Cryopreserved Amniotic Membrane Improves Clinical Outcomes Following Microdiscectomy

D. Greg Anderson, MD,* ‡ Victor Popov, MD, † Andrew L. Raines, PhD, ‡ and Julie O’Connell, PhD ‡

Study Design: Prospective, randomized controlled trial.

Objective: To compare pain, physical/mental functional recovery and recurrent herniation for patients following lumbar microdiscectomy with and without the use of a cryopreserved amniotic tissue graft.

Summary of Background Data: Although microdiscectomy procedures are routinely successful for patients with lumbar radiculopathy due to herniated disc disease, residual low back pain, and recurrent herniation remain unsolved clinical problems.

Methods: Following Investigated Review Board approval, 80 subjects were randomized in a 1:1 ratio to either receive cryopreserved amniotic (cAM) tissue or no tissue following elective lumbar microdiscectomy surgery. cAM grafts were applied to the annular defect at the conclusion of the procedure. Patients provided preoperative and postoperative clinical assessment data out to 24 months using the Oswestry Disability Index (ODI), Short Form-12 (SF-12) Health Survey, and Visual Analog Pain Scale for back and leg pain. Patients with symptomatic recurrent disc herniation were recorded.

Results: In total, 48 males and 32 females with an average age of 47.2 years were included. Mean ODI scores for subjects treated with cAM graft demonstrated statistically greater improvement at 6 weeks (14.49 vs. 21.82; \( P = 0.05 \)) and 24 months (6.62 vs. 14.40; \( P = 0.02 \)) compared with controls. Similarly, SF-12 Physical Component Scores demonstrated statistically greater gains in the cAM group at both the 6 weeks and 24 months. None of the subjects in the cAM graft group sustained a recurrent herniation at the same surgical level, whereas 3 patients in the control group sustained a recurrent herniation at the same surgical level, with 2 requiring fusion to manage persistent pain.

Conclusions: The data demonstrate statistically superior clinical outcomes following lumbar microdiscectomy as measured by ODI and SF-12 (physical composite scale) and a lower rate of recurrent herniation with the use of a cAM tissue graft compared with traditional microdiscectomy.

Key Words: amniotic membrane, microdiscectomy, outcome

Lumbar radiculopathy secondary to lumbar disc herniation (LDH) is a common health problem that presents a large economic burden to the medical system.1,2 Nonsurgical treatment options for LDH include activity limitations, pharmacologic therapy, manipulation, physical therapy; and epidural steroid injections.3 Although nonsurgical treatments are often successful, patients who are nonresponsive to conservative therapies or those with progressive neurological symptoms require surgical intervention.

Surgical treatment is generally successful in relieving or reducing radicular symptoms due to LDH.4,5 Unfortunately, with longer-term follow-up, residual/recurrent axial back pain and/or recurrent disc herniation with radiculopathy are significant unsolved problems, with studies reporting reoperation rates following surgery for LDH from 18.5%–25%.4,6 At present, there are no proven treatments available to reduce the incidence of postoperative axial back pain and recurrent disc herniation.

The amniotic membrane (AM) is a placental-derived tissue, sharing the same cellular origin as the developing fetus. A primary function of the AM is to protect the fetus from the maternal immune system and not surprisingly, the AM has recently been shown to be attributable to a unique glycoprotein complex within the extracellular matrix called the HC-HA/PTX3 complex.7

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From the *Department of Orthopaedic Surgery and Neurological Surgery, Thomas Jefferson University; †Rothman Institute, Philadelphia, PA; and ‡Amniox Medical Inc., Atlanta, GA.
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Reprints: D. Greg Anderson, MD, Departments of Orthopaedic Surgery and Neurological Surgery Thomas Jefferson University and Rothman Institute, 925 Chestnut St., 5th Floor, Philadelphia, PA 19107 (e-mail: davidgreganderson@comcast.net).
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