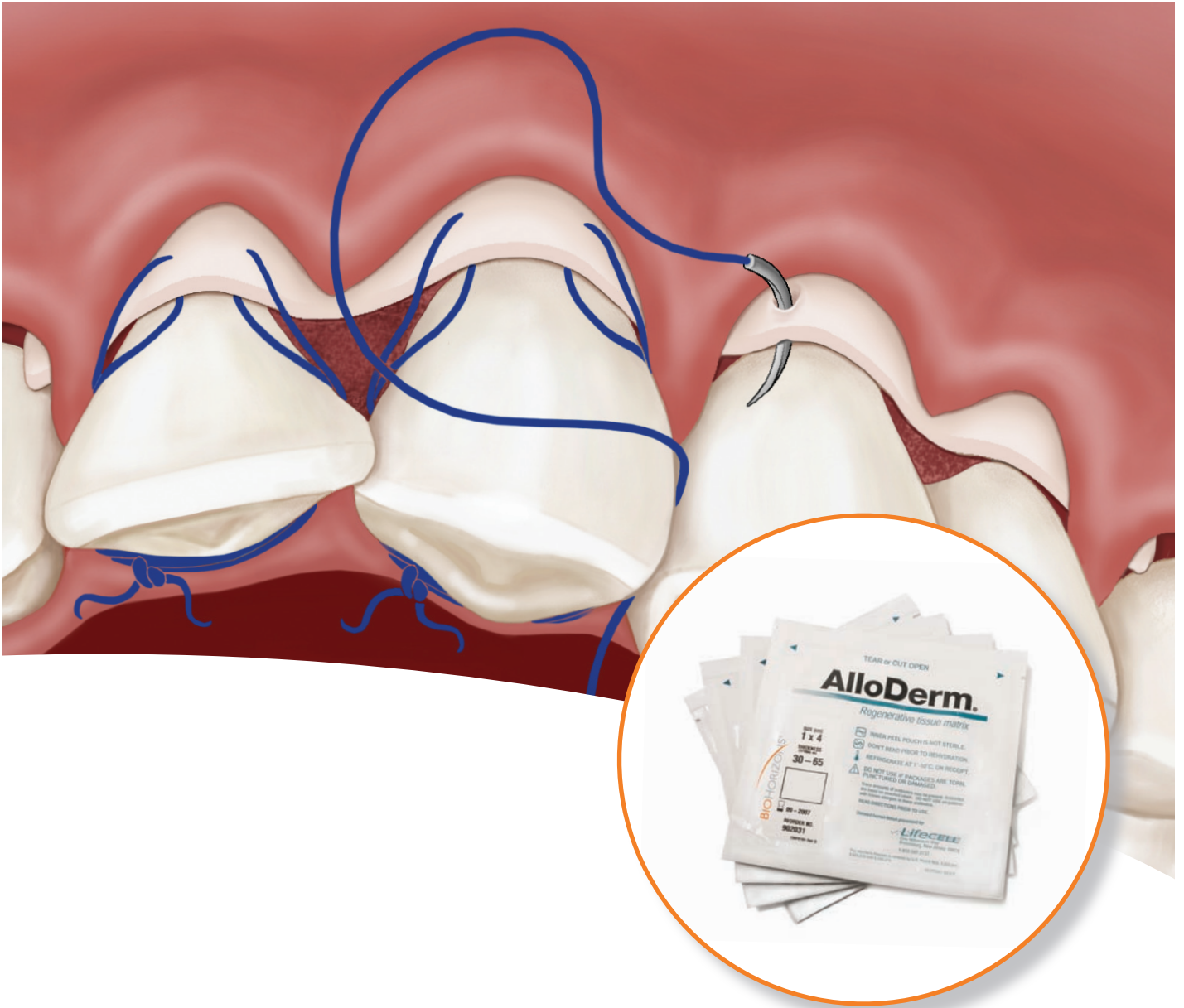


Clinical Abstract Review



BIOHORIZONS[®]
SCIENCE • INNOVATION • SERVICE



Multi-study Meta-Analysis

Acellular Dermal Matrix for Mucogingival Surgery: A Meta-Analysis

Ricardo Gapski, Christopher Allen Parks, and Hom-Lay Wang

Background: 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.

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. *J Periodontol* 2005;76:1814-1822.

Root Coverage: 12-Case Series

Management of Gingival Recession by the Use of an Acellular Dermal Graft Material: A 12-Case Series

A. Santos, G. Goumenos, and A. Pascual

Background: 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.

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.

Conclusion: 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. *J Periodontol* 2005;76:1982-1990.

Root Coverage - 2-year Follow-up

A 2-Year Follow-Up of Root Coverage Using Subpedicle Acellular Dermal Matrix Allografts and Subepithelial Connective Tissue Autografts

A. Hirsch, M. Goldstein, J. Goultschin, B.D. Boyan, and Z. Schwartz

Background: Coverage of roots exposed by gingival recession is one of the main objectives of periodontal reconstructive surgery. A large variety of mucogingival grafting procedures are available. However, the long-term effectiveness of this procedure is still not clear. This study compared the effectiveness of subpedicle acellular dermal matrix allografts with subepithelial connective tissue autografts in achieving root coverage 2 years postoperatively.

Methods: One hundred one (101) patients were treated with dermal matrix allografts (mean age, 28.4 ± 0.7 years; mean recession, 4.2 mm) and 65 patients treated with connective tissue graft (mean age, 30.1 ± 1.4 years; mean recession, 4.9 mm). All patients underwent full periodontal evaluation and presurgical preparation, including oral hygiene instruction and scaling and root planing. The exposed roots were thoroughly planed and covered by a graft without any further root treatment or conditioning. There were no differences in the average age, time of follow-up, or gender between the two groups. Patients were evaluated periodically between 1 and 2 years. Residual recession and defect coverage were assessed.

Results: Mean residual root recession after root coverage with acellular dermal matrix allograft was 0.2 ± 0.04 mm, with defect coverage of $95.9 \pm 0.9\%$. Frequency of defect coverage was 82.2%. Root coverage was $98.8\% \pm 0.2\%$, resulting in a frequency of root coverage of 100%. Gain in keratinized gingiva was 2.2 ± 0.04 mm and attachment gain was 4.5 ± 0.1 mm per patient. Connective tissue autografts resulted in mean residual root recession of 0.1 ± 0.04 mm, with percent defect coverage of $97.8\% \pm 0.6\%$ and frequency of defect coverage of 95.4%. Root coverage was $99.1\% \pm 0.2\%$, and frequency of root coverage was 100%. Gain in keratinized gingiva was 3.0 ± 0.1 mm and attachment gain was 5.3 ± 0.2 mm per patient. No significant differences in final recession and root coverage between the two treatment methods were found. However, autografts resulted in significant increases in defect coverage, keratinized gingival gain, attachment gain, and residual probing depth. The clinical results were stable for the 2-year follow-up period.

Conclusions: These results indicate that coverage of root by subpedicle acellular dermal matrix allografts or subepithelial connective tissue autografts is a very predictable procedure which is stable for 2 years post-operatively. However, subepithelial connective tissue autografts resulted in significant increases in defect coverage, keratinized gingival gain, attachment gain, and residual probing depth. *J Periodontol* 2005;76:1323-1328.

Amalgam Tattoo Management

Reconstructive Surgical Management of an Amalgam Tattoo Using an Acellular Dermal Matrix Graft: Case Reports

Terrence J Griffin, Susan A Banjar and Wai S Cheung, DDS, MS

Abstract: 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. *Compendium* 2005;26:853-859.

Root Coverage at Multiple Sites

Complete Root Coverage at Multiple Sites Using an Acellular Dermal Matrix Allograft

Michael J Mehlbauer and Henry Greenwell

Abstract: This study reports results of root coverage treatment with a coronally positioned flap and an acellular dermal matrix allograft. The same protocol was followed as in a previous university study to determine if the results could be duplicated in a private practice setting. Complete root coverage was obtained on most defects. Use of an acellular dermal matrix allograft avoided the postoperative morbidity associated with harvesting palatal connective tissue. The unlimited supply of the allograft allowed extended flaps to achieve multiple site root coverage, which proved to be a practical and predictable procedure in these cases. *Compendium* 2005;26:727-733.

Histologic Evaluation of Attachment

Histologic Evaluation of Autogenous Connective Tissue and Acellular Dermal Matrix Grafts in Humans

Lewis C. Cummings, Wayne B. Kaldahl, and Edward P. Allen

Background: 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.

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.

Conclusion: 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. *J Periodontol* 2005; 76: 178-186.

Ridge Preservation after Tooth Extraction

Acellular Dermal Matrix and Hydroxyapatite in Prevention of Ridge Deformities after Tooth Extraction

Sonia M. Luczyszyn, DDS, MS, Vula Papalexou, DDS, MS, Arthur B. Novaes Jr., DDS, MS, DSc, Marcio F. M. Grisi, DDS, MS, DSc, Sergio L. S. Souza, DDS, MS, DSc, and Mario Taba Jr., DDS, MS, DSc.

The aim of this study was to evaluate the role of acellular dermal matrix graft (ADMG) acting as a membrane, associated with a resorbable hydroxyapatite (RHA) in bone regeneration to prevent ridge deformities after tooth extraction. Fifteen patients who had at least 2 noncontiguous, uniradicular teeth indicated for extraction were selected. In group I, the extraction sockets were covered by ADMG alone; and in group II, the alveoli were filled with RHA before the placement of the ADMG. After 6 months, re-entry surgeries and biopsies were performed. Although ridge thickness had been preserved in both groups, the means were significantly greater ($P < 0.05$) for group II when compared to group I (6.8 ± 1.26 and 5.53 ± 1.06). The histologic analysis showed small bone formation in some samples for group II, where the presence of a highly vascularized fibrous connective tissue surrounding the particles was a common finding. Based on the results, it can be concluded that the ADMG was able to preserve ridge thickness and that the additional use of RHA favored the preservation of the ridges along with an increase in the width of keratinized tissue. *Implant Dent* 2005;14:176-184.

AlloDerm Around Implants

Hard and Soft Tissue Augmentation in Implant Therapy Using Acellular Dermal Matrix

Terrence J. Griffin, DMD, Wai S. Cheung, DDS, MS, and Hiroshi Hirayama, DDS, DMD, MS

The use of acellular dermal matrix to correct soft and hard tissue defects involving implants is described through three case reports. Correction of a ridge deformity caused by a root fracture, submerging of an existing implant and correction of recession defects around adjacent teeth, and ridge preservation for implant placement are presented. The use of acellular dermal matrix prevented the need for a second surgical site for donor material and the possible attendant postoperative complications. It also enhanced patient comfort and satisfaction with the procedure. All three cases demonstrated excellent functional and esthetic results for both the patients and professionals involved in the therapy. *Int J Periodontics Restorative Dent* 2004;24:352-361.

Surgical Approach

A 6-Month Comparative Clinical Study of a Conventional and a New Surgical Approach for Root Coverage With Acellular Dermal Matrix

Raquel R.M. Barros, Arthur B. Novaes Jr., Márcio F.M. Grisi, Sérgio L.S. Souza, Mário Taba Jr., and Daniela B. Palioto

Background: The acellular dermal matrix graft (ADMG) has become widely used in periodontal surgeries as a substitute for the subepithelial connective tissue graft (SCTG). These grafts exhibit different healing processes due to their distinct cellular and vascular structures. Therefore the surgical technique primarily developed for the autograft may not be adequate for the allograft. This study compared the clinical results of two surgical techniques – the “conventional” and a modified procedure – for the treatment of localized gingival recessions with the ADMG.

Methods: A total of 32 bilateral Miller Class I or II gingival recessions were selected and randomly assigned to test and control groups. The control group received the SCTG and the test group the modified surgical technique. Probing depth (PD), relative clinical attachment level (RCAL), gingival recession (GR), and width of keratinized tissue (KT) were measured 2 weeks prior to surgery and 6 months post-surgery.

Results: Both procedures improved all the evaluated parameters after 6 months. Comparisons between the groups by Mann-Whitney rank sum test revealed no statistically significant differences in terms of CAL gain, PD reduction, and increase in KT from baseline to 6-month evaluation. However, there was a statistically significant greater reduction of GR favoring the modified technique ($P = 0.002$). The percentage of root coverage was 79% for the test group and 63.9% for the control group.

Conclusion: We conclude that the modified technique is more suitable for root coverage procedures with the ADMG since it had statistically significant better clinical results compared to the traditional technique. *J Periodontol* 2004;75:1350-1356.

Root Coverage - Coronally Positioned Flap with or without AlloDerm

Coronally Positioned Flap With or Without Acellular Dermal Matrix Graft in the Treatment of Class I Gingival Recessions: A Randomized Controlled Clinical Study

Antonieta De Queiroz Côrtes, Ângela Guimarães Martins, Francisco H. Nociti Jr., Antonio Wilson Sallum, Marcio Z. Casati, and Enilson A. Sallum

Background: The aim of this study was to clinically evaluate the treatment of Class I gingival recessions by coronally positioned flap with or without acellular dermal matrix allograft (ADM).

Methods: Thirteen patients with comparable bilateral Miller Class I gingival recessions (≥ 3.0 mm) were selected. The defects were randomly assigned to one of the treatments: coronally positioned flap and acellular dermal matrix (ADM group) or coronally positioned flap alone (CPF group). The clinical parameters included: probing depth (PD), clinical attachment level (CAL), recession height (RH), recession width (RW), height of keratinized tissue (HKT), thickness of keratinized tissue (TKT), plaque index (PI), and gingival index (GI). The measurements were taken before the surgeries and after 6 months.

Results: The mean baseline recession was 3.4 mm and 3.5 mm for ADM group and CPF group, respectively. After 6 months, both treatments resulted in significant root coverage ($P < 0.01$), reaching an average of 2.6 mm (76%) in the ADM group and 2.5 mm (71%) in the CPF group. The difference in recession reduction between treatments was not statistically significant. There were no statistically significant differences between the treatments in PD, CAL, RH, RW, and HKT. However, the mean TKT gain was 0.7 mm for the ADM group and 0.2 mm for the CPF group ($P < 0.01$).

Conclusion: It can be concluded that both techniques could provide significant root coverage in Class I gingival recessions; however, a greater keratinized tissue thickness can be expected with ADM. *J Periodontol* 2004;75:1137-1144.

Root Coverage - Short-term and Long-term Follow-up

A Short-Term and Long-Term Comparison of Root Coverage With an Acellular Dermal Matrix and a Subepithelial Graft

Randall J. Harris

Background: Obtaining predictable and esthetic root coverage has become important. Unfortunately, there is only a limited amount of information available on the long-term results of root coverage procedures. The goal of this study was to evaluate the short-term and long-term root coverage results obtained with an acellular dermal matrix and a subepithelial graft.

Methods: An a priori power analysis was done to determine that 25 was an adequate sample size for each group in this study. Twenty-five patients treated with either an acellular dermal matrix or a subepithelial graft for root coverage were included in this study. The short-term (mean 12.3 to 13.2 weeks) and long-term (mean 48.1 to 49.2 months) results were compared. Additionally, various factors were evaluated to determine whether they could affect the results. This study was a retrospective study of patients in a fee-for-service private periodontal practice. The patients were not randomly assigned to treatment groups.

Results: The mean root coverages for the short-term acellular dermal matrix (93.4%), short-term subepithelial graft (96.6%), and long-term subepithelial graft (97.0%) were statistically similar. All three were statistically greater than the long-term acellular dermal matrix mean root coverage (65.8%). Similar results were noted in the change in recession. There were smaller probing reductions and less of an increase in keratinized tissue with the acellular dermal matrix than the subepithelial graft. None of the factors evaluated resulted in the acellular dermal graft having a statistically significant better result than the subepithelial graft. However, in long-term cases where multiple defects were treated with an acellular dermal matrix, the mean root coverage (70.8%) was greater than the mean root coverage in long-term cases where a single defect was treated with an acellular dermal matrix (50.0%).

Conclusions: The mean results with the subepithelial graft held up with time better than the mean results with an acellular dermal matrix. However, the results were not universal. In 32.0% of the cases treated with an acellular dermal matrix, the results improved or remained stable with time. *J Periodontol* 2004;75:734-743.

Root Coverage and Gingival Thickness

The Clinical Effect of Acellular Dermal Matrix on Gingival Thickness and Root Coverage Compared to Coronally Positioned Flap Alone

James G. Woodyard, Henry Greenwell, Margaret Hill, Connie Drisko, John M. Iasella, and James Scheetz

Background: 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.

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. *J Periodontol* 2004; 75:44-56.

Extraction Socket Grafting with Barrier Membrane

Extraction Sockets and Implantation of Hydroxyapatites With Membrane Barriers: A Histologic Study

Stuart Froum, DDS, Sang-Choon Cho, DDS, Nicolas Elian, DDS, Edwin Rosenberg, DDS, Michael Rohrer, DDS, Dennis Tarnow, DDS

The purpose of this pilot study was to investigate the effect on extraction socket healing when an absorbable hydroxyapatite (AH) and a nonabsorbable anorganic bovine bone mineral (ABB) covered with either an acellular dermal matrix allograft (ADMA) or expanded polytetrafluoroethylene (ePTFE) membrane barrier were left exposed to the oral cavity. Following tooth extraction, a total of 16 sockets in 15 patients with deficient buccal plates of ≥ 5 mm were randomly divided into 4 treatment groups: 1) AH covered with ADMA, 2) AH covered with an ePTFE membrane, 3) ABB covered with ADMA, and 4) ABB covered with an ePTFE membrane.

Primary coverage was not attempted or obtained in any of the 16 treated sockets. Six to 8 months post extraction at the time of implant placement, histologic cores of the treatment sites were obtained. These cores were processed, stained with Stevenel's blue/ van Gieson's picro fuchsin, and histomorphometrically analyzed. Vital bone, connective tissue and marrow, and residual graft particles were reported as a percentage of the total core. The mean vital bone was 34.5% (AH with ADMA), 41.7% (ABB with ADMA), 27.6% (ePTFE and AH), and 17.8% (ePTFE and ABB). The average percentage of vital bone in the 8 sockets covered with ADMA was 38% compared with an average percentage vital bone of 22% in the 8 sockets covered with ePTFE membrane barriers.

Because of the small number of specimens in the 4 groups, statistical analysis was not possible. However, in this pilot study, ADMA-covered sites resulted in more vital bone present 6 to 8 months post socket treatment than obtained in the ePTFE-covered sites regardless of bone replacement materials used. Further research is warranted to see if these results show a similar difference in bone-to-implant contact after implant placement. *Implant Dent* 2004;13:153-164.

Root Coverage - AlloDerm Versus Connective Tissue Grafts

Root Coverage of Advanced Gingival Recession: A Comparative Study Between Acellular Dermal Matrix Allograft and Subepithelial Connective Tissue Grafts

Haim Tal, Ofer Moses, Ron Zohar, Haya Meir, and Carlos Nemcovsky

Background: Acellular dermal matrix allograft (ADMA) has successfully been applied as a substitute for free connective tissue grafts (CTG) in various periodontal procedures, including root coverage. The purpose of this study was to clinically compare the efficiency of ADMA and CTG in the treatment of gingival recessions ≥ 4 mm.

Methods: Seven patients with bilateral recession lesions participated. Fourteen teeth presenting gingival recessions ≥ 4 mm were randomly treated with ADMA or CTG covered by coronally advanced flaps. Recession, probing depth, and width of keratinized tissue were measured preoperatively and 12 months postoperatively. Changes in these clinical parameters were calculated within and compared between groups and analyzed statistically.

Results: Baseline recession, probing depth, and keratinized tissue width were similar for both groups. At 12 months, root coverage gain was 4.57 mm (89.1%) versus 4.29 mm (88.7%) ($P = NS$), and keratinized tissue gain was 0.86 mm (36%) versus 2.14 mm (107%) ($P < 0.05$) for ADMA and CTG, respectively. Probing depth remained unchanged (0.22 mm/0 mm), with no difference between the groups.

Conclusions: Recession defects may be covered using ADMA or CTG, with no practical difference. However, CTG results in significantly greater gain of keratinized gingiva. *J Periodontol* 2002;73:1405-1411.

BioHorizons USA

2300 Riverchase Center
Birmingham, AL 35244

Customer Care / Servicio al Cliente:
888-246-8338 or 205-967-7880

BioHorizons Canada

21 Amber Street, Unit # 6
Markham, Ontario L3R 4Z3

Customer Care / Service à la Clientèle:
866-468-8338 or / ou 905-944-1700

BioHorizons Spain

Serrano Anguita, 10
28004 Madrid, Spain

Atención al Cliente:
+34 91 713 10 84

BioHorizons UK

180 Dukes Ride
Crowthorne, Berkshire RG45 6DS

Customer Care:
+44 8700 620 550

BioHorizons Germany

Marktplatz 3
79199 Kirchzarten

Kunden Service:
+49 7661-909989-0

BioHorizons Australia

25-33 Allen Street
Waterloo NSW 2012

Customer Service:
+61 2 8399 1520

BioHorizons Mexico

Kelvin 8 Int. 303
Col. Anzures
C.P. 11590, Mexico, D.F.

Servicio al Cliente:
+52 55 5545 1297

BioHorizons Chile

Juan Esteban Montero 5944
Las Condes
Santiago, Chile

Atención al Cliente:
+56 2 475 7230

As applicable, BioHorizons products are cleared for sale in the European Union under the EU Medical Device Directive 93/42/EEC. We are proud to be registered to ISO 13485:2003, the international quality management system standard for medical devices, which supports and maintains our product licences with Health Canada and in other markets around the globe.

Not all products are available in all markets. AlloDerm® and AlloDerm GBR™ must be shipped overnight and may not be returned or exchanged for credit due to specific guidelines regarding the storage of allograft tissue.

AlloDerm is a registered trademark of LifeCell Corp.

w w w . b i o h o r i z o n s . c o m

© 2008 BioHorizons Implant Systems, Inc. All Rights Reserved. MLD106 REV A FEB 2008

