A Randomized Controlled Trial in the Treatment of Degenerative Lumbar Disc Disease using Viable Allogeneic Disc Tissue Supplementation

Introduction:
Degenerative lumbar disc disease and the development of chronic low back pain (LBP) results from internal disc disruption within the nucleus pulposus. Cellular apoptosis and the loss of proteoglycans within the nucleus leads to altered biomechanical stresses across the disc that can accelerate painful degenerative changes. A viable disc tissue allograft has been developed to supplement tissue loss associated with degenerative lumbar discs.

Aim/Objective:
To evaluate safety and clinical outcomes of a novel allograft in patients with chronic discogenic LBP.

Methods:
A prospective, multicentered, blinded, randomized clinical trial (RCT). 218 patients with chronic LBP secondary to single or two-level degenerative disc disease were enrolled. Inclusion criteria included pre-treatment Visual Analogue Scale of Pain Intensity (VAS) ≥ 40 mm and Oswestry Disability Index (ODI) Score ≥ 40. Subjects were blinded and randomized to receive intradiscal injections of either allograft or saline, or to continue with non-surgical management (NSM). The NSM group could cross over to the allograft group after 3 months. Clinical outcomes were assessed at 6 and 12 months. Adverse events were continuously assessed.

Results:
At 12 months the VAS scores improved 30.5, 34.0, and 46.7 in the saline (S), active allograft (AA), and the crossover to allograft (COA) groups respectively, and the ODI scores improved 23.9, 27.4 and 36.4 in the same groups. This represents a 54% improvement in VAS and a 53% improvement in ODI in the active allograft group. NSM subjects following crossover attained a 65% improvement in pain at 12 months combined with a 64% improvement in ODI. Responder rates were clinically significant for both ODI and VAS with 76.5% of patients treated with AA showing improvement in ODI ≥ 15 points at 12 months versus 56.7% of patient treated in the S group (p=0.030) and 91.3% of the COA group versus 56.7% of the S group showing a ≥ 20-point improvement in VAS (p=.006). In the allograft group, 11 severe adverse events occurred in 141 subjects (3.5%). The safety profile of the supplemental allograft was demonstrated to carry a risk similar to discography.

Conclusions:
This large, prospective RCT showed safety and efficacy results demonstrating that viable disc tissue allograft is a safe treatment that produces improved function and pain at 12 months. This technique may be a beneficial non-surgical treatment for patients that have chronically painful lumbar degenerative discs.