Use of Cryopreserved Amniotic Membrane Patch to Improve Recovery from Microdiscectomy: Interim Results of a Two Year, Randomized study of 80 Patients

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Introduction: Introduction: Although traditional lumbar discectomy procedures are routinely successful for treating symptoms of severe radiculopathy, many patients have trouble with postoperative back pain and some will develop recurrent disc herniations at the same level. The goals of this study were twofold: (1) to determine whether the use of cryopreserved amniotic membrane (CLARIX™ 100) as a tissue graft at the site of annulotomy would improve patients symptoms following surgery, and (2) to determine if the use of the amniotic membrane would reduce the rate of recurrent disc herniation.

Methods: After receiving Investigational Review Board approval, eighty (80) subjects undergoing elective lumbar microdiscectomy for radiculopathy were randomized in a 1:1 ratio to receive either an amniotic membrane (CLARIX™ 100) or no tissue (control). The microdiscectomy procedures were performed through a 20 mm incision in a paramedian location using a tubular retractor system. After completing the microdiscectomy procedure, the CLARIX™100 amniotic membrane graft was applied to the defect in the annulus. Data was collected at baseline and again at 1, 2, 3, 4, 6, 9, 12 weeks, 6 months, 9 months, 1 year and 2 years after surgery. The outcome instruments utilized included the Oswestry Disability Index (ODI), the SF12 and a Visual Analog Scale. The primary analysis for this study was the change in ODI scores from baseline at the 6 week time point.

Results: 48 male and 32 female subjects with an average age of 47.2 years (range 20 to 73) reported outcomes from two weeks to one year post surgery. In comparison to controls, the ODI scores of patients treated with CLARIX 100 amniotic membrane had greater mean improvement from baseline at each time point up to week 24. The mean ODI scores for subjects in the amniotic membrane group demonstrated a statistically significant (p=0.045 with two-sided t-test) mean improvement from baseline at week 6 (48.63 reduced to 14.92) compared to controls (51.95 to 23.63). Patients treated with the amniotic membrane demonstrated no (0) recurrent herniations at the surgical level in comparison to 3 recurrent herniations at the same level in the control group (3/39 or 8%).

Discussion: The data from this study suggests a positive clinical effect on patient function as measured by ODI when amniotic membrane is placed at the site of the annular defect. In addition, the rate of reherniation may be reduced by the use of the amniotic membrane at the site of annulotomy. We hypothesize that these effect are due to the anti-inflammatory properties of the amniotic membrane which may allow improved healing at the site of the annular defect. Further study is required to validate the findings of the current study.

Significance: This study suggests a positive clinical effect for patients undergoing microdiscectomy when treated with the cryopreserved amniotic membrane.

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