

Dental Clinical Compendium

Representative Reports Regarding LifeNet Health® Dental Allografts



REPRESENTATIVE REPORTS REGARDING LIFENET HEALTH DENTAL ALLOGRAFTS

1. Clinical Reports: Particulate Bone

Chadwick JK, Mills MP, Mealey BL. Demineralized freeze-dried bone allograft versus platelet-rich fibrin for the treatment of periodontal intrabony defects in humans. J Periodontol. 2016 Nov;87(11):1253-1260. [PMID: 27353441](#)

- This randomized controlled trial compared Platelet-Rich Fibrin (PRF) to a control of DFDBA in the treatment of periodontal intrabony defects. Both treatments resulted in improvements in clinical attachment levels and bony fill.

Whetman J, Mealey BL. Effect of healing time on new bone formation after tooth extraction and ridge preservation with demineralized freeze-dried bone allograft: A randomized controlled clinical trial. J Periodontol. 2016 Sept;87(9):1022-1029. [PMID: 27133791](#)

- In a randomized controlled trial using LifeNet Health DFDBA, Whetman and Mealey showed significantly greater new vital bone formation occurs after tooth extraction and ridge preservation when sites healed 18-20 weeks compared to 8-10 weeks prior to dental implant placement.

Cecchi V, Mazzoni A, Breschi L, Felice P. Reconstruction of an atrophied posterior mandible with the inlay technique and allograft block versus allograft particulate: A case report. Int J Periodontics Restorative Dent. 2015 Mar-Apr;35(2):e20-7. [PMID: 25738350](#)

- This case report described the bilateral reconstruction of a severely atrophic posterior mandible in a 30-year-old woman illustrating the inlay technique. Cecchi et al. successfully employed cancellous blocks, mineralized particulate and decellularized dermis to greatly improve ridge dimensions bilaterally in order to prepare the patient for future implant treatment.

Wallace S. Histomorphometric and 3d cone-beam computerized tomographic evaluation of socket preservation in molar extraction sites using human particulate mineralized cancellous allograft bone with a porcine collagen xenograft barrier: A case series. J Oral Implantol. 2015 June;41(3):291-7. [PMID: 24987870](#)

- In this case series, Wallace evaluated the results of socket preservation after extraction using human particulate mineralized cancellous allograft bone and type I porcine collagen membranes as a guided bone regeneration barrier. Fourteen patients with a diagnosis of one or more unsalvageable teeth were treated. The results were evaluated clinically, histomorphometrically, and with cone-beam computerized tomographic scanning.

Ogihara S, Tarnow DP. Efficacy of forced eruption/enamel matrix derivative with freeze-dried bone allograft or with demineralized freeze-dried bone allograft in infrabony defects: A randomized trial. Quintessence Int. 2015 Jun;46(6):481-490. [PMID: 25918759](#)

- In a randomized clinical trial involving 69 patients, Ogihara and Tarnow examined bony fill and soft tissue healing. The test groups were combinations of enamel matrix derivative with either demineralized freeze-dried bone allograft or mineralized freeze-dried bone allograft. Both groups showed improvement in both hard and soft tissue healing compared to the controls.

Parashis AO, Kalaitzakis CJ, Tatakis DN, Tosios K. Alveolar ridge preservation using xenogeneic collagen matrix and bone allograft. Int J Dent. 2014:172852. [PMID: 25328523](#)

- In this clinical study, Parashis et al. corrected sites in patients (n=9) with a xenogeneic collagen membrane and LifeNet Health allograft. In all cases, the area was successfully augmented. The cases are supported with radiographic, tomography and histologic examples. This is a useful study illustrating the utility of bone grafting.



REPRESENTATIVE REPORTS REGARDING LIFENET HEALTH DENTAL ALLOGRAFTS

Bernardello F, Massaron E, Spinato S, Zaffe D. Two-stage crestal sinus elevation by sequential drills in less than 4 mm of residual ridge height: A clinical and histologic case report. *Implant Dent.* 2014 Aug;23(4):378-86. [PMID: 25025861](#)

- In this case report, Bernardello et al. illustrated the correction and preparation of a severely deficient maxilla using the minimally invasive transcresal technique and mineralized cortical allograft. This method is gaining in popularity and this case report shows how allograft can be successfully employed – even in the most challenging case.

Felice P, Checchi L, Pistilli R, Barausse c, Spinato S. The modified “Sandwich” technique: A novel surgical approach to regenerative treatment of horizontal bone defects in the posterior atrophic mandible. A case report. *Implant Dent.* 2014 Jun;23(3):232-238. [PMID: 24819804](#)

- Felice et al. described a case study about a novel surgical approach for the treatment of advanced defects in the posterior mandible. The technique involves a 2 stage modified “sandwich” osteotomy procedure kept in position with titanium mini-plates and mini-screws. The newly created defect area was filled with an allograft putty composed of a mixture of mineralized and demineralized human bone. Two implants were placed following a 3 month healing period with no complications reported.

Mastronikolas S. Case report maxillary implant. *Dental Tribune Middle East & Africa Edition.* 2014 May-June:36. [Click Here For Article](#)

- In a case report involving a maxillary implant, Mastronikolas extracted and performed site preservation on #5 [Eu. #16]. Demineralized freeze-dried bone allograft was used at the extraction site as well as a fascia lata membrane to guide bone formation. Approximately 3 months later, the patient underwent sinus augmentation at the same site utilizing freeze-dried bone allograft. Three months later, a CT scan was prescribed, which verified the successful elevation of the sinus floor.

Eskow AJ, Mealey BL. Evaluation of healing following tooth extraction with ridge preservation using cortical versus cancellous freeze-dried bone allograft. *J Periodontol.* 2014 Apr;85(4):514-524. [PMID: 23725026](#)

- A clinical study by Eskow et al. performed histological analysis of cortical and cancellous freeze-dried bone allograft following tooth extraction and ridge preservation in a non-molar model. After an average follow-up period of 18 weeks, the study reported no significant differences in new bone formation between the two groups.

Wallace S. Guided bone regeneration for socket preservation in molar extraction sites: Histomorphometric and 3D computerized tomography analysis. *J Oral Implantol.* 2013;29(4):503-509. [PMID: 23530854](#)

- In a case series, Wallace analyzed bone regeneration using histomorphometric and 3D computerized tomography analysis. Mineralized cancellous bone allograft was used to fill each socket and decellularized dermal matrix was applied over each socket site. Results showed 28.7% new bone formation after 12 weeks using these materials.

Sindler AJ, Behmanesh S, Reynolds MA. Evaluation of allogenic cellular bone graft for ridge augmentation: A case report. *Clin Adv Periodontology.* 2013;3(3):159-165. [Click Here For Abstract](#)

- From this case study, Sindler et al. illustrated the use of a novel cellular bone graft mixed with traditional allograft in providing a significant horizontal ridge gain prior to implantation. Recent advancements in tissue banking are illustrated and it shows how the reliability of allografts can be further enhanced.



REPRESENTATIVE REPORTS REGARDING LIFENET HEALTH DENTAL ALLOGRAFTS

Waasdorp J, Feldman S. Bone regeneration around immediate implants utilizing a dense polytetrafluoroethylene membrane without primary closure: A report of 3 cases. J Oral Implantol. 2013 Jun;39(3):355-361. [PMID: 21905904](#)

- A case series by Waasdorp et al. evaluated bone regeneration using a dense polytetrafluoroethylene membrane and, in some cases, freeze-dried cortical bone around immediately placed implants. Results of the study demonstrated successful use of the membrane to “augment horizontal defects associated with immediately placed implants.”

Wood RA, Mealey BL. Histologic comparison of healing after tooth extraction with ridge preservation using mineralized versus demineralized freeze-dried bone allograft. J Periodontol. 2012 Mar;83(3):329-336. [PMID: 21749166](#)

- In a randomized, comparative study, Wood and Mealey compared the efficacy of demineralization involving 40 patients implanted with either DFDBA or freeze dried bone allografts (FDBA). After 19 weeks follow-up, biopsies showed significantly greater amounts of new bone formation in patients implanted with DFDBA over the FDBA patients.

Yun JH, Jun CM, Oh NS. Secondary closure of an extraction socket using the double-membrane guided bone regeneration technique with immediate implant placement. J Periodontal Implant Sci. 2011 Oct;41(5):253-258. [PMID: 22087417](#)

- In this case study, Yun et al. achieved good healing around immediate implant placement using a combination of allograft with dense polytetrafluoroethylene (dPTFE) membrane.

Tsai BY. A method for obtaining peri-implant soft-tissue contours by using screw-retained provisional restorations as impression copings: A clinical report. J Oral Implantol. 2011 Oct;37(5):605-609. [PMID: 20553160](#)

- In this case study, Tsai used an allograft to quickly correct an unanticipated defect in a common missing tooth scenario in the esthetic zone. The case demonstrated the ease of use and predictability of allograft.

Beitlitum I, Artzi Z, Nemcovsky CE. Clinical evaluation of particulate allogeneic with and without autogenous bone grafts and resorbable collagen membranes for bone augmentation of atrophic alveolar ridges. Clin Oral Implants Res. 2010 Nov;21(11):1242-1250. [PMID: 20572833](#)

- In a prospective study comparing allograft only with allograft and autograft combination treatment, Beitlitum et al. used FDBA to augment the alveolar ridge deficiencies of 50 patients. The authors found that not only did the FDBA alone yield good clinical results but it was essentially equivalent to the results of the allograft and autograft combination treatment.

Vidal R, Greenwell H, Hill M, Papageorgakopoulos G, Scheetz JP. Success rate of immediate implants placed and restored by novice operators. Implant Dent. 2010 Feb;19(1):81-90. [PMID: 20147820](#)

- In a prospective study, Vidal et al. reported a 100% success rate in a study consisting of 51 patients who had immediate implant placements. While the total number of patients who received FDBA was not specified, FDBA along with a collagen membrane was grafted onto sockets that had >1mm distance to the implant surface.

El-Halaby A, Becker J, Bissada NF. Autogenous bone grafting in a patient on long-term oral bisphosphonate therapy: Case report. Int J Periodontics Restorative Dent. 2009 Dec;29(6):634-641. [PMID: 20072741](#)

- In this case study, El-Halaby et al. treated a patient with a history of oral bisphosphonate use for 7 years for the treatment of osteoporosis. An autogenous block was used as well as allograft particulate. Healing was uneventful at the donor and recipient sites.



REPRESENTATIVE REPORTS REGARDING LIFENET HEALTH DENTAL ALLOGRAFTS

West JD, Oates TW. Identification of stability changes for immediately placed dental implants. Int J Oral Maxillofac Implants. 2007 July-Aug;22(4):623-630. [PMID: 17929524](#)

- In a prospective study, West and Oates compared implant stability in non-grafted sites vs immediate placement into native bone with grafting. The study showed that immediate placement with grafting is a viable option.

2. Clinical Reports: Structural Bone

Sfasciotti GL, Trapani CT, Powers RM. Mandibular ridge augmentation using a mineralized ilium block: A case letter. J Oral Implantol. 2016 Apr;42(2):215-219. [PMID: 25961870](#)

- In this case study, Sfasciotti et al. treated a severely atrophic mandible in sextants 5 and 6. Blocks formed from an ilium strip were strategically placed and secured with titanium screws. Pre-planting was performed using computerized tomography and a surgical stent. Post-operative scans showed excellent early healing. A core was removed prior to implant placement and histology showed exceptional healing at 10 months. The case was successfully finished with implant placement.

Cecchi V, Mazzoni A, Breschi L, Felice P. Reconstruction of an atrophied posterior mandible with the inlay technique and allograft block versus allograft particulate: A case report. Int J Periodontics Restorative Dent. 2015 Mar-Apr;35(2):e20-7. [PMID: 25738350](#)

- This case report described the bilateral reconstruction of a severely atrophic posterior mandible in a 30-year-old woman illustrating the inlay technique. Cecchi et al. successfully employed cancellous blocks, mineralized particulate and decellularized dermis to greatly improve ridge dimensions bilaterally in order to prepare the patient for future implant treatment.

Fagan MC, Conte GJ, Kao RT. Implant site development with simultaneous block and soft-tissue graft. Clin Adv Periodontics. 2013;3(4):222-228. [Click Here For Abstract](#)

- In this case study, Fagan et al. corrected a site in the esthetic zone for a missing tooth. An ilium block was used thus allowing for subsequent implant placement. This is another example of the utility of structural grafts in compromised cases.

Nissan J, Mardinger O, Calderon S, Romanos GE, Chaushu G. Cancellous bone block allografts for the augmentation of the anterior atrophic maxilla. Clin Implant Dent Relat Res. 2011 Jun;13(2):104-111. [PMID: 19744202](#)

- From this case series, Nissan et al. published a follow-up to their 2008 study where they used 46 cancellous blocks to treat alveolar ridge deficiencies in 31 patients who required implants. They noted 98% implant success after a mean 34 month follow-up.

Wallace S, Gellin R. Clinical evaluation of freeze-dried cancellous block allografts for ridge augmentation and implant placement in the maxilla. Implant Dent. 2010 Aug;19(4):272-279. [PMID: 20683283](#)

- In this 12 patient follow-up case series, Wallace and Gellin reached the same conclusion as their initial study in 2008, that cancellous allografts could be an alternative to both cortical allografts and autogenous grafts (see original study below).



REPRESENTATIVE REPORTS REGARDING LIFENET HEALTH DENTAL ALLOGRAFTS

Chaushu G, Mardinger O, Calderon S, Moses O, Nissan J. The use of cancellous block allograft for sinus floor augmentation with simultaneous implant placement in the posterior atrophic maxilla. J Periodontol. 2009 Mar80(3):422-428. PMID: [19254126](#)

- In this prospective study, Chaushu et al. used cancellous blocks for maxilla sinus floor augmentation along with simultaneous implant placement for 28 patients. After a 27 months follow-up, the authors were encouraged by the high success rate and new bone formation.

Wallace S, Gellin R. Clinical evaluation of a cancellous block allograft for ridge augmentation and implant placement: A case report. Implant Dent. 2008 Jun;17(2):151-158. PMID: [18545046](#)

- In this case study with a 21 month follow-up, Wallace and Gellin used cancellous blocks to augment the maxillary ridge for implant placement. Not only did the authors find the graft successful but they supported the idea that cancellous allografts could be an alternative to both cortical allografts and autogenous grafts.

Pendarvis WT, Sandifer JB. Localized ridge augmentation using a block allograft with subsequent implant placement: A case series. Int J Periodontics Restorative Dent. 2008 Oct;28(5):509-515. PMID: [18991002](#)

- In this case series, Pendarvis and Sandifer demonstrated successful ridge augmentation using an iliac crest monocortical allograft. Nine patients in need of ridge augmentation for the placement of 16 dental implants were included in this series. Histology from one case after the 6-month healing period demonstrated newly formed woven bone with vascular ingrowth. Implants were successfully placed in all sites.

Nissan J, Romanos GE, Mardinger O, Chaushu G. Immediate nonfunctional loading of single-tooth implants in the anterior maxilla following augmentation with freeze-dried cancellous block allograft: A case series. Int J Oral Maxillofac Implants. 2008 Jul-Aug;23(4):709-716. PMID: [18807569](#)

- In this case series, Nissan et al. published a study where they augmented deficient alveolar ridges for single-tooth implants in 9 patients with cancellous blocks. After an 18 month follow-up, the authors concluded with support for the treatment.

3. Clinical Reports: Soft Tissue

Bernardello F, Bertasi G, Powers RM, Spinato S, Viaggi A, Bullock J, Felice P. Soft tissue enhancement and implant placement following partial mandibulectomy due to squamous cell carcinoma. J Oral Implantol. 2017 Jun 19. doi: 10.1563/aaid-joi-D-17-00013. [Epub ahead of print]. PMID: [28628354](#)

- This case report follows a patient who received radical surgery secondary to oral squamous cell carcinoma. Cancer treatment resulted in a partial mandibulectomy along with loss of soft tissue between the floor of the mouth and the vestibule. Treatment of the affected area with acellular dermis allowed for implant placement and improvement in the patient's ability to speak and eat.



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- This case report described the bilateral reconstruction of a severely atrophic posterior mandible in a 30-year-old woman illustrating the inlay technique. Cecchi et al. successfully employed cancellous blocks, mineralized particulate and decellularized dermis to greatly improve ridge dimensions bilaterally in order to prepare the patient for future implant treatment.

Sindler A (2014). Treatment of gingival recession using OrACELL decellularized dermis: Cases 1-4. Cases on file at LifeNet Health (68-20-101, 68-20-102, 68-20-103, 68-20-104).

- In this case series, Sindler described the use of decellularized dermis in four separate cases. In each case, soft tissue healing and expectations for aesthetics were achieved.

Mastronikolas S. Case report maxillary implant. Dental Tribune Middle East & Africa Edition. 2014 May-June:36. [Click Here For Article](#)

- In a case report involving a maxillary implant, Mastronikolas extracted and performed site preservation on #5 [Eu. #16]. Demineralized freeze-dried bone allograft was used at the extraction site as well as a fascia lata membrane to guide bone formation. Approximately 3 months later, the patient underwent sinus augmentation at the same site utilizing freeze-dried bone allograft. Three months later, a CT scan was prescribed, which verified the successful elevation of the sinus floor.

Wallace SC. Guided bone regeneration for socket preservation in molar extraction sites: Histomorphometric and 3D computerized tomography analysis. J Oral Implantol. 2013 Aug;39(4):503-509. PMID: 23530854

- A case series by Wallace analyzed bone regeneration using histomorphometric and 3D computerized tomography analysis. Mineralized cancellous bone allograft was used to fill each socket and decellularized dermal matrix was applied over each socket site. Results showed 28.7% new bone formation using these materials.

4. Non-Clinical Reports: Bone

Miron RJ, Zhang Q, Sculean A, Buser D, Pippenger BE, Dard M, Shirakata Y, Chandad F, Zhang Y. Osteoinductive potential of 4 commonly employed bone grafts. Clin Oral Investig. 2016 Nov;20(8):2259-2265. PMID: 26814714

- Miron and associates studied autograft, DFDBA, bovine xenograft and novel biphasic calcium phosphate (BCP) to investigate and compare their osteoinductive potentials as bone grafts. Of note, DFDBA from LifeNet Health was chosen from the multiple suppliers of DFDBA “due to previous handling and its ability to form ectopic bone formation in vivo”. In a rat intramuscular pouch model, both DFDBA and BCP demonstrated ectopic bone formation, xenograft demonstrated no ectopic bone formation and autograft resorbed rapidly. These results demonstrated that novel scaffolds composed of biphasic calcium phosphate are successfully able to induce new bone growth, similar to currently used DFDBA and scaffolds containing bone morphogenetic proteins.



REPRESENTATIVE REPORTS REGARDING LIFENET HEALTH DENTAL ALLOGRAFTS

Salem D, Natto Z, Elangovan S, Karimbux N. Usage of bone replacement grafts in periodontics and oral implantology and their current levels of clinical evidence - A systematic assessment. J Periodontol. 2016 Aug;87(8):872-879. PMID: 27058348

- A literature search by Salem et al. identified the amount of clinical evidence surrounding bone replacement grafts available in the United States for periodontics and oral implantology. “The majority of materials used were allografts (26 of 93 available in the United States), followed by alloplasts (15 of 30) and xenografts (11 of 21).” With the inclusion criteria used, the authors found limited published, peer-reviewed clinical evidence regarding commercially available bone grafts in periodontics and oral implantology. Many of the allograft references used LifeNet Health materials.

Falah M, Rayan A, Srouji S. Storage effect on viability and biofunctionality of human adipose tissue-derived stromal cells. Cytotherapy. 2015 Sep;17(9):1220-1229. PMID: 26276005

- Falah et al. investigated the impact of a mixture of PlasmaLyte A, heparin, glucose, human serum albumin, hyaluronic acid and LifeNet Health DFDBA particles on the cell viability and biofunctionality of adipose tissue-derived stromal cells (ASCs) for bone formation. Prior to mixing, ASCs were treated with rhBMP-2 for 14 days. In vitro assays revealed that ASCs maintained >80% viability early after incubation in the mixture but ASC viability was negatively impacted (50%) after 24 hours incubation. Using an athymic mouse subcutaneous implant model, no difference was found for in vivo bone formation between cells incubated in the transplantation mixture and non-incubated control cells.

Wei L, Miron RJ, Shi B, Zhang Y. Osteoinductive and osteopromotive variability among different demineralized bone allografts. Clin Implant Dent Relat Res. 2015 Jun;17(3):533-542. PMID: 23879664

- A study by Wei and others compared the osteoinductive and osteopromotive abilities of two commercially available DFDBAs (from Osteotech and LifeNet Health) using a rat model of femoral and intramuscular defects. Both allografts demonstrated osteoinductive potential at intramuscular defects early in the study, but LifeNet particles displayed increased new bone formation and osteopontin gene expression later in the study than Osteotech particles. Of note, Osteotech particles were fully resorbed by 4 weeks post-implantation. Femoral defects filled with LifeNet particles also demonstrated significantly more mineralized new bone formation than Osteotech particles or control ($p < 0.05$).

Kim SM, Fan H, Cho YJ, Eo MY, Park JH, Kim BN, Lee BC, Lee SK. Electron beam effect on biomaterials I: Focusing on bone graft materials. Biomater Res. 2015 Apr;19:10. PMID: 26331080

- Research by Kim et al. investigated the effects of electron beam irradiation on the bone regeneration capacity of 4 allogenic bone grafts (included LifeNet Health material), 6 xenogeneic bone grafts, and 6 synthetic bone grafts. After irradiation with varying linear accelerators and irradiation doses, Kim et al. analyzed bone regeneration using multiple microscopy methods and an in vivo rat calvarial defect model. The authors found that electron beam irradiation “has thermal, mechanical, and chemical effects on the cross-linking of biphasic calcium phosphate apatites.”

Andreescu CF. Commentary on “Are Bone Allografts Safe and Effective for Today’s Dental Practitioner?”. Dentistry 2015;5:299. [Click Here For Article](#)

- Commentary by Andreescu provided a positive review of the article “Are Bone Allografts Safe and Effective for Today’s Dental Practitioner?” Andreescu praised the authors’ thoroughness in evaluating the safety of allografts for dentistry and their in-depth discussion of factors that dental practitioners should consider when selecting bone allografts. Andreescu also commented on allograft processing methods, including irradiation to kill viruses while maintaining material strength, and the efficacy of some bone allografts in dental applications.



REPRESENTATIVE REPORTS REGARDING LIFENET HEALTH DENTAL ALLOGRAFTS

Samsell B, Moore M, Bertasi G, Spinato S, Bernardello F, Rebaudi A, Sfasciotti GL, Powers R. Are Bone Allografts Safe and Effective for Today's Dental Practitioner? *Dentistry*. 2014;4:260. [Click Here For Article](#)

- Samsell and associates reviewed currently available bone allografts used in dental applications. Disinfected and terminally sterilized grafts reviewed in this article included alloplasts, xenografts, autografts, and allografts. In particular, the authors focused on processing, sterilization, and clinical performance of bone allografts in dental applications. "One allograft option, referred to here as "OG bone allograft" or OraGraft, is provided sterile to a SAL of 10⁻⁶ and with an extensive history of published studies to support clinical efficacy, makes this type of graft a valid option for the dental practitioner to consider."

Malinin TI, Temple HT, Garg AK. Bone Allografts in Dentistry: A Review. *Dentistry* 2014;4(2):199. [Click Here For Article](#)

- Malinin, Temple, and Garg reviewed currently available bone allograft options for implant dentistry. Specifically, they reviewed the source of donor bone, various allograft processing methods, graft preparation techniques, and material properties with a particular focus on the safety of allografts for use in implant dentistry. The importance on restricting residual calcium to not less than 2% was stressed.

Srouji S, Ben-David D, Funari A, Riminucci M, Bianco P. Evaluation of the osteoconductive potential of bone substitutes embedded with schneiderian membrane- or maxillary bone marrow-derived osteoprogenitor cells. *Clin Oral Implants Res*. 2013 Dec;24(12):1288-1294. [PMID: 22882738](#)

- In a study by Srouji et al. four commercially available osteoconductive scaffolds (Bio-Oss, Bi-Ostetic, OraGraft, and ProOsteon) for sinus lifting and sinus augmentation procedures were analyzed for in vitro cell adherence and proliferation, and in vivo bone formation. Experiments included in vitro seeding of scaffolds with osteoprogenitor cells and in vivo implantation in an athymic mouse model. Osteoprogenitor cells adhered significantly better to OraGraft and ProOsteon particles, with OraGraft demonstrating more cell adherence than ProOsteon. Cell proliferation at day 13 post-seeding was significantly higher for cells on OraGraft particles ($p < 0.01$). OraGraft and ProOsteon implantation also resulted in significantly increased in vivo ectopic bone formation, with OraGraft (mineralized cortical) demonstrating more than ProOsteon (hydroxyapatite + CaCO₃). The authors concluded that this testing method was simple and effective to assess biomaterials for sinus lifting and augmentation.

Miron RJ, Bosshardt DD, Laugisch O, Dard M, Gemperli AC, Buser D, Gruber R, Sculean A. In vitro evaluation of demineralized freeze-dried bone allograft in combination with enamel matrix derivative. *J Periodontol*. 2013 Nov;84(11):1646-1654. [PMID: 23347347](#)

- Miron and associates examined the effects of an enamel matrix derivative (EMD) coating on the ability of DFDBA (LifeNet Health) to promote new bone formation and on gene expression associated with osteogenic differentiation. EMD coating did not negatively impact new bone formation or differentiation and proliferation of osteoblasts and PDL cells. EMD coating significantly increased cell proliferation of both PDL cells and osteoblasts, and also significantly increased gene expression of Runx2 associated with PDL cells but not osteoblasts. Finally, EMD coating also increased osteocalcin gene expression associated with PDL cells and osteoblasts.



REPRESENTATIVE REPORTS REGARDING LIFENET HEALTH DENTAL ALLOGRAFTS

Kuroshima S, Al-Salihi Z, Yamashita J. Parathyroid hormone related to bone regeneration in grafted and nongrafted tooth extraction sockets in rats. *Implant Dent.* 2013 Feb;22(1):71-76. [PMID: 23296032](#)

- Kuroshima et al. studied the effects of parathyroid hormone (PTH) therapy on bone formation during ridge preservation in a rat model. After 2-3 weeks of PTH therapy, grafted and non-grafted tooth extraction sockets demonstrated significantly greater bone fill compared to control. Additionally, PTH therapy for two weeks after extractions proved sufficient to increase bone fill of extraction sockets. However, one week of PTH therapy prior to extractions did not result in sufficient bone fill. Collagen, a xenograft, and LifeNet Health DFDBA were used as bone void fillers in the experiment.

Sato EY, Svec T, Whitten B, Sedgley CM. Effects of bone graft materials on the microhardness of mineral trioxide aggregate. *J Endod.* 2012 May;38(5):700-703. [PMID: 22515907](#)

- Sato and others tested the effect of four bone graft materials on the microhardness of white mineral trioxide aggregate (WMTA). Acrylic cylinders packed with WMTA were exposed to simulated body fluid and one of four graft materials (xenograft, freeze-dried bone allograft, demineralized freeze-dried bone allograft, or allograft). The authors found that DFDBA (from LifeNet Health) and the control group demonstrated significantly higher WMTA Knoop microhardness values than other graft materials at 2 weeks and 4 weeks. WMTA associated with FDBA, DFDBA, and control had significantly higher microhardness values at 4 weeks compared to 2 weeks ($P < 0.05$, $P < 0.01$, $P < 0.001$, respectively). Authors concluded, "demineralized and mineralized graft materials appear to have a differential effect on the microhardness of WMTA."

Schwartz Z, Hyzy SL, Moore MA, Hunter SA, Ronholdt CJ, Sunwoo M, Boyan BD. Osteoinductivity of demineralized bone matrix is independent of donor bisphosphonate use. *J Bone Joint Surg Am.* 2011 Dec;93(24):2278-2286. [PMID: 22258774](#)

- A study by Schwartz et al. investigated the effects of oral bisphosphonate usage on the osteoinductivity of demineralized bone matrix (DBM provided by LifeNet Health and other tissue processors) by using a 35-day muscle pouch nude mouse model. DBM donors who had taken oral bisphosphonates were age- and sex-matched with donors who had not. New bone formation and ossicle size evaluated by histomorphometric measurements were similar regardless of bisphosphonate usage.

Pietrzak WS, Ali SN, Chitturi D, Jacob M, Woodell-May JE. BMP depletion occurs during prolonged acid demineralization of bone: Characterization and implications for graft preparation. *Cell Tissue Bank.* 2011 May;12(2):81-88. [PMID: 20039143](#)

- Demineralization of allograft bone increased the bioavailability of matrix-associated bone morphogenetic proteins (BMPs), rendering these grafts osteoinductive. While osteoinductivity is related to BMP content, little is known about how the demineralization protocol, in particular, extended demineralization times, affects graft BMP levels. Pietrzak et al. characterized the BMP-7 content of $< 710 \mu\text{m}$ bovine bone powder demineralized under various conditions. Their results suggested the importance of not over demineralizing bone grafts (supporting studies by Zhang et al (1997)) and should stimulate further research that can be incorporated into the processing methodology followed by tissue banks.

Deatherage J. Bone materials available for alveolar grafting. *Oral Maxillofac Surg Clin North Am.* 2010 Aug;22(3):347-352. [PMID: 20713267](#)

- Deatherage reviewed the evolution of bone grafting materials for alveolar grafting beginning with animal materials and up to bone grown in the laboratory more recently. The author suggested that novel solutions for new bone allografts are necessary to address difficulties with restoring bone in alveolar reconstruction. OraGraft was listed as a grafting solution in Oral and Maxillofacial surgery.



REPRESENTATIVE REPORTS REGARDING LIFENET HEALTH DENTAL ALLOGRAFTS

Holtzclaw D, Toscano N, Eisenlohr L, Callan D. The safety of bone allografts used in dentistry: A review. J Am Dent Assoc. 2008 Sep;139(9):1192-1199. PMID: 18762629

- Holtzclaw et al. reviewed US government regulations, industry standards, scientific articles, and other guidelines for the use of human bone allografts in dentistry. To highlight the safety considerations when selecting a human bone allograft for dentistry, this review included an extensive discussion of procurement, processing, use, and tracking of human bone allografts. LifeNet Health and Tutogen experience in tissue processing was discussed and used to illustrate concepts important to the clinician. Based on “rigorous donor screening and aseptic proprietary processing programs” the authors concluded that human bone allografts are a safe and viable treatment option.

5. Non-Clinical Reports: Soft Tissue

Moore MA, Samsell B, Wallis G, Triplett S, Chen S, Jones AL, Qin X. Decellularization of human dermis using non-denaturing anionic detergent and endonuclease: A review. Cell Tissue Bank. 2015 Jun;16(2):249-259. PMID: 25163609

- An investigation by Moore and associates evaluated the effects of a novel decellularization technology (MatrACELL®) on the biomechanical properties of human dermis. A residual DNA content of ≤ 4 ng/mg wet weight indicated $>97\%$ DNA removal and resulted in an effective level of decellularization. Decellularized human dermis demonstrated biocompatibility and an ability to support cellular and vascular in-growth in a mouse skin excisional model. Clinical applications in wound healing, soft tissue reconstruction and augmentation also suggest the ability of the MatrACELL process to preserve the biomechanical properties of unprocessed human dermis.

Capito AE, Tholpady SS, Agrawal H, Drake DB, Katz AJ. Evaluation of host tissue integration, revascularization, and cellular infiltration within various dermal substrates. Ann Plast Surg. 2012 May;68(5):495-500. PMID: 22531405

- Capito and others studied host tissue integration, revascularization and recellularization of four commercially available acellular dermal matrices (AlloDerm, Dermacell, DermaMatrix, and Integra) in an in vivo rat model. Dermacell (LifeNet Health Acellular Dermal Matrix) and Integra demonstrated significantly increased cellular infiltration while AlloDerm demonstrated the lowest. Dermacell showed no bimodal cellular response while all other matrices showed a bimodal cellular response. A greater number of new vessels were found in Dermacell at Day 7 ($P < 0.001$) though Days 14 and 21 showed no significant difference between matrices. Minimal vessel formation was associated with Integra until Day 14. It is unknown if these differences significantly affect clinical outcomes.

Agrawal H, Tholpady SS, Capito AE, Drake DB, Katz AJ. Macrophage phenotypes correspond with remodeling outcomes of various acellular dermal matrices. Open Journal of Regenerative Medicine. 2012 Dec;1(3):51-59. [Click Here For Abstract](#)

- A study “compared the macrophage phenotype and tissue remodeling elicited by four different [acellular dermal matrices] ADMs (DermaMatrix®, AlloDerm®, Integra® and DermACELL®)”. Agrawal et al. used a rat model and immunohistologic identification of macrophage surface markers. DermaMatrix and Dermacell demonstrated peak pan-macrophage expression at day 14, while AlloDerm showed peak pan-macrophage expression at day 21. The highest influx of macrophages was found in Dermacell and the lowest in Integra. AlloDerm was associated with more “inflammatory type tissue remodeling” while the other ADMs displayed “more constructive tissue remodeling.”



REPRESENTATIVE REPORTS REGARDING LIFENET HEALTH DENTAL ALLOGRAFTS

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