Introduction:
Objectives: To determine whether IDET produces adequate temperatures to modify target tissues like nociceptive nerve fibers in the annulus fibrosus.

Study Design: Human cadaver lumbar spines were used to assess the temperature and thermal dose distribution during Intra-Discal Electrothermal Therapy (IDET) invitro.

Summary of Background Data: Several hypothesized mechanisms for the effect of IDET have been suggested and include: 1) shrinkage of the nucleus and/or the annulus fibrosus by contraction of collagen fibers; and 2) thermal ablation of sensitive nerve fibers in the outer annulus.

Temperature elevation of biological tissues is currently used for outright tissue destruction or as a modifier which may be used to enhance other therapies. For temperature exposures in excess of 45°C and/or longer duration, cellular repair mechanisms no longer function due to denaturation of key proteins or can’t keep up with the accumulating damage. Complete cell death and tissue necrosis are fully expressed in approximately 3-5 days. The concept of dose in pharmacy and radiation has long been established. The same concept can be attributed to thermal denaturation and aggregation of key protein structures. The accumulation of this thermal damage can be modeled using the Arrhenius rate process equation, which establishes a relationship between the rate of thermal damage and the duration and temperature of exposure [Dewey WC, Sapareto SA].

Methods: IDET was performed on twelve human lumbar cadaver motion segments in a 37.0°C water bath using the SpineCath® by Oratec®. Seven specimens had their posterior elements removed for additional biomechanical testing (separate study) while five specimens were left intact. Miniature multi-specimens had their posterior elements removed for additional biomechanical testing (separate study) while five specimens were left intact. Miniature multi-

Results: The highest temperature (out of 520 points) measured was 64.0°C every 30 s) during the initial 12.5 min, and then maintained at 90°C for 4 min for a total of 16.5 min treatment time. Temperatures were recorded simultaneously at 40 different locations in the disc every three seconds. The maximum temperatures attained at each thermal mapping location were determined at 16.5 min treatment time and used in subsequent analysis of temperature index plots. Thermal dose (=equivalent minutes (EM) 43.0°C [Dewey WC]) was calculated at each temperature point. Mean, standard deviation and group comparisons of percent index temperatures and thermal doses were made using Mann-Whitney U Rank Sum tests for 2 independent samples, with (n=5) and without posterior elements (n=7).

Discussion: The analysis of the thermal dose profiles indicated that sufficient thermal doses (240-640 EM43°C) capable of generating complete thermal damage to the nociceptive nerves fibers infiltrating the disc are limited to within ~6-7 mm of the IDET probe heating segment. For the seventeen min treatment duration of the standard protocol, the points with temperatures approaching 49-50°C toward the end of treatment achieved these therapeutic doses. However, the exact thermal dose threshold for destruction of nociceptive fibers is not available in the literature, thus in this work we interpolate from a conservative estimate of 240 EM43°C [Dewey WC].

Using a conductive heating source such as the SpineCath requires placement of the device in close proximity to the targeted tissue. However, due to variations of disc pathology and anatomy amongst patients, manipulation of the catheter in this ideal position adjacent to the posterior wall is difficult to accomplish and verify in practice.

Conclusions: Except for a very limited margin (1-2 mm) around the catheter, the temperature necessary to induce collagen shrinkage was not observed within the disc. Temperatures sufficient to ablate nerves were developed in some areas but were not reliably produced in areas that may be considered clinically-relevant – such as the posterior annulus.

References: