

Patient Experience with ViviGen® Cellular Bone Matrix in Anterior Posterior Lumbar Revision Surgery

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Introduction

A 50 year old female smoker initially presented in May 2012 with a two-year history of severe right lower extremity pain and accompanying paresthesia. Extensive conservative treatment was recommended including chiropractic, physical therapy, and three lumbar steroid injections. Despite these treatments, the patient reported no improvement.

An MRI study of the lumbar spine revealed evidence of mild disc protrusions from L3-S1, with a central annular tear at L5-S1 (Figure 1). An EMG study confirmed right L5 distribution radiculopathy and a provocative lumbar discography confirmed discogenic findings at L5-S1 with a grade 4 annular tear.

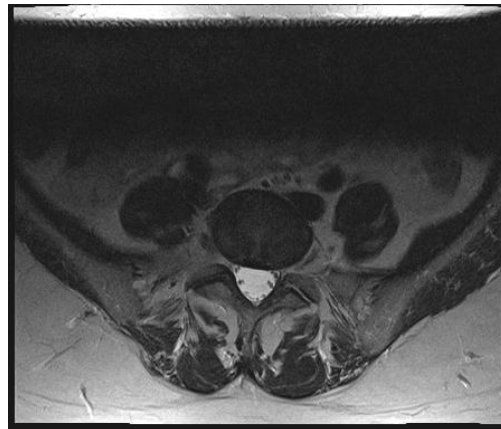


Figure 1. MRI showing mild disc protrusions from L3-S1, with a central annular tear at L5-S1

Surgical Procedure

Primary Case

The patient underwent an L5-S1 lumbar discectomy and transforaminal interbody fusion, with iliac crest autograft alone, transforaminal allograft spacer, and pedicle screw instrumentation. At her 4 month visit, the patient reported some recurrence of pain. Physical therapy and a trial of lumbar steroid injections were prescribed. A CT study revealed evidence of postoperative change with incomplete arthrodesis. An MRI study revealed evidence of postoperative change with some enhancing granulation tissue about the right L5 and S1 nerve roots. Despite further conservative management, her symptoms continued to worsen. At 8 months, her VAS score was 6 and her SF-36 was 41. A repeat CT study was

obtained 18 months postoperatively and continued to demonstrate evidence of incomplete arthrodesis (Figure 2).

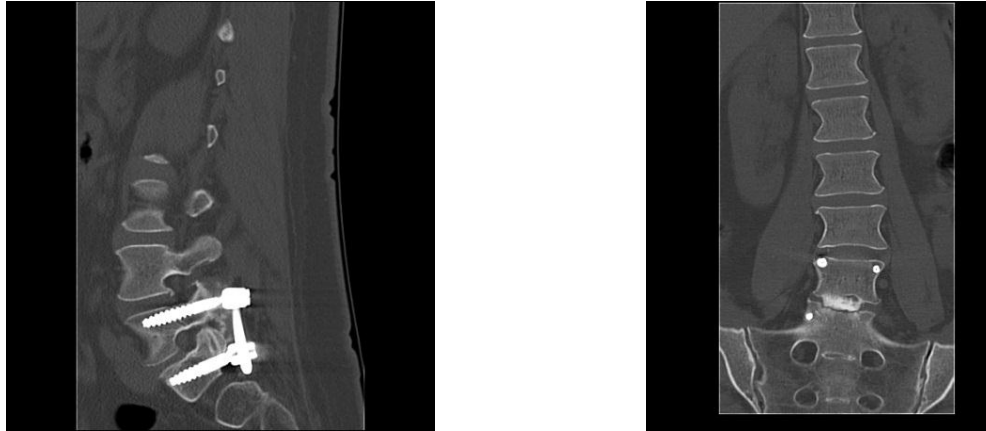


Figure 2. CT study showing incomplete arthrodesis at 18 months postoperative.

Revision Case

Once incomplete arthrodesis was confirmed the patient underwent an anterior-posterior revision surgery, including osteotomy. Removal of the incomplete arthrodesis was performed. A Spinal Correction Femoral Ring Allograft (FRA) spacer with approximately 5cc of ViviGen and an ANTEGRA-T™ Plate System were placed anteriorly, combined with a posterior revision, including supplemental pedicle screw instrumentation with EXPEDIUM® Spine System. Posterolateral bone grafting included 10cc of bone marrow aspirate (BMA) harvested from the iliac crest combined with 15cc of corticocancellous chips and 10cc of ViviGen.

Patient Results

At 1 month following surgery the patient's VAS score diminished to a 2 and physical therapy was prescribed. She continued to show significant improvements in both VAS and SF-36 results; 4 months- VAS score diminished to a 1, SF-36 improved to a 66, 7 months- VAS score remain at 1, SF-36 improved to a 71, 13 months- VAS score diminished to a 0-1, SF-36 function improved to a 78. A postoperative CT study conducted one year following her surgery demonstrated evidence of a complete fusion (Figure 3).

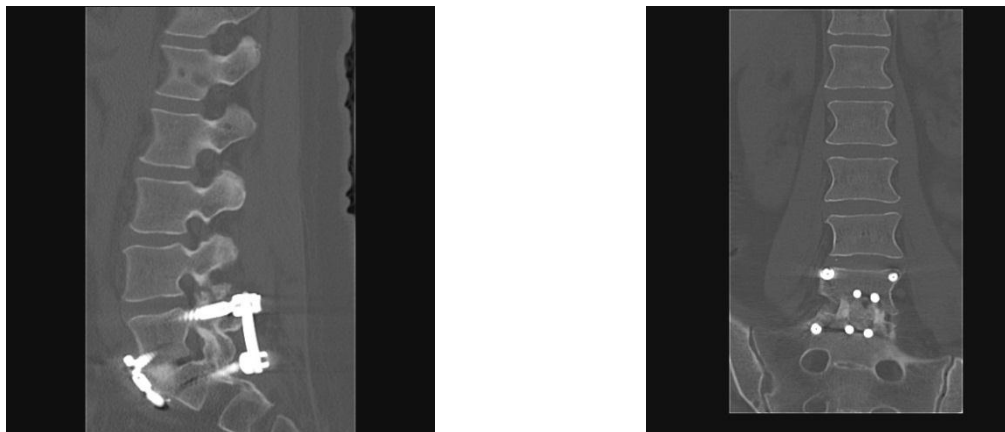


Figure 3. Postoperative CT study conducted one year following original surgery demonstrated evidence of a complete anterior and posterior fusion.

The patient was able to return to normal function, including day-to-day activities, exercise, and full-time employment. She was able to return to aerobic activities, including swimming and walking 3 miles daily.

About ViviGen® Cellular Bone Matrix

ViviGen comprises cryopreserved live, viable bone cells within a corticocancellous bone matrix and demineralized bone. ViviGen is processed from donated human tissue and is intended for repair, replacement, or reconstruction of musculoskeletal defects. ViviGen contains viable cells that are committed to produce bone in concert with the osteoconductive scaffold and osteoinductive signals naturally found within the demineralized bone¹.

1. Data on file LifeNet Health

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[DSUS/SPN/1015/1048a](#) 3/16 EX-16-052