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SOCKET PRESERVATION FOR DENTAL IMPLANT SITE DEVELOPMENT. A RANDOMIZED CONTROLLED CLINICAL TRIAL

Hesham Fathi Marei* *and* Mohamed Gafar Ahmed**

ABSTRACT

Aim of the study: To compare between the effect of two different bone grafting materials on the horizontal and vertical socket dimensional changes following posterior teeth extraction.

Materials and Methods: 30 patients (13 females &17 males) were enrolled in the current study according to specific inclusion and exclusion criteria. The patients were allocated to one of three groups. Group I involved socket preservation using demineralized allograft, group II involved socket preservation using cancellous particulate bovine bone xenograft, while group III served as a negative control group. Radiographic analysis using Cone Beam CT were performed at the time of socket preservation and 4 months later.

Results: At 4 months, there was no significant difference between the three groups on all the sites except at the height of the center of the socket (P = 0.029). Pairwise comparison showed that the mean of group I (10.54 ± 2.10) was statistically higher than group III (8.17± 2.26), while there was no significant difference between groups I and II.

Conclusion: Socket preservation following posterior teeth extraction using either allograft or xenograft did not significantly influence socket width change. However, the use of allograft can significantly decrease mid vertical height reduction compared with unassisted socket healing.

INTRODUCTION

Socket preservation is considered as a surgical procedure employed to preserve the ridge volume, which would allow later implant placement.[1] The goal of such procedure is to compensate the expected amount of horizontal and vertical alveolar bone resorption.

The final shape of the alveolar ridge after extraction varies depends on the position of the tooth in the alveolar bone, gingival biotype, presence of fenestration defects in the buccal bone, presence of periapical infection and the remaining amount of buccal bone of the socket.[2-5] It is stated that the buccal wall begins to resorb before the palatal wall

* Associate Professor and Consultant of Oral and Maxillofacial Surgery, College of Dentistry, University of Dammam, Dammam, Saudi Arabia and Assistant Professor of Oral and Maxillofacial Surgery, Faculty of Dentistry, Suez Canal University, Ismailia, Egypt.

** Specialist of Oral and Maxillofacial Surgery, King Fahad University Hospital, University of Dammam, Al-Khobar, Saudi Arabia.

with a final shift in the position of the alveolar crest toward the palatal or lingual site. Moreover, the reduction in alveolar width is more than the reduction in alveolar height, as it was demonstrated that the alveolar ridge is subjected to a mean loss in width and height of 3.8 mm and 1.24 mm within 6 months after tooth extraction.[1, 6] Such amount of reduction accounted for 26-63%, 11-22% of the alveolar ridge in a horizontal and vertical dimension respectively.[6]

The changes in alveolar ridge create an unfavorable situation for implant placement that might hinder the esthetic and functional outcomes. Immediate implant placement was considered as an option to take the advantages of socket healing and optimize availability of existing bone.[7] However, multiple studies showed that immediate implant placement do not prevent the resorption of the alveolar bone.[8] Moreover, it is coupled with a high risk of gingival recession if compared to early implant placement.[9]

In 2013, multiple systematic reviews showed that socket preservation procedures are effective in reducing horizontal and vertical ridge alterations. However, there is no evidence to support one technique over another,[10, 11]and there is no clear guidelines supported by evidence to recommend a specific biomaterial to be used.[12] Moreover, There is no evidence that ridge preservation procedures allow clinicians to place implants without the need for simultaneous grafting.[10, 11]

In 2015, a Cochrane systematic review[13] recommended further long term randomized controlled trails, as there is still no conclusive proof of any significant difference between different grafting materials and barriers used for socket preservation.[13] Therefore, clinicians' choice of socket preservation technique still depends on individual preferences.

In 2016, another systematic review came with the same conclusion. However, the authors stated that socket preservation results in a significant reduction only in the vertical bone dimensional change when compared to unassisted socket healing. The authors called for high-quality RCTs to evaluate differences in outcomes between different socket preservation procedures and unassisted socket healing.[14]

More recent clinical trials have provided even more divergent results. One clinical trial showed that alveolar process remodeling is unavoidable but acceptable following socket preservation using collagen enriched, bovine-derived xenograft blocks.[5] Another clinical trial showed that both hydroxyapatite bone and demineralized bone matrix with collagen membrane don't influence the dimensional changes when compared to unassisted socket healing.[15] Others showed that there is a significantly more reduction in ridge height in molar extraction sites without socket preservation, while there was no significant difference in reduction in width between grafted and non-grafted sockets using freeze-dried bone allograft covered by a non-resorbable dense polytetrafluoroethylene membrane.[16]

In 2017, a recent meta-analysis concluded that freeze-dried bone allograft graft plus membrane is successful in reducing loss of bone height. However, there was a call for more studies with larger samples and less risk of bias in order to further strengthen the results of the analysis.[17]

In order to better understand which materials might be more effective for socket preservation at posterior teeth and to strengthen the evidence that is relevant to the clinicians' choice of socket preservation materials, two different materials were compared in a randomized controlled approach. (1) Puros Demineralized Bone Matrix (DBM) Putty with Chips allograft covered by collagen membrane, and (2) Deprotonated bovine bone xenograft covered by collagen membrane. The independent variable is the grafting material while the dependent variables are the changes in socket height, and width;and ability of implant placement without the need for further grafting.

MATERIALS AND METHODS

Subjects' enrollment

Results of a recent a randomized, controlled, multi-center clinical trial of post-extraction socket preservation showed a mean statistical significant difference in ridge width of 1.76mm (±1.4) between the test and control groups.[18] Sample size calculation indicated a need for a sample size of 10 patients per group to obtain power 80% and α= 0.05.

Fifty patients were screened over a period of 6 months for possible inclusion in the study. The data was derived from the first 30 patients (13 females &17 males) that were enrolled in the current study according to the following inclusion and exclusion criteria (Figure 1).

Inclusion criteria:

1. Adult patient > 18 years old.
2. Single and or multi-rooted posterior teeth that are non-restorable.
3. Patients are keen to have implant placement at the extraction sites after 4 months of extraction.
4. Intact buccal bone after extraction, which was confirmed by visual inspection and clinical examination using a periodontal probe.
5. Patients are medically fit with no underlying systemic diseases.

Exclusion criteria:

1. Pregnant females.
2. Smokers.
3. Presence of any acute infection at the time of teeth extraction.

Subjects' allocation

A total of 30 patients (N = 30) were allocated to one of three groups as follow:

Group I: Socket preservation using allograft (Puros Demineralized Bone Matrix (DBM) Putty with Chips, Zimmer dental, Zimmer, USA) covered by membrane (size: 15x20mm) made of type I collagen fibers purified from bovine tendon (BioMend® Membrane, Zimmer dental, Zimmer, USA).

Group II: Socket preservation using cancellous particulate bovine bone xenograft (CopiOs® Cancellous Particulate, Zimmer dental, Zimmer, USA)covered by membrane (size: 15x20mm) made of type I collagen fibers purified from bovine tendon (BioMend® Membrane, 15x20mm, Zimmer dental, Zimmer, USA).

Group III: No grafting materials were placed, so it served as a negative control group.

Follow Up and analysis

All the patients were followed up from the time of extraction and socket preservation till 3 months after implant placement.

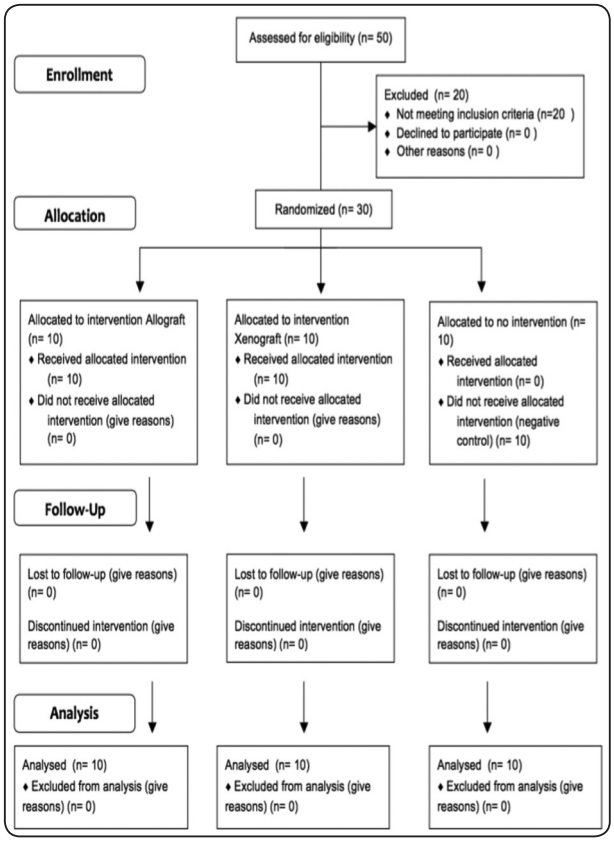

Fig. (1) Consort 2010 flow diagram.

Surgical protocol

Flapless tooth extraction was performed using elevators and extraction forceps. The buccal bone was kept intact; therefore, the site would be eligible for inclusion in the study. The socket was carefully inspected and any soft tissue in the socket was gently removed using curettes. Irrigation was done using normal saline (0.9% sodium chloride). Grafting materials were placed in the socket using bone condenser and then the collagen membrane was placed on the top of the grafting materials. Figure of eight suturing using 4/0 Vicryl suture material was performed on the top of the membrane to approximate the soft tissue on the buccal and palatal side of the socket in order to hold the grafting materials in place. The membrane was left partially exposed without any primary soft tissue closure. All patients were given Ibuprofen 400 mg (Sapofen®, Spimaco, Saudi Arabia) as a painkiller and were asked to rinse, three times daily, with a 0.2% solution of Chlorhexidine(Clorasept®, Spimaco, Saudi Arabia)(Figure 2).

Radiographic evaluation

Cone Beam Computed Tomography Scan (CBCT) was performed immediately after tooth extraction and socket grafting as a base line record and then 4 months later at the time of implant placement by CS 9300 unit (Carestream Health, Inc., USA). Image acquisition was performed (Volumetric dimension of 5*5cm for single socket or 10 * 10 for multiple sockets within the upper and lower jaw of the same patient) for 12-28s, voxel size: 500µm, gray scale: 14 bits, focal spot: 0.7 mm, image sensor: Amorphous silicon thin film transistors (TFT).

The radiographic measurements at the base line and 4 months later were performed in accordance with a previous published protocol by Araujo et al.[19]The DICOM" data generated by the CS9300 unit was transferred to an Implant planning software (Simplant, DENTSPLY, Belgium), in which the image analysis was carried out. The apex of the socket is identified by a line (A line), which is perpendicular to BIS line that divides the image of the socket into one buccal and one palatal portion. The coronal end of the socket is marked by a line that connects the buccal and palatal crests (BC- PC line) and perpendicular to the BIS line.The width of the ridge was measured at 1 mm (W1), 3mm (W3), and 6mm (W6) from the alveolar crest in a bucco-palatal/lingual direction (Figure 3).

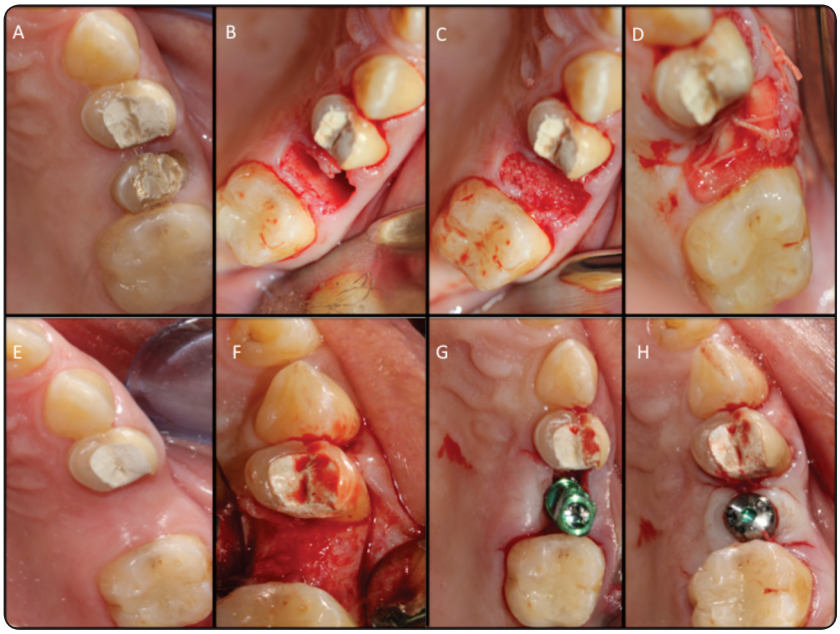

Fig. (2) A: Un-restorable tooth 25, B: Atraumatic extraction of tooth 25, C: Socket preservation using puros DBM putty with chips, D: Placement of college membrane, E: Soft tissue healing at 4 months postoperative, F: Crestal incision showing a healed extraction socket, G: Implant placement (Zimmer 4.1 *10 mm), H: Healing abutment in place.

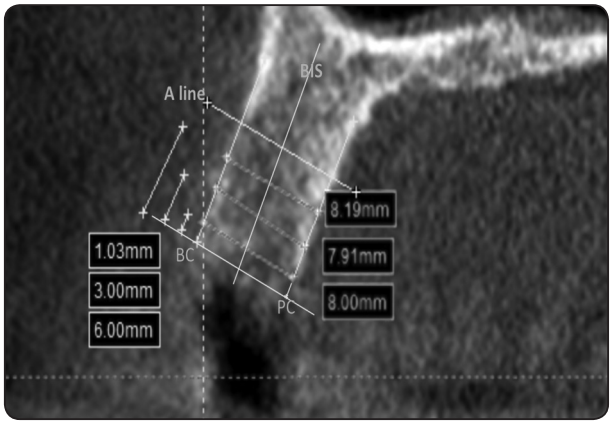

Fig. (3) BC-PC line demonstrating the coronal extension of the socket, W1= 8mm, W3 = 7.91mm, W6=8.19mm.

The height of the buccal(B-VH), lingual (L-VH) and center of the socket (M-VH) were measured by measuring the vertical distance between the A-line and BC and PC line (Figure 4). After 4 months of healing, all measurements were repeated after performing a new radiographic examination.

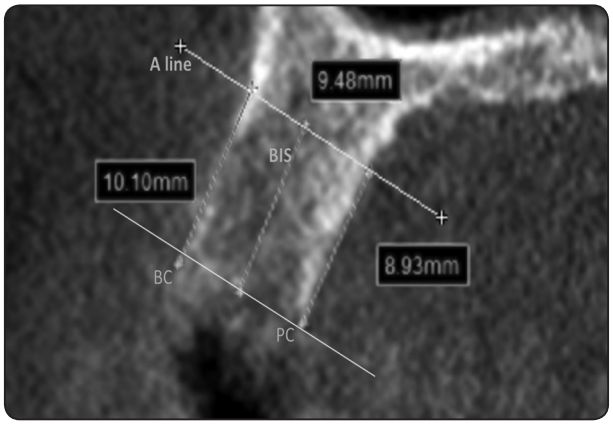

Fig. (4) BC-A line marking the buccal side of the socket, PC-A line is marking the palatal side of the socket. BIS is at the height at the Mid-socket. M-VH = 9.48, B-VH=10.10mm, L-VH = 8.93.

Clinical evaluation

All the sites were evaluated 7 days after extraction for the presence of the grafting materials, removing the suture materials and evaluation of any signs of infection, which was verified by pus discharge from the socket. The patients were recalled 4 months after grafting for clinical evaluation prior to implant placement.

Statistical analysis

All measurements were entered into an Excel sheet and then exported to SPSS for statistical analysis. Statistical analysis was completed on the radiographic measurements that were treated as a continuous data. ANOVA test was applied to find any difference between the three groups. Post-hock Turkey test was performed to provide any significant difference in pairwise comparisons. A *p*-value of <0.05 was considered statistically significant.

Ethical approval

The institutional review board (IRB number: IRB 201402277) approved the study proposal. All patients signed the consent form for enrollment in the study. The protocol was registered as a clinical trial on ClinicalTrails.gov. ID: NCT03112772

RESULTS

Thirty patients (13 females &17 males) were participated in the study with an age range from 22 to 65 (Mean = 41.68 ±12.19). Group I, II and III involved 16, 10 and 11 sockets respectively.

At base line, there was no significant difference between the three groups in term of socket width at 1, 3, 6 mm away from the crest of the socket or socket height at the buccal, palatal or mid part of the socket (Table 1). At 4 months later, there was no significant difference between the three groups on all the sites except at the height of the center of the socket (P = 0.029) (Table 2). Pair wise comparison using post-hok turkey test showed that the mean of group I (10.54 ± 2.10) was statistically higher than group III (8.17± 2.26), while there was no significant difference between groups I and II(Table 3).

All the sites showed no infection or wound dehiscence at the first postoperative week. All the 37 sockets have received implants without the need for further bone grafting. The selection of implant

diameter was based on the available bone, while considering at least 1mm at the buccal and palatal/ lingual side of the implant. The selection of the implant length was based on leaving at least 2 mm from the nearest vital structure.

All premolar sites have received 21 implants (Zimmer TSV MTX, Zimmer dental, Zimmer, USA) with either 3.7 or 4.1mm in diameter while all molar sites have received 16 implants, which are 4.7 mm in diameter. All sites were received implants of at least 10 mm in length.

TABLE (1) Mean and standard deviation of socket dimensions immediate after extraction and socket preservation (Base line measurements).

		N	Mean	Std. Deviation	*P Value*
W1	Allograft	16	.4294	1.65609	.478
	Xenograft	10	.7740	1.55456	
	Control	11	1.1727	1.36386	
W3	Allograft	16	-.0044	1.25947	.111
	Xenograft	10	.2690	1.52011	
	Control	11	1.1800	1.55137	
W6	Allograft	16	.0919	.94728	.206
	Xenograft	10	.3740	1.23233	
	Control	11	1.0073	1.71941	
M-VH	Allograft	16	.7588	1.69698	.491
	Xenograft	10	.8970	1.20075	
	Control	11	1.5300	1.99510	
B-VH	Allograft	16	.8900	1.56441	.826
	Xenograft	10	1.1450	1.05386	
	Control	11	1.2382	1.77122	
L-VH	Allograft	16	.9225	1.65061	.971
	Xenograft	10	.7730	1.31423	
	Control	11	.9564	2.43692	

**** P value is less than 0.05 = Significant***

TABLE (2) Mean and standard deviation of socket dimensions 4 months postoperative.

		N	Mean	Std. Deviation	*P Value*
W1	Allograft	16	8.6938	3.11840	.963
	Xenograft	10	8.8460	1.93490	
	Control	11	8.5373	2.14280	
W3	Allograft	16	10.0688	2.96562	.810
	Xenograft	10	10.0000	2.04117	
	Control	11	9.4273	2.60678	
W6	Allograft	16	10.4219	2.92361	.861
	Xenograft	10	10.6060	1.65789	
	Control	11	9.9945	2.95742	
M-VH	Allograft	16	10.5488	2.10804	.029*
	Xenograft	10	9.3240	2.16043	
	Control	11	8.1782	2.26824	
B-VH	Allograft	16	9.4563	2.01045	.443
	Xenograft	10	8.9110	2.49948	
	Control	11	8.3900	1.89771	
L-VH	Allograft	16	9.9344	2.41991	.103
	Xenograft	10	9.0890	1.92224	
	Control	11	8.1273	1.68406	

**** P value is less than 0.05 = Significant***

Table (3) Pairwise comparison between the three different groups at 4 months postoperative.

Dependent Variable	(I) Graft material	(J) Graft material	Sig.
W1	Allograft	Xenograft	.988
		Control	.987
	Control	Xenograft	.959
W3	Allograft	Xenograft	.998
		Control	.810
	Control	Xenograft	.874
W6	Allograft	Xenograft	.984
		Control	.912
	Control	Xenograft	.859
M-VH	Allograft	Xenograft	.352
		Control	.023*
	Control	Xenograft	.456
B-VH	Allograft	Xenograft	.800
		Control	.414
	Control	Xenograft	.841
L-VH	Allograft	Xenograft	.582
		Control	.085
	Control	Xenograft	.551

**** P value is less than 0.05 = Significant***

DISCUSSION

The influence of socket preservation on socket dimensional changes in the anterior region has been well investigated and it has been shown that it is effective in compensating ridge resorption. However, there is limited evidence in regard to the influence of socket preservation on the dimensional changes in the posterior region. The current study has investigated the influence of two different bone-grafting materials on the socket horizontal and vertical dimensional changes following extraction of premolars and molars teeth.

The study showed that there is no significant effect of any of the bone grafting materials on the dimensional changes of socket width. Our results are consistent with Walker et al. [16] that showed that the ridge width loss was not significantly decreased when the sockets of molars were grafted with freeze-dried bone allograft covered by a non-resorbable dense polytetrafluoro-ethylene membrane. The similarity in the results between the current study and Walker et al. study could be attributed to the same protocol that was followed by both studies. Both studies have investigated the width of the socket at three points on the buccal and lingual sides. However, the current study used a resorbable membrane instead of non-resorbable membrane, which further indicates that the type of membrane has no influence on the horizontal dimensional changes following extraction of posterior teeth.

In regard to socket height, the current study showed a significant effect of using allograft on vertical dimensional changes. Sockets of extracted teeth that were preserved with allograft and covered by collagen membrane have showed significantly less reduction in socket mid height when compared with control group. The same results were attained by Walker et al.[16] However the authors found significant less reduction in the buccal ridge height. For the lingual aspect, there was no significant difference in vertical height change, which was similar to our results.Moreover, our results are in agreement with a recent Bayesian Network meta-analysis, which indicates that freeze-dried bone allograft plus membrane is the most likely effective in the reduction of bone height remodeling.[17]

The results of the current study are different from Natto et al. study.[20] The authors showed that the use of allograft combined with collagen matrix seal or college spongy significantly minimized ridge resorption in all dimensions. The difference in results between the current study and Natto etal.[20] study could be due to the teeth that were extracted. The authors included single rooted teeth. Their sample included maxillary incisors (39.3%) among the extracted teeth. It is well known that the buccal bone thickness in the anterior region is smaller than that of posterior region.[21, 22] Thickness of buccal bone is one of the factors that affect the socket dimensional changes after teeth extraction. Thin bone wall with a buccal bone wall thickness of 1 mm or less showed bone loss with a vertical loss of 7.5 mm, whereas sockets with thick bone wall revealed a vertical loss of 1.1 mm.[4]

The main clinical implication of the current study is that it showed that there is no need for socket preservation following extraction of posterior teeth unless the extraction socket is in close proximity to the inferior alveolar nerve canal or the maxillary sinus. In such cases, socket preservation using allograft covered by a college membrane might compensate for the vertical resorption, which would facilitate future implant placement without the need for either the use of short implants or sinus graft surgery. The main limitation of the current study is the inability to achieve a completely blinded study, as the operator who performed the socket preservation was the same who performed the implant placement 4 months later.

CONCLUSION

The current study concludes that, after teeth extraction in the posterior region, socket preservation using either allograft or xenograft did not significantly influence socket width change. However, the use of allograft can significantly decrease mid vertical height reduction compared with unassisted socket healing.

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