

# Representative Clinical Reports Using LifeNet Health Allografts & Technology in Craniofacial/Dental Procedures





## Representative Clinical Reports Using LifeNet Health Allografts & Technology in CMF/Dental Procedures

### Particulate Grafting Studies:

- In a study designed to test for donor-specific HLA antibodies, Quattlebaum et al. (1987) used FDBA to treat periodontal osseous defects in 20 patients. The authors were unable to detect any antibodies at intervals over a 3 month time period. All allografts were judged clinically successful. ([click here for abstract](#))
- Callan (1993) used both DFDBA and freeze-dried fascia lata femoris to fill and protect (respectively) an osseous defect in a surgical case. The author recommended both allograft types. ([click here for abstract](#))
- Fucini et al. (1993) compared small vs large particle in periodontal defects. There was no statistically significant difference between particles in the 250 to 500  $\mu$ m and the 850 to 1,000  $\mu$ m ranges. ([click here for abstract](#))
- Chen et al. (1995) compared DFDBA with a collagen membrane to the use of a collagen membrane alone in periodontal defects. Both treatments promoted significant fill of the defects with no adverse reactions. ([click here for abstract](#))
- Kassolis et al. (2000) concluded their study of 15 patients with support for using FDBA for maxillary sinus grafting. ([click here for abstract](#))
- Landi and Sabatucci (2001) published a technique report which described utilizing DFDBA to successfully treat defects in the mandibular ridge to prepare the location for implantation. ([click here for abstract](#))
- After using OraGraft demineralized freeze-dried bone allograft (DFDBA) in a 20 patient, randomized study comparing calcium sulfate (CS) and polytetrafluoroethylene, Aichelmann-Reidy et al. (2004) concluded with support for using CS combined with DFDBA for treating intrabony defects. ([click here for abstract](#))
- In a randomized, single-masked study involving 40 patients, Gurinsky et al. (2004) compared DFDBA and DFDBA combined with enamel derived matrix (ECM) to treat intrabony periodontal defects. They concluded that while the DFDBA and ECM combination worked best, both treatments significantly improved the defect. ([click here for abstract](#))
- Schwartz et al. (2006) reported positive results in a case report where FDBA was mixed with an enamel matrix derivative to fill a palatal bony defect located on the maxillary incisor. ([click here for abstract](#))
- West and Oates (2007) 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. ([click here for abstract](#))
- El-Halaby et al. (2009) 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. ([click here for abstract](#))
- Vidal et al. (2010) 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  $>1$ mm distance to the implant surface. ([click here for abstract](#))

- In a prospective study comparing allograft only with allograft and autograft combination treatment, Beitlitum et al. (2010) 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. (click here for abstract)
- Yun et al. (2011) achieved good healing around immediate implant placement using a combination of allograft with dense polytetrafluoroethylene (dPTFE) membrane. (click here for abstract)
- Wood and Mealey (2012), in the first study of its kind, compared the efficacy of demineralization in a randomized, comparative study 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. (click here for abstract)
- Menoni et al. (2013) reported on a novel method to treat a severely atrophied mandible using a “BoxTechnique” that incorporated mineralized particulate to achieve outstanding vertical and horizontal regeneration. (click here for abstract)
- A clinical study by Eskow et al. (2013) performed histological analysis of cortical and cancellous freeze-dried bone allograft following tooth extraction and ridge preservation in a non-molar model. The study reported no significant differences in new bone formation between the two groups. (click here for abstract)
- A case series by Waasdorp et al. (2013) 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.” (click here for abstract)
- A case series by Wallace et al. (2013) 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. (click here for abstract)
- In a case report involving a maxillary implant, Mastronikolas (2014) extracts and performs 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.
- In a randomized trial involving 69 patients, Ogihara and Tarnow (2014) 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.
- Felice et al. (2014) describes 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.



## Representative Clinical Reports Using LifeNet Health Allografts & Technology in CMF/Dental Procedures

### Structural Grafting Studies:

- Lyford et al. (2003) used cancellous blocks to augment the alveolar ridge in a case series of 3 patients. The authors believe their work is the first published study of such treatment and concluded with support for allograft use. ([click here for abstract](#))
- Nissan et al. (2008) 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. ([click here for abstract](#))
- In a case study of a single patient with a 21 month follow-up, Wallace and Gellin (2008) 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. ([click here for abstract](#))
- Chaushu et al. (2009) 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. ([click here for abstract](#))
- Wallace and Gellin (2010) reached the same conclusion when they followed this initial study up with a published 12 patient case series. ([click here for abstract](#))
- Nissan et al. (2011) 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. ([click here for abstract](#))
- In this case, Sfasciotti (2014) treats 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.

## Soft Tissue Grafting Studies:

- Callan (1993) used both DFDBA and freeze-dried fascia lata femoris to fill and protect (respectively) an osseous defect in a surgical case. The author recommended both allograft types. ([click here for abstract](#))
- LifeNet Health (2011). Early Clinical Success Utilizing Decellularized Dermis [PowerPoint Slides]. Data on File at LifeNet Health (68-10-104).
  - Holtzclaw D. Guided bone regeneration in the maxillary anterior.
  - Rosen PS. Congenitally missing maxillary lateral incisors
  - Holtzclaw D. Correction of root exposure in the maxillary arch.
  - Holtzclaw D. Combination extraction socket grafting and horizontal augmentation of resorbed ridge.
  - Holtzclaw D. Simultaneous extraction with open sinus lift.
- A case series by Wallace et al. (2013) 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. ([click here for abstract](#))
- In this series, Sindler (2014) describes the use of decellularized dermis in four separate cases. In each case, soft tissue healing and expectations for aesthetics were achieved.



## Representative Clinical Reports Using LifeNet Health Allografts & Technology in CMF/Dental Procedures

### **OsteoCleanse Autograft Cleaning System:**

- Graham et al. (2007) detail two successful cases using the Allowash XG tissue processing technique to decontaminate autologous cranial bone flaps. Two patients, one adult and one teenage, underwent cranial flap removal. The flaps were transported to LifeNet Health for processing followed by gamma irradiation. Both patients underwent uncomplicated replacement of the Allowash-processed flaps. At 7 and 3 months, respectively, following re-implantation of the flaps, there were no complications.
- Current salvage options for contaminated or at risk cranial bone flap autografts are inadequate due to economic, cosmetic, graft incorporation, and biocompatibility reasons. In a pilot study, Eisenlohr et al. (2008) illustrated the effectiveness of OsteoCleanse™ at salvaging otherwise non-implantable autografts based on clinical outcomes in 3 cases.
- Ecarius and Malionek (2010) present a method for decontamination and storage of autograft cranial flaps utilizing OsteoCleanse®.
- Gatin et al. (2010) describe salvage options for cranial flap autografts utilizing LifeNet Health's proprietary OsteoCleanse™ service. This methodology was developed for neurosurgeons and is especially useful where the autograft has been contaminated or is deemed too high risk for safe implantation. OsteoCleanse adheres to AATB standards for recovery, packaging, labeling, and processing. Patient consent and privacy protections follow cGCP and HIPAA.

References:

- Aichelmann-Reidy M, Heath C, Reynolds M. Clinical evaluation of calcium sulfate in combination with demineralized freeze-dried bone allograft for the treatment of human intraosseous defects. *J Periodontol.* 2004;75(3):340-347
- Beitlitum I, Artzi S, Nemcovsky C. 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;21(11):1242-1250
- Callan D. Guided tissue regeneration without a stage 2 surgical procedure. *Int J Periodontics Restorative Dent.* 1993;13:173-179
- 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;80(3):422-428
- Chen C, Wang H, Smith F, Glickman G, Shyr Y, O'Neal R. Evaluation of a collagen membrane with and without bone grafts in treating periodontal intrabony defects. *J Periodontol.* 1995;66:838-847.
- Ecarius K, Malionek S. The bone flap solution. Presented at Annual AORN Meeting. Denver, CO; March, 2010.
- El-Halaby A, Becker J, Bissada N. Autogenous bone grafting in a patient on long-term oral bisphosphonate therapy: case report. *The International Journal of Periodontics and Restorative Dentistry.* 2009;29(6):634-641
- Eisenlohr L, Graham RS, Cameron B, Tye G, McCluskey A, Ford L, Gatin M. Salvage of contaminated cranial bone flap autografts using OsteoCleanse™ - Pilot study case reports. Presented at Annual AATB Meeting. Chicago, IL; September 6-9, 2008.
- Eskow A, Mealey B. Evaluation of healing following tooth extraction with ridge preservation using cortical versus cancellous freeze dried bone allograft. *J Periodontol.* Published ahead of print
- Felice P, Checchi L, Pistilli R, Barausse, 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;23(3):232-8.
- Fucini S, Quintero G, Gher M, Black B, Richardson A. Small versus large particles of demineralized freeze-dried bone allografts in human intrabony periodontal defects. *J Periodontol.* 1993;64(9):844-847
- Gatin M, Neubauer P, Osborne D, Kuhn C, Bergevin M, Eisenlohr L. Salvage of cranial flap autografts using OsteoCleanse. *Cell Tissue Bank.* 2010;11:168.
- Graham RS, Eisenlohr L, Hillyer A, Tye G. Salvage of contaminated cranial bone flaps using tissue banking decontamination techniques. Presented at Annual AANS Meeting. Washington, DC; April 14-19, 2007.
- Gurinsky B, Mills, M., and Mellonig, J. Clinical evaluation of demineralized freeze-dried bone allograft and enamel matrix derivative versus enamel matrix derivative alone for the treatment of periodontal osseous defects in humans. *J Periodontol.* 2004;75:1309-1318
- Kassolis J, Rosen P, Reynolds M. Alveolar ridge and sinus augmentation utilizing platelet-rich plasma in combination with freeze-dried bone allograft: case series. *J Periodontol.* 2000;71(10):1654-1661
- Landi L, Sabatucci D. Plastic surgery at the time of membrane removal around mandibular endosseous implants: a modified technique for implant uncovering. *Int J Periodontics Restorative Dent.* 2001;21(3):1-7
- LifeNet Health (2011). Early Clinical Success Utilizing Decellularized Dermis [PowerPoint Slides]. Data on File at LifeNet Health (68-10-104).

# Representative Clinical Reports using LifeNet Health Allografts & Technology in CMF/Dental Procedures



- Lyford R, Mills M, Knapp C, Scheyer E, Mellonig J. Clinical evaluation of freeze-dried block allografts for alveolar ridge augmentation: a case series. *Int J Periodontics Restorative Dent.* 2003;23(5):417-425
- Mastronikolas S. Case report maxillary implant. *Dental Tribune Middle East & Africa Edition.* May-June, 2014, p36.
- Menoni A, Bernardello F, Spinato S, Zaffe D. Full-arch vertical reconstruction of an extremely atrophic mandible with “box technique.” A novel surgical procedure: A clinical and histologic case report. *Implant Dent.* 2013;22(1):2-7.
- Nissan J, Mardinger O, Calderon S, Romanos G, Chaushu G. Cancellous bone block allografts for the augmentation of the anterior atrophic maxilla. *Clin Implant Dent Relat Res.* 2011;13(2):104-111
- Nissan J, Romanos G, 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;23(4):709-716
- Ogihara S, Tarnow DP. Efficacy of enamel matrix derivative with freeze-dried bone allograft or with demineralized freeze-dried bone allograft in infrabony defects: A randomized trial. *J Periodontol.* 2014;Epub ahead of print.
- Quattlebaum J, Mellonig J, Hensel N. Antigenicity of freeze-dried cortical bone allograft in human periodontal osseous defects. *J Periodontol.* 1987;59(6):394-397
- 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).
- Schwartz S, Koch M, Deas D, Powell C. Combined endodontic-periodontic treatment of a palatal groove: a case report. *Journal Endod.* 2006;32(6):573-578
- Vidal R, Greenwell H, Hill M, Papageorgakopoulos G, Scheetz J. Success rate of immediate implants placed and restored by novice operators. *Implant Dent.* 2010;19(1):81-90
- 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;29(3):355-61
- Wallace S. Guided bone regeneration for socket preservation in molar extraction sites: Histomorphometric and 3D computerized tomography analysis. *J Oral Implantol.* 2013;29(4):503-9
- Wallace S, Gellin R. Clinical evaluation of a cancellous block allograft for ridge augmentation and implant placement: a case report. *Implant Dent.* 2008;17(2):151-158
- Wallace S, Gellin R. Clinical evaluation of a cancellous block allograft for ridge augmentation and implant placement in the maxilla. *Implant Dent.* 2010;19(4):272-279
- West J, Oates T. Identification of stability changes for immediately placed dental implants. *The Int J Oral Maxillofac Implants.* 2007;22(4):623-630
- 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;83(3):329-336
- Yun J-H, Jun CM, Oh N-S. Secondary closure of an extraction socket using the double-membrane guided bone regeneration technique with immediate implant placement. *J Periodontal Implant Sci.* 2011;41:253-258





LifeNet Health helps to save lives and restore health for thousands of patients each year. We are the world's most trusted provider of transplant solutions, from organ procurement to new innovations in bio-implant technologies and cellular therapies—a leader in the field of regenerative medicine, while always honoring the donors and healthcare professionals that allow the healing process.

1864 Concert Drive  
Virginia Beach, VA 23453  
1-888-847-7831 (US & Canada)  
1-757-464-4761 ext. 2000 (OUS)

**[www.AccessLifeNetHealth.org](http://www.AccessLifeNetHealth.org)**

The LifeNet Health logo is a registered trademark of LifeNet Health, Inc.

©2014 LifeNet Health. All rights reserved.

68-20-081 REV.03

