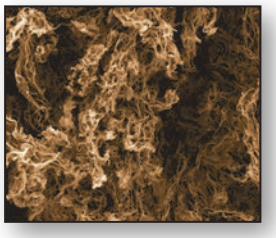
biologics
clinical review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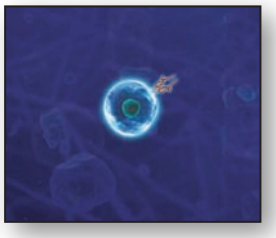
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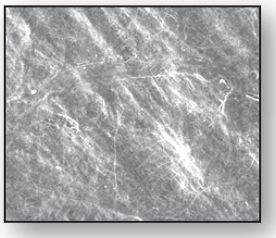
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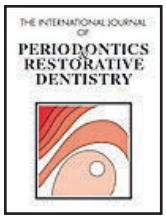

A modified tensionless gingival grafting technique using acellular dermal matrix

JB Taylor, RC Gerlach, RW Herold, FC Bisch, DR Dixon
Int J Periodontics Restorative Dent. 2010; 30:513–521

Abstract: Conventional surgical procedures designed for autogenous tissue material may not be appropriate when using acellular dermal matrix (ADM) for the treatment of gingival recessions. This article describes a new surgical technique that addresses the unique and sensitive aspects of ADM specifically to improve esthetic outcomes and gain increased clinical predictability when treating Miller Class I and II gingival recession defects. In this paper, a root coverage case is described and the specific steps and rationale for this new technique are explained. This technique has been predictable clinically, with results comparable to those achieved using autogenous tissue.

Postoperative complications following gingival augmentation procedures

TJ Griffin, WS Cheung, AL Zavras, PD Damoulis
J Periodontol. 2006; 77:2070-2079

Background: Postoperative pain, swelling, and bleeding are the most common complications following soft tissue grafting procedures; however, detailed documentation is sparse in the literature. The aims of this prospective study were as follows: 1) to compare the frequency of complication occurrence after free soft tissue grafting (FSTG) or subepithelial connective tissue grafting (SCTG) procedures; 2) to evaluate the use of an acellular dermal matrix (ADM) as the donor tissue alternative to an FSTG or SCTG; and 3) to identify possible predictors for these complications.

Methods: Seventy-five FSTG and 256 SCTG procedures were performed in 228 patients by a single operator. In five free soft tissue and 84 bilaminar graft procedures, an ADM was used instead of autogenous tissue. Variables such as the duration and location of procedures, smoking history, gender, and age were recorded. Patients were asked to fill out a questionnaire 1 week after the surgeries regarding postoperative pain, swelling, and bleeding. Data were analyzed using the chi2 test and logistic regression analysis. Odds ratios were calculated for moderate and severe adverse outcomes grouped together.

Results: The duration of surgical procedures was highly correlated with pain or swelling post-surgically (P = 0.001). Current smokers were three times more likely to experience post-surgical swelling (P = 0.01). Patients who underwent FSTG procedures were three times more likely to develop post-surgical pain (P = 0.002) or bleeding (P = 0.03) compared to those who received SCTG procedures. When an ADM was applied instead of autogenous tissue, the probability of swelling or bleeding was significantly reduced (odds ratio [OR] = 0.46, P = 0.02 and OR = 0.3, P = 0.001, respectively).

Conclusions: Long surgical procedures and smoking may increase the severity and frequency of certain post-surgical complications after gingival augmentation procedures. FSTG procedures incur a higher likelihood for postoperative pain or bleeding than SCTG procedures, whereas the application of an ADM may significantly reduce the probability of swelling and bleeding.

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Histologic evaluation of autogenous connective tissue and acellular dermal matrix grafts in humans

LC Cummings, WB Kaldahl, EP Allen
J Periodontol. 2005; 76:178-186

Objectives: The clinical success of root coverage with autogenous connective tissue (CT) or acellular dermal matrix (ADM) has been well documented. However, limited histological results of CT grafts have been reported, and a case report of a human block section has been published documenting an ADM graft. The purpose of this study is to document the histological results of CT grafts, ADM grafts, and coronally advanced flaps to cover denuded roots in humans.

Materials and Methods: This study included four patients previously treatment planned for extractions of three or more anterior teeth. Three teeth in each patient were selected and randomly designated to receive either a CT or ADM graft beneath a coronally advanced flap (tests) or coronally advanced flap alone (control). Six months postoperatively block section extractions were performed and the teeth processed for histologic evaluation with hematoxylin-eosin and Verhoeff's stains.

Results: Histologically, both the CT and ADM were well incorporated within the recipient tissues. New fibroblasts, vascular elements, and collagen were present throughout the ADM, while retention of the transplanted elastic fibers was apparent. No effect on the keratinization or connective tissue organization of the overlying alveolar mucosa was evident with either graft. For both materials, areas of cemental deposition were present within the root notches, the alveolar bone was essentially unaffected, and the attachments to the root surfaces were similar.

Conclusions: Although CT and ADM have a slightly different histological appearance, both can successfully be used to cover denuded roots with similar attachments and no adverse healing.

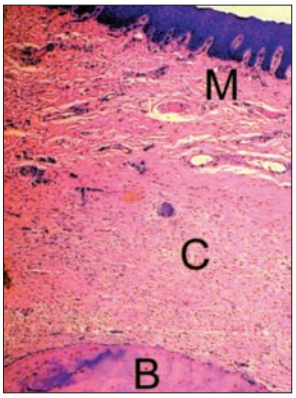

Fig 1. Connective tissue specimen demonstrating mucosal tissue (M) overlying dense grafted connective tissue (C) and osseous crest (B). Original magnification 40X; hematoxylin and eosin (H&E) staining.

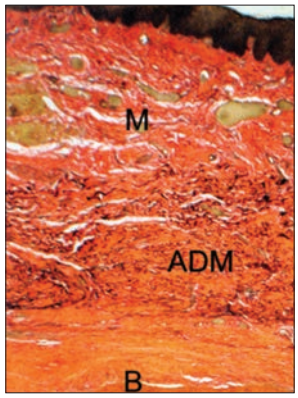

Fig 2. Acellular dermal matrix specimen demonstrating mucosal tissue (M) overlying the area of graft placement (ADM) and osseous crest (B). Original magnification 40X. Verhoff solution stained elastin fibers help differentiate graft area from host tissue.

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Acellular dermal matrix for mucogingival surgery: A meta-analysis

R Gapski, CA Parks, HL Wang
J Periodontol. 2005; 76:1814-1822

Objectives: Many clinical studies revealed the effectiveness of acellular dermal matrix (ADM) in the treatment of mucogingival defects. The purpose of this meta-analysis was to compare the efficacy of ADM-based root coverage (RC) and ADM-based increase in keratinized tissues to other commonly used mucogingival surgeries.

Materials and Methods: Meta-analysis was limited to randomized clinical trials (RCT). Articles from January 1, 1990 to October 2004 related to ADM were searched utilizing the MEDLINE database from the National Library of Medicine, the Cochrane Oral Health Group Specialized Trials Registry, and through hand searches of reviews and recent journals. Relevant studies were identified, ranked independently, and mean data from each were weighted accordingly. Selected outcomes were analyzed using a meta-analysis software program. The significant estimates of the treatment effects from different trials were assessed by means of Cochrane's test of heterogeneity.

Results: 1) Few RCT studies were found to compile the data. In summary, selection identified eight RCT that met the inclusion criteria. There were four studies comparing ADM versus a connective tissue graft for root coverage procedures, two studies comparing ADM versus coronally advanced flap (CAF) for root coverage procedures, and two studies comparing ADM to free gingival graft in augmentation of keratinized tissue. 2) There were no statistically significant differences between groups for any of the outcomes measured (recession coverage, keratinized tissue formation, probing depths, and clinical attachment levels). 3) The majority of the analyses demonstrated moderate to high levels of heterogeneity. 4) Considering the heterogeneity values found among the studies, certain trends could be found: a) three out of four studies favored the ADM-RC group for recession coverage; b) a connective tissue graft tended to increase keratinized tissue compared to ADM (0.52-mm difference; P = 0.11); c) there were trends of increased clinical attachment gains comparing ADM to CAF procedures (0.56-mm difference; P = 0.16).

Conclusions: Differences in study design and lack of data precluded an adequate and complete pooling of data for a more comprehensive analysis. Therefore, considering the trends presented in this study, there is a need for further randomized clinical studies of ADM procedures in comparison to common mucogingival surgical procedures to confirm our findings. It is difficult to draw anything other than tentative conclusions from this meta-analysis of ADM for mucogingival surgery, primarily because of the weakness in the design and reporting of existing trials.

Management of gingival recession by the use of an acellular dermal graft material: a 12-case series

A Santos, G Goumenos, A Pascual
J Periodontol. 2005; 76:1982-1990

Objectives: Different soft tissue defects can be treated by a variety of surgical procedures. Most of these techniques require the palatal area as a donor site. Recently, an acellular dermal graft has become available that can substitute for palatal donor tissue.

Materials and Methods: This study describes the surgical technique for gingival augmentation and root coverage and the results of 12 clinical cases. A comparison between the three most popular mucogingival procedures for root coverage is also presented.

Results: The results of the 12 patients and the 26 denuded surfaces have shown that we can obtain a mean root coverage of 74% with the acellular dermal graft. Thirteen out of the 26 denuded surfaces had complete root coverage. The average increase in keratinized tissue was 1.19 mm. It seems that the long-term results of the cases are stable.

Conclusions: The proposed technique of root coverage with an acellular dermal graft can be a good alternative to soft tissue grafts for root coverage, and it should be part of our periodontal plastic surgery armamentarium.

Reconstructive surgical management of an amalgam tattoo using an acellular dermal matrix graft: case reports

TJ Griffin, SA Banjar, WS Cheung
Compendium. 2005; 26:853-859

Amalgam tattoos in the gingiva and mucosa can interfere with esthetics and present a barrier to surface-to-bone contact at implant sites. Two clinical cases are used to illustrate the effectiveness of acellular dermal matrix allografts in the treatment of these lesions. Very esthetic results were obtained with minimal discomfort and postoperative complications because of the prevention of a second surgical site or additional procedure.

The clinical effect of acellular dermal matrix on gingival thickness and root coverage compared to coronally positioned flap alone

JG Woodyard, H Greenwell, M Hill, C Drisko, JM Iasella, J Scheetz
J Periodontol. 2004; 75:44-56

Objectives: The primary aim of this randomized, controlled, blinded, clinical investigation was to compare the coronally positioned flap (CPF) plus an acellular dermal matrix (ADM) allograft to CPF alone to determine their effect on gingival thickness and percent root coverage.

Materials and Methods: Twenty-four subjects with one Miller Class I or II buccal recession defect of ≥3 mm were treated with a CPF plus ADM or a CPF alone. Multiple additional recession sites were treated with the same flap procedure, and all sites were studied for 6 months. Tissue thickness was measured at the sulcus base and at the mucogingival junction of all teeth, with an SDM ultrasonic gingival thickness meter.

Results: For the ADM sites, mean initial recession of 3.46 mm was reduced to 0.04 mm for defect coverage of 3.42 mm or 99% ($P < 0.05$). For the CPF group, mean initial recession of 3.27 mm was reduced to 1.08 mm for defect coverage of 2.19 mm or 67% ($P < 0.05$). The difference between ADM and CPF groups was statistically significant ($P < 0.05$). Marginal soft-tissue thickness was increased by 0.40 mm ($P < 0.05$) for the ADM group, whereas the CPF group remained essentially unchanged. Keratinized tissue was increased for the ADM group by 0.81 mm ($P < 0.05$), whereas the CPF group increased by 0.33 mm ($P > 0.05$). No additional root coverage was gained due to creeping attachment between 2 and 6 months for either group.

Conclusions: Treatment with a CPF plus an ADM allograft significantly increased gingival thickness when compared with a CPF alone. Recession defect coverage was significantly improved with the use of ADM.

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Clinical evaluation of acellular allograft dermis for the treatment of human gingival recession

ME Aichelmann-Reidy, RA Yukna, GH Evans, HF Nasr, ET Mayer
J Periodontol. 2001; 72:998-1005

Background: Periodontal root coverage procedures to treat recession areas are indicated for unesthetic, exposed, and/or painful root surfaces. Many methods, most using autogenous soft tissue grafts, have been utilized, but with associated morbidity at the donor sites. An alternative donor material would reduce the morbidity and provide for sufficient available donor tissue.

Methods: An acellular allogeneic dermal connective tissue matrix (AD) and autogenous palatal connective tissue (CT) were compared as subepithelial grafts for the treatment of gingival recession. Twenty-two patients with similar isolated gingival recession of ≥2 mm on 2 separate teeth were treated with the subepithelial graft technique. Exposed roots were hand root planed only and, by random allocation, either a fitted AD or fitted CT graft was secured in place and covered by coronally positioned flaps.

Results: Mann Whitney U test analysis found the following changes at 6 months for AD and CT, respectively, compared to presurgical conditions: root coverage of 1.7 ± 1.2 (65.9%) and 2.2 ± 1.1 mm (74.1%) (both P <0.01), increase in keratinized tissue (KT) of 1.2 ± 1.3 and 1.6 ± 1.9 (both P ≤0.01), and an increase in gingival thickness with both; 83.2% of expected root coverage was obtained with AD and 88.6% with CT (P = 0.43). There were no significant differences between treatments for any parameter. Global assessments by clinicians and patients suggested a more esthetic clinical result with AD.

Conclusions: These results suggest that acellular allogeneic dermal matrix may be a useful substitute for autogenous connective tissue grafts in root coverage procedures.

Predictable multiple site root coverage using an acellular dermal matrix allograft

RD Henderson, H Greenwell, C Drisko, FJ Regennitter, JW Lamb, MJ Mehlbauer, LJ Goldsmith, G Rebitski
J Periodontol. 2001; 72:571-582

Background: The primary aim of this randomized, controlled, blinded clinical investigation was to determine if orientation of an acellular dermal matrix (ADM) allograft, basement membrane side against the tooth or connective tissue side against the tooth, affected the percent root coverage. Additional aims were to: 1) compare results of this study with results obtained from other root coverage studies; 2) determine if multiple additional sites could be successfully covered with the same surgery; 3) determine the effect of the procedure on keratinized tissue; and 4) evaluate the amount of creeping attachment obtained.

Methods: Ten patients with 2 Miller Class I or II buccal recession defects > or =3 mm were treated with a coronally positioned flap plus ADM and followed for 12 months. Test sites received ADM with the basement membrane side against the root (AB), while the control sites received the connective tissue side against the root (AC). Multiple additional recession sites were treated with the same flap procedure.

Results: Mean baseline recession for the AB sites was 4.2 mm and for the AC sites, 3.7 mm. Mean root coverage of 95% was obtained for both AB and AC sites. Sixty-eight additional Class I or II AB and AC sites obtained about 93% root coverage. The mean increase in keratinized tissue for both treatments was 0.80 mm. No additional root coverage was gained due to creeping attachment between 2 and 12 months.

Conclusions: Treatment with ADM was an effective and predictable procedure for root coverage. The orientation of the material did not affect the treatment outcome for any of the parameters tested.

The influence of the bucco-palatal distance on sinus augmentation outcomes

G Avila, HL Wang, P Galindo-Moreno, CE Misch, RA Bagramian, I Rudek, E Benavides, I Moreno-Riestra, T Braun, R Neiva

J Periodontol. 2010; 81:1041-1050

Background: Maxillary sinus augmentation is one of the most reliable implant site development options to increase vertical bone height. However, graft consolidation requires adequate angiogenesis and migration of cells involved in osteogenesis and bone remodeling. It is speculated that these biologic events are greatly determined by the dimensions of the maxillary sinus cavity. Hence, the purpose of this study is to assess the influence of the distance from the lateral to the medial wall of the maxillary sinus on the outcomes of sinus augmentation procedures.

Methods: A total of 25 patients in need of sinus augmentation were recruited for the study. After initial examination, customized radiographic and surgical guides were fabricated and a cone-beam computerized tomography scan was obtained per patient. The bucco-palatal distance (BPD) was measured at 8, 10, and 12 mm from the alveolar crest. Sinus grafting was performed by a lateral window approach using a particulated allograft material. Patients were followed-up for 6 months. At the time of implant placement, bone core biopsies were harvested using the radiographic-surgical guide. Sections of the bone cores at 8, 10, and 12 mm from the alveolar crest were histomorphometrically analyzed. The proportion of vital bone (%VB) was correlated with the BPD using a statistical model.

Results: Twenty-one patients underwent sinus augmentation for a total of 24 sinuses; however, the data analyzed contained only one sinus per patient. One sinus developed an infection after grafting, resulting in a 96% success rate for the sinus grafting procedure. Twenty sinuses were used in the final statistical analysis. Histomorphometric analysis revealed that mean %VB was 22.71 ± 19.08, mean percent of remaining allograft was 23.39 ± 20.85, and average percent of non-mineralized connective tissue was 53.90 ± 13.23. Analysis of the correlation between %VB and BPD by linear regression, using the actual values of BPD showed a strong negative association (R2 = 0.141; P <0.001).

Conclusions: The findings suggest that the %VB formation after maxillary sinus augmentation is inversely proportional to the sinus BPD.

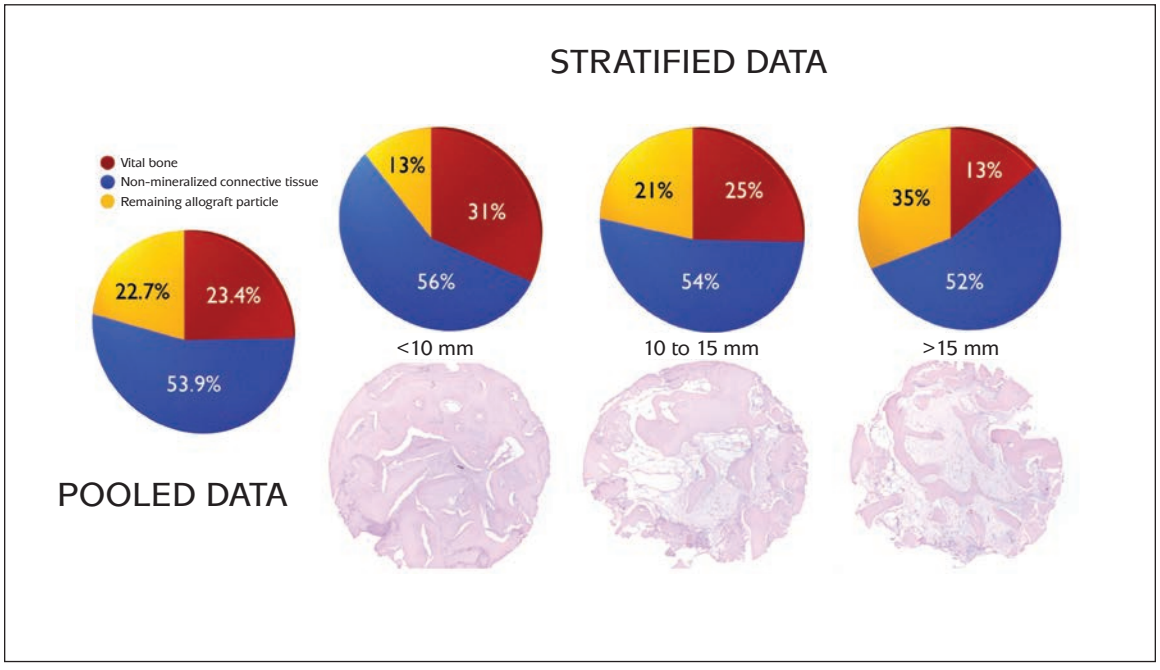

Fig 1. Diagrams showing the total mean values of each element analyzed in the histologic samples, including vital bone, remaining allograft particle, and non-mineralized connective tissue (left, pooled data), and the variation in percentage of vital bone, percentage of remaining allograft particle, and percentage of remaining non-mineralized connective tissue expressed in function of three categories of bucco-palatal distance (right, stratified data). Categories are matched with representative histologic samples (bottom).

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Clinical and histologic outcomes after the use of a novel allograft for maxillary sinus augmentation: A case series

G Avila, R Neiva, CE Misch, P Galindo-Moreno, E Benavides, I Rudek, HL Wang

Implant Dent. 2010; 19:330–341

Purpose: To document the clinical and histologic outcomes of sinus augmentation using a novel allogenic bone substitute as a sole grafting material.

Materials: Patients in need of sinus augmentation before implant placement were recruited for this study. Sinus augmentation procedures were performed following a lateral approach, using a freeze-dried allograft as the only grafting material. Patients were followed up postoperatively for 6 months. Plaque score, wound healing, and patient discomfort were recorded at each follow-up visit. Implants were placed between 6 and 7 months after sinus augmentation and restored 6 months later. Bone core biopsy specimens were harvested at the time of implant placement and processed for histologic and histomorphometrical analysis. Vital bone, remaining allograft (RA) particles, and nonmineralized tissue percentages were assessed on each sample. Results were expressed as mean percentages with SD.

Results: Of the 23 sinus patients, 20 patients underwent sinus augmentation surgery. All patients had satisfactory postoperative healing in the absence of complications. A total of 39 implants were placed. One implant failed and was replaced 3 months later. Histologic analysis revealed the presence of well-organized lamellar bone, in direct contact with RA particles. Mean vital bone was 23.02 ± 19.11%, mean RA was 22.25 ± 20.30%, and average nonmineralized tissue was 54.73 ± 13.51%.

Conclusions: Clinical and histologic findings support the suitability of an allograft consisting of a combination of cortical and cancellous chips for sinus augmentation procedures.

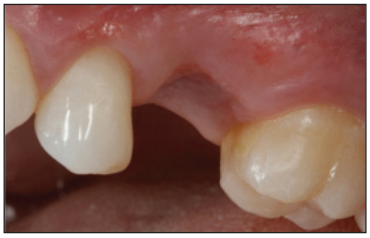

Fig 1. Preoperative view of surgical area

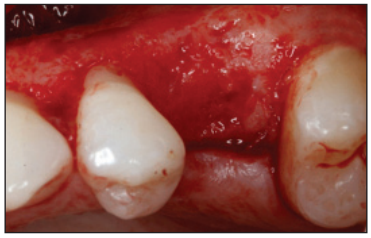

Fig 2. Elevation of mucoperiosteal flap

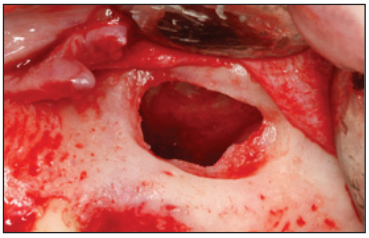

Fig 3. Lateral window

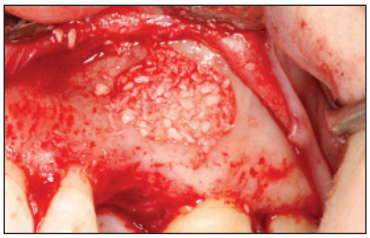

Fig 4. Sinus cavity filled with the allograft

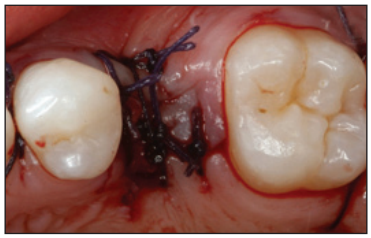

Fig 5. Primary closure achieved after suture

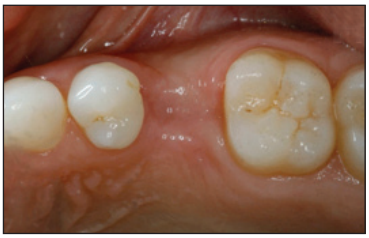

Fig 6. Postoperative aspect at 2 months

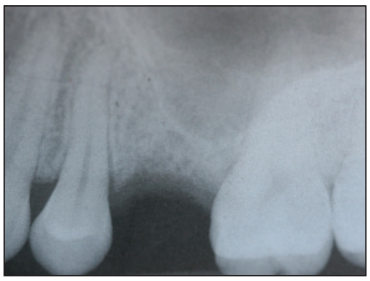

Fig 7. Baseline periapical radiograph

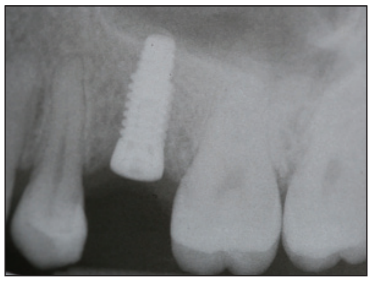

Fig 8. Implant placement

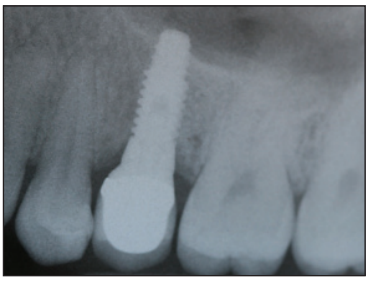

Fig 9. Final restoration delivery

Esthetic zone implant therapy: A sequential protocol for soft- and hard-tissue regeneration of single-tooth extraction sites

MA Pikos, DDS

Inside Dentistry. 2009 FEB; 28-30, 32-35

Abstract: With the profession's increasing focus on conservative esthetic dentistry, single-tooth implant reconstruction has become the therapy of choice for tooth replacement in the presence of adjacent healthy natural dentition and dentoalveolar tissues. In contrast to the posterior single-tooth implant, the esthetic zone single-tooth implant can provide a myriad of technical, surgical, and regenerative challenges for the surgeon directly proportional to localized clinical pathology and remaining hard- and soft-tissue extraction-socket architecture. In an ongoing effort to restore and mimic nature, this article presents a sequential management protocol for anterior single-tooth extraction sites that can result in predictable tissue regeneration appropriate to the demands of an optimized esthetic zone implant rehabilitation.

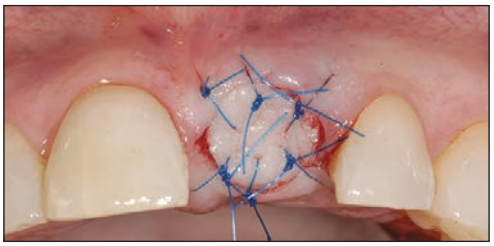

Fig 1. Completed socket graft with free gingival palatal graft.

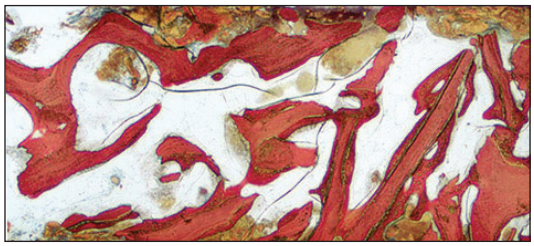

Fig 2. Histomorphometic analysis revealed 87% vital bone; type II quality bone.

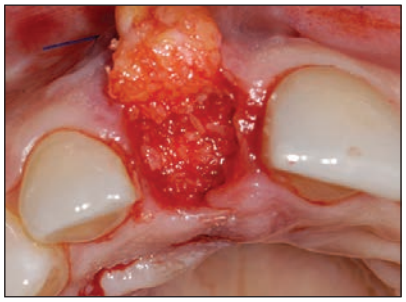

Fig 3. Socket grafted with mineralized irradiated bone allograft.

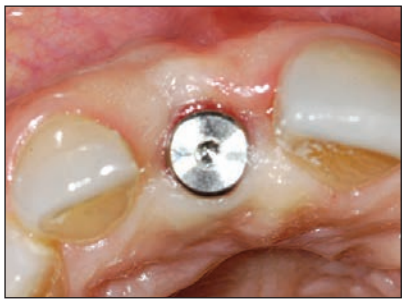

Fig 4. Positive labial plate contour, 3 months after graft placement.

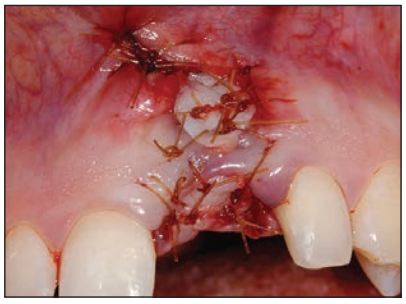

Fig 5. Socket graft completed with mineralized bone allograft, connective tissue graft, and two free gingival tissue grafts.

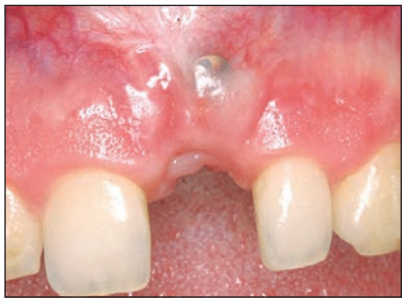

Fig 6. Mandibular block graft for lateral bone augmentation, 4 months after initial socket grafts.

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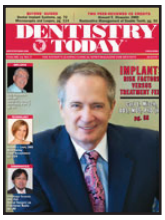


Socket grafting and alveolar ridge preservation

CE Misch, DDS, MDS, PhD, JT Silc, DDS, MS

Dentistry Today. 2008 OCT; 146, 148, 150, 152

Abstract: There are 2 fundamental concepts that determine the position of an individual implant within a treatment plan: biomechanics and aesthetics. Both of these concepts require adequate bone volume to accomplish their goals. If the available bone is inadequate, bone augmentation is indicated. At some point in time, the dental practitioner may decide to remove a natural tooth. Hopeless or unrestorable teeth may be related to periodontal, endodontic, prosthetic, and/or orthodontic failures. Once the extraction of a natural tooth is indicated, methods to maintain (or obtain) the surrounding hard and soft tissues are in order. Over the last decade, there has been an increased interest in socket grafting in order to maintain or obtain bone for implant insertion after a tooth is extracted.

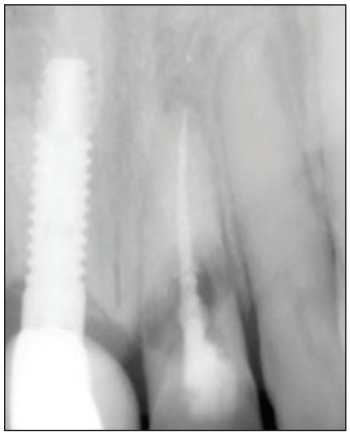


Fig 1. An x-ray of a maxillary central incisor with internal resorption and a 6-year postop implant replacing the other central incisor.

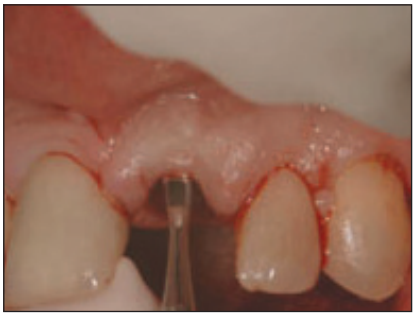


Fig 2. The tooth is removed. Since the labial plate of bone is thin (or absent), a periostome is used to form a subperiosteal tunnel over the site.

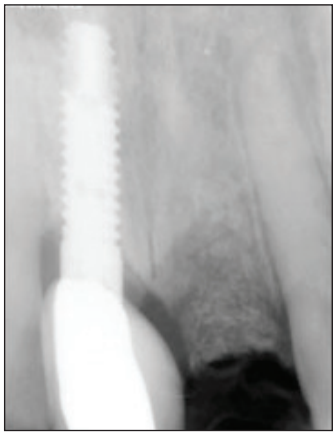


Fig 3. An immediate postop radiograph demonstrates the extraction site with FDB (MinerOss) in situ.

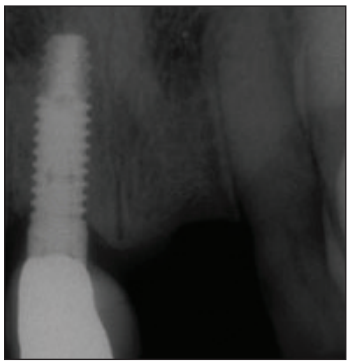


Fig 4. A 4-month postop radiograph demonstrates a lack of lamina dura from the extraction site and most of the graft is incorporated into the area.

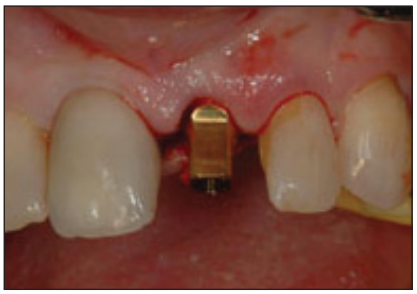


Fig 5. An implant (BioHorizons Maestro) is inserted into the site, 5 months after the socket graft.

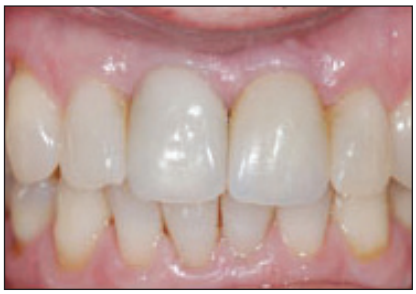


Fig 6. 4 months after implant insertion, a crown is cemented onto the implant.

Histological, histomorphometric, and radiographic evaluation of a sinus augmentation with a new bone allograft: A clinical case report

R Gapski, C Misch, D Stapleton, S Mullins, C Cobb, A Vansanthan, M Reissner
Implant Dent. 2008; 17:430-438

Purpose: This case report documents the histological, histomorphometric, and radiographic effects of a new radiated-preserved bone allograft for sinus elevation procedures.

Materials and Methods: This unique bone substitute differs from other forms of bone allograft processed through the standard cryopreservation method. Histology from bone biopsy core samples revealed newly formed bone with a well-organized lamellar bone structure in general and remaining particles were observed in contact with surrounding newly-formed bone.

Results: Histomorphometric results demonstrated an average new bone formation of 31.8%. Radiographic linear data demonstrated an 8.49% ± 6.77% graft resorption from baseline to 6 months.

Conclusions: The outcome of this report suggests that this bone allograft could be successfully used in sinus lifting procedures. It encourages further research of this radiated-preserved bone allograft material in oral and maxillofacial reconstruction.

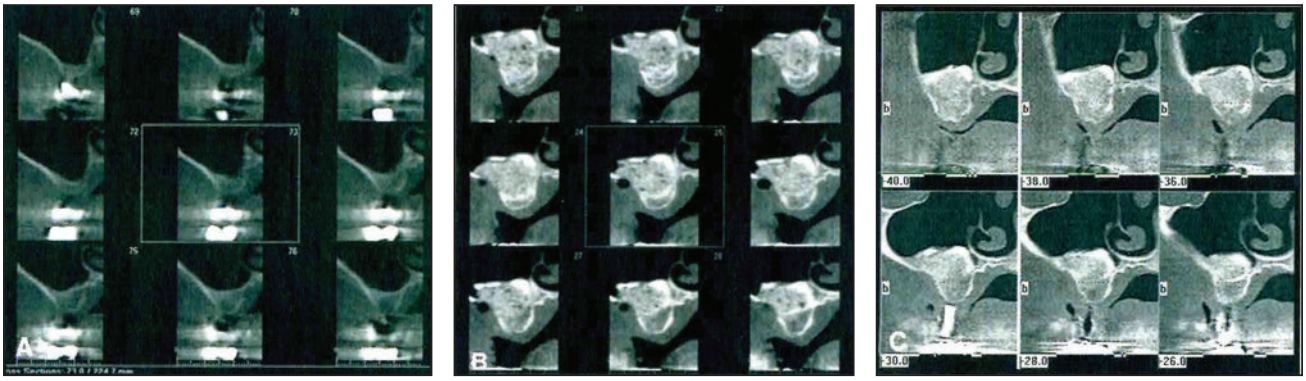
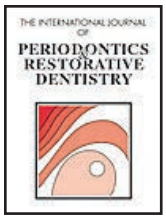


Fig 7. Cone beam CT scans at before surgery (A), baseline [day of the graft (B) and 6 months postop (C)]. Radiographic linear data have shown an 8.49 ± 6.77% graft resorption from baseline to 6 months. Interestingly, the bone allograft seemed very similar to the original host bone since baseline on CBCT images (B-C).

Grafton® DBM



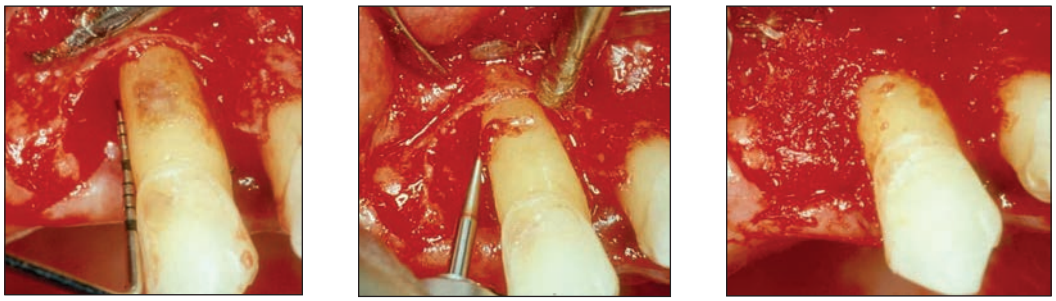
Histologic and clinical evaluation of an allogeneic bone matrix for the treatment of periodontal osseous defects

JT Mellonig

Int J Periodontics Restorative Dent. 2006; 26:561-569

The objective of this study was to evaluate the potential of an allogeneic bone matrix (Grafton DBM) to regenerate new bone, new cementum, and a new periodontal ligament around teeth previously contaminated by bacterial plaque. Four patients with chronic advanced periodontitis and who were scheduled for full-mouth extraction were enrolled in the study. One patient dropped out from the study before any therapy began. One tooth with an intraosseous defect in each patient was selected for treatment.

Measurements of probing depth, gingival recession, and clinical attachment level were made. After flap reflection, a root notch was placed at the apical level of calculus, the root was debribed, and allogenic bone matrix was inserted into the defect. After 6 months of healing, the teeth were removed en bloc and evaluated histologically for a new attachment apparatus. Two of the three teeth demonstrated regeneration of new bone, cementum, and periodontal ligament.



A) B) C)

Fig 1. A) The gingival tissue is reflected, demonstrating calculus on the root surface and a two- to three-walled, noncontained osseous defect. B) A notch through the root can be observed. The osseous is debribed and the root surface planed. C) The osseous defect is grafted with Grafton DBM.

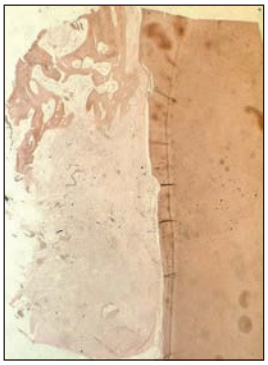


Fig 2 (left). Histologic section of the distal of the maxillary right canine (H&E; x 10).

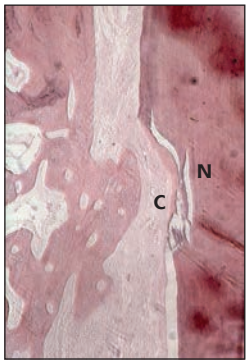


Fig 3 (right). Area of root notch (N), artifactual separation of new cementum (C) from root surface, and new bone (H&E; x 25).

Histologic analysis of implant sites after grafting with demineralized bone matrix putty and sheets

DP Callan, SL Salkeld, NL Scarborough

Implant Dent. 2000; 9:36-42

Grafting to restore lost alveolar bone is frequently used to enable placement of endosseous implants and improve cosmesis. Conflicting reports concerning the osteoinductivity of demineralized bone matrix (DBM) and historical use of synthetic bone graft substitutes has limited the use of DBM in oral and maxillofacial applications. Implant placement after bone grafting provides the unique opportunity to biopsy and histologically evaluate new bone formation. Bone grafting of the mandible or maxilla was performed to fill extraction sockets and restore ridge structures in a consecutive series of eight patients. DBM prepared as malleable putty (Grafton DBM Putty) or flexible sheets (Grafton DBM Flex) was used.

Biopsies were taken at re-entry, and histologic analysis determined the amount and quality of regenerated bone. Extensive new bone formation and minimal residual bone graft matrix were observed at an average of five months postoperative. The pattern of new bone maturity and remodeling varied by patient and the time in situ. Putty and Flex regenerated excellent bone height and width for the placement of dental implants, were easy to handle intraoperatively, and readily conformed to bony defects.

MASTERGRAFT® Granules

Histologic evaluation of human alveolar sockets treated with an artificial bone substitute material

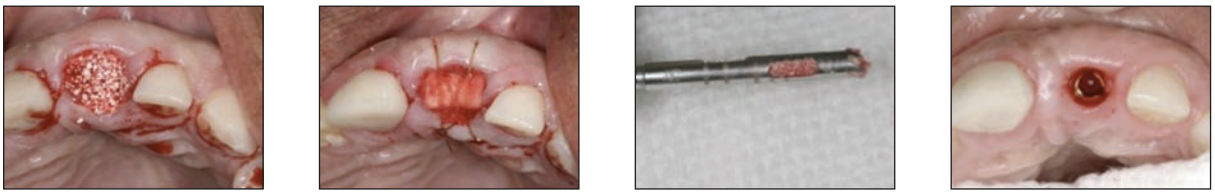
M Wakimoto, T Ueno, A Hirata, S Iida, T Aghaloo, PK Moy

J Craniofac Surg. 2011; 22:490-493

Abstract: This study involved a histologic, enzyme histologic, immunohistologic, and three-dimensional microstructure evaluating the extent of osteogenesis and repair in the human alveolar extraction socket achievable with an artificial bone substitute. After tooth extraction in 7 patients, extraction sockets were filled with MASTERGRAFT (15% hydroxyapatite, 85% A-tricalcium phosphate complex). Radiomicrographs and histologic examinations were performed on samples obtained during dental implant placement procedure. On microcomputed tomography, new bone was observed in all collected samples, and osteogenesis was observed to have taken place around the artificial bone substitute. Histologically, active osteogenesis was found throughout the region observed. Addition of new bone around the MASTERGRAFT was observed, and osteoblast-like cells were present. Cells that had partially invaded the artificial bone included tartrate-resistant acid phosphate-positive and CD34-positive cells. These findings indicate that the MASTERGRAFT artificial bone induced osteogenesis in the jawbone and seemed effective for repairing bone defects.

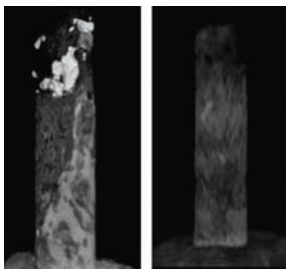
Patients: This study included 7 patients in good general health (2 men and 5 women; mean age, 55.9 ± 18.5 y; range, 35-82 y). All patients required tooth extractions for reasons such as advanced periodontitis or tooth trauma and replacement with dental implants. Informed consent was obtained from all patients for all phases of surgical treatment. Grafts were performed using MASTERGRAFT (Medtronic, Minneapolis, MN), a composite consisting of 15% HA and 85% β-TCP. This material has a porosity rate of 80%, a mean pore size of 500 µm, and an interconnected diameter of 125 µm.

Histologic, Enzyme Histologic, and Immunohistochemical Observations: Specimens were fixed with 4% paraformaldehyde in 0.1 M phosphate buffer (pH 7.4) at 4°C for 24 hours and then decalcified in 5% ethylenediaminetetraacetate in 0.1 M phosphate buffer (pH 7.4) for 20 days. After dehydration in a graded ethanol series and embedding in paraffin, sections cut to a thickness of 6 µm were mounted on glass slides and rehydrated. Some slides were stained with hematoxylin and eosin for light microscopic observation. The remaining slides were immersed in 5 mM periodic acid for 10 minutes to inhibit endogenous peroxidase before blocking with 10% bovine serum in phosphate-buffered saline (PBS) for 30 minutes at room temperature. Slides for detection of CD34, as a marker of vascular endothelial cell surface antigen, were exposed to anti-CD34 monoclonal antibody (Nichirei Biosciences, Inc, Tokyo, Japan). Slides for OPN, as a marker of bone formation, were exposed to anti-OPN polyclonal antibody (donated by Dr. Nakamura, Matsumoto, Japan) and diluted 1:1000 in PBS containing 3% bovine serum albumin at 4°C overnight. After incubation, slides were exposed to Histofine Simple Stain MAX-PO (Multi) (Nichirei Biosciences, Inc) for 60 minutes at room temperature. After washing in PBS, slides were incubated for 5 minutes at room temperature in a solution containing 0.05% 3,3'-diaminobenzidine tetrahydrochloride, 0.01% hydrogen peroxide, and 0.05 M Tris-HCl (pH 7.6) to visualize the immune complexes. Sections were counterstained with hematoxylin. As a positive control, rabbit and mouse IgG preimmune serum were used to confirm immunoreaction. For a negative control, some slides were incubated with 3% bovine serum albumin in PBS instead of the primary antibody. To detect osteoclastic cells, TRAP staining was performed.



A) B) C) D)

Fig 1. Intraoperative photograph. A) MASTERGRAFT granules placed into the extracted socket as a graft material. B) MASTERGRAFT granules were covered with a cellulose sponge. C) Bone core samples were taken from the grafted sites at 4 months after grafting. D) Installed implant into the grafted site at 4 months after grafting.



A) B)

Fig 2. Micro-CT scan of core samples. A) Core samples from MASTERGRAFT granules. Clearwhite radiopaque images show MASTERGRAFT granules, and dark radiopaque shows new bone formation. B) Core samples from normal alveolar bone.

INFUSE® Bone Graft

De novo bone induction by recombinant human bone morphogenetic protein-2 (rhBMP-2) in maxillary sinus floor augmentation

PJ Boyne, LC Lilly, RE Marx, PK Moy, M Nevins, DB Spagnoli, RG Triplett
J Oral Maxillofac Surg. 2005; 63:1693-1707

Purpose: This phase II study was designed to evaluate 2 concentrations of recombinant human bone morphogenetic protein-2 (rhBMP-2) for safety and efficacy in inducing adequate bone for endosseous dental implant in patients requiring staged maxillary sinus floor augmentation.

Materials and Methods: Patients were treated with rhBMP-2 (via an absorbable collagen sponge [ACS]), at concentrations of 0.75 mg/mL (n=18), 1.50 mg/mL (n=17), or with bone graft (n=13). Bone induction was assessed by alveolar ridge height, width, and density measurements from computed tomography scans obtained before and 4 months after treatment and 6 months post-functional loading of dental implants (density only).

Results: Mean increases in alveolar ridge height at 4months after treatment were similar among the groups; 11.3 mm, 9.5 mm, and 10.2 mm, respectively, in the bone graft, 0.75 mg/mL, and 1.50 mg/mL rhBMP-2/ACS treatment groups. Mean increases in alveolar ridge width (buccal to lingual) at the crest of the ridge were statistically different among the treatment groups; 4.7 mm, 2.0 mm, and 2.0 mm, respectively, in the bone graft, 0.75 mg/mL, and 1.50 mg/mL treatment groups ($P \leq .01$ vs 0.75 mg/mL; $P < .01$ vs 1.50 mg/mL). At 4 months postoperative new bone density was statistically different among the treatment groups; 350 mg/cc, 84 mg/cc, and 134 mg/cc for the bone graft, 0.75 mg/mL, and 1.50 mg/mL rhBMP-2/ACS treatment groups, respectively ($P = .003$ vs 0.75 mg/mL, $P = .0137$ vs 1.50 mg/mL, $P = .0188$; 1.50 mg/mL vs 0.75 mg/mL). Core bone biopsies obtained at the time of dental implant placement confirmed normal bone formation. The proportion of patients who received dental implants that were functionally loaded and remained functional at 36 months post-functional loading was 62%, 67%, and 76% in the bone graft, 0.75 mg/mL, and 1.50 mg/mL rhBMP-2/ACS treatment groups, respectively.

Conclusion: This study is the first randomized controlled trial demonstrating *de novo* organ tissue growth in humans from a recombinant human protein. rhBMP-2/ACS safely induced adequate bone for the placement and functional loading of endosseous dental implants in patients requiring staged maxillary sinus floor augmentation.

Table 1: Newly Induced Bone Density (mg/cc)

Variable	Statistic	Bone Graft (n-13)	rhBMP-2/ACS 0.75 mg/mL (n=18)	rhBMP-2/ACS 1.5 mg/mL (n=17)	*P* Value
Density at 4 mos	N (observed)	13	18	15	.0003*‡
	Mean	350	84	137	
	SD	243	50	77	
	Max	41	23	33	
	Median	337	68	121	
	Min	797	240	335	
Density at 6 mos post-functional loading	N (observed)	8	11	11	.6452†
	Mean	448	456	508	
	SD	213	131	126	
	Max	81	244	353	
	Median	494	532	456	
	Min	689	615	705	

* *P* value is from non-parametric Kruskal-Wallis test.
† *P* value is from ANOVA F-test.
‡ Indicates the *P* value is less than .05.

INFUSE® Bone Graft

Pivotal, randomized, parallel evaluation of recombinant human bone morphogenetic protein-2/absorbable collagen sponge and autogenous bone graft for maxillary sinus floor augmentation

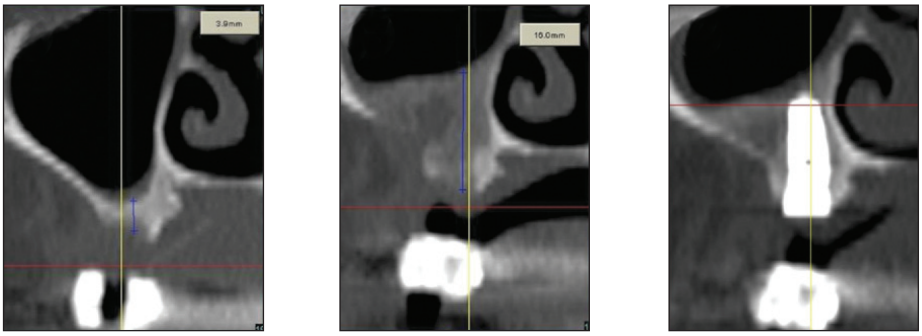
RG Triplett, M Nevins, RE Marx, DB Spagnoli, TW Oates, PK Moy, PJ Boyne
J Oral Maxillofac Surg. 2009; 67:1947-1960

Purpose: The purpose of this prospective study was to evaluate the safety and effectiveness of recombinant human morphogenetic protein-2 (rhBMP-2) on an absorbable collagen sponge (ACS) compared with an autogenous bone graft when used for 2-stage maxillary sinus floor augmentation. The study assessed new bone formation, placement integration, and functional loading after 6 months and long term for 2 years.

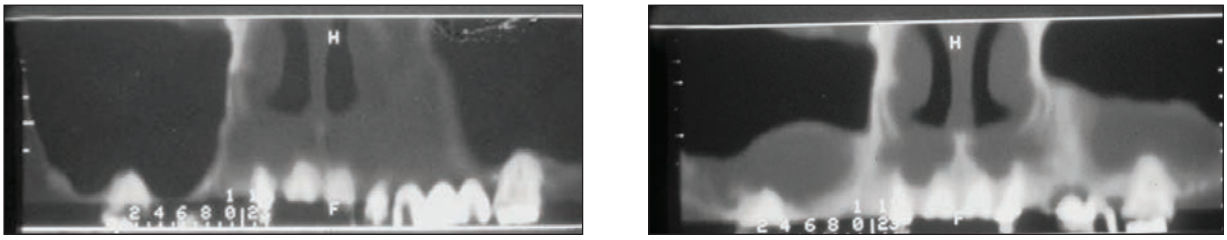
Materials and Methods: A total of 160 subjects were randomized, enrolled, and followed from January 1999 to February 2004 at 21 centers in the United States. The subjects with less than 6 mm of native bone height were treated with 1.50 mg/mL rhBMP-2/ACS or with an autograft. The height and density measurements were quantified by computed tomography scans. Core biopsies were obtained at dental implant placement and used for histological analysis. Safety was evaluated by oral examinations, radiographs, serum chemistries, and hematology.

Results: A significant amount of new bone was formed by 6 months postoperatively in each group. The mean change in bone height in the rhBMP-2/ACS subjects was 7.83 ± 3.52 mm versus 9.46 ± 4.11 mm for the bone graft subjects. At 6 months after dental restoration, the induced bone in the rhBMP-2/ACS group was significantly denser than that in the bone graft group. No marked differences were found in the histologic parameters evaluated between the 2 groups. The new bone was comparable to the native bone in density and structure in both groups. The success rate for the rhBMP-2/ACS group was 79% (64 of 81 subjects), and 201 of 251 implants placed in the bone graft group and 199 of 241 implants placed in the rhBMP-2/ACS group were integrated, retained, and functional at 6 months after loading. No adverse events were deemed related to the rhBMP-2/ACS treatment. The autograft group was noted to have a 17% rate of long-term parasthesia, pain, or gait disturbance related to the bone graft harvest.

Conclusions: The results of our multicenter, randomized, prospective, clinical trial have shown the effectiveness and safety of rhBMP-2/ACS compared with bone graft for sinus floor augmentation. The study's primary endpoint was exceeded, and the implants placed in rhBMP-2/ACS and bone graft groups performed similarly after functional loading.



A) B) C)



D) E)

Fig 1. Representative CT scans from A) preoperatively (baseline), B) 6 months after treatment, and C) after dental implant placement in rhBMP-2/ACS subject. Bone height increased from 3.9 mm at baseline to 16.0 mm at 6 months postoperatively. D) Preoperative panoramic radiograph revealing deficient bone in posterior maxilla and E) panoramic radiograph 6 months after treatment revealing *de novo* bone formation.

INFUSE® Bone Graft

Randomized study evaluating recombinant human bone morphogenetic protein-2 for extraction socket augmentation

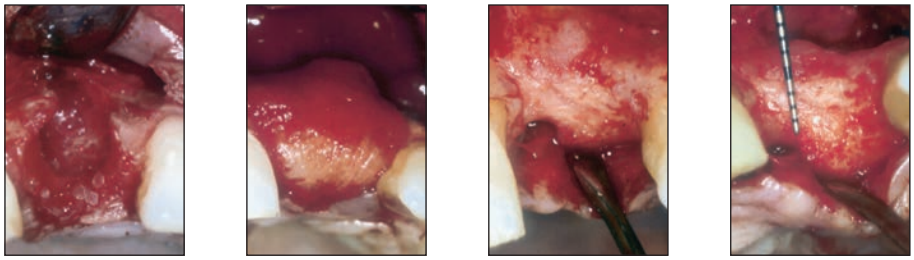
JP Fiorellini, TH Howell, D Cochran, J Malmquist, LC Lilly, D Spagnoli, J Toljanic, A Jones, M Nevins
J Periodontol. 2005; 76:605-613

Background: Conventional dentoalveolar osseous reconstruction often involves the use of grafting materials with or without barrier membranes. The purpose of this study was to evaluate the efficacy of bone induction for the placement of dental implants by two concentrations of recombinant human bone morphogenetic protein-2 (rhBMP-2) delivered on a bioabsorbable collagen sponge (ACS) compared to placebo (ACS alone) and no treatment in a human buccal wall defect model following tooth extraction.

Methods: Eighty patients requiring local alveolar ridge augmentation for buccal wall defects (≥50% buccal bone loss of the extraction socket) of the maxillary teeth (bicuspids forward) immediately following tooth extraction were enrolled. Two sequential cohorts of 40 patients each were randomized in a double-masked manner to receive 0.75 mg/ml or 1.50 mg/ml rhBMP-2/ACS, placebo (ACS alone), or no treatment in a 2:1:1 ratio. Efficacy was assessed by evaluating the amount of bone induction, the adequacy of the alveolar bone volume to support an endosseous dental implant, and the need for a secondary augmentation.

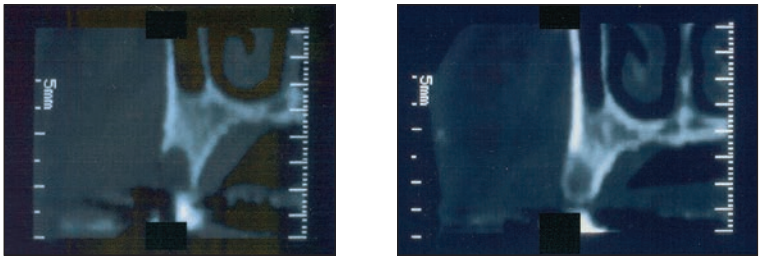
Results: Assessment of the alveolar bone indicated that patients treated with 1.50 mg/ml rhBMP-2/ACS had significantly greater bone augmentation compared to controls ($P \leq 0.05$). The adequacy of bone for the placement of a dental implant was approximately twice as great in the rhBMP-2/ACS groups compared to no treatment or placebo. In addition, bone density and histology revealed no differences between newly induced and native bone.

Conclusion: The data from this randomized, masked, placebo-controlled multicenter clinical study demonstrated that the novel combination of rhBMP-2 and a commonly utilized collagen sponge had a striking effect on *de novo* osseous formation for the placement of dental implants.



A) B) C) D)

Fig 1. A) Extraction site (tooth #9) exhibiting greater than 50% buccal bone height loss. B) Treatment site with 1.5 mg/ml rhBMP-2/ACS contour to reconstruct alveolar ridge. C) and D) Extraction site following 4 months of healing.



A) B)

Fig 2. A) 1.5 mg/ml rhBMP-2/ACS at Baseline. B) 1.5 mg/ml rhBMP-2/ACS at 4 months.

Mem-Lok®

A resorbable, reconstituted type I collagen membrane for guided tissue regeneration and soft-tissue augmentation

D Yuen, C Junchaya, G Zuclich, JB Ulreich, HB Lin, ST Li
Sixth World Biomaterials Congress Transactions

Introduction: There are several requirements that a resorbable membrane should meet in order for it to be useful for guided tissue regeneration (GTR) and soft tissue augmentation applications. The membrane should be resorbable, have sufficient mechanical strength to permit suturing of the membrane to the host, be permeable to nutrients and be biocompatible. The particular medical application will define the specifications of each requirement. We present here a new resorbable, reconstituted type I collagen membrane for use in GTR or as a patch for soft tissue augmentation. The results of a comparison between this membrane and a collagen membrane currently marketed for GTR applications are also discussed.

Methods: Collagen Membrane: Two types of collagen membrane were fabricated from purified type I collagen fibers. The collagen fibers were dispersed in an acid solution (pH 2.5), homogenized, filtered, reconstituted, freeze dried, crosslinked, and sterilized by irradiation. Characterization: Suture pull-out strength: A size 3-0 silk suture was passed through the membrane, 1.5 cm x 2.0 cm, at about 3 mm from the edge and a loop was tied. The membrane was hydrated in 0.01 M phosphate buffer, pH 7.0, for 10 minutes. The loop was attached to a force gauge (Chatillon, Greensboro, NC) and the sample was secured onto a clamping fixture. The sample was pulled at a rate of 1 inch per minute until the suture was pulled out. The force was recorded. Permeability: The permeability of the membrane was determined by inserting a sample, 2.0 cm x 2.0 cm, into a specially designed chamber, which is separated into two isolated compartments. On one side of the chamber, a fixed volume of phosphate buffered saline (PBS) containing 50 µg of carbonic anhydrase (CA) (MW 29,000) per ml was added. The opposite side was filled with the same volume of PBS only. The chamber containing the membrane was allowed to equilibrate for 24 hours and the CA assay was conducted on the side initially without CA by the Coomassie plus assay.* *In Vivo* Resorption Studies: A total of 11 rats were used. Each rat received a 1cm^2 membrane implanted subcutaneously. Animals were sacrificed at 4, 8, 12, and 24 weeks after implantation. The explants were evaluated histologically for collagen membrane remaining, tissue reaction and new collagen deposition using standard histologic techniques. Biocompatibility: Biocompatibility testing was conducted on the collagen membrane in accordance with FDA guidelines.

Results: Table 1 summarizes the characterization studies on the two types of collagen membranes, A and B compared to the commercial product Biomend®. The average suture pull-out strength was 350 g and 290 g, respectively for A and B. This strength is significantly higher than for Biomend®. The total resorption time was obtained through extrapolation via curve fit of the experimental data. The resorption times for the membranes were 27 and 18 weeks respectively for A and B. Both membranes A and B were significantly more stable *in vivo* than Biomend®. Both membranes A and B were permeable to CA, which has a size similar to the Biomend® pore structure, and biocompatible.

Discussion: The use of a membrane for GTR in oral surgery often requires the membrane to be permeable for nutrients but not cells so that the membrane can serve as a cell barrier to guide the specific tissue regeneration. Both membranes A and B and Biomend® can serve that function. Very often, the membrane is required to be stabilized with sutures. In this regard, membranes A and B offer advantages over Biomend® in that they have a higher suture pull-out strength. In addition, the *in vivo*, stability of membranes A and B are significantly longer than the Biomend®. Although the significance of this difference is not known, it would be logical to expect that a longer *in vivo* stability may provide an additional margin of efficacy in using the membrane as a cell barrier. The characteristics of membranes A and B also offer potential applications as soft tissue augmentation devices such as patch material for hernia and heart surgeries.

Table 1: Characterization of Collagen Membranes

Test	Membrane A	Membrane B	Biomend®
Suture pull-out strength (g)	350 ± 80	290 ± 70	74 ± 10**
Pore structure	Permeable to CA	Permeable to CA	0.004 µm**
In vivo resorption (weeks)	27	18	4-8**

* Bradford, M.M. Anal. *Biochem.* 72:248, 1976. **Reported from 510K (K924408)

AlloDerm GBR® RTM

Comparison of dermal matrix and polytetrafluoroethylene membrane for socket bone augmentation: A clinical and histologic study

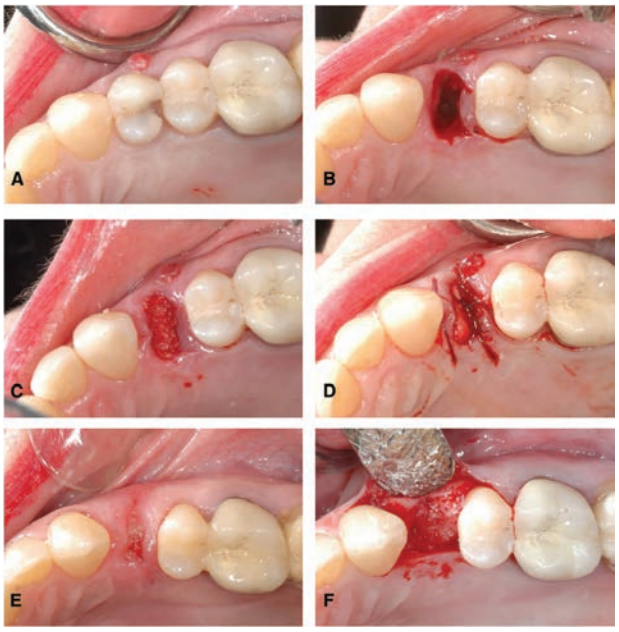
PD Fotek, RF Neiva, HL Wang
J Periodontol. 2009; 80:776-785

Background: Remodeling and resorption of the alveolar crest, specifically at the buccal aspect, characterize the healing extraction socket. These result in narrowing and shortening of the alveolar ridge, which compromise esthetics and complicate restoration. Alveolar ridge augmentation has been proposed to facilitate future site restoration by minimizing ridge resorption. Therefore, the purpose of this study was to compare extraction socket healing and alveolar ridge alteration after socket augmentation using bone allograft covered with an acellular dermal matrix (ADM) or polytetrafluoroethylene (PTFE) membrane.

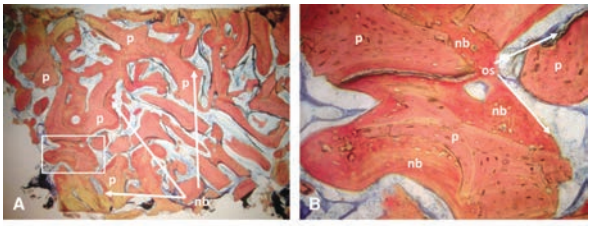
Methods: Twenty non-smoking healthy subjects were selected. Each subject required maxillary premolar, canine, or central incisor tooth extraction. The extraction sites were debrided and grafted with a mineralized bone allograft that was covered with an ADM or PTFE membrane. Postoperative appointments were scheduled at 2, 4, and 8 weeks. After 16 weeks of healing, final measurements were performed, and trephine core biopsies were obtained for histomorphometric analysis. Implants were placed immediately after biopsy harvesting.

Results: Eighteen subjects completed the study. All sites healed without adverse events and allowed for implant placement. PTFE membranes exfoliated prematurely, with an average retention time of 16.6 days, whereas the ADM membranes appeared to be incorporated into the tissues. Buccal plate thickness loss was 0.44 and 0.3mm, with a vertical loss of 1.1 and 0.25 mm, for ADM and PTFE, respectively. Bone quality assessment indicated D3 to be the most prevalent (61%). Histomorphometric analysis revealed 41.81% versus 47.36% bone, 58.19% versus 52.64% marrow/fibrous tissue, and 13.93% versus 14.73% particulate graft remaining for ADM and PTFE, respectively. No statistical difference was found between the two treatment groups for any of the parameters.

Conclusion: All sites evaluated showed minimal ridge alterations, with no statistical difference between the two treatment modalities with respect to bone composition and horizontal and vertical bone loss, indicating that both membranes are suitable for alveolar ridge augmentation.

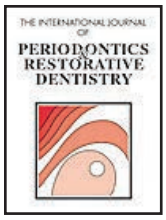


ADM treatment group. A) Hopeless maxillary premolar. B) Site after atraumatic extraction. C) Socket filled with solvent-preserved mineralized cancellous allograft under light pressure. D) Membrane trimmed and placed over bone graft. E) Postoperative 2-week healing. F) Site evaluation at 16 weeks.



Histology of bone cores. A) Bone core specimen from ADM group showing allograft particles (p) with new bone (nb) formation in its surface. B) Magnified view of rectangle in A.

AlloDerm GBR® RTM



Management of localized buccal dehiscence defect with allografts and acellular dermal matrix

SH Park, HL Wang

Int J Periodontics Restorative Dent. 2006; 26:589-595

This case series presents the use of acellular dermal matrix (ADM) as a barrier membrane in reconstructing non-spacemaking buccal dehiscences associated with simultaneous implant placement in locally deficient ridges. Five sites in four healthy nonsmoking patients were treated with a combination of the mucogingival pouch flap technique, sandwiched layering of mineralized human cancellous and cortical bone grafts, and ADM as a barrier membrane. Three sites encountered 2 to 4 mm of membrane exposure after 2 weeks of healing time. However, all sites were completely covered at 3 months. None of the cases exhibited implant exposure throughout the entire healing period. At the 6-month re-entry surgery, ADM-assisted guided bone regeneration achieved a mean of 86.5% height gain and critical bone thickness of 1.8 mm or greater, with clinical bone density equivalent to that of the native bone.

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1. Please see BioHorizons literature ML0130.

2. Heat production by 3 implant drill systems after repeated drilling and sterilization.
Chacon GE, Bower DL, Larsen PE, McGlumphy EA, Beck FM. *J OralMaxillofac Surg.* 2006 Feb;64(2):265-9.

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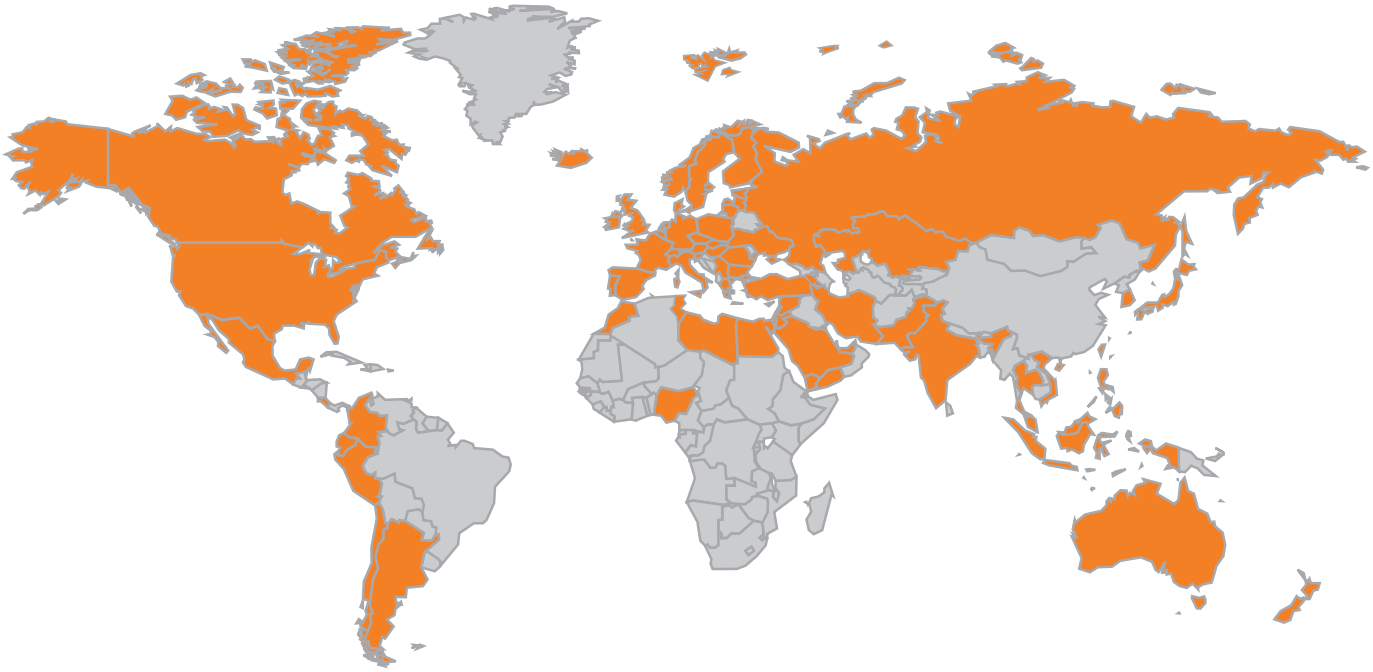

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