Can an Annular Repair Device Prevent Recurrent Disc Herniation and Interrupt Degenerative Disc Disease? A New Motion Preserving Annular Repair Device Prevents Recurrent Herniation and Maintains Disc Height

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Lumbar disc herniation is a common symptom of low back pain and often requires surgical intervention. The outcome of the surgery is a factor of the surgical proficiency, annular wall competency, disc degeneration and patient expectations. There are many publications describing discectomy techniques, outcome measures, reherniation and reoperation rates and disc height changes. These reports suggest reherniation and reoperation rates can occur in about 15% of patients and poor patient outcomes can occur in about 28% of patients with most recurring symptoms manifesting within twelve months of the discectomy procedure.

A novel PEEK annular repair device has been developed with a complex geometry to be inserted into an annular defect following discectomy surgery. The device is self retaining with a feature for retention and occupying a voided space within the disc space; structurally supports disc height between adjacent vertebrae; and, seals the annular defect while promoting a fibrous capsule response on the posterior aspect of the device. Biomechanical testing was completed to demonstrate safety and led to a feasibility study by the authors.

A prospective study for patients with single level lumbar disc herniation was initiated. Patients failed conservative therapy, had MR confirmation of disc herniation before surgery and met inclusion and exclusion criteria before consenting to the study. Baseline ODI and VAS scores were measured prior to surgery. Discectomy surgeries were performed either open or using MIS techniques. Following the discectomy the disc space was measured and prepared for the implant. Follow-up intervals are post-op, 6 weeks, 3, 6 and 12 months from surgery and include clinical assessment, evaluations and imaging.

Twenty patients were enrolled in the study. Mean age was 43±14 years and 50% of the patients were male. All patients were discharged one day after surgery. All patients have completed minimum six month follow-up visits and eight patients have one year follow-up. There are no recurrent disc herniations. Disc height and sagittal alignment have been maintained. Flexion and extension radiographs demonstrate segment motion preservation. MR images provide evidence of a thin fibrous cap covering the posterior aspect of the implant and annular defect. CT images confirm dense bone surrounding the implant at the adjacent vertebrae without observation of latent patient pain. Mean baseline ODI was 77%±8%; mean six month ODI was 7%±6% and mean one year ODI was 2%±2%. Mean baseline VAS was 72mm±10mm, mean six month VAS was 9mm±10mm and mean one year VAS was 4mm±5mm. Two patients required revision surgery unrelated to a recurrent herniation.

The new annular repair device does not affect the discectomy procedure and is easy to use. The implantation step adds approximately seven minutes to OR time. The device is retained and there have been no observations of recurrent disc herniation. Imaging results and pain scores confirm annular repair implant benefits. Study data for ODI and VAS demonstrate continued improvement in patient outcomes over one year follow-up whereas published discectomy patient benefits typically plateau after three months. Does disc height, motion preservation or a physiologic response to the annular repair device improve patient outcomes? Longer term follow-up data is being collected.