## Disc Repair with Autologous Chondrocytes: A Pilot Clinical Study

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**INTRODUCTION:** This pilot study was designed to assess whether autologous disc chondrocyte transplantation will prevent disc degeneration in patients that have undergone discectomy. Cultured autologous cells were transplanted into the nucleus pulposus by a closed procedure. While it has been shown previously that disc cells sustain a phenotype in culture and that transplantation into canine disc demonstrates appropriate integration, the fate of transplanted cells in a human population has not been reported.

**METHODS:** Patients were actively recruited for this study from a population that was to be surgically treated for single level disc herniation. To be included in this study, patients could not have modic changes and must have failed previous conservative treatment. Patients were evaluated by VAS, Jenny neurological score, and an assessment of spine mobility was made. Intervertebral discs were also assessed qualitatively by MRI for disc height, degenerative changes (Modic), and fluid content. Disc material was removed by open microdiscectomy and intra-operative diagnosis of the disc (I-IV) was made. Cells were commercially expanded for transplantation under GMP conditions and maintained in culture with serum taken from individuals prior to their surgery. Transplantation occurred 3 months after the microdiscectomy procedure. Patients were hospitalized for 2 days following cell transplantation and required to wear a lumbar orthosis for the follwing 3 weeks. Follow-up occurred at 3, 6, 12, 24, and 36 months after the procedure.

**RESULTS:** MR images demonstrated changes at the surgical site that were characteristic of normal disc morphology. Introduction of cells had a positive affect on cell height, MRI signal, and matrix appearance. MRI changes were positive over time; showing enhanced central disc signal, and reduction in endplate effusion. All patients in the study showed improvement in the level of their low back pain and spine mobility was preserved or enhanced in 87.5% of the patients in this study. By 3 months, approximately 73% of the patients regained full motor sensation, and 82% of the patients sensory achieved recovery. Remaining symptoms were slight and in most cases not residual. Assessment on the VAS scale demonstrated pre-operative a mean of approximately 76mm that was reduced to 19mm in the final assessment. No secondary instability or degenerative change at adjacent levels was seen nor was progressive degenerative change at the treated intervertebral disc documented.

DISCUSSION & **CONCLUSIONS:** Autologous cells transplanted into a damaged intervertebral disc appear to retard degeneration. Evidence of matrix production and suppressed inflammation was evident by MRI, radiography, and by clinical assessment of pain. From these clinical results, autologous disc chondrocyte cell transplantation appears to offer the promise of retarding degeneration, maintaining intervertebral height, and stimulating matrix regeneration after microdiscectomy. Relief of pain, matrix production integration, and no evidence and of degeneration suggest autologous cell transplantation may be a valuable clinical tool for use in treating disc herniation.