CLINICAL ABSTRACT

"Summary of Clinical Outcome related to the Use of Human Amnion Tissue Allograft in Right L4-L5 Decompression Procedure"

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January 27, 2010

INTRODUCTION: Post-operative epidural fibrosis resulting from surgical intervention to the lumbar spine is often a contributing factor to persistent pain post-op and increases the surgical complication rate associated with a revision procedure if one becomes necessary. The complications associated with scar tissue formation include tethering of the nerve roots and adherence of the scar tissue to the underlying dura. Separating the fibrotic mass from the dura mater significantly increases both the risk of a dural tear and the operative time necessary to perform a revision procedure.

MEDICAL HISTORY: 44 year old female patient with a history of severe right leg pain due to herniated discs at the right L5-S1 level and the right L4-L5 level. Patient underwent a right L5-S1 discectomy with decompression of the S1 nerve root in January 2007. The BioDfence nonadherent allograft patch was not used during this procedure. In September 2009, a second lumbar discectomy was performed at the right L4-L5 level and a 2x2 cm BioDfence allograft was placed in the epidural space to form an adhesion barrier between the dura and the surrounding soft tissue. Due to continued symptoms, in January 2010 a decompression and fusion procedure was performed on the right L4-L5 level and the right L5-S1 level.

POST-OPERATIVE CLINICAL OBSERVATIONS: The intraoperative findings at the right L4-L5 level where the BioDfence allograft had previously been placed included essentially no scar tissue and no adhesions to the underlying dura resulting in plane preservation between the dural sac and the surrounding soft tissue. This finding was in distinct contrast to the scar tissue formation at the right L5-S1 level where there was abundant scar tissue formation and adherence to the underlying dura making the revision procedure at this level significantly more difficult. In addition, it was observed that the patch had been completely resorbed by the patient with no visible evidence of its presence at the surgical site.

CONCLUSION: The use of the BioDfence nonadherent barrier significantly reduced both scar tissue formation and adherence to the underlying dura in this patient. The lack of scar tissue and associated plane preservation between the dural sac and the surrounding soft tissue significantly decreased the operative time required to perform the revision procedure.

* Dr. Ploska owns a 1% equity interest in BioD, LLC, the manufacturer of the BioDfence allograft.