RESEARCH PAPER

"COMPARATIVE EVALUATION OF FREEZE DRIED BONE ALLOGRAFT AND PORCINE BONE XENOGRAFT IN COMBINATION WITH TYPE-I COLLAGEN MEMBRANE FOR GUIDED BONE REGENERATION AROUND IMMEDIATE IMPLANTS: A CLINICO-RADIOGRAPHIC STUDY"

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Background: The preservation of alveolar bone volume following tooth extraction is a significant challenge in implant dentistry. While immediate implant placement offers reduced treatment time and improved esthetics, it often results in peri-implant bone defects, particularly in the buccal plate. Guided Bone Regeneration (GBR), utilizing barrier membranes and bone grafts, has become the standard technique to reconstruct these deficiencies.

Aim and Objective: The aim of this prospective, randomized clinical study was to evaluate and compare the efficacy of Freeze-Dried Bone Allograft (FDBA) and Porcine Bone Xenograft when used in combination with a Type-I Collagen Membrane for GBR around immediate implants.

Materials and Methods: The study included 20 implant sites in 20 systemically healthy patients (aged 18–60 years), divided into two groups: Group A: GBR using FDBA and Type I Collagen Membrane (n=10) and Group B: GBR using Porcine Bone Xenograft and Type I Collagen Membrane (n=10). Clinical evaluations (Plaque Index [PI], Modified Gingival Index [MGI], Probing Depth [PD], and Pink Esthetic Score [PES]) and radiographic assessments (Alveolar Bone Width [BW] via CBCT) were performed at baseline, 6 months, and 9 months.

Results: Clinical Health: Both groups maintained stable peri-implant health. There were no statistically significant intergroup differences in PI, MGI, or PD at any time interval ($p > 0.05$). Whereas for Esthetics Outcomes Group A reached a mean score of 9.90 ± 0.73, while Group B reached 9.50 ± 0.52. Both groups showed a highly significant longitudinal improvement in Pink Esthetic Scores ($p < 0.001$), with no significant difference between Allograft and Xenograft outcomes ($p > 0.05$) and Radiographic Outcomes in Group A bone width increased from 5.20 mm to 6.85 mm and Group B increased from 5.10 mm to 6.70 mm, indicating active bone remodeling. Intergroup comparison of the alveolar width measured from palatal plate to buccal cortical plate
{Bone Width (BW)} showed no significant difference, suggesting both materials are equally effective in bone regeneration ($p > 0.05$).

Conclusion: Immediate implant placement combined with GBR is a highly predictable treatment modality. Both FDBA and Porcine Bone Xenograft provide comparable and successful clinical, esthetic, and radiographic outcomes. While FDBA is noted for potentially faster initial formation due to its osteoinductive properties, Porcine Xenograft offers excellent structural stability. Both materials are recommended for routine clinical use in managing peri-implant defects.

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Introduction

Single-tooth immediate implant insertion and provisionalization, especially in the aesthetic zone, is a highly reliable treatment modality for replacing a failing tooth[1]. Increasing patient expectations for reduced treatment time and improved esthetics and comfort have shifted research interest from implant survival toward optimal preservation of soft and hard tissue[2]. The success of immediate implants depends significantly on the quality and quantity of surrounding bone tissue[3]. Guided bone regeneration (GBR) techniques have emerged as valuable tools in augmenting bone volume around implants, thereby enhancing their stability and long-term prognosis[4]. Among the numerous graft materials and barrier membranes available for GBR procedures, allografts and porcine bone substitutes are commonly utilized due to their osteoconductive properties and favorable biocompatibility[5].

During implant placement into fresh extraction sockets, gaps usually remain between the implant surface and the inner wall of the facial plate of the bone[6]. Moreover, following tooth extraction, the alveolar bone-supporting tooth undergoes constant significant atrophy during the first 3 months[7]. A marked reduction in the height of the alveolar ridge has been shown to consistently occur following tooth extraction; additionally, implant installation into the fresh extraction socket does not interfere with the process of bone remodeling[8]. The inadequate bone volume frequently limits the placement of endosseous dental implants in atrophic anterior and posterior regions of the jaws[9].

Different approaches have been advocated to preserve or improve the dimension and contour of the ridge following tooth extraction, including the use of various graft or filler materials, such as autografts, allografts, xenografts, and synthetic grafts, and/or barrier membranes[10]. The rationale for the use of graft materials and membranes is to prevent the migration of cells from the gingival epithelium and connective tissues into this gap, thus permitting osteoprogenitor cells to occupy the established gap and eventually regenerate the bone tissue, supporting osseointegration[11]. Moreover, these grafts are used to partially prevent horizontal and vertical resorption following extraction and to augment the buccal bone to achieve at least a 2\text{-mm}-thick bony plate buccal to the implant surface[12].

FDBA is derived from human bone tissue obtained from cadaveric donors[13]. The bone is processed to remove cellular components while preserving the mineral matrix and growth factors essential for bone regeneration[14]. Porcine bone xenograft is composed of mineralized bone matrix derived from porcine sources[15]. The bone undergoes processing to remove organic components while retaining the mineral structure ensuring long term volumetric stability[16].

The use of type I collagen membranes in conjunction with graft materials for site preservation offers a ersatile

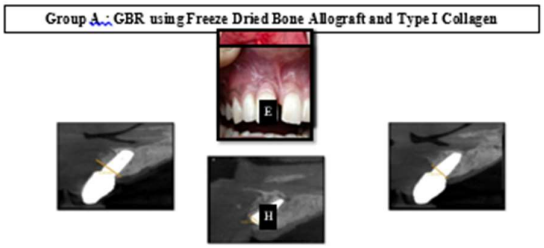

Fig – 1: [A] Preoperative photo, [B] Tooth Extraction, [C] Implant Placement, [D] Graft and Membrane Placed, [E] Permanent prosthesis delivered, [F] CBCT at baseline, [G] CBCT at 6 months, [H] CBCT at 9 months

and effective approach to enhancing bone regeneration,

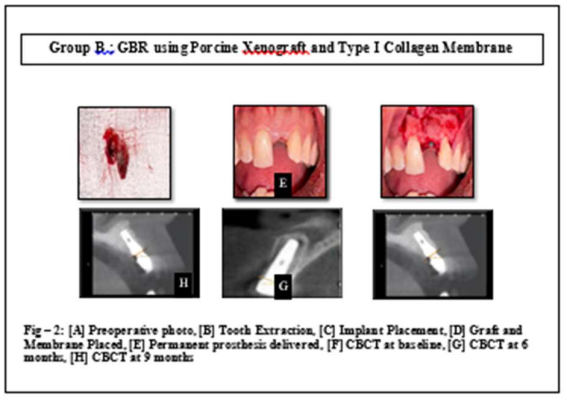

Fig – 2: [A] Preoperative photo, [B] Tooth Extraction, [C] Implant Placement, [D] Graft and Membrane Placed, [E] Permanent prosthesis delivered, [F] CBCT at baseline, [G] CBCT at 6 months, [H] CBCT at 9 months

bone regeneration, maintaining bone volume, and optimizing outcomes in implant dentistry[17]. Therefore, the purpose of the present study was to clinically and radiographically evaluate and compare the efficacy of Freeze Dried Bone Allograft with Type-I Collagen Membrane (Group A) and Porcine Bone Xenograft in combination with Type-I Collagen Membrane (Group B) for Guided Bone Regeneration around Immediate Implants.

Materials and Methods

Study Design and Population

This was a comparative, prospective, randomized clinical study which included 20 implant sites in a total of 20 patients, 10 in each group. The selection was balanced across sexes within an age group ranging from 18 to 60 years visiting the outpatient Department of Periodontology, Narsinhbhai Patel Dental College and Hospital, SPU, Visnagar, Gujarat. The study was approved by the Institutional Ethics Committee.

To be eligible for participation in this study, patients were suppose to meet all of the following inclusive criteria i.e participants must be systemically healthy individuals between the ages of 18 and 60 years. From a clinical perspective, candidates must present with a compromised extraction socket—defined as buccal plate being thinner than 1 mm, dehisced, or fenestrated—resulting from periodontal disease, periapical pathologies, or a traumatic extraction. Furthermore, the target site must exhibit a bucco-lingual alveolar crest width of at least 3.5 mm, alongside a

minimum of 5 mm of solid bone apical to the alveolus to guarantee initial implant stability. Finally, the tooth designated for extraction must maintain functional occlusion and be completely free of active periapical pathology or infection.

Individuals were excluded from study participation if they meet any of the conditions like the subjects were not enrolled if they present with untreated periodontal disease, poor oral hygiene, or clinical signs of bruxism. Additionally, individuals with a history of oral substance abuse, including smoking or tobacco chewing, were excluded. Due to anatomical and physiological safety considerations, candidates with inadequate mouth opening or structural jaw constraints were ineligible, as are women who were pregnant or lactating.

Clinical and Radiographic Evaluation

Ancillary parameters including the Plaque Index (PI)[18] and Modified Gingival Index (MGI)[19] were evaluated. Clinical parameters included Probing Depth (PD)[20] measured using a plastic probe at the mesial and distal aspects, alongside the Pink Esthetic Score (PES) based on seven soft-tissue variables graded 0-1-2[21]. Radiographic parameters involved measuring the absolute Alveolar Bone Width (BW) from the palatal plate to the buccal cortical plate at the implant crest using Cone Beam Computed Tomography (CBCT) scanned at baseline, 6 months, and 9 months.

Surgical and Prosthetic Protocols

Following local anesthesia administration (2% Lignocaine HCl with 1:80,000 epinephrine), teeth were extracted atraumatically without fracturing cortical plates. Full-thickness mucoperiosteal flaps were reflected, granulation tissue debrided, and sequential osteotomy prepared under copious chilled saline irrigation at 800–1200 rpm. Implants were inserted with torque values between 35 and 40 Ncm. For Group A sites, defects were packed with Freeze-Dried Bone Allograft (RegenerOss CC); for Group B sites, Porcine Bone Xenograft (RegenerOss Resorbable Xenograft) was placed. Both groups received a Type-I Collagen Membrane (BioMend) adapted over the graft material before tension-free primary suturing. Antibiotics, analgesics, and 0.12% chlorhexidine rinses were prescribed postoperatively. Permanent prosthetic restorations were delivered out of occlusion at 6 months.

Statistical Analysis

Data analysis was completed using SPSS Version 23.0 utilizing paired t-tests for intragroup comparisons and independent unpaired t-tests for intergroup differences .Normality of the data was confirmed, allowing the use of parametric tests. The level of significance was set at $p < 0.05$.

Results

The study population consisted of 20 systemically healthy patients divided equally into two groups of 10 participants each. Group A comprised 8 males and 2 females patients with a mean age of 22.70 $\pm$ 8.52 years. Group B comprised 7 males and 3 females patients with a mean age of 23.4
$\pm$ 9.97 years (Table 1, Table 2). Intergroup analysis showed no statistically significant differences regarding age or gender distribution between the cohorts ($p > 0.05$).

Parameter	Group	Total number of population	Male	Female
Demographic data	Group A	10	8	2
	Group B	10	7	3

Both groups were balanced in terms of age and sex distribution.A 100% implant survival rate was observed across both groups throughout the 9-month follow-up window.

Clinical and Radiographical Parameters	Groups	Baseline			6 Months			9 Months		
		Mean	SD	P value	Mean	SD	P value	Mean	SD	P value
Plaque Index (PI)	Group-A	1.10	0.31	0.130*	0.50	0.21	0.330*	0.15	0.00	>0.05*
	Group-B	1.44	0.52		0.40	0.25		0.10	0.11	
Modified Gingival	Group-A	0.40	0.51	>0.05*	0.25	0.15	>0.05*	0.10	0.20	>0.05*

Index (MGI)	Group-B	0.50	0.70		0.22	0.000		0.000	0.000	
Probing Depth (Mesial)	Group-A	2.60	0.69	0.550*	2.35	0.42	0.170*	2.00	0.000	>0.05*
	Group-B	2.80	0.78		2.50	0.52		2.40	0.000	
Probing Depth (Distal)	Group-A	2.70	0.69	0.400*	2.40	0.51	0.670*	2.25	0.000	>0.05*
	Group-B	2.90	0.87		2.50	0.52		2.000	0.000	
Pink Esthetic Score (PES)	Group-A	5.000	0.66	0.210*	7.82	0.63	0.160*	9.90	0.70	0.110*
	Group-B	4.70	0.48		7.50	0.52		9.50	0.52	
Bone Width (BW)	Group-A	5.20	0.78	0.700*	6.10	0.31	0.310*	6.85	0.67	0.640*
	Group-B	5.10	0.73		6.30	0.67		6.70	0.67	

Plaque Index (PD)

Intragroup comparison for both cohorts revealed a statistically very highly significant reduction in mean plaque scores from baseline to 6 months and baseline to 9 months ($p < 0.001$), with no significant changes occurring between 6 and 9 months ($p > 0.05$) (Table 3). Intergroup comparisons revealed no statistically significant variance between Group A and Group B at any evaluated time interval ($p > 0.05$)

Modified Gingival Index (MGI)

Intragroup analysis demonstrated a statistically very highly significant decrease in soft-tissue inflammation indicators for Group A from baseline to 6 months and baseline to 9 months ($p < 0.001$). Group B demonstrated significant baseline reductions at the 6-month and 9-month targets ($p = 0.03$) (Table 5). Intergroup cross-matching presented no statistically significant differences across baseline, 6-month, or 9-month intervals ($p > 0.05$)

Probing Depth (Mesial)

In intragroup monitoring, both Group A ($p = 0.02$) and Group B ($p = 0.009$) displayed a statistically significant drop in mesial pocket probing depths from baseline to the final 9-month analysis (Table 7). Intergroup cross-analysis demonstrated no statistically significant differences between the FDBA and porcine xenograft designs across baseline ($p = 0.55$), 6 months ($p = 0.17$), or 9 months ($p > 0.05$)

Probing Depth (Distal)

Intragroup evaluation established a significant longitudinal decrease in distal probing configurations by the 9-month window for Group A ($p = 0.03$) and Group B ($p = 0.006$) (Table 9). Intergroup assessment confirmed that differences in mean distal values between both clinical subsets were completely non-significant across all individual timelines ($p > 0.05$)

Pink Esthetic Score (PES)

Intragroup evaluation revealed a statistically very highly significant progressive increase in objective soft-tissue aesthetic scores within both Group A and Group B across all evaluated intervals from baseline to 6 months, baseline to 9 months, and 6 to 9 months ($p < 0.001$) (Table 11). Intergroup variance measurements remained non-significant at baseline ($p = 0.21$), 6 months ($p = 0.16$), and 9 months ($p = 0.11$)

Bone Width (BW)

Three-dimensional CBCT verification established a very highly significant continuous increase in absolute alveolar crest width within both Group A ($p < 0.001$) and Group B ($p < 0.001$) when comparing baseline landmarks to the 6-month and 9-month steps (Table 13). Intergroup analysis of structural bone regeneration width revealed no statistically significant variation between the allograft and porcine xenograft frameworks across baseline ($p = 0.70$), 6 months ($p = 0.31$), or 9 months ($p = 0.64$)

Discussion

The rehabilitation of completely and partially edentulous patients with dental implants has shown high success due to long-term predictability and satisfactory

functioning and aesthetics[1]. Immediate implants offer advantages such as reduced treatment time and preservation of soft and hard tissue architecture, but they are often associated with peri-implant bone defects, especially in the buccal cortical plate[3]. Guided bone regeneration (GBR) has therefore become a widely accepted technique to enhance bone volume and ensure long-term implant stability[4].

In the present study, demographic details showed results which are not statistically significant for differences in age and gender, confirming that the study groups were demographically comparable. Both groups demonstrated a highly significant longitudinal improvement in clinical health indicators over the 9-month follow-up. The observed decrease in Plaque Index and Modified Gingival Index scores safely reflects consistent plaque control by the patient and repeated reinforcements of oral hygiene measures given by the clinician[22]. Stable, healthy probing depths below clinical thresholds were maintained across both cohorts, which indicates proper peri-implant soft-tissue health stability with no progressive increases or inflammatory updates over time[23].

Considering the aesthetic importance of an implant-supported restoration in the anterior area, clinicians should address the different aspects of the aesthetic result and long-term stability of the soft tissues[2]. At the 6-month interval, a marked improvement in Pink Esthetic Scores was observed in both groups, which further improved by the 9-month follow-up due to progressive soft tissue healing, maturation, and adaptation around the implant restoration. The absence of statistically significant differences between the groups at all time intervals indicates that the type of graft material—whether allograft or xenograft—does not significantly alter the objective aesthetic outcome when combined with a protective collagen membrane[24].

Alveolar width measured from the palatal plate to the buccal cortical plate (BW) via CBCT was used to monitor definitive hard-tissue adaptations. Both cohorts showed statistically significant increases in bone thickness over the follow-up period, demonstrating active bone remodeling and continuous maturation within the initial year[8]. The lack of significant intergroup variance at baseline, 6 months, and 9 months proves that Freeze-Dried Bone Allograft and Porcine Bone Xenograft are similarly effective in supporting peri-implant bone regeneration when paired with a type I collagen barrier[25]. While minor variations in absolute mean metrics exist, they provide no definitive clinical superiority of one material over the other, confirming that both agent classifications are highly biocompatible and structurally secure alternatives for routine clinical application.

Limitations of the study

Despite the encouraging results observed in the present clinico-radiographic study, certain limitations must be acknowledged while interpreting the outcomes.

- The sample size was relatively small, which limits the ability to generalize the findings; studies with larger populations are needed for more reliable conclusions.
- The follow-up period was short 3 months post loading of the implant making it difficult to assess the long-term reliability of the procedure.
- The lack of histological evaluation makes it hard to assess the true regeneration type.
- In this study limited parameters were assessed. Thus, more clinical and radiographic parametres could have been considered.

Conclusion

Both Freeze-Dried Bone Allograft and Porcine Bone Xenograft used in combination with a Type-I Collagen Membrane proved to be highly effective treatment modalities for Guided Bone Regeneration around immediate implants. Both groups demonstrated satisfactory clinical and radiographic outcomes with successful implant integration, stable peri-implant tissue health, and favorable aesthetic results. Within the limitations of this study, both graft alternatives can be safely recommended for the predictable management of localized peri-implant bone defects around immediate dental implants.

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