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Preliminary Observations from a Prospective, Multi-center, Randomized, Controlled Clinical Trial Evaluating Anular Repair after Lumbar Discectomy

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Introduction: Outcomes after lumbar microdiscectomy are generally favorable, but the potential remains for reherniation with an unrepaired annulus fibrosus. Devices and techniques for repairing the annulus fibrosus after lumbar discectomy have recently been suggested to mitigate the need for potential secondary surgery due to reherniation. This on-going prospective, randomized, controlled clinical trial seeks to provide clinical evidence for the primary benefit of anular repair, namely reduction in reoperations for reherniation, with comparatively similar clinical outcomes.

Methods: Patients (n=750) from a fully-enrolled clinical study are being followed up to two years post-discectomy. This study was performed at 34 investigative sites in the USA by 58 surgeons. Randomization of repaired annulus fibrosus (RAF; n= 500 pts) versus no repair (NR; n= 250 pts) occurred in a 2:1 schema at the conclusion of the discectomy; anular repair was accomplished using a commercially-available device (Xclose™ Tissue Repair System, Anulex Technologies, Minnetonka MN). In twenty-cases, the repair was attempted but the device was not able to be implanted, therefore the repaired treatment group consists of 478 patients. At the time of this preliminary analysis (Oct 1, 2009), the average follow-up was 13.1 +/- 6.4 months (range: 1 to 30 months). Patient outcomes measured by visual analogue scales (VAS), Oswestry disability index, and SF-12 were collected pre-operatively and 2 wks, 6 months, and yearly post-discectomy. In order to account for anomalies associated with randomization at low enrolling sites, only patients (458:235; RAF: NR) from surgeons (n=41) who enrolled five or more cases were included in this observational cohort. A Kaplan-Meier analysis with Cox Proportional Regression analysis was used to estimate the risk of post-discectomy reoperations with specific emphasis on those due to recurrent herniation. Positive treatment effect attributable to anular repair was also estimated by comparing reoperation rates in the control, unrepaired group versus the repaired, treatment group stratified according to surgeon groups with a minimum number of enrolled patients (range: 5 to 30 patients).

Results: Similar clinical outcomes were noted in the two groups with similar occurrence rates of adverse events. Based on current data available, there was a trend toward a 1.75 times greater risk over time of reherniation in the control group requiring a second surgery and an overall 57% reduction in the risk of reherniation with the device. As the number of enrolled patients per surgeon increased, the beneficial treatment effect of anular repair to reduce reoperation due to recurrent herniation increased; ranging from 28% to 57% with the greatest effect seen in the experience of the surgeons' who enrolled twenty or more patients in the trial.

Conclusions and discussion: Increased awareness of the need to reduce reoperation after lumbar discectomy has led to the idea of repairing the annulus fibrosus. The data from this large multi-center/multi-surgeon clinical study provides evidence in support of the beneficial effect of anular repair. Additionally, the treatment benefit was generally more evident as the number of treated patients increased. Continued follow-up will provide additional confirmation of these early results.