Name :-

Age :-

Sex :-

Chief complain :-

TEST GROUP

1. At baseline

Clinical evaluation :-

- HORIZONTAL RIDGE HEIGHT
  - At alveolar crest
  - At mid crest

- SOFT TISSUE THICKNESS
  - Buccal
  - Lingual/Palatal

Radiographic evaluation (with grid) :-

2. 3 months post operative

Clinical evaluation :-

- HORIZONTAL RIDGE HEIGHT
  - At alveolar crest
  - At mid crest

- SOFT TISSUE THICKNESS
  - Buccal
  - Lingual/Palatal

Radiographic evaluation (with grid) :-

CONTROL GROUP

1. At baseline

Clinical evaluation :-

- HORIZONTAL RIDGE HEIGHT
  - At alveolar crest
  - At mid crest

- SOFT TISSUE THICKNESS
  - Buccal
  - Lingual/Palatal

Radiographic evaluation (with grid) :-

2. 3 months post operative

Clinical evaluation :-

- HORIZONTAL RIDGE HEIGHT
  - At alveolar crest
  - At mid crest

- SOFT TISSUE THICKNESS
  - Buccal
  - Lingual/Palatal

Radiographic evaluation (with grid) :-

ANNEXURE 7

Statistical analysis

STATISTICAL ANALYSIS

The data for the present study was entered in the Microsoft Excel 2007 and analyzed using the SPSS statistical software 23.0 Version. The descriptive statistics included mean, standard deviation frequency and percentage. The level of the significance for the present study was fixed at 5%.

The intergroup comparison will be done using the independent t test and intragroup comparison was done using the Paired t test The Shapiro–Wilk test was used to investigate the distribution of the data and Levene's test to explore the homogeneity of the variables.

Mean

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

Where:

$\overline{X}$ = the data set mean

$\sum$ = the sum of

X = the scores in the distribution

N = the number of scores in the distribution

Range

$$range = X_{highest} - X_{lowest}$$

Where:

$X_{highest}$ = largest score

X_{lowest} = smallest score

Variance

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

The simplified variance formula

$$SD^2 = \frac{\Sigma X^2 - \frac{(\Sigma X)^2}{N}}{N}$$

Where:

SD^2 = the variance

$\sum$ = the sum of

X = the obtained score

$\overline{X}$ = the mean score of the data

N = the number of scores

Standard Deviation (N)

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

The simplified standard deviation formula

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

Where:

SD = the standard deviation

$\sum$ = the sum of

X = the obtained score

$\overline{X}$ = the mean score of the data

N = the number of scores

Independent t-test

Independent t Test can be used to determine if two sets of data are significantly different from each other, and is most commonly applied when the test statistic would follow a normal distribution. The independent samples *t*-test is used when two separate sets of independent and identically distributed samples are obtained, one from each of the two populations being compared

$$t = \frac{\bar{X}_1 - \bar{X}_2}{\sqrt{\left(\frac{(N_1 - 1)s_1^2 + (N_2 - 1)s_2^2}{N_1 + N_2 - 2}\right)\left(\frac{1}{N_1} + \frac{1}{N_2}\right)}}$$

Where X1 =Mean of the first Group, X2 =Mean of the Second Group

Paired t test

$$t = \frac{\bar{x} - 0}{SE(d)} = \frac{\bar{x}\sqrt{\quad}}{SD(x)}$$

A paired t-test is used to compare two population means where you have two samples in which observations in one sample can be paired with observations in the other sample. Examples of where this might occur are: - Before-and-after observations on the same subjects (e.g. students' diagnostic test results before and after a particular module or course) or A comparison of two different methods of measurement or two different treatments where the measurements/treatments are applied to the same

ANNEXURE -8

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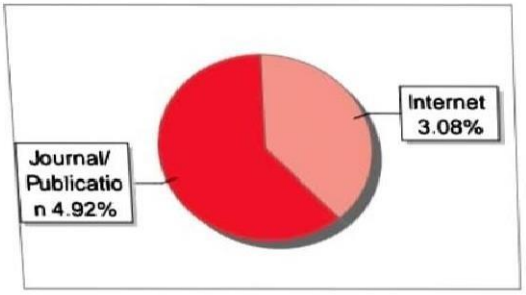

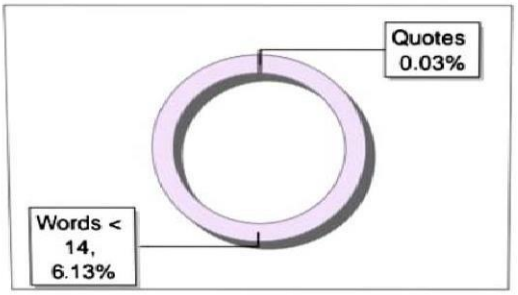

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