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Biomechanical Investigation of a New Annulus Reconstruction Implant after a Provoked Nucleus Extrusion
H.-J. Wilke¹, L. Widmann¹, N. Graf¹, F. Heuer¹
¹University of Ulm, Institute of Orthopaedic Research and Biomechanics, Ulm, Germany

Introduction: A common method to treat herniated discs is to remove the sequester followed by a partial or the complete removal of the nucleus to avoid a reherniation. Removing too much nucleus material can lead to a non-physiological biomechanical behavior of the treated segment, whereas removing too little material can increase the risk of a re-herniation. Therefore it would be desirable to close the annulus defect in order to preserve as much nucleus material as possible. The aim of this in vitro study was to determine the reliability of a new annulus reconstruction implant in a disc herniation model.

Methods: To simulate a worst case scenario, human spinal segments were inspected until three L2-3 and three L4-5 segments could be selected for the tests. All specimens had to prove during intradiscal pressure measurement that the nucleus still features hydrostatic behavior. In all six specimens with a median age of 58 years a rectangular defect was created with 6 x 10 mm (height x width) at the posterior annulus. Subsequently a complex cyclic load was applied until a visible nucleus extrusion occurred. The extruded material was pushed back into the disc and the annulus defect was treated with the Barricaid ARD implant (Annulus Reconstruction Device, Intrinsic Therapeutics Inc.). The ARD consists of a metal anchor that was inserted below the superior endplate of the inferior vertebra and a mesh that was placed inside the disc to seal the annulus internally (figure).
Disc height and flexibility of the specimens was measured in all three main motion planes with a spine tester (intact, defect and implanted). Afterwards a cyclic loading test was conducted to provoke re-herniation. The specimens were mounted in a servo hydraulic material testing machine and loaded with 4-24 Nm at 5 Hz while they could rotate with 360°/s.

Results: Compared to the intact state, the provoked herniation caused a median reduction of the disc height of 0.6 mm that could be restored up to 0.2 mm with the implant. The increase of the range of motion (ROM), however, could only be improved slightly. In contrast the fundamental result was that in no case a re-herniation was visible in the macroscopic inspection after 100,000 cycles.

Discussion: This in vitro study showed that, in general, it seems that it is possible to reliably seal an annulus defect with an implant. On the basis of previous investigations we tried to simulate a worst case scenario with this herniation model. The nucleus of the specimens showed still hydrostatic behavior in all cases so that nucleus extrusion during cyclic loading was presumable. After the implantation of the ARD this risk was still existent. Concluding the new generation of the Barricaid ARD seems be able to prevent the nucleus from re-herniation.