Reconstructing the Anulus: Complete One-year and Initial Two-year Results from the Intrinsic Therapeutics Barricaid® Endoprosthesis Pilot Study

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Introduction: Closing anular defects with a mechanical barrier may reduce the incidence of reherniations and recurrent pain and may better maintain disc height by retaining nuclear material. The purpose of this single-arm, prospective, multi-center study was to evaluate the safety and performance of the Intrinsic Therapeutics Barricaid. This evaluation involved a comparison to a separate single-arm, prospective multi-center study of discectomy patients with similar inclusion criteria.

Material/methods: The Barricaid endoprosthesis consists of a woven-polyester mesh intended to block an anular defect. The mesh is anchored to one of the adjacent vertebral bodies by a titanium bone anchor.

Patients were treated in Rijeka and Zagreb, Croatia. The study population consists of 30 primary discectomy patients treated between April 2008 and July 2009. Inclusion criteria included sciatica unresponsive to conservative therapy for six weeks, minimum ODI and VAS leg (ipsilateral) scores of at least 40 out of 100, and radiographic confirmation of herniation as the cause. Follow-ups occur at 6 weeks, 3, 6, 12, and 24 months postop. VAS (back and both legs), ODI, and x-rays were obtained at each follow-up. MRs and CTs were taken at 12 and 24 months.

A second group of patients were treated as part of a separate study at these two, as well as three other, European centers. This study consists of 137 primary discectomy patients treated since January 2003 who were not implanted with the device.

Results: All patients have passed the one-year timepoint, and 14 patients have passed the two-year timepoint. Importantly, there have been no recurrent herniations in Barricaid patients. The reherniation rate at one year in the control group was 11% (p=0.044).

At 12 months, Barricaid patients exhibited lower VAS back scores (13.2 vs. 23.8, p=0.019), lower VAS ipsilateral leg scores (3.9 vs. 16.3, p=0.002), and similar ODI scores (15.6 vs. 19.3, p=0.317). Defining clinical significance as a reduction of at least 20 points in VAS or at least 15 points in ODI, all implanted patients exhibited clinically significant reductions in VAS ipsilateral leg (vs. 82% control) and ODI (vs. 80% control). 93% demonstrated a clinically significant reduction in VAS back (vs. 54% control).

Control patients have lost an average of 13.5% of their preop disc height by 12 months, compared to 9.6% for Barricaid patients. At 24 months, control patients lost 15.8% of their preop disc height vs. 10.3% for Barricaid patients.

Discussion: Implantation of the Barricaid has been shown to be safe and easy, with no implantation failures, and no device-related adverse events at any timepoint. To date, the device is performing its function of retaining nuclear material within the disc, and the implanted patients have experienced excellent clinical outcomes superior to control, particularly in VAS back scores.