

Peer-reviewed clinical publications for ViviGen® Cellular Bone Matrix use in spine

Elgafy H, Wetzell B, Gillette M, et al. Lumbar Spine Fusion Outcomes Using a Cellular Bone Allograft with Lineage-committed Bone-forming Cells in 96 Patients. 2021; BMC Musculoskelet Disord 22, 699.

- Single-arm retrospective study of Instrumented Posterolateral Fusion (IPLF) ± Transforaminal Lumbar Interbody Fusion (TLIF) using ViviGen with follow-up of 6 to 45 months; fusion assessed with CT scan.
- 96 patients. Average number of levels fused was 2.3.
- Overall fusion rate: 91.7% in highly comorbid patients: diabetes (n=22; 90.9%), currently using tobacco (n = 19; 84.3%), history of tobacco use (n = 53; 90.6%), pseudarthrosis at the same level (n = 6; 100%)
- Patient-reported ODI and VAS for back and leg pain were significantly reduced after surgery.
- The mean OR time was 192.7 minutes, which is substantially less than those reported with autograft or BMP-2 in similar procedures.

Gibson AW, Feroze AH, Greil ME, et al. Cellular allograft for multilevel stand-alone anterior cervical discectomy and fusion. Neurosurg Focus. 2021 Jun;50(6):E7.

- Retrospective study of multilevel stand-alone ACDF using either ViviGen (28 patients) or demineralized bone matrix (DBM) allograft (25 patients) in either cages or with spacers.
- Average number of levels was 2.6, and average follow up time was one year.
- Neck Disability Index (NDI) scores were significantly improved in the ViviGen group.
- Fusion, as measured with CT scan, was 92.9% in the ViviGen group compared to 84.0% in the DBM group.
- ViviGen provided better fusion rates and better patient-reported scores compared to the DBM group.

Hall JF, McLean JB, Jones SM, et al. Multilevel Instrumented Posterolateral Lumbar Spine Fusion with an Allogeneic Cellular Bone Graft. J Orthop Surg Res. 2019;14:372.

- Retrospective study evaluating the fusion in 150 patients IPLF surgery using ViviGen.
- A total of 613 levels were treated with 59.3% of patients having 3 or more levels fused.
- Overall fusion rate in these complex cases was 98.7% despite significantly comorbid patients: diabetes (n = 43), tobacco history (n = 78), current tobacco use (n = 18), previous cancer diagnosis (n = 20), and previous spinal fusion (n = 14).
- Post-operative VAS scores ranged from 0 to 4 and patients with successful fusion reported high satisfaction.
- Average OR time was 211 ± 87.3, which is substantially less than those reported with autograft or BMP-2 in similar procedures.

Divi SN, Mikhael MM. Use of Allogeneic Mesenchymal Cellular Bone Matrix in Anterior and Posterior Cervical Spinal Fusion: A Case Series of 21 Patients. Asian Spine J. 2017;11(3):454-462.

- Retrospective study evaluating the use of ViviGen in 21 patients who underwent anterior and posterior cervical spinal fusion (ACDF, ACCF, PCF).
- Fusion mass was observed for all patients on radiographs taken at 2 weeks, 3 months, 6 months, and 12 months post-operative. Bridging fusion mass was demonstrated for all patients who received CT scans.
- At 12 months post-operative, Visual Analog Scale scores (VAS) for pain and neck disability index (NDI) scores improved by an average 81.4% and 85.9%, respectively.

Peer-reviewed health economics publications for ViviGen use in spine:

Wetzell B, McLean JB, Moore MA, et al. A Large Database Study of Hospitalization Charges and Follow-up Diagnoses in US Lumbar Fusion Surgeries Using a Cellular Bone Allograft (CBA) versus Recombinant Human Bone Morphogenetic Protein-2 (rhBMP-2). *J Orthop Surg Res.* 2020; 15(544).

- Retrospective healthcare database study for lumbar fusion surgery: ViviGen (n = 6,588) or Infuse (n = 9,584) with a 12 month follow up.
- Hospital charges (in 2018 US dollars) and resource utilization (reported lengths of stay [LOS] in days) for hospitalizations at index and cumulatively during the 12 month follow-up period were assessed.
- Potentially relevant re-admissions during the 12 month follow-up period were reported: subsequent lumbar fusion procedures, cardiac complications, deep vein thrombosis, hematoma, nervous system complications, pneumonia, pulmonary embolism, sepsis, surgical-site infection, and urinary tract infection.
- Adjusted mean hospital costs for index and 12-month follow up hospitalizations were significantly lower in the ViviGen group (\$109,061 and \$108,315, respectively) versus the Infuse group (\$160,191 and \$130,406, respectively).
- The mean LOS at index were significantly lower in the ViviGen group (3.77 days) versus the Infuse group (3.88 days).
- Rates of subsequent lumbar fusion procedures were similar between ViviGen and Infuse, in spite of the fact that the ViviGen group had significantly higher rates of index comorbidities with the potential to negatively impact clinical outcomes.

Corso KA, Etter K, Menzie AM, et al. Characteristics and Rate of Subsequent Lumbar Spine Fusion Surgery Among Patients Treated with Allogenic Cellular Bone Matrix for Posterior Lumbar Spinal Fusion. *Value in Health.* 2018;21:S106. (abstract)

- Retrospective evaluation of patient characteristics, length of hospital stay, and subsequent lumbar spine fusion in 685 patients who received ViviGen during posterior lumbar spinal fusion.
- Hypertension (61.9%), diabetes (22.3%), depression (20.3%) and obesity (17.3%) were among the observed comorbidities.
- The mean length of hospital stay was 2.8 ± 1.8 days.
- At one year follow-up, 1.7% of the 178 patients who met follow-up criteria had had subsequent lumbar spine fusion. The literature reports historical rates of up to 6%.

Peer-reviewed clinical publications for ViviGen use in Trauma/CMF:

Moran TE, Sequeria S, Park JS. A Retrospective Analysis of Outcomes from Foot and Ankle Arthrodesis and Open Reduction and Internal Fixation using ViviGen Bone Graft Augmentation. *Foot and Ankle Specialist*. 2020. Aug 31:1938640020952301.

- Retrospective of foot and ankle arthrodesis, and open reduction and internal fixation (ORIF) in 153 patients using ViviGen.
- The surgeons reported satisfactory arthrodesis fusion rates (85.8%) and overall complication rate of 19.5%, suggesting that ViviGen is an efficacious and safe alternative for fusion and ORIF procedure of the foot and ankle.

Marschall JS, Kushner GM, Flint RL, et al. Immediate Reconstruction of Segmental Mandibular Defects With Nonvascular Bone Grafts: A 30-Year Perspective. *J Oral Maxillofac Surg*. 2020 Nov;78(11):2099.e1-2099.e9. doi: 10.1016/j.joms.2020.03.035.

- In this review of 30 years of experience, the surgeons describe challenges and strategies for treating large segmental defects of the mandible.
- They reported on 2 successful cases using ViviGen, tibial bone graft, and platelet rich fibrin for defects averaging 7.4cm. The historic cut off point for using nonvascular grafts has been 6cm.
- Notably, the surgeons state that they have stopped using rhBMP-2 due to cost and excessive facial swelling.
- These results suggest that ViviGen, bone graft and platelet rich fibrin, may be efficacious in these large (7.4 +/-0.8 cm) and difficult to treat mandibular defects.

Roukis TS, Wetzell B, McLean JB, et al. A Retrospective Comparison of Clinical and Patient Reported Outcomes in Foot and Ankle Arthrodesis Procedures Using Two Cellular Bone Allografts. *Clin Res Foot Ankle*. 2020;8:300.

- Retrospective comparison of 47 consecutive patients who underwent various foot and ankle arthrodesis procedures using ViviGen (n = 31) versus a Mesenchymal Stem Cell (MSC)-based allograft (n = 16).
- The use of ViviGen led to significantly higher rates of ankle fusion at 6 months (100.00% vs 50.00%), equitable subtalar fusion rates (89.29% vs 71.43%), and significantly fewer complications (6.45% vs 62.50%).
- Additionally, 100.00% of patients who received ViviGen were satisfied with their postsurgical outcomes (versus a significantly lower 68.75% in the Trinity group).
- ViviGen patients reported a significantly lower average postsurgical VAS of 1.40 points (a reduction of 7.52 points from presurgical), compared with 3.15 points in the Trinity group (4.84-point reduction).
- Use of ViviGen in these foot and ankle fusion was associated with more pain relief and better fusion rates as compared to an MSC-base allograft (Trinity)

Ryu B, Abraham C, Polido WD. Treatment of Mandibular Non-union Using Patient Specific Crib Cage Plates and Cellular Bone Allograft: A Case Report. *Craniofacial Trauma & Reconstruction Open*. January 2021. doi:10.1177/24727512211005949

- In this case study, the authors describe the use of ViviGen and autologous bone graft in combination with customized crib cage for mandibular reconstruction after three self-inflicted gunshots to the face of a 72-year-old man.
- The multiple gunshots caused challenging comminuted fractures.
- Seven months after surgery, the combination of ViviGen Bone Graft and the custom crib cages restored the patient's mandible and ability to chew without pain or infection despite the severity of the injuries and advanced age.

Shahrdar C, McLean J, Gianulis E, Softic D, Qin X, Moore M, Chen J. Clinical Outcome and Explant Histology After Using a Cellular Bone Allograft in Two-stage Total Hip Arthroplasty. *J Orthop Surg Res.* 2020;15:16.

- Two case reports described the use of ViviGen Formable® Cellular Bone Matrix during the first stage of two-stage total hip arthroplasty to fill bone voids left by previous hardware.
- Each patient had a distinctly different health profile: a 49-year old otherwise healthy male and a 64-year-old female with Type 1 diabetes and severe osteoporosis.
- During the second stage (performed at 7 weeks post-backfill in the male patient and at 12 weeks in the female), bone containing ViviGen was removed to accommodate the hip implant and examined histologically for evidence of bone matrix, mineralization, and neovascularization.
- Explants from both patients showed substantial new bone formation and neovascularization, albeit at different levels of maturity.
- The authors concluded that ViviGen appears to facilitate new bone formation in healthy, as well as metabolically challenged patients.

Roukis TS. Use of Living Cellular Bone Matrix for Treating a Failed Ankle Arthroplasty: An Abbreviated Technique and Case Study. *Clin Res Foot Ankle.* 2018;6:282.

- Case of ViviGen Formable showing salvage of a failed Agility total ankle replacement that had been complicated by two failed previous failed replacement surgeries.
- 73-year-old, former smoker, female presented with pulmonary hypertension, chronic obstructive pulmonary disease, and in a great amount of pain. The patient underwent a failed primary Agility total ankle replacement in 2003 and a failed revision Agility total ankle replacement 10 years later in 2013.

- After 18 months following the failed revision procedure, an arthrodesis salvage operation was performed using 10 cc of ViviGen that was impaction grafted into the osseous defect, bone surfaces, and a femoral head allograft.
- The case was complicated by talar component subsidence and degenerative joint disease in the subtalar joint on the right ankle and hindfoot.
- At 5 months post-operative, the patient was weight-bearing and experienced significant pain reduction. No complications were observed as of the last follow-up at 23 months post-operative.

Roukis TS, Samsell B. A New Approach to Ankle and Foot Arthrodesis Procedures Using a Living Cellular Bone Matrix: A Case Series. *Clin Res Foot Ankle.* 2018;6:274.

- Case series with four foot and ankle arthrodesis cases in which ViviGen or ViviGen Formable were used.
- The cases included ankle arthrodesis, double arthrodesis of the hindfoot, tibiototalcalcaneal arthrodesis, and revision Lapidus to correct hypermobility of the first tarsal-metatarsal joint.
- Fusion was observed within 7.5 to 10 weeks for all patients.
- Patients were all weight bearing within two to three months.
- No complications were observed in any case during the follow-up periods ranging from 8 to 20 months.

Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.

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