Abstract: 285

The Effect of Anular Repair on Sciatica Patients Receiving a Micro-discectomy Procedure

A. Araghi[1], *C.E. Sugden*[2]

[1]Texas Back Institute, Phoenix, AZ, USA, [2]Anulex Technologies Inc., Minnetonka, MN, USA

Introduction: Sciatica is the most common symptom associated with a lumbar disc herniation. Surgical treatment of this condition includes a micro-discectomy procedure which aims to alleviate this radicular pain by eliminating the impinging disc fragment on the exiting nerve root. More often than not, this results in an anulus fibrosus defect, of which closure is not included as standard of care. Repairing this defect following the micro-discectomy procedure may prevent recurrent herniations.

Methods: Patients from an on-going multi-center, prospective, randomized study were analyzed to evaluate the effect of anular repair on patients with sciatica (predominant radicular pain). Inclusion criteria for this analysis included a preoperative leg pain score of 5 or greater and a preoperative back pain score of less than 5 on a 0-10 Visual Analog Scale (VAS). Additionally, only those patients with a minimum of 6 months follow-up were included in this study cohort. Demographic information such as age, gender, and BMI was collected. Pain and disability assessments (VAS and ODI) as well as a quality of life questionnaire (SF-12) were used to evaluate patient outcomes. This data was collected preoperatively and at 2 week, 6 month and 12 month follow-up intervals. Information such as work activity, work status and adjunctive therapies was also obtained as well as untoward event rates including reoperation.

Results: A 2:1 randomization schema (anular repair “Repair”; no anular repair “Control”) resulted in 221 patients (75 Control and 146 Repair patients). The groups were appropriately comparable demographically and operatively. For example, the control and repair groups were 61 and 62 percent male with an average BMI of 29.5 and 28.3 respectively. The mean age in both groups was 44 years. Preoperative VAS, ODI and SF-12 mean scores showed no significant differences between study groups including mean preoperative VAS leg pain scores of 8.1 and 7.8 and back pain scores of 2.1 and 2.2 (control:repair). Each group saw a significant improvement in their mean outcome measures as compared to pre-operative scores at all post-op follow-up intervals with no significant differences between the study groups. For instance, at 6 months post-op, the mean scores included 1.2 on leg VAS in both groups and 1.6:1.7; (control:repair) for back VAS. The difference between the study groups was evident with regard to reoperations, particularly re-do discectomies for recurrent herniation. The overall reoperation rate in the control was 8.0% as compared to 4.1% for repair. Re-do discectomy for recurrent herniation had a rate of 6.7%:3.4% (control:repair).

Conclusions: This study shows repairing the anulus fibrosus following a micro-discectomy procedure has the potential to decrease the reoperation rate by 48.8% when comparing patients with anular repair to those without repair. Additionally, it was observed that there were no negative effects as a result of the repair (specifically the perceived irritation potential from the knot of the repair device on the nerve root) as the repair study group did not have an increased incidence of leg pain as reported by VAS. As such, anular repair should be strongly considered an essential part of the micro-discectomy procedure.