# Initial Cadaver Evaluation of a Mechanical Nucleus Removal Device

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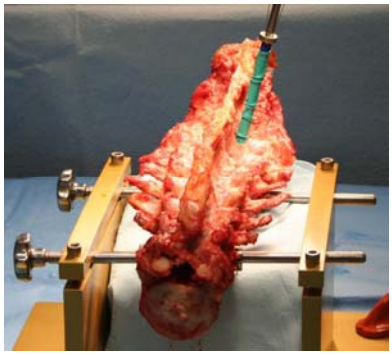
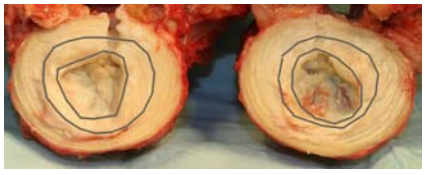
**Purpose:** A device has been designed for improved nucleus removal to aid in optimum placement and performance of nucleus replacements and other minimally invasive spinal implants. An evaluation of the device's ability to remove nucleus tissue was performed.

**Methods:** The device incorporates a rotational shaver that can extend from an articulating tip that can bend over 90º, providing access to the entire nucleus cavity from even a unilateral posterior approach. The device uses a central lumen for aspiration of cut nucleus tissue. The cutting head geometry and related cutting parameters are designed to minimize damage to adjacent annulus and cartilaginous endplate tissue.

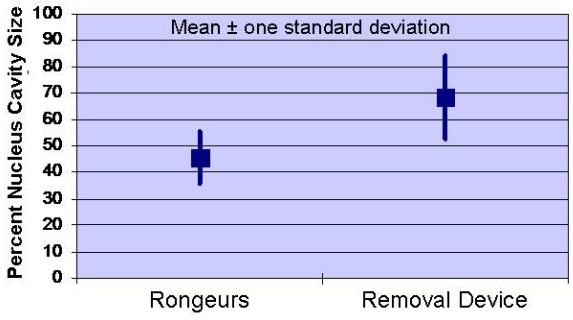
Five intervertebral discs (L3 – S1) from three cadaver lumbar spines (mean age = 59yr) were used to evaluate the ability of a prototype device to remove nucleus tissue. The spines were mounted in a frame for unilateral posterior access. Access to the discs was performed via a hemilaminectomy (preserving the facet) and a stab incision through the annulus the full height of the disc. A small amount of nucleus material was removed with an IVD rongeur to create an initial cavity for the prototype device. The prototype device was inserted into the disc space, activated, and manipulated in the nucleus cavity with aspiration for a maximum of 10 minutes. As the prototype device was not designed with an irrigation port, water was occasionally injected into the disc space to hydrate the nucleus and prevent adherence of the cut tissue within the evacuation lumen. The device was occasionally flushed with water to further clear the aspiration tubing. All cut tissue was collected in a filter trap.



The intact discs were dissected, photographed, and analyzed using a visual measurement method. The annulus/nucleus and enucleated cavity borders of each specimen were delineated, then measured with digital video measurement software (Universal Desktop Ruler, avpsoft.com) that converts video pixel count into area after calibration against a known scale. The enucleated cavity area was compared to the total nucleus cavity to calculate a percent of maximum nucleus removed. The results were compared to an earlier nucleus removal study using standard rongeurs in nine lumbar disc levels (Sherman, 2006).



**Results:** The cavity created by the prototype device averaged 68.2% of the total nucleus area compared to 45.7% using just rongeurs, statistically significant with $p < 0.05$. An analysis of the material remaining in the quadrant of the disc contralateral to the annulus access showed a 34.0% increase in the cavity with the prototype device compared to standard rongeurs ($p = 0.05$). Visual examination of the disc cavities enucleated with the prototype device showed no damage to the annulus in any of the specimens, and only minor removal of some the cartilage of the endplates (compared to significant damage to the endplates common in the study using rongeurs).




**Conclusions:** The prototype device created a larger nucleus cavity than with a rongeur, and damage to the annulus and endplates was minimized. These results will lead to refinements in the device design.