Poster #81

Limitations of Nucleus Pulposus Removal using Traditional Methods via the Posterior Approach

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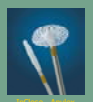
BACKGROUND

Prosthetic nucleus and annulus repair devices are new classes of spinal implants that have unique requirements for the degree and location of nucleus pulposus removal compared to the typical unilateral discectomy procedure. Many prosthetic nucleus designs, especially those considered load-bearing, require complete nucleus removal prior to device implantation. Depending on the design of the implant, an incomplete nucleus removal can result in:

- incomplete filling of the nucleus cavity, reducing the effectiveness of the implant
- off-center filling of the nucleus cavity, resulting in uneven load distribution and potentially leading to a pseudo-scoliosis condition
- undesired implant movement or dislocation


Dascor - Disc Dynamics


InClose - Anulex


PDN - Raymedica


NuBac - Pioneer Medical


NeuDisc - Replication Medical

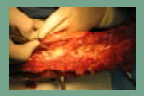
Annulus repair devices that are intended to be anchored to the annulus near the defect may be secured in place better with meticulous removal of the nucleus adjacent to the annulus defect.

An additional challenge to the nucleus removal procedure for these implants is the preservation of the integrity of the annulus and vertebral endplates. Load-bearing prosthetic nucleus devices are intended to share the load on the spine with the annulus, and all prosthetic nucleus implants rely on an intact annulus for containment. The anchoring method for annulus repair devices will be most effective in the most intact annulus tissue. An annulus damaged by the nucleus removal procedure, either directly by cutting or indirectly by multiple instrument insertions, is less able to function in concert with the nucleus implant. For all of these implants, damage to the endplates increases the risk of device subsidence and initiation of the fusion cascade. It is expected that the care needed to preserve these tissues may contribute to a less aggressive nucleus removal.

The current standard method for nucleus removal is with the use of IVD rongeurs, which many have recognized qualitatively as having significant limitations in adequate removal of the nucleus tissue prior to implantation of these new spinal implants, especially when used via the posterior approach.

This study measured the effectiveness of IVD rongeurs in site preparation for these new spinal implants by quantifying the amount and identifying the location of nucleus material removal with rongeurs via the posterolateral approach. This study also investigated the impact that extensive surgeon education may have on nucleus removal with rongeurs.

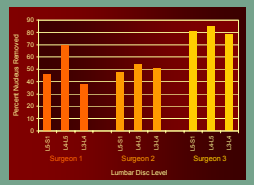
METHODS

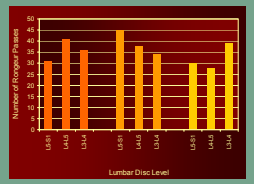


Three fresh frozen human cadaver lumbar spine specimens (52 yr male, two 65 yr female) were mounted in a fixture to allow posterolateral access to the disc. Three experienced spine surgeons each treated three disc levels between L3-S1. One of these surgeons possessed an extensive self-education in complete nucleus removal, having performed the procedure on scores of cadaver spines followed by disarticulation of the segments to provide immediate learning feedback. A partial laminectomy was performed to access the disc parallel to the endplates for minimizing trauma to the superior endplate from the rongeurs. An incision was made through the annulus. A variety of common straight and angled IVD rongeurs were used by the surgeons, whose goal was to perform as complete a removal of the nucleus from each disc as possible without damaging the endplates or annulus. The time for nucleus removal and the weight of the nucleus removed was recorded for each disc. Upon completion of this procedure the disc was dissected and photographed to determine the location of nucleus removal. Any remaining nucleus was removed using rongeurs and weighed, with the weight used to calculate the total weight of nucleus for each disc.

RESULTS

The amount of nucleus removed prior to dissection ranged between 37.9% and 84.6%, with a mean of 81.1% (n = 3) for the surgeon experienced in complete nucleus removal and 50.9% (n = 6) for the other two surgeons for an overall mean of 60.9% (n = 9). The greater removal by the surgeon experienced in complete nucleus removal was statistically significant (t-test for unequal variances, $p < 0.003$). For all surgeons, the nucleus remaining prior to dissection was located primarily in the areas adjacent to the annulus access and contralateral to the annulus access. The time devoted to nucleus removal following the annulus incision ranged from 6 to 13 minutes, with a mean of 9.9 minutes. The number of insertions of the rongeurs through the annulotomy ranged from 28 to 45, with an average of 36 insertions before the surgeons determined that no more material could be removed.






L3 - L4 after nucleus removal via posterolateral approach


L4 - L5 after nucleus removal via posterolateral approach


L3 - L4 after complete nucleus removal following disarticulation


L4 - L5 after complete nucleus removal following disarticulation

CONCLUSION

The physical limitations of the posterior elements of the spine combine with the generally oval geometry of the disc to limit the reach of standard IVD rongeurs in the disc space using the posterior approach. As a result, a complete nucleus removal using rongeurs in this approach will rarely be achieved, if at all, and is independent of the skill level of the surgeon. This study indicates that nearly 50% of the nucleus material is likely to remain in the disc cavity following as thorough of a cleanout as possible for an experienced spine surgeon using this approach. A surgeon with extensive training specifically for complete nucleus removal will still likely leave nearly 20% of the nucleus material. As expected, much of the remaining material is located contralateral to the site of entry into the nucleus.

For prosthetic nucleus designs that require total nucleus removal, these results show that reliance on rongeurs alone may result in an inadequate site preparation. Similarly, the inability of rongeurs to provide adequate nucleus removal adjacent to the annulus access may have an impact on proper placement of annulus repair devices. These results suggest that improvements either in technique, instrumentation, or both are necessary for the type of nucleus removal required for successful placement of prosthetic nucleus and annulus repair devices via the posterior approach.

This study was produced with the support of CoreSpine Technologies, LLC, Minnetonka, MN