**Introduction: Study Design:** Human cadaver lumbar spines were used to assess the acute effects of Intra-Discal Electrothermal Therapy (IDET) invitro.

**Objectives:** To determine whether IDET produced acute changes in disc histology and motion segment stability.

**Summary of background data:** The IDET procedure (IntraDiscal Electrothermal Therapy) has been introduced in recent years as a minimally-invasive, non-operative treatment for discogenic low back pain. This procedure may be considered for those who fail conservative measures and wish to avoid surgical interventions. Briefly, the procedure is performed by percutaneously introducing a catheter into the disc under fluoroscopic guidance. The catheter tip is then heated up to 90 degrees C for 16-17 minutes. Several hypothesized mechanisms for the effect of IDET have been suggested and include: 1) shrinkage of the nucleus and/or sealing the annulus fibrosus by contraction of collagen fibers; and 2) thermal ablation of sensitive nerve fibers in the outer annulus. Despite growing acceptance of this procedure, the beneficial mechanisms of IDET are unclear. There are few reports on the temperature distribution in the disc from IDET and even fewer biomechanical or histological outcome studies.

**Methods:** IDET was performed with the Spinecath® by Oratec on nineteen fresh/frozen human lumbar cadaveric scis. Prior to testing all specimens were graded with discography using a modified Dallas grading scheme. All catheters were introduced into the disc via a custom alignment jig that assured reproducible placement of the IDET catheter along the border between annulus and nucleus. The correct catheter placement was confirmed by anterior-posterior, lateral and superior-inferior radiographs. Each test run consisted of six stability experiments: flexion/extension, right/left lateral bending, and right/left axial torsion. The protocols included a constant 200N compressive load superimposed on pure moments up to 5.0 Nm in each direction. The compressive load was maintained by a servohydraulic materials testing system (MTS Bionix 858, Minneapolis, MN) while the moments were produced by two synchronized torque motors (25 Nm torque motors). Oriental Motor Corp, Tokyo Japan), one acting on the superior vertebra and the second acting on the inferior vertebra. Eight specimens were tested biomechanically in combination with a temperature mapping protocol. This involved five sequential test runs: 1) with the specimen intact; 2) after instrumentation with IDET and thermometry needles but before heating; 3) after executing the heating protocol with the specimen in a 37 degree C water bath and instrumentation still in place; 4) with the thermometry needles and thermocouples removed; and 5) with the Spinecath removed. Five additional motion-segments were tested in two runs: before and after the IDET protocol. These specimens were not instrumented with the thermometry needles. Each specimen was pre-heated in a 37° C saline water bath for one hour before testing. These five specimens were subjected to the same six stability tests as described earlier.

Six additional specimens were heated with IDET, the resulting canals was backfilled with a silicone rubber compound to allow co-localization of the catheter and annular architecture. The specimens were then fixed in 10% buffered formalin for a week, then decalcified and embedded in paraffin. Five micron sections were cut and stained with Hematoxylin&Eosin, Mason Trichrome and Saffranin O to demonstrate tissue architecture. Polarized light microscopy was used to emphasize collagen birefringence as well as the yellow elastomer, and thereby localize the original catheter placement and region of adjacent heated tissue.

**Data Analysis** The mean angle and specimen stiffness (applied torque/angular displacement) and group comparisons were made using Wilcoxon Signed Rank Test for paired tests before and after treatment in the same specimen and Friedman statistics for multiple treatments in the same specimen.

**Results:** Placement of the catheter and thermocouples produced an increase in stiffness in flexion and in lateral bending. After executing the heating protocol, the stiffness decreased by 2 to 17 percent. The specimens lost additional stiffness after removal of the thermometry needles and the Spinecath®, (between 24 and 49 percent total).

There was also a decrease in stiffness after IDET for the five specimens that were instrumented with the spinecath only, however this was of lesser magnitude than observed with the thermometry needles -instrumented specimens. After executing the heating protocol, the stiffness decreased by between 6 and 12 percent (p<0.05 for flexion and left rotation). In no case was the stiffness increased after IDET There was a consistent pattern of increased motion and decreased stiffness.

Elastomer within the Spinecath canal could be visualized in all six histology specimens. The average catheter position was approximately 10-15 mm from the outer border of the posterior annulus. None of the specimens demonstrated significant alteration of the annular fiber morphology in the vicinity of the canal after heating when compared to non-heated regions of the same disc. No clustering or clumping of nuclear or annular collagen around the canal could be discerned. Collagen fibers demonstrated birefringence in close contact with the canal.

**Discussion:** We questioned whether motion-segment stability is improved and annular architecture is altered acutely after the standard clinical IDET protocol. Based on our thermometry data (separate study), we demonstrated that temperatures sufficient to denature collagen (60-65° C) were not achieved at any sites other than at the IDET catheter itself. After the heating protocol, there was a decrease in stability of between 6 and 12 percent depending on the plane of motion. While we could not demonstrate stabilization from IDET, stiffening may occur after biological remodeling. In vivo, collagen denaturation is followed by fiber fusion and fibroblastic cell death which, in turn, may lead to a robust healing phase. This healing may lead to stiffening after a variable period of time. Future in vivo study is required to determine whether this similarly occurs in the disc after IDET.

The results of this study are limited in that instrumentation to measure tissue temperatures confound the biomechanical assessments. For instance, the introduction of thermometry needles systematically increased the specimen stiffness in flexion and lateral bending (13 to 14 percent), and significantly lengthened the testing period which raises concerns regarding in vivo specimen degradation. To overcome this, we biomechanically tested another group of specimens that were subjected to the IDET clinical protocol only. As expected, changes in motion and stiffness were less dramatic for this group and achieved statistical significance in flexion and left rotation only. Nevertheless, a consistent trend of about 10% increase of motion and 10% decrease of stiffness in flexion/extension and lateral bending could be observed. Axial rotation was decreased at approximately 6%. The clinical relevance of the acute IDET affects we observe remains to be determined.

The data of our histological study suggest that the tissue temperatures measured during IDET are insufficient to coagulate collagen in regions beyond the immediate vicinity of the catheter. In particular, we did not observe alterations in annular birefringence surrounding the catheter canal after heating. None of the specimen showed a gross displacement of the normal lamellar architecture. Annular architecture was not grossly affected within the vicinity of the catheter by the heating protocol.

**Conclusion:** Our data suggest that the temperatures developed during IDET were insufficient to alter collagen architecture or stiffen the treated motion segment acutely.