Preclinical Study of Human Allograft Amniotic Membrane as a Barrier to Epidural Fibrosis in the Early Wound of a Postlaminectomy Rat Model

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Purpose: Epidural fibrosis and adhesive dural scarring poses potential problems in lumbar spine revision cases and may in part be responsible for recurrent post-operative pain. The purpose of the current study is to evaluate the use of human amniotic membrane for prevention of dural adhesions in a well established post-laminectomy animal model.

Methods: Thirty two mature male Harlan Sprague-Dawley rats had bilateral laminectomies (L5 and L6) and a right unilateral “joystick” disc injury (L5-6). Sixteen rats received no treatment (control group) whereas the other sixteen animals received the human amniotic roofing barrier (Amnioshield™, Alphatec Spine, Carlsbad, CA) over the entirety of the laminectomy site. Animals survived for 8 weeks. For each group, 8 animals were dedicated to histological analysis. The other 8 animals were allocated to biomechanical testing with dissection and exploration of the scar-dura interface post-testing. Histology analysis involved formalin fixation, ethanol dehydration, polymethylmethacrylate embedding, milling to approximately 100-micron axial sections and staining with Masson-Goldner Trichrome (collagen). Intervertebral foramen fibrosis of the right L5 spinal nerve was quantified using a biomechanical methodology measuring the load-to-failure of the nerve as it is pulled free from the intervertebral foramen. The segmental L5 spinal nerve proximal and distal to the intervertebral foramen were freely dissected, isolating the segment of the nerve within the intervertebral foramen. The nerve was displaced distally at a constant velocity of 1cm/min along the axis of the spinal nerve and load-to-failure (grams) was measured for each animal. Behavioral changes to assess pain were monitored daily during the post-operative period for all animals. Tactile allodynia (behavioral changes) was evaluated utilizing von Frey hairs of logarithmically increasing stiffness to assess the withdrawal response at specific forces (grams) (indicative of pain).

Results: Histological analysis demonstrated clearly demarcated borders of the amniotic barrier separating the epidural fibrosis from the dura while the group with no barrier demonstrated epidural scar directly on the dura with visual obstruction of the dural sac (Figure 1). The axial pullout force required to remove the right L5 nerve root for the no barrier group (194.5±154.2g) demonstrated an approximately 50% greater force required than for the group with a barrier (98.1±98.4g). The barrier group also demonstrated significantly greater tolerance to pain (14.4±1.2g) than the no barrier group (11.1±5.4g) during behavioral testing (30% difference). Dissection of each specimen found that the scar could not be separated from the dura in the no barrier group while the barrier group demonstrated a clear tissue plane and the scar was easily removed without disruption to the dura.

Conclusion: The barrier group consistently demonstrated evidence that the dura was not as affected/adhesed to the epidural scar as the no barrier group when evaluated via histology, biomechanical evaluation of foraminal adhesions, tissue dissection/exploration and pain tolerance.
Figure 1: Histology of no barrier (left) and barrier (right) groups demonstrating scar formation and location.