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Comparative Evaluation of Soft Tissue Healing after Socket Preservation Technique Using Gelatin Sponge with or Without iPRF, In Systemically Healthy Adult Individuals: Split-Mouth Randomized Controlled Clinical Trial.

(ocket preservation using iPRF and Gelatin Sponge)

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KEYWORDS
iPRF, Gelatin Sponge, Tissue Engineering, Preventive medicine, socket preservation.

ABSTRACT:

Introduction: Post-dental extraction, the alveolar ridge undergoes changes that compromise the surrounding soft and hard tissues. A randomized clinical trial was performed to compare the soft tissue healing after socket preservation technique using gelatin sponge with/without iPRF, over a 6-weeks follow-up period.

Material and Methods: The present study was carried out at 46 sites, of which 23 sockets received gelatin sponge soaked in injectable platelet rich fibrin (iPRF) (test) and other 23 sockets received gelatin sponge only (control). Horizontal and vertical dimension of alveolar ridge were measured at baseline and 6-weeks and wound healing was assessed at 1, 3 and 6-weeks postoperatively.
Results: The findings indicated that the intervention significantly reduced both buccal and palatal ridge loss compared to the control group (p=0.01). As for the healing index, the test group had a mean healing index of 4.15, which was higher than the control group's 3.05 (p = 0.01). These results indicate that the

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intervention led to superior tissue healing throughout the study period.

Conclusion: The horizontal and vertical bone loss was less in the test group than in the control group. It also significantly improved soft tissue healing after tooth extraction at 1, 3 and 6-weeks postoperatively.

Introduction

Post tooth removal, the consecutive resorptive process leads to the formation of soft tissue defects in vertical and horizontal dimensions.[1] These alterations present challenges in creating a natural-looking soft tissue contour around dental implants.[2] The aesthetic zone, particularly sensitive to soft tissue nuances, demands thoughtful preservation strategies to avoid undesirable outcomes and functional issues in subsequent tooth replacements.[3] Major changes in the extraction socket occur over the first year, with two-thirds of the bone loss occurring within the first 3-months. Although bone deposition in the socket will continue for several months, it will not reach the level of the coronal bone of the surrounding teeth. Due to the restoration of the buccal bone plate, the buccolingual dimension of the alveolar ridge will often be reduced by 50% after healing of the removed socket. The buccal wall degenerates more than the lingual wall because the buccal bone is mostly made up of bundle bone, which becomes inactive after extraction since it no longer receives nutritional input from the periodontal ligament.[4] Van der Weijden et al[5], reviewed the literature and concluded that the clinical loss in width was greater than the loss in height. In cases of FPD (fixed partial dentures), the aesthetic in pontic region is sometime adversely affected due to significant loss of soft tissue under the pontic making the clinician to keep the pontic long or making the patient difficult to maintain oral hygiene in that region. Soft tissue management is emerging as a pivotal factor in ensuring not only functional success but also aesthetic excellence. Preserving the integrity of soft tissue during socket healing is paramount, not only for immediate implant placement but also for ensuring the long-term stability of implants and overall patient satisfaction.

Gelatin sponge, recognized for its biocompatibility[6], has demonstrated versatility in various medical applications, including the treatment of calvarial defects, socket extraction, and iliac bone procurement.[7-9] The unique properties of gelatin sponge include platelet adhesion induction and the release of α-granule contents.[6] Additionally, its application extends to serving as a carrier matrix for mesenchymal stem cells.[10] Functioning as a local hemostatic agent, gelatin sponge plays a crucial role in accelerating and stabilizing clot formation at wounds and bleeding areas. Its inherent porosity, flexibility, and biocompatibility makes it an ideal scaffold or carrier for pharmaceutical compounds within wounds, especially those with osseous defects. This characteristic not only enhances bone renewal but also expedites wound recovery.[11] The multifaceted attributes of gelatin sponge position it as a valuable component in the context of various medical procedures, including dental socket preservation techniques.

Among the various platelet concentrates, injectable-Platelet Rich Fibrin (i-PRF)[12] is considered to have higher number of leukocytes, favours more growth factor release and thus improved tissue wound healing. i-PRF has excellent biocompatibility, induce a significant number of cell migration and proliferation and when compared to PRP (Platelet rich plasma) promoted more osteogenic differentiation.[13] Nagrani T et al[14], evaluated the use of i-PRF accompanied by bone graft in socket endurance and their study results demonstrated that i-PRF possesses the potential to regenerate and heal in the tooth extracted socket.

In the study conducted by Alhalbi et al., the utilization of gelatin sponge soaked with platelet-rich plasma (PRP) in extraction sockets demonstrated significant benefits in soft tissue healing. Their findings underscored the role of growth factors, highly concentrated in platelets, which, when activated during wound situations, catalyse inflammatory cell responses, stimulate new blood vessel formation, induce mitosis, and promote fibroblast differentiation. This mechanistic insight into the healing process provides a foundation for exploring enhanced soft tissue healing methodologies.[15] Landsberg CJ [16] concluded from their study that socket seal surgery is an efficacious procedure for ridge preservation and is effective in providing the necessary conditions for the development of functional and esthetic pontic sites.

Jinno et al[17], studied a comparison of conventional collagen sponge (CS) and collagen-

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gelatin sponge (CGS) in wound healing. The effects on epithelialization, granulation, and vascularization of wound healing demonstrated that, as a scaffold, CGSs are equal or superior to conventional CSs. However, only gelatin sponge with iPRF was never studied in wound healing. Thus, the aim of this study was to evaluate the difference between soft tissue healing after socket preservation technique using gelatin sponge with or without iPRF, in systemically healthy adult individuals at 6-weeks follow-up period. The objective was to compare the healing index by Landry, Turnbull and Howley and compare the soft tissue contour changes over time by sectioning the plaster cast prepared immediately after socket preservation technique using gelatin sponge, with or without i-PRF and at 6-weeks follow-up.

Materials and Methods

The present randomized controlled study was conducted on patients indicated for flapless extraction of at least two posterior teeth who visited the Department of Periodontology and Oral Surgery of this institute. The present study was conducted as per the ICMR guidelines and following Helsinki declaration, (IEC approval letter number: MGV/KBHDC/222; dated: 18/06/2022) and (CTRI/2023/01/048767). The minimum sample size calculated was 20 sites per group. Considering few drop outs, we considered a sample size of 23 sites per group, making the total sample size as 46.

A convenient sampling technique was used from the pool of patients who fulfilled the inclusion and exclusion criteria, were willing to be a part of clinical research and could manage to come for recommended follow-up visits. Inclusion criteria were as follows: patients aged between 20 to 60 years, were systemically healthy patients and not under any medications. Were indicted for atraumatic extraction of whole tooth maxillary or mandibular posteriors. The clinical probing depth was not more than 3mm at buccal and/or lingual side. Patients were non-alcoholic, non-tobacco chewer and non-smoker. If it was discovered that there was a fracture of alveolar crest while extraction of teeth, or patient was pregnant or lactating then those patients were excluded from the study. Also excluded were extraction sites where the extracted tooth had large periapical pathology (>5mm). Patients were withdrawn from existing study if they did not turn up for follow-up, wants to undergo treatment in another institute, patient migrated to another city during the study, patient not following the study protocol as instructed or if any systemic condition/disease occurs during the follow-up period.

Informed consent of all the participants of the study was obtained after the nature of the procedure, possible discomfort and risk had been explained in the language they understand. A planned case study, including medical history, complete dental history, and thorough evaluation was obtained from all the participants along with the necessary laboratory investigation. Following the screening examination, all the patients were given appropriate oral hygiene instructions after thorough scaling and root planning. Among the total sample size of fourty-six (46) sites, 23 sites received gelatin sponge only (control sites) and 23 sites received gelatin sponge soaked with i-PRF (test sites) after atraumatic flapless extraction of posterior teeth. After the procedure, following measurements were taken with respect to both control and test sites.

Methods of measurements (assessment of parameters):

1. Horizontal and vertical dimension of alveolar ridge- (Fig.1)

Immediate Post-operative measurement.

After the socket preservation surgery, alginate impression was taken and poured. Customized acrylic stent was fabricated on cast to serve as fixed reference guides for measurement of vertical and horizontal dimensional change of alveolar ridge at a later follow-up. The cast along with acrylic stent was sectioned midway along the edentulous site of interest. At this stage the coronal, buccal and lingual walls of the ridge was in close contact with the inner surface of acrylic stent such that the base line gap between them was zero.

Late Postoperative measurements.

After 6-weeks, alginate impression was taken again and poured and sectioned midway of the edentulous span. On this cast, fabricated stent (obtained from cast immediately after socket preservation) was placed and horizontal and vertical dimension of alveolar ridge was taken by digital Vernier calliper.

Vertical measurement at areas where there was a reduction of ridge during healing, a gap of variable thickness would be present between the original stent and the newly formed ridge. A mean of three

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measurements at mid crestal region was measured by Vernier calliper and recorded. The average of these three readings was considered for further calculations.

Horizontal measurement at areas where there was bucco-lingual reduction of ridge during healing, a gap of variable thickness would be present between the original stent and the newly formed ridge. A mean of three sites at buccal crest and lingual crest was measured by digital Vernier calliper and recorded.

2. Measurement of Wound Healing by Healing index given by Landry, Turnbull and Howley.[18]

A decision about which site to be allocated to test or control was randomly done by the coin toss method. After allocation treatment was started. Preoperative photographs of occlusal view and of radiographs were taken (Fig: 2). Under all aseptic precautions, local anesthetics were given (Lignocaine 1:80000) followed by crevicular incision and atraumatic whole tooth extraction was done with forceps in both test and control groups (Fig. 3A). Extraction sockets were thoroughly cleaned to remove granulation tissue followed by irrigation and rinsing with saline (Fig. 3B). Evaluation was performed for presence of intact bony walls of the socket was done to confirm patients' eligibility in the study.

For i-PRF preparation, 10 ml of whole blood without anticoagulant, in plastic tube, was centrifuged at 700 rpm for 3 min (60×g) at room temperature. The upper liquid layer was collected as i-PRF. In Test group, socket was filled with gelatin sponge (10x10x10 mm), soaked with i-PRF for 1 min and was placed (Fig. 3C). In Control group, gelatin sponge (10x10x10 mm) was placed in the socket (Fig. 3D). Gelatin sponge at both sites were secured by simple interrupted 3-0 silk sutures. Alginate impression was taken and poured and stent were fabricated on customized sectioned cast for measurement of baseline data such as measurement of horizontal, vertical dimension of alveolar ridge. Postoperative instructions and medications were prescribed.

The patients were recalled after 1-week for suture removal. Evaluation of soft tissue healing at control and test site were done and relevant parameters recorded (Fig. 4A). The patients were later recalled again after 3-weeks (Fig. 4B) and 6-weeks (Fig. 4C), when evaluation of soft tissue healing at control and test site was done. Horizontal and vertical alveolar ridge measurements were recorded by taking alginate impression at 6-weeks and parameters were evaluated at test and control site by placing previously made acrylic stent on sectioned cast. Relevant readings were taken using digital Vernier Callipers in mid crestal (Fig. 5A); palatal (Fig. 5B) and buccal (Fig. 5C) areas and data was tabulated.

A flowchart of the study design is given in Fig. 6, which shows the number of participants from enrolment to 6-weeks follow-up and grouping of study participants. A total of 3 patients were lost to follow-up during the study period. Two patients were lost to follow-up at 1-week of the study itself and one patient at 6-weeks follow-up visit.

Results

All the parameters recorded were subjected to statistical analysis by using SPSS software version 18. Probability $p<0.05$, was considered as significant as alpha error set at 5% with a confidence interval of 95% set in the study. The power of the study was set at 80% with a beta error set at 20%. The intragroup difference was assessed by the repeated measures ANOVA and the intergroup by independent t-test.

All the patients who participated in the study were in the age group of 30-65 years. The mean age of the patient in both the test and control group was 46 $\pm$ 10.11 years. Gender-wise distribution showed that in the test group and control group out of 20 patients, 12 were male and 8 were female.

Horizontal (Buccal and Palatal Measurements) and Vertical Alveolar Ridge Loss at 6-weeks

The intergroup comparison of means for buccal (B1) and palatal (P1) measurements for horizontal alveolar ridge loss and of vertical alveolar bone loss at 6-weeks are depicted in table-1. The independent t-test showed statistically significant differences between the control and test groups for buccal and palatal measurements ($p=0.01$) These results indicate that the test group exhibited significantly less horizontal alveolar ridge loss (both buccal and palatal) compared to the control group at 6-weeks. The independent t-test also confirmed a statistically significant difference between the control and test groups for vertical alveolar ridge loss ($p=0.01$). These findings

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suggest that the test group experienced significantly less vertical alveolar ridge loss compared to the control group at 6-weeks.

Healing Index

Intergroup and intragroup comparison of the healing index for the control and test groups at different time points (Weeks 1, 3 and 6) is shown in table-2. The independent t-test showed statistically significant differences in the healing index between the control and test groups at all measured time points ($p = 0.01$). These results demonstrate that the test group showed significantly better healing at all measured time points compared to the control group. For intragroup comparison within control group, the repeated measures ANOVA revealed a significant difference across the time intervals.

Post Hoc Comparison for Control Group

The post hoc comparison between different time intervals for the control group using the Bonferroni test is shown in table 3. These comparisons indicate significant differences in the healing index between all the time intervals for the control group and test groups.

Discussion

In absence of proper preservation techniques after tooth extraction, the socket can undergo significant dimensional changes, leading to ridge resorption and compromised implant placement in the future.[19] The present randomized controlled study was conducted on patients indicated for flapless extraction of at least two posterior teeth. These sites were selected to evaluate the difference between soft tissue healing after socket preservation technique using gelatin sponge with or without i-PRF. A total of 20 sites each for the control and test group completed the total follow-up of 6-weeks. A customized acrylic stent was fabricated on dental plaster model/cast to serve as fixed reference guides for measurement of vertical and horizontal dimensional change of alveolar ridge at 6-weeks follow-up. This approach ensured consistent placement, reflecting the precise anatomy of the extraction sites and reproducible measurements of soft tissue changes over time. The use of acrylic stents is consistent with a study by Verma et al,[20] and Buser et al.[21] who showed that customized acrylic stents facilitate accurate measurement of soft tissue levels, enabling precise replication of measurement sites and controlled evaluation of changes over time.

Majority of dimensional changes in the alveolar ridge occur within the first 6-weeks[22] to 3 months of healing. Moreover, 50% of crestal width is lost in 12 months (corresponding to 6.1mm; range 2.7 to 12.2mm), 2/3rd of which (3.8mm; 30%) occurred in the first 12-weeks. A substantial portion of this resorption was observed within the first six weeks, emphasizing the critical nature of this early healing phase. Pietrokovski and Massler[23] stated that bone loss after extraction proceeds at an average of 0.5-1.0% per year for the entire life. Based on the above theory, most of the dimensional changes at the alveolar crest occur in the first few months, a follow-up period of 6-weeks was included in the present study.

Absorbable gelatin sponges (AGSs) are known as a surgical material, planned for application to bleeding surfaces as a hemostatic.[24-26] Moslemi et al and Fridrich et al shown that the use of AGS resulted in a decreased incidence of dry sockets within the extracted tooth due to the retention of the clot by the gelatin sponge in the extracted tooth.[27,28] Célien et al compared a collagen matrix to a hemostatic gelatin sponge as a socket seal in alveolar ridge preservation. He concluded that there are no significant differences in hard tissue outcomes suggests that both the collagen matrix and hemostatic gelatin sponge effectively sealed the extraction socket and supported bone preservation.[29] Studies, such as those by Cochran et al[30] and Carano & Filvaroff,[31] have shown that gelatin sponges provide a suitable scaffold for cell migration and proliferation, which are crucial for wound healing and tissue regeneration. Hwang et al[32] demonstrated that gelatin sponges can be easily manipulated to fit irregular wound sites, ensuring better contact with the wound surface and enhancing hemostatic effectiveness. In the context of socket preservation, the gelatin sponge's ability to absorb and release growth factors is particularly advantageous. It can be used as a carrier for injectable platelet-rich fibrin (iPRF), which further enhances its regenerative properties.

Mourão et al[33] and Al-Maawi et al.[34] highlighted the synergy between gelatin sponges and i-PRF in promoting soft tissue healing and bone regeneration Several studies have utilized the preparation of i-PRF at 700 rpm for 3 minutes, demonstrating its efficacy in enhancing soft tissue and bone healing. A similar preparation protocol

was supported by others [13,35-37] showing improved clinical outcomes in dental surgeries, socket preservation and various other clinical applications. These studies showed that the combination leads to improved clinical outcomes, such as faster soft tissue closure and better preservation of alveolar ridge dimensions. Considering all these properties, the choice of material was gelatin sponge as compared to collagen sponge in this study.

The result of the present study indicated that test group exhibited significantly less horizontal alveolar ridge loss compared to the control group at 6-weeks. Similarly, the test group experienced significantly less vertical alveolar ridge loss compared to the control group (0.79 against 1.67 respectively). The healing index, assessed at weeks-1, 3, and 6, showed significant ($p<0.05$) differences between the control and test groups, and the test group exhibited significantly better healing at all measured time points compared to the contro l group.

Lydia et al. compared guided bone regeneration (GBR) and injectable platelet-rich fibrin (i-PRF) before implant placement to prevent bone resorption and enhance alveolar ridge dimensions.[38] They suggested that i-PRF with its high growth factor composition promotes predictable bone formation, which aligns with our findings of reduced ridge resorption and enhanced healing indices with i-PRF application. Kumar et al[39] evaluated wound healing and bone density following socket preservation using collagen plug versus injectable platelet-rich fibrin (i-PRF) in mandibular molar extraction sites. Results from their study indicated that 85.7% of patients treated with i-PRF showed very good wound healing compared to 14.3% in the collagen plug group. These findings are consistent with our present study's observations regarding the efficacy of i-PRF in promoting wound healing and reducing initial postoperative symptoms.

Within the limitation of the study, it can be concluded that the application of iPRF facilitated enhanced soft tissue healing, as evidenced by consistently higher healing index scores at 1, 3, and 6-weeks compared to the control group. It can also be concluded that the use of gelatin sponge soaked with injectable platelet-rich fibrin (iPRF) significantly reduced horizontal and vertical soft tissue alveolar ridge loss compared to the control group treated with a gelatin sponge alone.

Conflict of Interest: Nill

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Tables:

Table 1: Intergroup comparison of means for buccal (B1) and palatal (P1) measurements for horizontal alveolar ridge loss and of vertical alveolar bone loss at 6-weeks.

	Groups	N	Baseline values (mm)	Values of 6-weeks follow-up (Mean+SD)	p-Value
			Horizontal Bone Loss Measurements		
B1	Control Group	20	0	1.79±0.10	0.01*
	Test Group	20	0	1.12±0.10	
P1	Control Group	20	0	1.69±0.12	0.01*
	Test Group	20	0	0.65±0.11	
			Vertical Bone Loss Measurements		
Bone loss	Control Group	20	0	1.67 ± 0.11	0.01*
	Test Group	20	0	0.79±.078	

*Statistically significant

Table 2: Intergroup Comparison of Means for Healing Index

	Groups	N	Mean± SD	p-Value
		Inter group comparison		
1 Week	Control Group	20	2.00± 0.00	0.01*
	Test Group	20	2.95±0.39	
3 Week	Control Group	20	3.05±0.22	0.01*
	Test Group	20	4.15±0.36	
6 Week	Control Group	20	4.00±0.45	0.01*
	Test Group	20	4.85±0.36	
		Intra group comparison		
1 Week	Control Group	20	2.00±0.00	0.01*
3-weeks		20	3.05±0.22	
6-weeks		20	4.00±0.45	

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1 Week	Test Group	20	2.95±0.39	
3-weeks		20	4.15±0.36	0.01*
6-weeks		20	4.85±0.36	

*Statistically significant

Table 3: Post Hoc Comparison for Control Group and Test Groups.

Time_Intervals (I)	**Time_Intervals (J)**	**Control Group**		**Test Group**	
		Mean Difference (I - J)	**P – value**	**Mean Difference (I - J)**	**P – value**
1 Week	3-weeks	-1.05*	0.01*	-1.20	.01*
	6-weeks	-2.00*	0.01*	-1.90	.01*
3-weeks	1 Week	1.05*	0.01*	1.20	.01*
	6-weeks	-.95*	0.01*	-.70	.01*
6-weeks	1 Week	2.00*	0.01*	1.90	.01*
	3-weeks	.95*	0.01*	.70	.01*

*Statistically significant value

Figures with legends

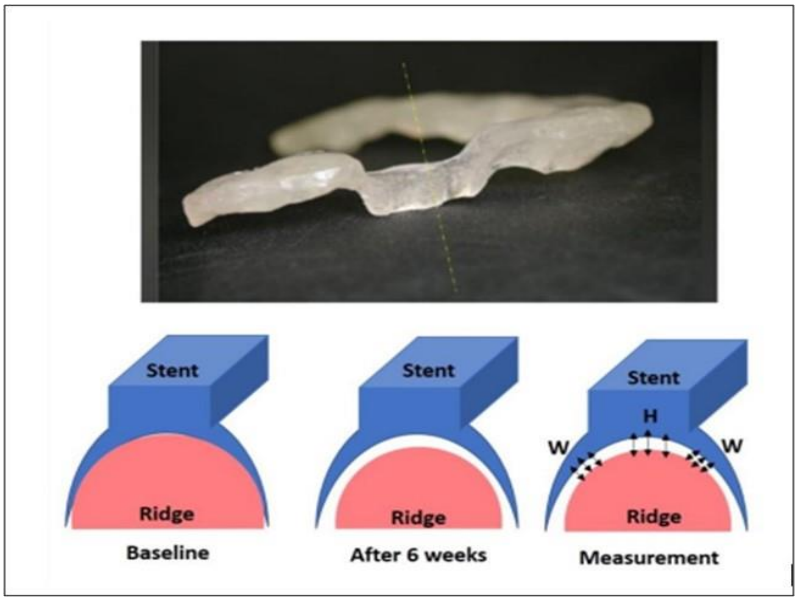

Figure 1: Graphical representation of Horizontal and vertical measurement of alveolar ridge using the customized acrylic stent.

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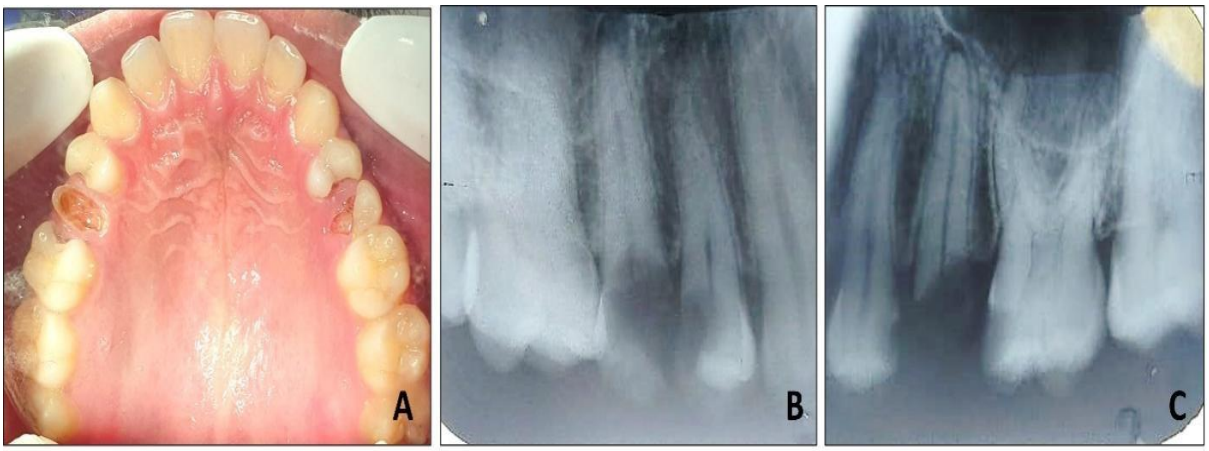

Figure 2: Preoperative images. (A) Occlusal view showing fractured teeth #15 and #25; (B) Intra Oral Periapical Radiographs of teeth #15; (C) Intra Oral Periapical Radiographs of teeth #25

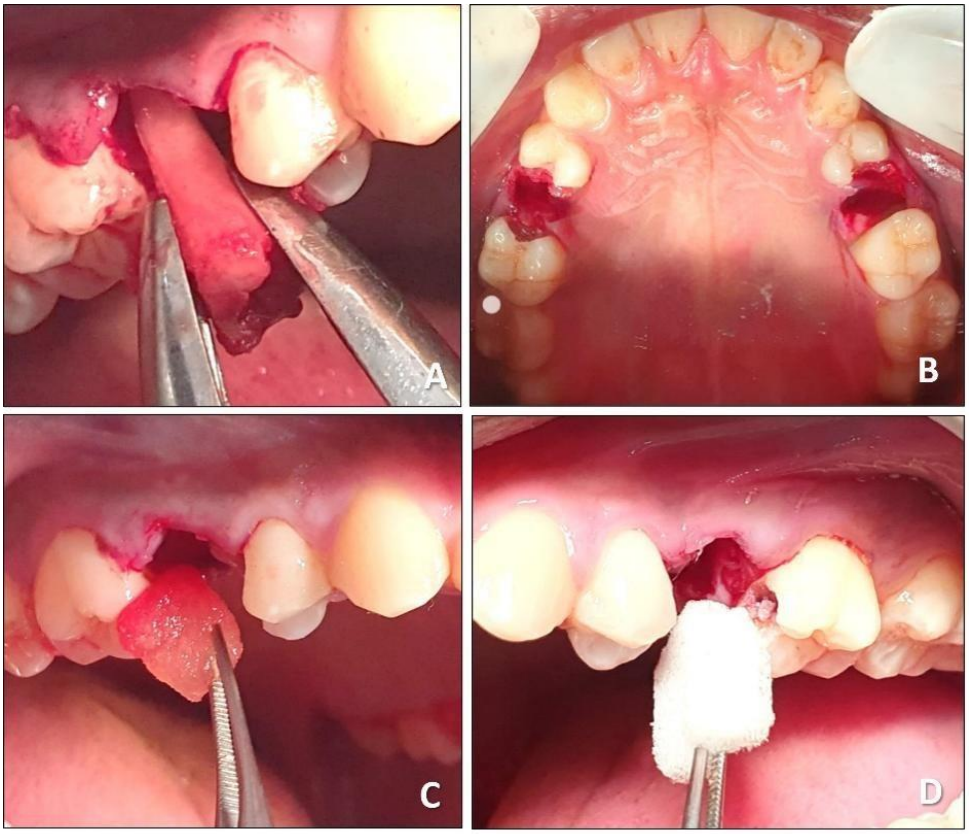

Figure 3: Intraoperative photographs. (A) Extraction forceps application and atraumatic whole tooth extraction; (B) Bilateral extraction sockets; (C) Test site receiving gelatin sponge soaked in iPRF; (D) Control site receiving gelatin sponge only.

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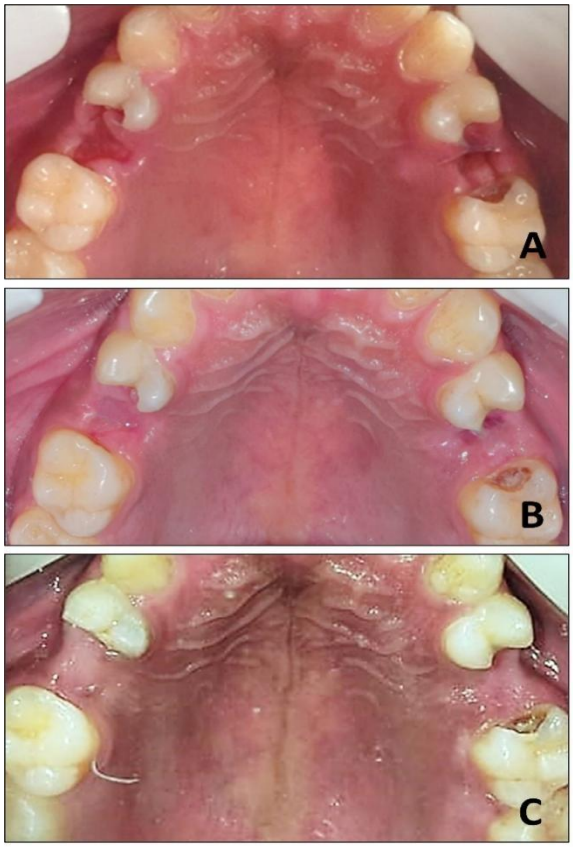

Figure 4: Clinical occlusal photographs of extraction sites. (A) 1-week follow-up; (B) 3-week follow-up; (C) 6-week follow-up view.

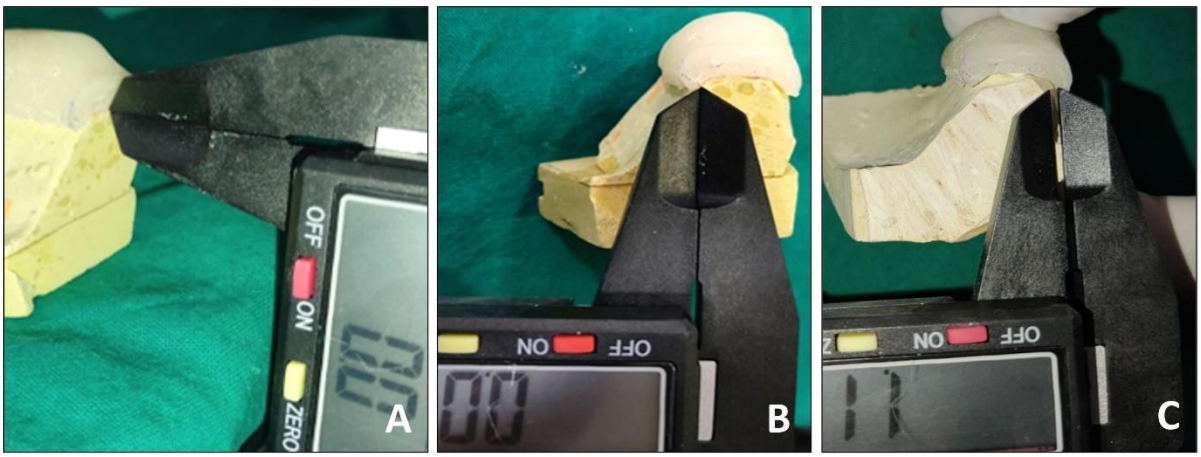

Figure 5: Measurements using vernier calipers. (A) Horizontal measurement at baseline, (B) Vertical measurement at baseline; (C) Horizontal measurement at 6-week follow-up.

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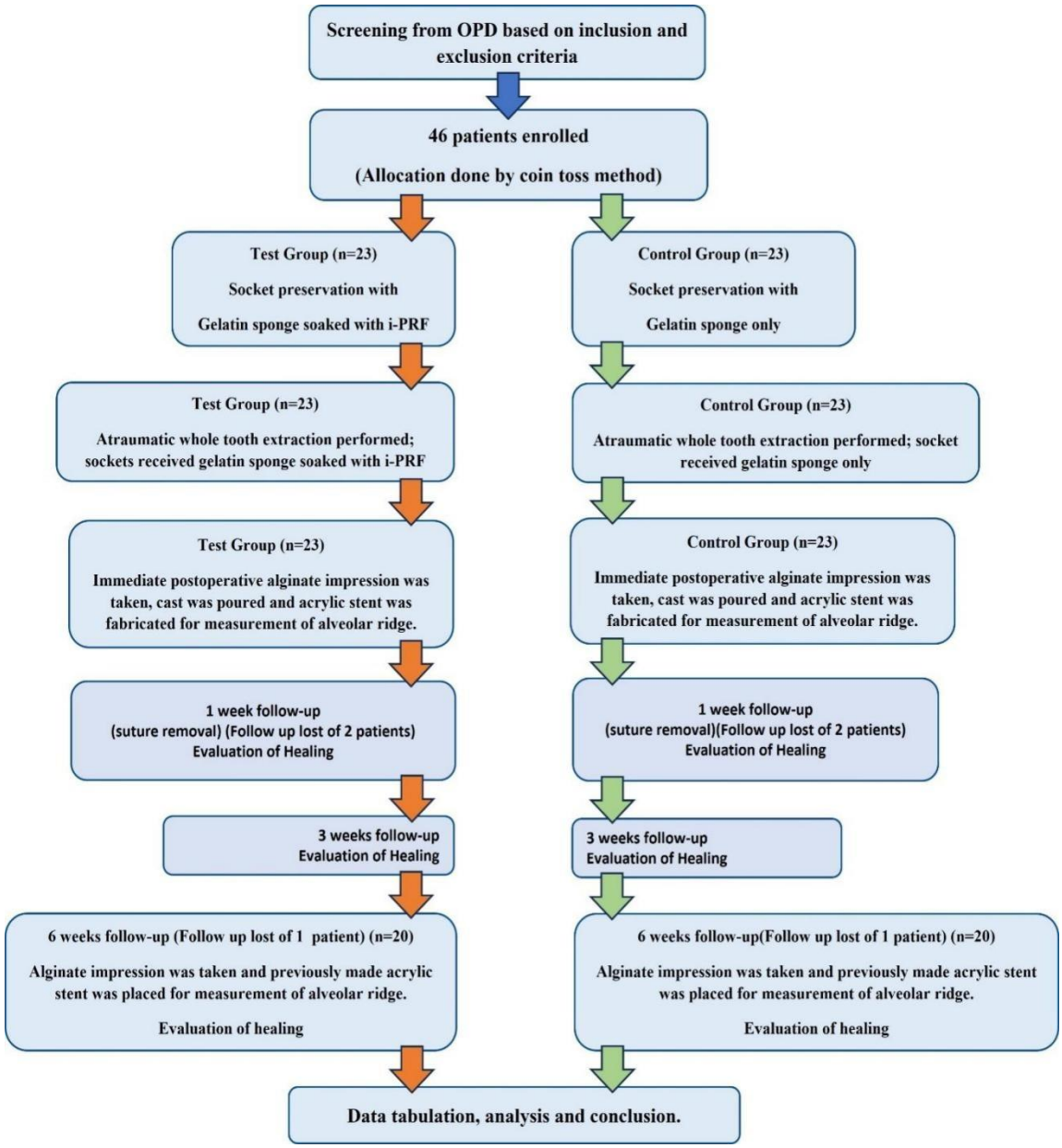

Figure 6: Flow Chart of Study Design.