BARRICAID

Can prevention of a reherniation be investigated? Establishment of a herniation model and experiments with an anular closure device

Spine (Phila Pa 1976). 2013 May 1;38(10):E587-93. https://doi.org/10.1097/BRS.0b013e31828ca4bc H-J Wilke, L Ressel, F Heuer, N Graf, S Rath

Abstract

Study Design: Biomechanical in vitro study.

Objective: To establish a reliable in vitro herniation model with human cadaver spines that enables evaluation of anular closure devices.

Summary of Background Data: Biomechanically, it is desirable to close anulus defects after disc herniation to preserve as much nucleus as possible. Multiple anular closure options exist to prevent reherniation. A reliable test procedure is needed to evaluate the efficacy and reliability of these implants.

Methods: Two groups of human lumbar segments (n = 6 per group) were tested under cyclic loading until herniation occurred or 100,000 load cycles were applied. One group contained moderate/severe degenerated discs. A second group had mild degenerated discs. Intradiscal pressure was measured in the intact state to confirm disc quality. If herniation occurred, the extruded material was reinserted into the disc and the anulus defect was treated with the Barricaid anular closure device (Intrinsic Therapeutics, Inc., Woburn, MA). Disc height and 3-dimensional flexibility of the specimens in the intact, defect, and implanted states were measured under pure moments in each principal motion plane. Afterwards, provocation of reherniation was attempted with additional 100,000 load cycles.

Results: Likelihood of herniation was strongly linked to disc degeneration and supported by the magnitude of intradiscal pressure. In moderate/severe degenerated discs, only 1 herniation was created. In mild degenerated discs, herniations were reliably created in all specimens. Using this worst-case model, herniation caused a significant reduction of disc height, which was nearly restored with the implant. In no case was reherniation or implant migration visible after 100,000 load cycles after Barricaid implantation.

Conclusion: We established a human herniation model that reliably produced nucleus extrusion during cyclic loading by selecting specimens with low disc degeneration. The Barricaid seems to prevent nucleus from reherniating. The reliability of this method suggests the opportunity to investigate other anulus closure devices and nucleus replacement techniques critically.

Financial disclosure:







One or more authors have received financial compensation from Intrinsic Therapeutics. Full financial disclosures can be found in the respective manuscript.

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