

Tissue Consumption Analysis Using the SpineJet™ MicroResector MD 2.5 in a Cadaveric Study

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Objective:

This study was created to prove that the MicroResector MD 2.5 removes spinal tissue at a predictable rate.

Summary of Background Data:

A previous study of the SpineJet MicroResector from HydroCision demonstrated predictable tissue consumption of nucleus pulposus in spinal discs for a broad range of tissue conditions and ages. A bench study was conducted to demonstrate that a new design, indicated for the microdiscectomy procedure, has the same predictable nature.

Methods:

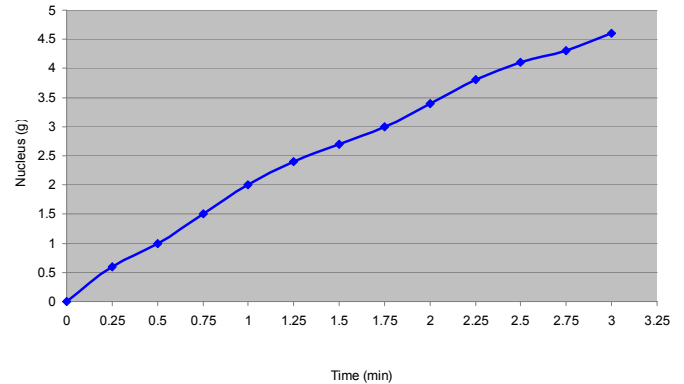
A cadaver was used to determine the tissue consumption rate of nucleus with a SpineJet MicroResector MD 2.5. A SpineJet Power Console was used to power the disposable handpiece. The system pressurizes sterile saline up to 15,000 PSI into a collimated fluid jet. The jet exits a 0.1mm nozzle at the device tip and is collected in a 2.4 mm diameter tube that evacuates the fluid and morcellated tissue to a waste canister. An explanted human spine - segmented and from a 77-year old male - was used in the study. Six discs levels (T12/L1 to L5/S1) were excised from the explanted spine, and nucleus tissue removal was performed using a SpineJet MicroResector MD 2.5.

The SpineJet was operated for 15-second intervals and the disc weight subsequently recorded. The net weight of disc nucleus material was calculated from the difference in weight for each 15-second interval. All disc levels were subjected to 12 intervals for a total of 180 seconds (3 minutes) for each level. An average nucleus removed per interval was determined from the mean of the six levels for each interval.

Results:

The MicroResector MD 2.5 removed an average of 2.0 grams of tissue in the first minute, 1.4 grams in the second minute and 1.2 grams in the third minute from the 77-year-old male cadaver.

Average Cumulative Nucleus Removed*



Discussion:

Fluid jets are extremely precise tissue cutting tools, requiring minimal mechanical force and present no risk of thermal damage. The SpineJet MicroResector MD 2.5 is specifically designed to remove nucleus material during a microdiscectomy procedure. It has the unique ability to simultaneously cut and remove nucleus pulposus. These properties result in a faster, more predictable rate of nucleus removed compared to other technologies.

The rate of nucleus removal is important in a microdiscectomy procedure. This study demonstrates that the SpineJet MicroResector MD 2.5 removes tissue at a predictable rate. The table shows the rate for each three-minute period. This rate decreases over time as there is less tissue remaining in the disc space for the resector to contact.

	Time (min)		
	1	2	3
Cadaver	Average Nucleus Removed (g**)		
77 M	2.0	1.4	1.2

Conclusion:

The SpineJet MicroResector MD 2.5 demonstrated predictable tissue consumption rates for nucleus removal in this study. The MicroResector MD 2.5 is designed to safely access a targeted area of the disc during a microdiscectomy procedure.

*Data on file

**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.

¹ Growler, 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.]