

HydroDiscectomy™: Tissue Consumption Analysis Using the SpineJet™ MicroResector in a Cadaveric Study

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Hypothesis:

The SpineJet MicroResector from HydroCision demonstrates predictable tissue consumption of nucleus pulposus in spinal discs independent of age and tissue characteristics.

Method:

Two cadavers were used to measure tissue consumption rates of nucleus removed with a SpineJet MicroResector. A SpineJet Power Console was used to power the disposable handpiece. The system pressurizes sterile saline up to 15,000 PSI into a collimated fluid jet. The jet exits a 0.1mm nozzle at the device tip and is collected in a 2mm diameter tube that evacuates the fluid and morcellated tissue to a waste canister. Two explanted human spines (segmented) were procured for use in the study: One from a 39-year-old female, and one from a 69-year old male. Five lumbar discs were evaluated from each of the explanted spines, and nucleus tissue removal was performed using a SpineJet MicroResector. Time for nucleus removal was recorded and net weight of removed nucleus material was determined by weight reduction of the disc.

Discussion:

Fluidjets possess the properties of extremely precise tissue cutting tools, requiring minimal mechanical force and present no risk of thermal damage. The SpineJet MicroResector is specifically configured for precise access and removal of nucleus material. It has the unique ability to cut and simultaneously remove nucleus pulposus. These properties result in a faster, more predictable rate of nucleus removed compared to other technologies, and decreased time required to perform the discectomy.

Many automated discectomy devices are sensitive to the condition of the disc and are therefore less predictable. In this study, the two specimens were representative of the extremes likely to be encountered clinically for this procedure. The discs of the 39 year-old female were healthy and well hydrated, and those of the 69 year-old were desiccated and somewhat degenerated.

Results:

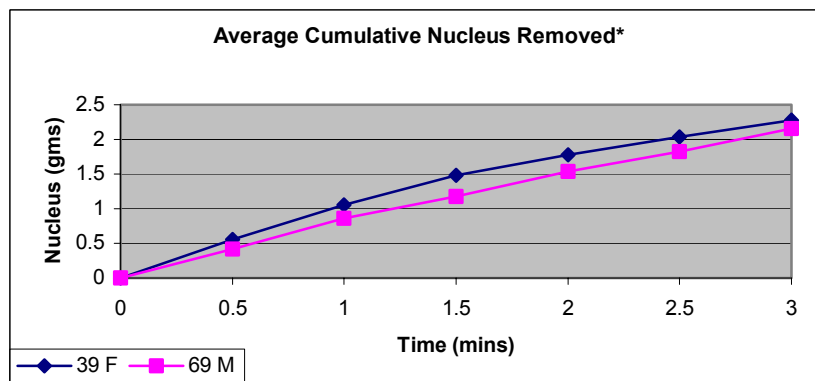
The MicroResector removed an average of 1.1 grams of tissue in the first minute, 0.7 grams in the second minute and 0.5 grams in the third minute from the 39-year-old female. It removed an average of 0.9 grams in the first minute, 0.7 grams in the second minute and 0.6 grams in the third minute from the 69-year-old male.

	Time (minutes)		
	1	2	3
Cadaver	Average Nucleus Removed (grams**)		
39 F	1.1	0.7	0.5
69 M	0.9	0.7	0.6

Conclusion:

The SpineJet MicroResector demonstrates predictable tissue consumption rates for nucleus removal of a broad range of tissue conditions and ages. The MicroResector is designed to safely access a targeted area of the disc. The diminishing rate of consumption is attributed to the evacuation of nucleus in the targeted area.

**For volumetric conversion use a density of 1g/cc for nucleus. Thus, 1.1g of nucleus removed is equivalent to 1.1cc. This is based off published information that 85% to 95% of the nucleus pulposus is made up of water¹ and that most soft tissues of the body have densities close to 1g/cc².
[¹Growler, et al. (1969) Age-Related Variations in Protein-Polysaccharid from Human Nucleus Pulposus, Annulus Fibrosus and Costal Cartilage, J. Bone Joint Surg. 51A 1154-1162; ²Kaye and Laby (1995), Tables of physical and chemical constants 16th edition.]



*Data on file