Early Two-Year Safety Data for an Anular Closure Device: Interim Results from a Multicenter, Prospective, Randomized Clinical Trial

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Objective

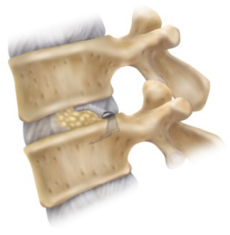
Lumbar discectomy is the most commonly performed spine surgery, generally resulting in immediate relief of symptoms from herniated or bulging discs. Long term results are less encouraging, with many patients suffering reherniations and/or continued degeneration. Studies have shown that limited nucleus removal results in reduced back pain in the long term. However, limited nucleus removal also leads to more frequent reherniation, particularly in patients with large anular defects. Implantation of an anular closure device (ACD) may allow for the advantages of limited nucleus removal without increased reherniation risk as well as the potential degeneration associated with aggressive nucleus removal. We report here interim results of an ongoing randomized clinical trial (RCT) of an ACD.

Methods

The Barricaid® ACD (Intrinsic Therapeutics; Woburn, MA, USA) consists of a polyester mesh that occludes the anular defect, and is held in place by a titanium bone anchor. This CE-marked device is currently being marketed and is also being studied in a multicenter, post-marketing, randomized, controlled trial in Europe (http://clinicaltrials.gov/ct2/show/NCT01283438). Randomization (1:1, Barricaid:Discectomy-only) is web-based and is performed intra-operatively, following discectomy and confirmation of anular defect size (minimum 4x6mm, maximum 6x10mm).

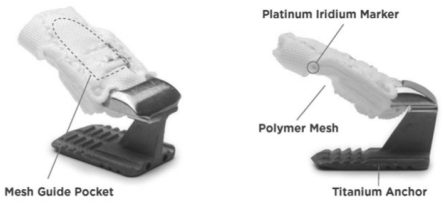
Inclusion criteria include six weeks conservative care, no prior surgery at the index level, minimum Oswestry (40/100) and minimum leg pain (40/100). Reoperations and adverse events are tracked prospectively, and patients are evaluated clinically and radiographically at 6 weeks; 3 and 6 months; and annually until the last patient enrolled has reached 24 months.

Barricaid Device



Model of the Barricaid device anchored in the cover plate and the disc space

Barricaid Device

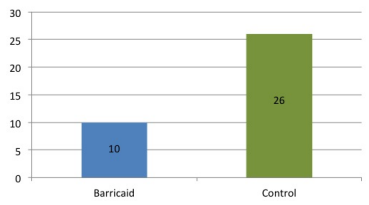


Implant with titananchor and multilayer polyester mesh and platinum iridium marker

Results

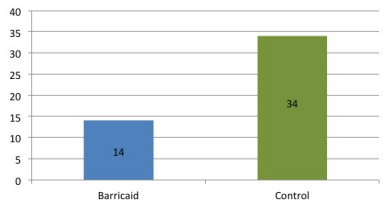
421 patients have been enrolled through September 2013, with 251 past one year and 90 past two years. Similar numbers of patients in each group have reported an adverse event (Barricaid 49%=102/210, Control 53%=112/211), with fewer serious adverse events (SAE) reported for Barricaid patients (40 vs 63). The Barricaid group had 62% fewer symptomatic reherniations, (10 vs 26), 59% fewer reoperations at the index level (14 vs 34), and 74% fewer reoperations following recurrence including repeat reoperations (7 vs 27).

Symptomatic Reherniations



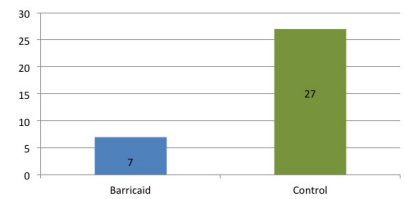
- 62% fewer symptomatic reherniations index level in the Barricaid Group vs Control (10 vs 26).

Fewer reoperations for any reason



- 59% fewer reoperations for any reason at index level in the Barricaid Group vs Control (14 vs 34).

Fewer reoperations following recurrence



- 74% fewer reoperations following recurrence including repeat operations Barricaid Group vs Control (7 vs 27)

Conclusions

Interim data from a postmarketing RCT indicate that including an anular closure device during lumbar discectomy surgery may result in better patient outcomes, fewer reoperations, lower postoperative health care expenditures, and favorable cost-effectiveness.