



EVALUATION OF AMNION CHORION MEMBRANE (ACM) BARRIER WITH 100% BETA TRICALCIUM PHOSPHATE IN ALVEOLAR RIDGE PRESERVATION: A CLINICO-RADIOGRAPHICAL STUDY

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ABSTRACT

Background and Objectives: Alveolar ridge preservation is an arduous task to achieve. Amnion-chorion membrane (ACM) is a relatively recent entrant in the field of barrier regeneration that holds promise as an alternative to conventional materials such as collagen. The present study was carried out to evaluate clinically and radiographically and compare the efficacy of ACM barrier with 100% beta tricalcium phosphate compared to collagen membrane barrier with 100% beta tricalcium phosphate in alveolar ridge preservation.

Methods: 15 subjects requiring bilateral single-tooth extractions in the same arch were selected from the Outpatient Department, Rungta College of Dental Sciences and Research, Bhilai, Chhattisgarh. Atraumatic extraction sites will be treated with ACM, collagen membrane & beta tricalcium phosphate.

Results: The data obtained from Clinical and Radiovisiography measurements for 15 subjects in Test and Control group (30 sites; 2 sites in each group) at baseline, 12th week & 24th. The mean \pm

SD values at baseline and 7th day were ((**t=6.43; p<0.001***); (**t=5.84; p<0.001***)) for Test and Control Group, respectively. The Radiovisiography measurement- Alveolar Crest height at baseline, 12th week & 24th week (**F=0.413; p=0.664**); (**F=0.86; p=0.148**) for Test and Control Group, respectively. The clinical measurements- Alveolar Ridge Width at baseline, 12th week & 24th week for (**F=0.754; p=0.284**); (**F=3.821; p=0.052**) Test and Control Group, respectively.

Conclusion: Within the limits of the present study, it can be concluded that both the therapies showed improvement throughout the study period.

Keywords: Alveolar Ridge Preservation, Barrier, Amnion Chorion Membrane, Collagen Membrane, Beta-Tricalcium Phosphate, Socket Augmentation.

INTRODUCTION

Socket preservation at the time of extraction has evolved as one of the most significant procedures in the modern periodontal paradigm for maintenance of health & function. It provides for greater control and greater predictability while preventing site collapse and esthetic compromise. The term socket preservation was first coined by Cohen (1988) for a procedure designed for prosthetic socket maintenance, ridge preservation, and ridge augmentation. The first attempts to preserve the alveolar ridge loss were first described by Greenstein (1985) and Ashman and Bruins (1985).¹

A number of studies have shown that with-out treatment, significant alterations in most extraction ridge dimensions will occur. Following the removal of a single tooth or multiple teeth, the ridge at the site markedly diminishes and most of the hard & soft tissue components of the ridge are lost. The magnitude of this change was studied and reported by **Pietrokovski and Massler in 1967** who reported that the center of the edentulous site shifted toward the lingual or

palatal aspect of the ridge as a result of the tissue modeling.²

These observations made by them were supported by findings presented by **Tan et al, in 2012**, who suggested that horizontal bone loss (29–63%, 2.46–4.56 mm, weighted mean 3.79 mm at 6 months) was more substantial than vertical bone loss (11–22%, 0.8–1.5 mm, weighted mean 1.24 mm at 6 months) after tooth extraction. The buccal aspect generally displayed more resorption than the lingual/ palatal aspect. There is a resorption pattern of rapid reduction in the first 3– 6 months, followed by gradual reduction thereafter, throughout life.³

The need of the hour is to arrest or reverse this process of resorption which can be achieved by either laying down new bone or simply arresting the process, requiring cells and tissue matrix that lay down the bone or osseous structure. Alveolar ridge preservation can be accomplished successfully using a variety of materials such as allografts, xenografts, autografts, and alloplast. Due to the relatively low cost, lack of need of secondary donor site, and well documented history of success, the use of allografts for alveolar ridge preservation is increasing.⁴

βeta-TCP is a synthetic material gaining increasing preferences in regenerative procedures, particularly ridge preservation. Beta-TCP is known to be non-antigenic and non-infective owing to its synthetic nature and there is no limit to the quantity required. Protecting the alloplastic material under a barrier membrane has proven to be a crucial step in alveolar ridge preservation. ACM membrane has gained application as a barrier material in several surgical procedures. Apart from its protective functions, it acts a rich source of various growth factors that enhance the healing process.⁵

The purpose of this study was to evaluate the efficacy of alveolar ridge preservation on placing particulate b-tricalcium phosphate (b-TCP) graft in combination with ACM after atraumatic tooth extraction.

MATERIALS AND METHOD:

The present study was designed as a double blinded, randomized, controlled clinical trial. Ethical clearance for the present study was obtained from Institutional Ethical Committee of Rungta College of Dental Sciences and Research, Bilai Chhattisgarh, India, and Trial registry was done at Clinical Trials Registry India- ICMR: National Institute of Medical Statistics. CTRI/2022/04/042223(Registered on: 27/04/2022 - Trial Registered Prospectively).

Sample size calculation gave an estimate of minimum 24 sites required for the study. The following criteria were considered:

Inclusion criteria:

- Subjects needing bilateral single-rooted teeth extractions in the same arch.
- Between 18 to 75 years of age.

Exclusion criteria:

- Inability or anticipated failure to maintain adequate oral hygiene.
- Evidence of active periodontitis.
- Evidence of moderate to severe mobility.
- Evidence of severe alveolar bone loss.
- Pregnant & breastfeeding mothers.
- Unstable systemic diseases or with compromised immune system.

15 subjects satisfying the above criteria, thus accounting for 30 sites, were included in order to compensate for drop-outs if any. Patient's written consent was taken prior to commencement of study.

The following clinical and radiographic parameters were measured:

- Visual analog scale (VAS) and modified soft tissue healing index (Landry) at baseline, 3rd day, 2nd weeks and 6th weeks.
- Alveolar ridge width in mm at baseline, 12th weeks & 24th weeks.
- Measurement of vertical ridge height recorded at baseline, 12th weeks & 24th weeks.

A customized occlusal stent was prepared with radio-opaque resin to measure the alveolar ridge width. Two holes were made 5 mm apical to the mid-facial and mid-lingual gingival margin of the teeth to be extracted. Ridge width was measured at baseline through the prepared holes of stent using Castroviejo calipers.

Ridge height gain was measured on IOPA radiographs, standardized with long cone paralleling technique at exposure parameters of 70kVp, 10mA and exposure time of 0.18 seconds. A millimeter grid mount was superimposed on the radiograph and distance from the cemento-enamel junction (CEJ) to the alveolar crest (mesial and distal).

All the study subjects underwent phase I therapy and re-evaluation was done after 4 weeks.

The selected sites in each subject were randomly divided into Test & Control sites of 15 each, by coin toss method:

- Test group – 15 sites to be treated with amnion chorion membrane & beta tricalcium phosphate.
- Control group – 15 sites to be treated with collagen membrane & beta tricalcium phosphate.

Surgical procedure:

The patients were prepared for the surgery following proper aseptic techniques and all procedures were performed under local anesthesia. Crevicular incision was initially given around the tooth with 15C scalpel in order to dissect the crestal fibers followed by atraumatic extraction using luxators, periotomes & forceps.

Thorough socket debridement was performed and the integrity of socket walls was checked. 100 % beta tricalcium phosphate was incrementally placed in the socket and subsequently covered with amnion chorion membrane (ACM) allograft barrier (Tata Memorial Centre, Mumbai) or collagen membrane (HealiGuide, Advance Biotech, Chennai), in test and control sites respectively as per the randomization protocol. The membranes were inserted under the slightly elevated flap surrounding the socket and secured with 4-0 polyglactin 910 sutures (Vicryl, Ethicon- Johnson & Johnson) with the central membrane portion partly exposed. Analgesics and antibiotics were prescribed and subjects were recalled after 1 week for suture removal. Subsequently they were recalled at baseline, 6th weeks, 12th weeks, 24th weeks for re-evaluation and recording of parameters.

STATISTICAL ANALYSIS

All the data obtained after clinical and radiographic examination was compiled and subjected to statistical analysis carried out using statistical software (Statistical Packages for Social Science Software version 22.0 for Windows, IBM). Descriptive statistics and statistical Test were applied.

The demographic data of study was assessed using Chi square test. The data for each parameter was analyzed for difference by use of one-way Analysis of Variance (ANOVA), using a significance level of 0.05 to determine mean differences. The data for each parameter was analyzed for difference by use of one-way Repeated Measured Analysis of Variance RM ANOVA and independent t-test for intragroup and inter-group comparisons, respectively. Paired t test was used to compare VAS scores at different time periods. Significance was determined at 0.5 level of confidence.

RESULTS

The study population belong to age distribution was almost equal with 9 subjects below 40 years of age group and 6 subjects above 40 years of age group. The gender distribution was almost equal with 7 females and 8 males.

The inter group and intra group comparison of VAS scores at baseline to 7 days. The mean \pm SD values at baseline and 7th day were (4.00 \pm 2.26); (1.13 \pm 1.50) respectively for Test and (4.93 \pm 2.18) and (2.0 \pm 1.85) respectively for Control. The values slightly decreased in both groups from baseline to 7 days in both the groups. Highly significant differences on intragroup comparison from baseline to 7 days, were observed in both groups. However, the inter group comparison at different interval of time period did not reveal significant differences. (**t=6.43; p<0.001***); (**t=5.84; p<0.001***).

Table-1: Inter and Intra-group comparison of VAS Scores between various intervals:

Time Period	Group 1		Group 2		p value (Independent t Test)
	Mean	SD	Mean	SD	
Baseline	4.00	2.26	4.93	2.18	0.261
7 days	1.13	1.5	2.0	1.85	0.171
p value (Paired t Test)	<0.001*		<0.001*		

Statistical Test: Independent t Test; RM ANOVA; (p ≤0.05- significant)

The inter group and intra group comparison of Soft Tissue Healing Index at baseline to 6 weeks was done. The mean ± SD values at baseline 3rd day, 2nd week and 6th week were (2.88 ± 0.35); (2.46 ± 0.51); (1.66 ± 0.61) and (0.73 ± 0.70) respectively for Test and (2.73 ± 0.45) and (2.53 ± 0.51); (1.73 ± 0.70) and (0.86 ± 0.99) respectively for Control. The values slightly decrease in both groups from baseline to 6 weeks. Highly significant differences on intragroup comparison from baseline to week 6, were observed in both groups. However, the inter group comparisons at different interval of time period did not reveal significant differences. (F =42.105;p<0.001**); (F =22.26;p=0.001**).

Table-2: Inter and Intra-group comparison of Soft Tissue Healing Index between various intervals:

Time period	Group 1		Group 2		p value (Independent t Test)
	Mean	SD	Mean	SD	
Baseline	2.88	0.35	2.73	0.45	0.326

Day 3	2.46	0.51	2.53	0.51	0.726
Week 2	1.66	0.61	1.73	0.70	0.785
Week 6	0.73	0.70	0.86	0.99	0.674
p value (RM-ANOVA)	<0.001** (F =42.105)		0.001* (F =22.26)		

Statistical Test: Independent t Test; RM ANOVA; (p ≤0.05- significant)

The inter group and intra group comparison of alveolar crest height at baseline to 24 weeks. The mean ± SD values at baseline 12th week and 24th week were (1.59 ± 0.62); (1.70 ± 0.62) and (1.80 ± 0.62) respectively for Test and (2.08 ± 1.00) and (1.98 ±1.00) and (1.88 ±1.00) respectively for Control. In Test value increases from baseline to 24 weeks, but in Control the values slightly decrease from baseline to 24 weeks. Highly significant on intragroup comparison from baseline to 24 weeks were observed in both groups. Inter group comparisons at different interval of time period were not significant in both groups. (F=0.413; p=0.664); (F=0.86; p=0.148).

Table-3: Inter and Intra-group comparison of Alveolar Crest Height between various intervals:

Time Period	Group 1		Group 2		p value
	Mean	SD	Mean	SD	
Baseline	1.59	0.62	2.08	1.00	0.12
Week 12	1.70	0.62	1.98	1.00	0.35
Week 24	1.80	0.62	1.88	1.00	0.77

p value	0.664 (F=0.413)	0.86 (F=0.148)	
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Statistical Test: Independent t Test; RM ANOVA; (p ≤0.05- significant)

The inter group and intra group comparison of alveolar ridge width at baseline to 24 weeks. The mean ± SD values at baseline 12th week and 24th week were (7.33 ± 0.63); (7.42 ± 0.63) and (7.51 ± 0.64) respectively for Test and (6.70 ± 1.12); (5.78 ±1.21) and (5.58 ±1.20) respectively for Control. In test value increases from baseline to 24 weeks, but in Control the values slightly decreased from baseline to 24 weeks. Highly significant on intragroup comparison from baseline to 24 weeks were observed in both groups. However, the inter group comparison showed changes that were statistically significant at weeks 12 and 24.(F=0.754; p=0.284); (F=3.821; p=0.052).

Table-4: Inter and Intra-group comparison of Alveolar ridge Width between various intervals:

	Group 1		Group 2		p value (Independent t Test)
	Mean	SD	Mean	SD	
Baseline	7.33	0.63	6.70	1.12	0.066
Week 12	7.42	0.63	5.78	1.21	<0.001*
Week 24	7.51	0.64	5.58	1.20	<0.001*
p value(RM-ANOVA)	0.754 (F=0.284)		0.03* (F=3.821)		

Statistical Test: Independent t Test; RM ANOVA; (p ≤0.05- significant)

DISCUSSION

Socket preservation is a necessity associated with increased risk of tooth loss and eventual alveolar bone resorption. The goal of socket preservation is to minimize external resorption of the ridge and maximize bone formation within the socket and for anticipation of an implant placement or fixed partial denture site thus, reducing the need for later bone augmentation. But also, to compensate for the resorption of the facial bone.⁶

Intragroup comparison in this study did not find significant differences from baseline to 7 days & 6 weeks, in both groups. However, the inter group comparison showed changes that were statistically significant at 7th days & 6th weeks, in both groups. Mean reduction VAS Score and Healing Index was significant in control as compared to Test. Results of this study are similar to findings with previous study by **Mozzati et al.**, who reported no significant improvement in **Landry's healing index score and VAS-score** compared to baseline while treating post-operatively in diabetes patient with use of PRGF.⁷

In this study it was evaluated that ACM have a tendency of an inhibitory effect from fetal chorioamniotic membranes against a range of gram-negative bacteria, thus, imperatively giving better healing index score and less VAS Score in Test site.

Intragroup comparison did not find significant differences from baseline to 24 weeks, in both groups. However, the inter group comparison showed changes that were statistically significant at weeks 12 and 24. Mean reduction in alveolar ridge height was significant in control as compared to Test. Results of this study are similar to findings of **Leventis M et al., 2018**⁸. **Munhoz EA et al.**, reported approximately similar findings with the radiographic aspect of the healing of extraction sockets.⁹ However, **Mardas et al, and Ferreira 2018**, observed the alveolar crest height at the mesial and distal aspects of the socket radiographically and the mean

differences between the two groups were not statistically significant.¹⁰

In this study the alveolar ridge width of the healing extraction socket was measured with custom stents and calipers. It showed marginal gain in the alveolar ridge width with ACM treated site than compared to CM site. In the Test group although accidental exposure of ACM membrane was noted in two cases but did not change healing outcome. Thus, ACM imperatively gave better barrier effect and marginal gain in ridge width although not significant as compared to Control.

These findings can be correlated with those of **Maksood M et al., 2018**, with efficacy of tissue expansion of dental extraction sockets using dehydrated human amnion/chorion membrane that showed expedited healing with no loss of the underlying bone graft material and minimal loss of the buccolingual dimension.¹¹ Similarly, **Faraj SA et al., 2020**, mentioned that the use of dehydrated human amnion-chorion and type 1 bovine collagen membranes in alveolar ridge preservation, did not change healing, compromise ridge dimensions or affect bone vitality, the mean differences between the two groups were not statistically significant.¹²

Despite of promising findings of this study, it has a few limitations to be considered. Surgical re-entry could have provided direct evidence of alveolar crest height gained and alveolar ridge width gained and the same was not considered due to ethical concerns and difficulty in obtaining patients acceptance. In present study Radiovisiography was used for radiographic assessment. Use of more advanced technique CBCT should yield better results. Longer follow up period may provide better data on healing and regeneration at Tested sites.

CONCLUSION

Within the limits of this study, it was evaluated that the response of ACM membrane in socket preservation in combination with β -tricalcium phosphate and collagen membrane. The results demonstrated that when compared to baseline data, significant improvement was seen in clinical as well as radiographical parameters with each membrane. The observations over a 24th week period showed that findings of Test were marginally significant when compared to Control.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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