Patient Experience with ViviGen® Cellular Bone Matrix in Transforaminal Lumbar Interbody Fusion

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Introduction

A 68 year old female presented with a seven year history of progressive back problems initially associated with lifting furniture while moving into her home. The patient reports back and bilateral lower extremity pain, right greater than left, with pain involving the lateral thigh, lateral calf, across the dorsum of the foot to the great toe, with severe symptoms of neurogenic claudication, pain worsened with standing and walking, improved by sitting or lying down and improved by leaning forward, for example leaning on a shopping cart. She failed two programs of physical therapy and two lumbar epidural steroid injections. MRI showed severe spinal stenosis at L4-5 with a grade II spondylolisthesis, moderate central disc herniation and spinal stenosis at L5-S1. EMG confirmed L4-5 radiculopathy. X-rays confirmed the spondylolisthesis at L4-5 with movement detected on flexion-extension studies and degenerative changes at the L5-S1 disc level (Figure 1).

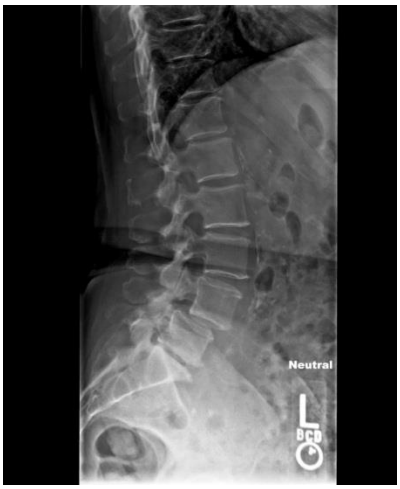

Figure 1. Preoperative x-ray

Surgical Procedure

The patient underwent L4-5 and L5-S1 lumbar laminotomies/foraminotomies combined with transforaminal lumbar interbody fusion in T-PLIF™ Allograft spacers and pedicle screw instrumentation with gradual relief in symptoms. Posterolateral bone grafting was done with 10cc of BMA harvested from the iliac crest combined with 10cc of ViviGen® Cellular Bone Matrix and 15cc of corticocancellous chips.

Patient Results

The patient's VAS scores improved from 8 to 2 and SF-36 function improved from a 58 to 82 over a 6 month period time following surgery. 6 months post-op, the patient was reinjured in her home lifting a table. She reported left leg pain, primarily from the buttock, across the anterolateral thigh to the knee with accompanying numbness in an L3 distribution and weakness of the left quadriceps muscle. MRI showed a new left foraminal disc herniation at L3-4, cephalad to her

L4-S1 spinal fusion. A CT at 6 months following initial surgery (Figure 2) showed a solid interbody and posterolateral fusion from her initial surgery, despite the short interval following the surgery.

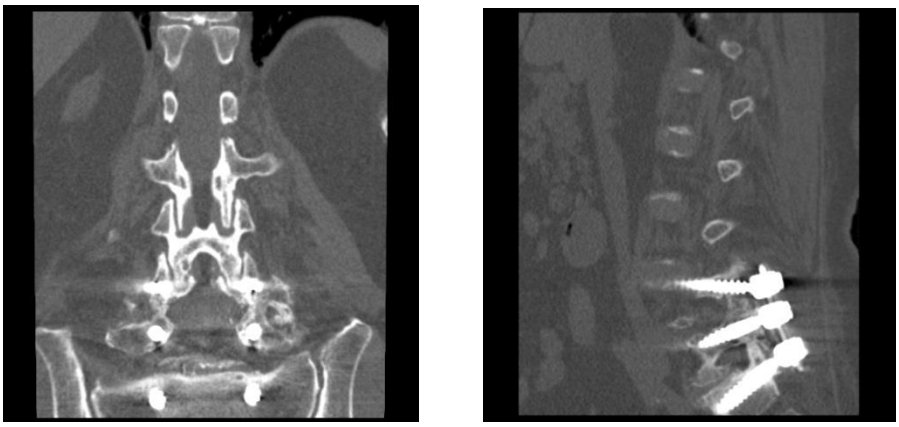

Figure 2. CT scan at 6 months post-op.

Given severe neurologic deficits in the left leg, revision surgery to remove the disc herniation and incorporate the L3-4 level into her spinal fusion was offered. Following this recent surgery, the patient has improved significantly. She will continue to be followed.

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 bone[1].

1. Data on file LifeNet Health

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EX-16-082