



Ridge Preservation Comparing a Nonresorbable PTFE Membrane to a Resorbable Collagen Membrane: A Clinical and Histologic Study in Humans

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Various techniques of ridge preservation have been reported, including use of a membrane alone, an osseous graft alone, or a combined membrane plus graft treatment, any of which may be supplemented using an available biologic. When an osseous graft is used, it may be placed within the confines of the socket alone as an intrasocket graft or it can be used in combination with a facial overlay graft.¹⁻³ The purpose of the overlay graft is to maintain the original buccal contours.¹ The overlay may be indicated when it is desirable to preserve original contours and ridge dimensions, especially in maxillary esthetic zone sites.¹

Previous reports have shown that extraction alone leads to a mean loss of 3.7 mm or 45% of horizontal ridge

Purpose: The primary aim of this randomized, controlled, blinded clinical trial was to compare the effect of a resorbable collagen membrane (CM group) versus a nonresorbable high-density polytetrafluoroethylene membrane (PTFE group) on the clinical and histologic outcomes of a ridge preservation procedure.

Materials and Methods: All 24 sites received an intrasocket cancellous allograft and a buccal overlay bovine derived xenograft.

Results: The change in horizontal crestal ridge width was -1.4 ± 1.2 mm for the CM group, whereas the PTFE group lost -2.2 ± 1.5 mm, which was not statistically significant between groups ($P > 0.05$). Vertical ridge height change was

-1.2 ± 1.5 for the CM group, whereas the PTFE group lost -0.5 ± 1.6 , which was not significantly different between groups ($P > 0.05$). The percent vital bone was similar and not significantly different between groups. Primary closure was not obtained and the exposed membrane portion over the socket opening healed with keratinized tissue.

Conclusion: The choice of a resorbable versus a nonresorbable barrier membrane did not affect the clinical or the histologic outcome of ridge preservation treatment. (Implant Dent 2016;25:128-134)

Key Words: cancellous allograft, xenograft, facial overlay graft, guided bone regeneration

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dimension,⁴⁻¹² whereas sites treated with ridge preservation show a mean loss of 1.5 mm or 18%.^{1-7,9-32} Thus, ridge preservation is a highly effective procedure to prevent most of the loss of horizontal ridge dimension associated with tooth extraction.^{1-7,9-32} Because some horizontal loss occurs, even with ridge preservation, it is important to know which sites are most susceptible to loss of ridge width. It has previously been reported that maxillary anterior esthetic zone sites may lose up to 25% to 30% of

the horizontal ridge dimension, whereas other sites may lose substantially less.¹

Osseous allograft options include mineralized cortical or cancellous particulate, a mineralized corticocancellous particulate mix, demineralized cortical allograft, or any of numerous available demineralized bone matrix products, which are usually putty-type materials. Cancellous grafts heal by creeping substitution where the osteoblastic phase occurs first, whereas cortical graft heals by reverse creeping

substitution where the osteoclastic phase occurs first. The net histologic effect is that cancellous grafts heal with a higher percentage of vital bone, whereas cortical grafts result in a greater percentage of fibrous encapsulation.³³ For this reason, a cancellous allograft is a good choice for an intrasocket graft to provide increased vital bone in the site of implant placement, whereas a slow resorbing xenograft may be the best choice for an overlay graft.

The influence of the membrane on final ridge dimensions or histologic composition of the graft is less clear because most studies have not evaluated the effect of membrane alone. Fotek et al³² compared a tissue incorporated allograft with a nonresorbable membrane, acellular dermal matrix (ADM) allograft versus a high-density polytetrafluoroethylene (hdPTFE) barrier, both used with a mineralized particulate allograft and found no clinically or statistically significant differences in clinical ridge dimensions or histologic outcome. A collagen barrier with an extended resorption period of 9 to 12 months provides a long-term barrier function than faster resorbing collagen membranes and may provide a better comparison material for a nonresorbable membrane.

The primary aim of this randomized, controlled, blinded clinical trial was to determine the clinical and histologic effect of a slow resorbing collagen versus a nonresorbable hdPTFE barrier membrane.

METHODS

Study Design

A total of 24 patients participated in this 4-month randomized, controlled, blinded clinical trial of ridge preservation in sequentially entered single extraction sites of nonmolar teeth to be replaced by a dental implant. All 24 sites received an intrasocket cancellous allograft (300–1000 μ m, MinerOss Cancellous; BioHorizons, Inc., Birmingham, AL) plus a facial overlay xenograft (250–1000 μ m, Bio-Oss; Geistlich Pharma North America, Inc., Princeton, NJ). Twelve positive control patients were randomly selected, using a coin toss, to receive a nonresorbable

high-density polytetrafluoroethylene membrane (PTFE group, Cytoplast; Osteogenics Biomedical, Inc., Lubbock, TX), whereas the 12 test patients received a resorbable porcine collagen membrane (CM group, MatrixDerm Extend; Collagen Matrix, Inc., Oakland, NJ). Four months after the grafting procedure, the implant placement surgery was performed and a trephine core was removed from the osteotomy site for histologic analysis. All surgical procedures were completed by one operator (H.A.) under the direction of one mentor (H.G.). The surgeon was trained in the procedures until considered proficient. All blinded measurements were performed by one blinded examiner (N.D.A.), who was unaware of the treatment assignment at all time points. The mentor performed the coin toss after flap reflection and immediately before graft placement and verified the measurements taken by the blinded examiner. All patients signed an informed consent approved by the University of Louisville Institutional Review Board (#14.0430) in October 2012. This study was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2000. The study was conducted between October 2012 and November 2013 in the Graduate Periodontics Clinic at the University of Louisville.

Outcome Variables

The primary outcome variable was crestal horizontal ridge width, and the power analysis was based on this variable. Other variables evaluated included vertical ridge dimension change and histologic assessment of vital bone, nonvital bone, and trabecular space.

Inclusion/Exclusion Criteria

Subjects met the eligibility criteria if they were at least 18 years of age and had 1 nonmolar tooth requiring extraction that would be replaced by a dental implant. Extraction sites were bordered by at least 1 tooth. Exclusion criteria included: (1) debilitating systemic diseases or diseases that have a clinically significant effect on the periodontium; (2) molar extraction sites; (3) presence of or history of osteonecrosis of the

jaws; (4) history of IV bisphosphonate treatment; (5) history of oral bisphosphonate treatment for more than 3 years; (6) pregnancy or lactation; (7) known allergy to any material or medication used in the study; (8) required antibiotic prophylaxis; (9) previous head and neck radiation therapy or a history of chemotherapy in the past 12 months; (10) long-term steroid or nonsteroidal anti-inflammatory drug therapy; or (11) failure to sign an informed consent approved by the Human Studies Committee. Patients were excluded post-treatment if they developed infection or had an adverse reaction to any of the materials used in the study.

Clinical and Radiographic Parameters

Clinical parameters on adjacent teeth assessed at baseline and at the 4-month reentry included Plaque Index, Gingival Index, bleeding on probing (dichotomous), keratinized tissue width, recession, probing depth, clinical attachment level, CEJ to alveolar crest distance, and tooth mobility.^{34,35} Horizontal ridge width was recorded with a modified digital caliper measuring to the nearest 10^{-2} at the mid-socket crestal level and 5 mm apically. Vertical distance from the acrylic stent to the alveolar crest was measured mesially, mid-socket, and distally on all buccal, occlusal, and lingual surfaces using a 15-mm North Carolina periodontal probe.⁷

Surgical Treatment

Full thickness flaps were elevated to expose both the facial and the palatal/lingual aspects of the alveolar ridge. The flaps were extended one tooth mesial and distal to the preservation site on the buccal, and vertical incisions were placed on the buccal and palatal. Papillae preservation incisions were used to keep the papilla height intact.³⁶ The teeth were extracted as atraumatically as possible using periotomes, elevators, and forceps. After the extraction, the socket was carefully curetted to remove all soft tissue remnants.

The allograft was hydrated in a 20 mg/mL solution of doxycycline. The socket allograft was placed to the level of the alveolar crest, and the facial

overlay xenograft was placed over the buccal wall of the extraction socket from the alveolar crest to about 12 mm apical and was extended about half a tooth to the mesial and distal. The collagen membrane was trimmed to completely cover the socket and extended at least 5 mm past the alveolar crest and at least 5 mm past the lateral and apical borders of the facial xenograft. The membrane overlying the central portion of the socket was left exposed. The hdPTFE membranes were placed in a similar fashion (Fig. 1, A–G). Flaps were replaced or slightly coronally positioned. If needed, an apical periosteal split was performed to permit adequate flap release for tension-free closure. Flaps were sutured with a 4-0 polytetrafluoroethylene suture (Cytoplast; Osteogenics Biomedical, Inc.). Patients were given a postsurgical regimen consisting of 375 mg of naproxen (twice a day for 1 week), 50 mg of doxycycline hyclate (once a day for 2 weeks), and narcotic analgesics as needed. Patients were seen every 2 weeks until soft tissue closure was complete and then monthly until the 4-month implant placement.

Implant Placement

Full-thickness flaps were elevated on the buccal and palatal/lingual using a papilla preservation technique. All baseline clinical measurements were repeated and a standardized radiograph was taken. A 2.7 × 6.0-mm trephine bur was used with copious chilled saline irrigation to remove a core from the osteotomy site before implant placement. The core was subsequently placed in 10% buffered formalin for histologic processing. A dental implant was placed and flaps were replaced and sutured with 4-0 silk or the polytetrafluoroethylene sutures previously described. Bone density was subjectively scored at the time of implant placement as either type I, type II, type III, or type IV.³⁷

Histologic Analysis

Trephine cores (2.7 × 6 mm) were decalcified and 12- to 15-step serial sections were taken from the center of each longitudinally sectioned core. The sections were stained with hematoxylin and eosin. Ten slides per patient were prepared, each containing at least 4 sections.

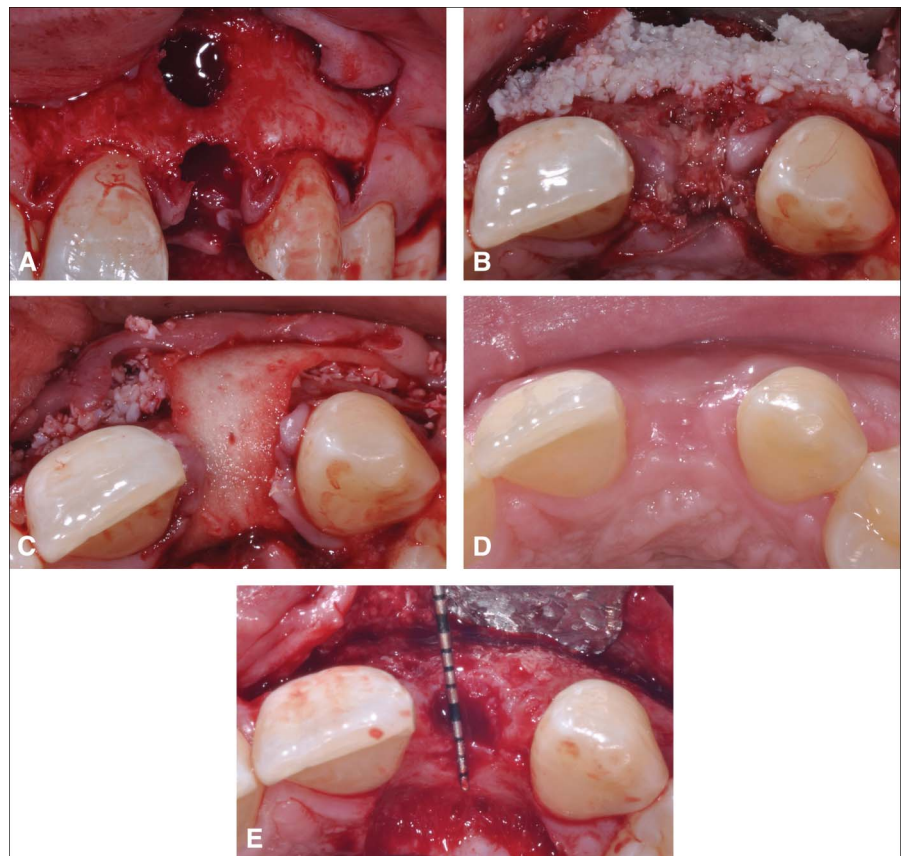


Fig. 1. **A**, Postextraction #10. Note facial fenestration due to a periapical lesion. **B**, Intrasocket cancellous allograft mixed with 20 mg/mL of doxycycline solution and the facial overlay graft of bovine derived xenograft. **C**, The collagen membrane is trimmed to cover the osseous graft material. **D**, Posttreatment 4-month healing before reentry for implant placement. **E**, Exposed ridge before trephine core removal and implant placement.

Six randomly selected fields, 1 per section if possible, were used to obtain percent cellular bone, acellular bone, and trabecular space using an American Optics light microscope at ×150 with a ×10 objective and ×15 reticle eyepieces.⁷

Statistical Methods

Means and SDs were calculated for all parameters. A paired *t* test was used to evaluate the statistical significance of the differences between initial and final data. An unpaired *t* test was used to evaluate statistical differences between

the test and control groups. The sample size of 12 per group gave 80% statistical power to detect a difference of 1 mm between groups for crestal ridge width. Power calculations were based on data from previous studies.^{7,14}

RESULTS

A total of 24 patients were entered in this study. For the CM group, 7 women and 5 men with a mean age of 53 ± 15 years, ranging from 25 to 73 years, were

Table 1. Horizontal Ridge Width for Collagen and PTFE Sites Shown as the Mean ± SD (in Millimeter)

	Initial	Final	Change	Range
Collagen at crest	8.5 ± 1.3	7.0 ± 1.7	-1.4 ± 1.2*	-4.6 to 0.0
PTFE at crest	8.9 ± 1.7	6.7 ± 2.5	-2.2 ± 1.5*	-5.3 to -0.1
Collagen at 5 mm	8.8 ± 1.4	8.4 ± 1.7	-0.4 ± 1.2	-3.3 to 1.0
PTFE at 5 mm	9.3 ± 1.5	8.3 ± 2.3	-0.9 ± 1.4*	-3.1 to 0.8

**P* < 0.05 between initial and 4-month values.

enrolled, whereas 8 women and 4 men with a mean age of 52 ± 15 years, ranging from 30 to 73 years, were enrolled in the PTFE group. The CM group consisted of 4 maxillary incisors, 1 maxillary canine, 6 maxillary premolars, and 1 mandibular premolar. The PTFE group consisted of 2 maxillary incisors, 9 maxillary premolars, and 1 mandibular premolar. There were 2 smokers enrolled in the PTFE group and 1 smoker in the collagen group. The reason for extractions in the PTFE group was 11 due to caries, 1 due to apical periodontitis; in the CM group, 9 were extracted due to caries and 3 due to apical periodontitis. There were no adverse events that occurred due to this treatment.

Clinical Indices

Plaque index, gingival index, and bleeding on probing had low initial values for both groups, ranging from 0.1 ± 0.2 to 0.4 ± 0.4 , and were virtually unchanged at the 4-month implant placement visit. There were no significant differences between initial and final values or between the test and the control groups ($P > 0.05$).

Horizontal Ridge Width Changes

Both the PTFE and CM group had a statistically significant mean loss of crestal width, 2.2 ± 1.5 mm for the PTFE group versus 1.4 ± 1.2 mm for collagen group ($P > 0.05$, Table 1). The difference between the 2 groups was not statistically significant ($P > 0.05$). At 5 mm apical to the crest, the PTFE group had a significant mean loss of 0.9 ± 1.4 mm ($P < 0.05$), whereas the collagen group showed a loss of 0.4 ± 1.2 mm ($P > 0.05$). The difference between the test and control groups was not statistically significant ($P > 0.05$, Table 1).

Vertical Ridge Height Change

On the mid-buccal, the PTFE group lost a mean of 0.5 ± 1.6 mm ($P > 0.05$), whereas the collagen group lost 1.2 ± 1.5 mm ($P < 0.05$). The difference between the test and control groups was not statistically significant ($P > 0.05$, Table 2). Data and statistical significance for the mid-lingual, the mesial and the distal portion of the socket are shown in Table 2.

CEJ to Osseous Crest Changes

Mesial CEJ to osseous crest distance for the PTFE group showed

Table 2. Vertical Ridge Height Change for Collagen and PTFE Sites Shown as the Mean Change $\pm$ SD (in Millimeter)

Location	Mean Change $\pm$ SD in mm		Range in mm	
	Collagen	PTFE	Collagen	PTFE
Mid-buccal	$-1.2 \pm 1.5^*$	-0.5 ± 1.6	-4.0 to 0.5	-3.0 to 3.0
Mid-lingual	-0.6 ± 1.3	-0.8 ± 1.7	-2.5 to 1.0	-4.0 to 1.0
Mesial	-0.3 ± 0.8	-0.8 ± 0.9	-2.0 to 0.7	-3.0 to 0.0
Distal	$-0.3 \pm 0.4^*$	$-1.0 \pm 1.2^*$	-1.2 to 0.3	-2.7 to -0.7

* $P < 0.05$ between initial and 4-month values.

Table 3. Histologic Data at Implant Placement for Collagen and PTFE Sites Shown as the Mean $\pm$ SD (in Percentage)

Group	Time (mo)	n	% Vital	% Nonvital	% Trabecular
Collagen	4	10	24 ± 16	25 ± 17	51 ± 15
PTFE	4	9	30 ± 23	22 ± 12	48 ± 14

a mean loss of 0.4 ± 0.9 mm, whereas the collagen group had a mean loss of 0.1 ± 0.9 mm, which was not statistically significant ($P > 0.05$). Distal CEJ

to osseous crest distance for the PTFE group showed a mean loss of 0.5 ± 1.2 mm, whereas the Collagen group had a mean gain of 0.1 ± 0.6 mm, which

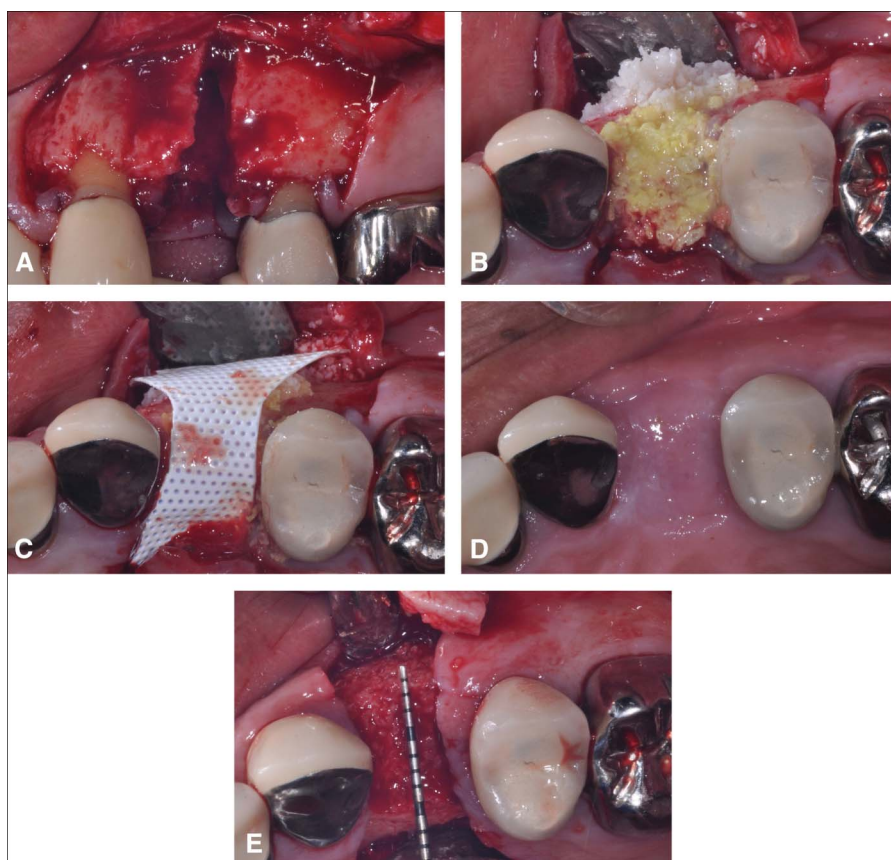


Fig. 2. A, Postextraction #12. Note facial dehiscence due to a vertical root fracture. B, Intrasocket cancellous allograft mixed with 20 mg/mL of doxycycline solution and the facial overlay graft of bovine derived xenograft. C, The hdPTFE membrane is trimmed to cover the osseous graft material. D, Posttreatment 4-month healing before reentry for implant placement. E, Exposed ridge before trephine core removal and implant placement.

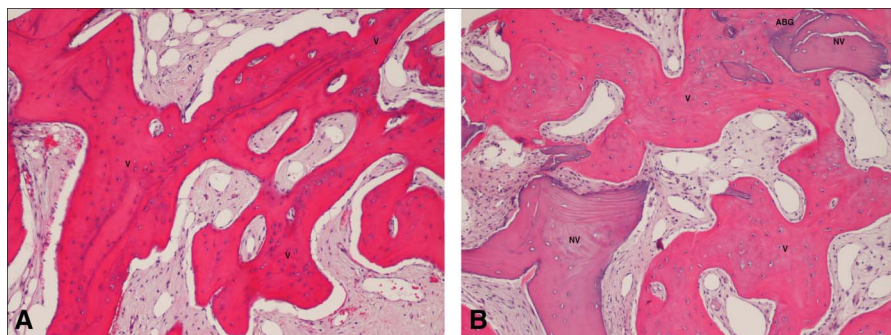


Fig. 3. **A**, Vital bone (V) from site of implant placement, all the bone shown is vital, $\times 100$, hematoxylin and eosin stain. **B**, Vital (V) and nonvital (NV) from site of implant placement. Note appositional bone growth (ABG) where vital bone is growing on nonvital bone; the nonvital bone is residual graft particles, $\times 100$, hematoxylin and eosin stain.

was not statistically significant ($P > 0.05$). There were no statistically significant differences between groups for either mesial or distal sites.

Bone Quality

For the PTFE group, 9 trephine cores were obtained and 6 were scored Type 2 while 3 were scored Type 3. For the Collagen group, 10 cores were obtained, and 7 sites were scored as Type 2 bone while 3 were scored Type 3.

Histologic Evaluation

The PTFE group healed with a mean of $30 \pm 23\%$ vital bone, $22 \pm 11\%$ nonvital bone, and $48 \pm 14\%$ trabecular space, whereas the CM group healed with a mean of $24 \pm 16\%$ vital bone, $25 \pm 17\%$ nonvital bone, and $51 \pm 15\%$ trabecular space. There were no statistically significant differences between the PTFE and CM groups for vital or nonvital bone or trabecular space ($P > 0.05$, Table 3).

DISCUSSION

In this study, comparing the clinical and histologic effect of a resorbable collagen membrane to a nonresorbable hdPTFE membrane, there were minimal clinical and histologic differences. Loss of crestal ridge width was not statistically significant between groups. The mean loss for the collagen group was -1.4 ± 1.2 mm versus -2.2 ± 1.5 for the hdPTFE group. Likewise for vertical mid-buccal loss of ridge height, there were no statistically significant differences between groups. The mean loss for

the collagen group was -1.2 ± 1.5 versus -0.5 ± 1.6 for the hdPTFE group. This means that, from a clinical standpoint, both membranes work well for preserving ridge dimensions. The histologic outcome was also similar for both membranes and the percent vital bone for the collagen group was $24 \pm 16\%$ versus $30 \pm 23\%$ for the hdPTFE group. Thus, both membranes support substantial vital bone formation (Fig. 2, A and B, Fig. 3). Fotek et al³² compared ADM to hdPTFE and found no significant clinical or histologic differences. The findings in this study were similar, although the comparison was a resorbable collagen to hdPTFE rather than an incorporated soft tissue allograft to hdPTFE.

Poulias et al¹ reported that maxillary preservation sites tend to have greater loss of initial ridge width compared to mandibular sites, about 18% versus 6%, or 3 times greater loss for maxillary sites.¹ Based on previous experience, it was anticipated that this study would have a greater number of maxillary sites; therefore, the grafting technique chosen included a buccal overlay xenograft as previously reported by Poulias et al.¹ The results of this study differed in that loss of crestal ridge width was not prevented. The authors speculate that the difference may be attributed to the greater rigidity of the polylactide membrane used in that study, which resisted crestal compression at the time of suturing. This suggests that the technique reported by Poulias et al¹ is not dependent on grafting technique alone but that the combination of grafting technique and membrane may be necessary to duplicate that outcome.

The collagen membrane used in this study had an extended resorption period of 9 to 12 months. Despite this, the exposed portion overlying the socket was usually resorbed before the 8-week visit. This loss of barrier function over the socket entrance did not seem to have any clinical or histologic consequences. In general, the healing and contours of the tissue in this area were excellent. Thus, primary closure over the socket entrance may not be required for good clinical and histologic outcomes with this collagen membrane.

The design of the interim prosthesis is important, especially in the maxillary anterior esthetic zone. In general, a tooth-supported prosthesis is preferred over a tissue-supported prosthesis, which may impair ridge healing or cause a tissue defect. In this study, 3 cases that received a tissue-supported interim partial denture had poor healing and tissue contours resulting in a hard and soft tissue defect. In these sites, implants could not be placed and additional grafting was performed. Thus, this type of prosthesis maybe contraindicated, especially in the maxillary esthetic zone, and may significantly compromise both soft and hard tissue outcomes.

There are many membrane choices for ridge preservation procedures. In this study, either a resorbable collagen or a nonresorbable hdPTFE membrane produced similar results. When this study is compared to a previous study with a facial overlay graft, the result suggests that a more rigid polylactide membrane maybe useful to prevent compression of the crestal ridge graft so that the original ridge contour can be preserved as reported by Poulias et al.¹

CONCLUSION

In this study, there were no significant differences between a resorbable collagen and a nonresorbable PTFE membrane in ridge width or height dimensions or in histologic bone composition. Primary closure was not attempted and the exposed collagen membrane portion over the socket opening was resorbed by 8 weeks. Membrane exposure seemed to have no adverse effect on osseous healing, and the exposed area healed with keratinized tissue.

DISCLOSURE

The authors claim to have no financial interest, either directly or indirectly, in the products or information listed in the article.

APPROVAL

All patients signed an informed consent approved by the Louisville Institutional Review Board (#14.0430). This study was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2000.

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