



## REPRESENTATIVE REPORTS USING VERTIGRAFT® AND I/C GRAFT CHAMBER®

LifeNet Health provides the only allograft bio-implants backed by an entire body of published clinical data. In fact, our allograft bio-implants are proven in more applications than any other. The result? The kind of confidence that only comes with the world's most trusted provider of transplant solutions.

### Clinical Reports using VertiGraft in Cervical ACDF

**Abla A, El Kadi H, Bost J, Maroon J, and Wert M. Allograft Composite Cortical and Cancellous Bone Graft for Anterior Cervical Fusion. Contemporary Neurosurgery: A Biweekly Publication for Clinical Neurosurgical Continuing Medical Education. 2005;27(8):1-6.**

- The authors used the LifeNet Health (LNH) VG2 cervical bio-implant in ACDF surgery for patients with cervical spine stenosis or spondylosis. This prospective study evaluated the ACDF surgery results of 74 patients. The authors reported favorable outcome results with no graft failures and 90% patient satisfaction at 12 months follow-up.

**Fox B, Gopez A, Sukovich W, and Kerner M. Anterior Cervical Spine Fusion Rates Using a Frozen Laminated Composite Allograft and Plating. The Internet Journal of Spine Surgery. 2005; 2(1).**

- The authors used VG2 cervical allografts in ACDF surgery for patients with cervical disc herniation and cervical Spondylosis. This was a retrospective, cohort study with 92 enrolled patients and a 2 year follow-up. The results suggested that 138 of 146 (94.5%) of attempted levels showed solid fusion. The VG2 graft was considered successful with the authors noting that the VG2 “demonstrates fusion rates similar or better than those reported for [iliac autografts and other types of allografts].”  
[Click here for link.](#)

**Rodway I, and Gander J. Comparison of Fusion Rates between Glycerol-Preserved and Frozen Composite Allografts in Cervical Fusion. International Scholarly Research Notices. 2014; 2014:960142.**

- Investigators compared fusion rates after anterior cervical discectomy and fusion using frozen state and glycerol-preserved VG2 cervical allografts. This retrospective, two cohort series study consisted of 67 patients with a minimum 1 year follow-up. One hundred percent fusion rate was determined for both treatment groups at 12 months, and each had similar rates at short-term follow-ups. Authors noted “While not generalizable, these results are encouraging and support the use of [Preservon] allografts for ACDF surgery.” [Click here for link.](#)

**McAnany SJ, Ahn J, Elboghdady IM, Marquez-Lara A, Ashraf N, Svovrlj B, Overly SC, Singh K, Qureshi SA. Mesenchymal Stem Cell Allograft as a Fusion Adjunct in One- and Two-level Anterior Cervical Discectomy and Fusion: A Matched Cohort Analysis. The Spine Journal. 2016; (16): 163-167.**

- This matched cohort study compared the fusion rates between the use of mesenchymal cell allografts and non-mesenchymal allografts (Vertigraft) in 57 patients who underwent ACDF. Results showed that 50 of 57 (87.7%) of MSC cohort versus 54 of 57 (94.7%) of non-MSC cohort showed solid fusion at 1-year follow-up. The authors also reported that 7 (12.3%) patients with MSC grafts were considered failed fusions at 1 year. The authors concluded that although rates between the two cohorts were not statistically significant, patients treated with MSC allografts showed lower fusion rates compared with matched non-MSC allografts. [Click here for link.](#)

**Miller LE & Block JE. “Safety and Effectiveness of Bone Allografts in Anterior Cervical Discectomy and Fusion Surgery.” 2011 White Paper (68-20-014)**

- This systematic review compared clinical and radiographic outcomes of ACDF using allograft, autograft, cages with and without bone graft substitute, and cervical arthroplasty for the treatment of cervical disc disease. The authors concluded that bone allograft is a safe and effective option in ACDF treatment and offers advantages such as high fusion rates, no donor site morbidity, and low incidence of adverse events. [Click here for link.](#)

## Clinical Reports using VertiGraft in Lumbar ALIF

**Thalgott J, Fogarty M, Giuffre J, Christenson S, Epstein A, and April C. A Prospective, Randomized, Blinded, Single-Site Study to Evaluate the Clinical and Radiographic Differences Between Frozen and Freeze-Dried Allograft When Used as Part of a Circumferential Anterior Lumbar Interbody Fusion Procedure. Spine. 2009; 34(12): 1251-1256.**

- This study compared the clinical and radiographic success of both freeze-dried and frozen Vertigraft in anterior lumbar interbody fusion (ALIF). This prospective, blinded, and randomized study consisted of 50 patients with a minimum 2 year follow-up. Radiographic evidence showed that fusion was observed at 40 levels (71.4%). ODI and SF-36 scores improved by 10 points in 62.5% and 27.5% of patients. The authors found no significant difference in clinical outcomes between the two preservation types. [Click here for link.](#)

**Potter BK and Kuklo TR. Symptomatic Degenerative Disk Disease Following Posterior Spinal Fusion. Orthopedics. 2004; 27(11): 1202. Allograft used in case was VG1 ALIF, not VG2 as reported.**

- This article described a case study following a 35 year-old patient who underwent revision anterior-posterior spinal fusion using VG2 allograft bone spacers. Postoperative radiographs showed good sagittal alignment and screw placement. The authors confirmed that the patient's latest follow-up showed favorable results. [Click here for link.](#)

## Clinical Reports using VertiGraft in Lumbar TLIF/PLIF

**Potter BK, Freedman BA, Verwiebe EG, Hall JA, Polly DW, Kuklo TR. Transforaminal Lumbar Interbody Fusion: Clinical and Radiographic Results and Complications in 100 Consecutive Patients. Journal of Spinal Disorders and Techniques. 2005; 18(4):337-346.**

- This retrospective study evaluated the results of transforaminal lumbar interbody fusions (TLIFs) in 100 consecutive patients. All patients received bilateral pedicle screw-rod titanium implants, posterolateral fusion bone graft consisting of either autologous or corticocancellous allograft, and interbody fusion using VertiGraft VG2 or a bioabsorbable spacer. The results showed that 69% of patients demonstrated posterolateral fusion and 83% demonstrated interbody fusion. Overall, 93% of patients showed solid posterolateral and/or interbody fusion at 12 months postoperatively. The authors concluded that “TLIF is a safe and effective method of achieving lumbar fusion with 93% radiographic fusion success and a nearly 80% rate of overall patient satisfaction.” [Click here for link.](#)

**Groth A, Kuklo T, Klemme W, Polly DW, and Schroeder T. Comparison of Sagittal Contour and Posterior Disc Height Following Interbody Fusion: Threaded Cylindrical Cages versus structural Allograft versus Vertical Cages. Journal of Spinal Disorders and Techniques. 2005; 18(4):332-336.**

- The authors used VG2 in posterior lumbar fusion interbody fusion (PLIF) or transformaminal lumbar interbody fusion (TLIF) for segmental restoration of sagittal contour. The study involved 49 patients with 59 intervertebral levels of which 25 levels received the VG2 allografts. The authors found using the VG2 in combination with transpedicular instrumentation resulted in clinical improvement. [Click here for link.](#)

## Reports using I/C Graft Chamber

**Ganski L, Gaskins B, Moore M, Malmstrom D, Holy C. Effects of Gamma Irradiation on the Osteoinductive Potential of Demineralized Bone Matrices in an Athymic Rat Posterolateral Spine Fusion Model. The Spine Journal. 2007; 7(5):415-425.**

- Investigators evaluated the effects of gamma irradiation on 2 commercially available DBMs, I/C graft Chamber and Collect, as well as these DBMs' ability to induce spinal fusion in 48 athymic male rats. The 2 DBMs were gamma-irradiated at a dose of 15kG in a low temperature environment. Radiographic evidence showed 100% fusion rates post-mortem (8weeks). It was noted that the irradiated groups showed more evidence of fusion compared to the non-irradiated control groups. The investigators concluded that gamma-irradiation at 15kGy does not significantly affect the osteoinductivity of DBMs.

**Triplett S, Gaskins B, Moore MA, Chen J, Wolfinbarger L. Effects of Gamma Irradiation on the Osteoinductive Potential of Demineralized Bone Matrices in an Athymic Rat Posterolateral Spinal Fusion Model. AATB. 2007.**

- Investigators evaluated the effects of a 22kGy dose of gamma-irradiation on two LifeNet Health bioimplants, Collect and I/C Graft Chamber, in athymic male rat posterolateral spinal fusions. Radiographic evidence showed that all groups demonstrated either unilateral or bilateral fusion. Higher percentages of bilateral fusion were seen in the non-irradiated I/C Graft Chamber group (83%) and the 22kGy gamma-irradiated Collect group (71%). The investigators concluded that a 22kGy dose of gamma-irradiation did not negatively affect the graft materials with respect to posterolateral spinal fusion.

**Moore M. "Safe and Effective Osteobiologic Options." 2008 Bio-Implants Brief. (68-20-008)**

- This paper describes factors affecting bone formation and healing and the role demineralized bone matrices (DBMs) can play in treating fractures and bone defects. The paper also discusses the role of LifeNet Health's AllowashXG sterilization process in order to maximize allograft safety while maintaining bone matrix osteoinductivity.

## Reports using AlloWash XG® Process and Preservon® Technology

**Graham RS, Samsell BJ, Proffer A, Moore MA, Vega RA, Stary JM, and Mathern B. Evaluation of Glycerol-Preserved Bone Allografts in Cervical Spine Fusion: a Prospective, Randomized Controlled Trial. Journal of Neurosurgery: Spine. 2015;22(1):1-10.**

- Investigators compared fusion and subsidence rates for freeze-dried and glycerol-preserved Cloward dowel allografts in a prospective, randomized controlled trial. Fifty-three patients were assigned to each group, resulting in 113 levels of surgery for the glycerol-preserved group and 114 levels for the freeze-dried group. At six months follow-up, the glycerol-preserved group demonstrated an average 2.73 mm of subsidence and the freeze-dried group showed an average 2.83 mm subsidence, though this difference was not significant (p=0.1705). Fusion rates were considered to be > 95%, with one subject in each group where fusion was unclear but these two patients were asymptomatic and did not require further surgeries. Adverse event reports were also similar between the two groups. The authors concluded with support for the use of glycerol-preserved allografts in ACDF procedures. [Click here for link.](#)

**Rodway I, and Gander J. Comparison of Fusion Rates between Glycerol-Preserved and Frozen Composite Allografts in Cervical Fusion. International Scholarly Research Notices. 2014; 2014:960142.**

- Investigators compared fusion rates after anterior cervical discectomy and fusion using frozen state and glycerol-preserved VG2 cervical allografts. This retrospective, two cohort series study consisted of 67 patients with a minimum 1 year follow-up. 100% fusion rate was determined for both treatment groups at 12 months, and each had similar rates at short-term follow-ups. [Click here for link.](#)

**Micarelli A, Moore M, & Peycelon F. “Variations in Allograft Sterility Levels: Understanding the Clinical and Economic Implications.” 2009 Bio-Implants Brief. (68-20-010)**

- This paper summarizes the findings of various studies which discuss the clinical and economic implications of allograft sterility. Through literature the paper compares aseptic processes and their sterilization abilities and properties. It is stated that “through its proprietary AllowashXG process, LifeNet Health bio-implants achieve the highest sterility assurance rating possible without compromising function or durability.”

**Eisenlohr LM. “Allograft Tissue Sterilization Using Allowash XG®” 2007 Bio-Implants Brief. (68- 0089)**

- This article summarizes numerous studies that investigated the effect AllowashXG sterilization process on various types of allografts. The author concludes that “the Allowash XG process does not adversely affect the biomechanical or biochemical properties of tissues needed for the intended clinical application.”

**Slivka M, Giorgio P, Webeck I, Serhan H. “Biomechanical Strength of Bone Allografts Following the Allowash XG™ Allograft Sterilization System.” 2004 White Paper. (68-20-035)**

- This study compared the biomechanical properties of 3 VertiGraft configurations (VG2C, VG2 PLIF, and VG1 ALIF) after sterilized with AllowashXG. The 3 grafts were tested in axial compression, compressive shear, and static torsion under the ASTM standard F2077 guidelines. There were no statistical differences in axial compression and compressive shear between the grafts processed with AllowashXG and standard Allowash (control). Although the torsional strength of the AllowashXG graft was lower than the control (2.5 Nm and 3.95 Nm) it was still 1.6 times the torque needed to produce full range of motion in the cervical spine. The authors concluded that AllowashXG sterilization is safe to use with VertiGraft allografts.

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68-20-165 .01

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