Cadaveric Study

Cadaveric Intervertebral Disc Temperature Mapping During Disc Biacuplasty

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Background: Disc Biacuplasty is a procedure for treating discogenic pain through neuron ablation by heating intervertebral disc tissue using cooled, bipolar radiofrequency (RF) technology. This study demonstrates temperature profiles created by disc biacuplasty in human cadavers.

Objective: To assess temperature profiles created by disc biacuplasty in human cadaver discs.

Design: The design of the experiment is a cadaver study with temperature monitoring in the intervertebral disc during disc biacuplasty.

Method: Seven human cadaver discs were sectioned from 2 cadavers. Each disc was instrumented with 11 temperature sensors and 2 cooled radiofrequency probes. Correct placement was verified with the aid of fluoroscopy. The discs were then immersed in a 37°C thermostatic water bath and the treatment protocol was applied. Temperatures were monitored as the discs were heated.

Results: At 13 minutes, with the settings used in this study, the posterior longitudinal ligament (PLL) temperature reached 40±3°C. The anterior disc reached 41±3°C. The outer layer of the posterior annulus fibrosus was heated to 54±6°C and the inner two-thirds of the posterior annulus fibrosus reached temperatures of 60±6°C.

Conclusions: The anterior disc and PLL remained at safe temperatures below 45°C while temperatures throughout the center posterior and posterolateral disc were all raised above 45°C, sufficient for neural ablation.

Key words: denervation, intervertebral disc, discogenic pain, radiofrequency ablation, transdiscal, disc biacuplasty

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Chronic, discogenic low back pain is a common affliction (1,2). Until recently this condition was poorly understood and few treatment options were available, beyond conservative, non-invasive management. The most common treatment options were disc removal and/or arthrodesis, which are invasive procedures with inherent risks and variable results (3). Recent investigation has led to a greater understanding of the pathophysiology of the intervertebral disc and pathogenesis of discogenic pain (4-7). In particular, the extent of disc innervation has been shown (8), and that painful discs are associated with an increase in fissuring and innervation extending to the inner third of the posterior annulus fibrosus (5,6). This understanding has led to new technological options for treating chronic discogenic pain. The subject of this paper is disc biacuplasty, a minimally invasive, non-surgical procedure for treating chronic discogenic pain by heating the nociceptors in the diseased disc.

For over 40 years, radiofrequency (RF) technology has been applied to heat tissue for treating a number of conditions including cardiac arrhythmia, benign prostatic hyperplasia, cancer tumors, and chronic pain. One of the more common applications for treating chronic pain with RF is percutaneous RF ablation of the medial branch to address chronic zygapophysial joint pain. In these procedures, a controlled amount of electrical energy alternating at a very high frequency, typically 450 kHz, is applied to tissue using an active delivery electrode on a delivery device such as a needle or catheter and completing the electrical circuit with a dispersive electrode placed on the skin surface. Ions present in the tissues close to the active electrode vibrate at the high frequency resulting in increased temperatures. Histological studies have shown that temperatures as low as between 42°C and 50°C for 2 minutes are cytotoxic to nerve fibers (9-12). Thus applying directed RF energy to a nerve can interrupt pain pathways by heating the nerve. The physics pertaining to this technology have been well studied (13-16), and considerations such as thermodynamics, electrophysiology, and tissue properties are taken into account when applying this technology to different applications.

Disc biacuplasty is a novel procedure for treating chronic discogenic pain by heating disc tissue with RF to ablate sensitized nociceptors and aberrant neural in-growth within the annulus fibrosus. The equipment used in this procedure (TransDiscal™ System, Baylis Medical, Montreal, QC, Canada) incorporates technical considerations allowing for a desired heating profile within the disc, which has unique thermal and electrical properties and numerous widely dispersed nociceptors (17). In this procedure, 2 electrodes are placed in the disc. By placing 2 electrodes in the disc in a bipolar arrangement, RF is concentrated in the disc. Water circulating in the electrodes gently cools the electrode surfaces, which allows for greater power delivery while at the same time not overheating tissue local to the electrodes (17). A cooled RF electrode heats a larger volume of tissue. This bipolar, cooled RF electrode system results in raising the temperature of tissue across the posterior aspect of the disc while avoiding overheating.

The use of RF and cooled RF has been closely studied and developed for applications such as treating ventricular tachycardia, cancer tumors, and benign prostatic hyperplasia (18-20). An animal study of the histological effects and the thermal distribution of disc biacuplasty in an In vivo porcine model has shown the biacuplasty procedure to achieve suitable temperatures for neural ablation in the disc while showing no evidence of damage to adjacent nerve roots (17). Kapural et al (21) have reported a cadaver study on temperature distribution of disc biacuplasty in which temperatures were shown to be sufficient to ablate nerves in the disc while maintaining safe temperatures in the epidural space and neural foramina. Subsequently, Kapural et al (22) reported favorable results of a clinical study on disc biacuplasty.

The objective of the disc biacuplasty procedure is to heat the disc tissue until it reaches a temperature of 44° to 55°C. As previously stated, these temperatures are cytotoxic to nerve fibers. Furthermore, this temperature range is known to be safe on the disc as evidenced by procedures done with other devices that are in the market such as the intradiscal electrothermal (IDETTM) procedure (Smith and Nephew, Andover, MA). IDET was shown to achieve temperatures in this range in cadaver studies (10,23). Clinical studies on IDET (24-26) have shown no evidence of harm attributed to the temperature rise in the disc.

In the present study we have further investigated intervertebral disc thermal profiles achieved by disc biacuplasty in sections of spine taken from human cadavers.

Methods

Seven lumbar spine segments (L1-S1) were obtained from 2 previously frozen cadavers. The segments were dissected into sections containing an intervertebral disc with connecting portions of its adjacent vertebral bodies and posterior elements with intact musculature. In this way, the sections of spine closely resembled clinical in vivo conditions. Sections included disc levels L1-L2 through to L4-L5. The L5-S1 discs from both cadavers were not used because one was damaged when extracted and the other was severely degenerated and obstructed by boney overgrowth. MRI revealed the remaining discs to range from healthy with normal T2 signal intensity, disc height, and shape, to moderately degenerated with mild or moderate signal strength loss, disc height loss, and bulge or protrusions no greater than 4 mm.

Each disc section was placed into a radiolucent alignment jig (Fig. 1) which allowed it to be instrumented with the assistance of multiplanar fluoroscopic imaging. Two electrically insulated 17 gauge TransDiscal introducer trocars were directed into the posterolateral aspects of each intervertebral disc. Next, the TransDiscal probes, containing RF electrodes, were advanced through the introducers into opposite sides of the disc to create the bipolar configuration. Appropriate placement within the annulus fibrosus was confirmed by ensuring that the electrode of each probe was placed within margins defined by ring apophyses of the vertebral bodies, as seen on anterior-posterior, lateral, and axial fluoroscopic imaging. A total of 11 thermocouples (28 gauge constantan-stainless steel with 0.001-inch Parylene electrical insulation) were placed in each disc to measure temperature: one was placed in the posterior longitudinal ligament (PLL), one was placed in the mid-anterior disc, 3 were placed in a linear array with 5 mm spacing in the center-posterior annulus, 3 were placed in a similar array in the left posterolateral annulus, and another 3 were placed in an array in the right posterolateral annulus. Figure 2 illustrates the locations of probes and thermocouples in the disc. Figure 3 is an axial X-ray image showing an example of the actual probe and thermocouple placement.

Prior to treatment, the prepared spine sections were placed in a 37°C water bath and thermal equilibrium (37°C ± 2°C) in the disc was reached. Temperatures and treatment data, including generator power output, impedance, and probe temperatures were recorded using computer software at 1.0 and 0.2 sec-

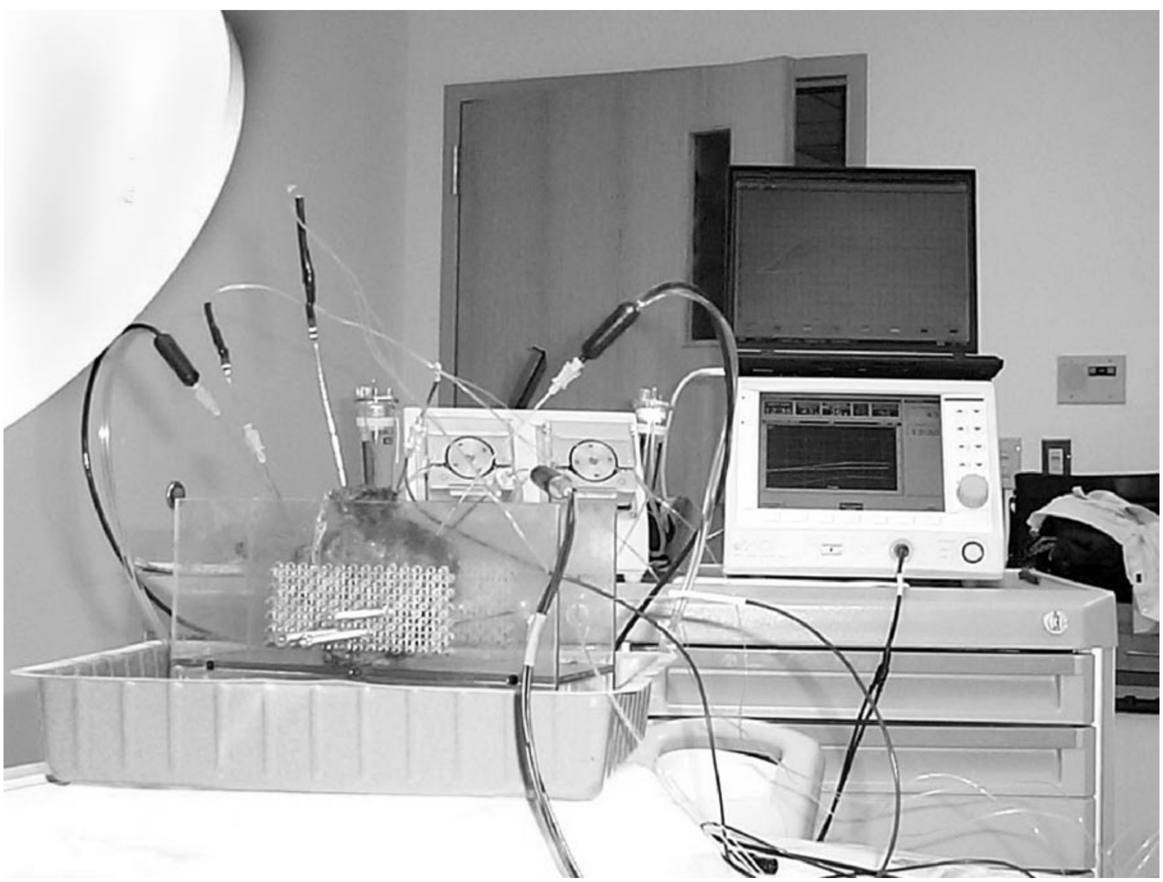

Fig 1. *Spinal section instrumented with probes and thermocouples.*

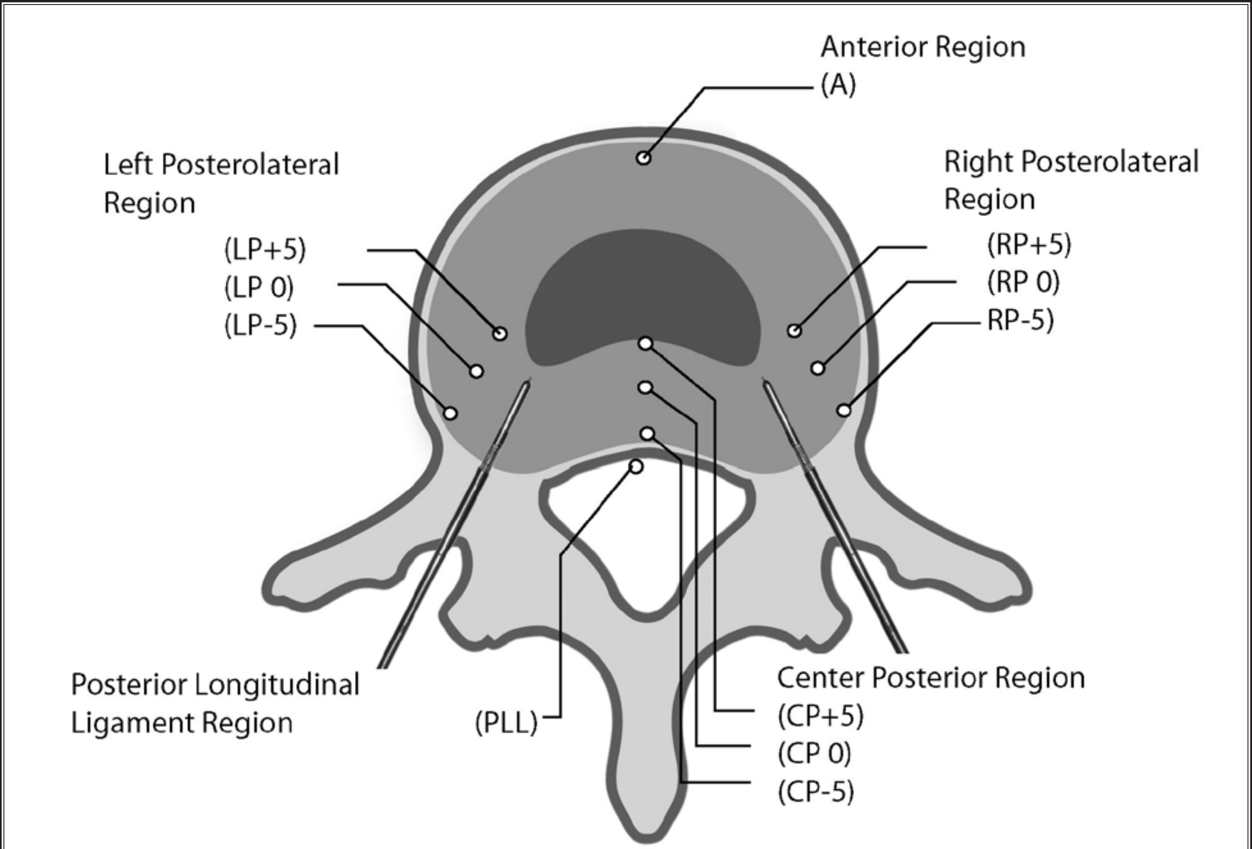

Fig. 2. *Location of thermocouples.*

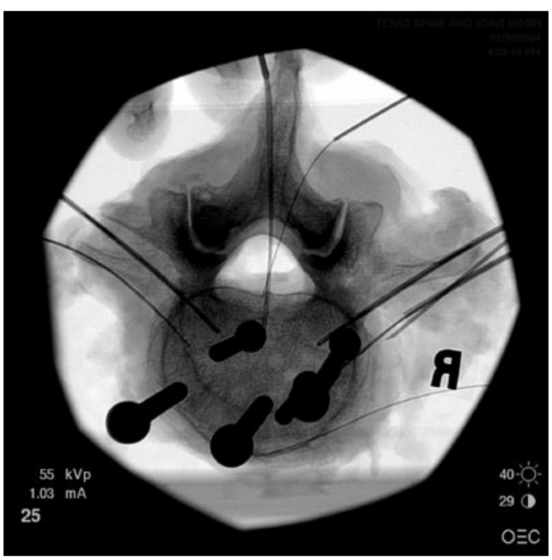

Fig. 3. *X-ray image of disc 1 showing placement of transdiscal probes and 11 thermocouples.*

ond intervals respectively. Radiofrequency heating was performed using a computerized RF generator (Baylis Medical, Montreal, QC, Canada). A treatment protocol delivered power to raise the electrode temperature at a rate of 2°C/min until a set temperature of 43° or 45°C was reached and maintained. The total treatment time ranged between 13 and 15 minutes. Temperature and treatment data was imported into data analysis software for evaluation. Table 1 contains treatment parameters employed for the spine sections. The treatment protocol and parameters were selected based on suggestions from the developer of the TransDiscal System.

Table 1. *Treatment parameters for each disc.*

Case	Specimen	Level	Set Temperature	Ramp Rate	Treatment Time	Probe Separation Distance
Disc 1	02L143	L1-L2	45 °C	2.0 °C/min	13 min	20.9 mm
Disc 2	02L143	L3-L4	45 °C	2.0 °C/min	15 min	21.4 mm
Disc 3	02L168	L1-L2	45 °C	2.0 °C/min	13.5 min	25.4 mm
Disc 4	02L168	L2-L3	45 °C	2.0 °C/min	13.5 min	23 mm
Disc 5	02L168	L3-L4	43 °C	2.0 °C/min	14 min	32.8 mm
Disc 6	02L168	L4-L5	43 °C	2.0 °C/min	14 min	38.6 mm
Disc 7	02L143	L4-L5	43 °C	2.0 °C/min	14 min	31.6 mm

Table 2. *Temperature measurements in all discs at 13 minutes.*

	LP-5	LP 0	LP+5	CP-5	CP 0	CP+5	RP-5	RP0	RP+5	PLL	A
Disc 1	45.8	51.6	48.9	51.9	60.5	60.2	41.3	46.4	52.1	38.7	38.0
Disc 2	41.6	47.0	50.4	62.0	66.9	61.0	46.7	49.7	51.8	37.8	41.9
Disc 3	49.8	54.5	58.1	51.8	57.1	58.5	48.2	57.9	58.6	44.0	41.0
Disc 4	41.2	45.6	47.3	59.0	64.3	61.3	48.9	53.6	50.2	43.2	37.7
Disc 6	46.4	55.1	54.8	48.1	51.4	52.4	56.8	61.1	55.2	41.6	42.3
Disc 7	38.5	47.0	*	50.1	58.1	63.7	44.0	51.1	61.1	38.5	44.3
Average	43.9	50.1	51.9	53.8	59.7	59.5	47.7	53.3	54.8	40.6	40.9
Standard Deviation	4.2	4.1	4.5	5.5	5.5	3.9	5.3	5.4	4.3	2.7	2.6

* indicates a missing data point due to a faulty thermocouple.

Results

In total, 7 discs (2x L1-L2, 1x L2-L3, 2x L3-L4, and 2x L4-L5) were used in testing. Disc 5 data was discarded because the position of the thermocouples in the disc moved significantly, as revealed by fluoroscopy following the treatment. The separation distance of the electrodes in the 6 discs varied between 20.9mm (L1-L2 disc) and 38.6mm (L4-L5 disc) due to varying disc widths. The temperature measurements in all discs at 13 minutes are listed in Table 2. The region of the outer center posterior (P-5) was heated to an average of 53.8°C (± 5.5). The region 5 mm deeper in the center posterior disc (P 0) was heated to 59.7°C (± 5.5). The region 5 mm deeper in the P+5 region was heated to an average of 59.5°C (± 3.9). The lateral posterior region on the outer left (LP-5) was heated to an average of 43.9°C (± 4.2). The region LP 0 reached 50.1°C (± 4.1). And 5 mm deeper in the LP+5 region was heated to 51.9°C (± 4.5). The lateral posterior region on the outer right (RP-5) was heated to an average of 47.7°C (± 5.3). The regionRP 0 was heated to 53.3°C (± 5.4). The deepest region on the right lateral (RP+5) was heated to 54.8°C (± 4.3).

The anterior disc (A) was heated to 40.9°C (± 2.6). The posterior longitudinal ligament (PLL) was heated to 40.9°C (± 2.6).

Three thermocouples were placed within the center of the posterior annulus at increasing depths. The temperature reached in this center posterior annulus region was greater than 45ºC in 6 out of 6 (100%) disc measurements.

The temperatures reached in the posterolateral disc were greater than 45ºC in 31 of 36 (86%) of the thermocouples used in the 6 discs treated.

Temperature in the mid-anterior area of the disc remained below 45°C in 6 of the 6 (100%) discs tested.

The thermocouple contacting the posterior surface of the posterior longitudinal ligament remained below 45°C in 6 of the 6 (100%) discs tested.

There was no significant difference in temperature results that can be correlated to level of degeneration.

Discussion

These study data demonstrate the ability of the disc biacuplasty procedure, applied in a human cadaver model, to raise intradiscal tissue temperature to levels appropriate for neural ablation while maintaining temperatures below 42°C in the cauda equina. Temperatures tended to be warmer towards the inner layers of the disc, likely due to the position of the electrodes as well as the ability of the disc tissue to hold heat while the surrounding muscle tissue and thermostatic bath had a thermal dissipative effect. A similar effect, likely caused by blood flow, was found in an in vivo animal study (17).

Characteristics of thermal profiles generated include a very small temperature elevation in the posterior surface of the PLL and anterior disc relative to the center posterior and posterolateral regions of the disc. Maintaining low temperatures in the PLL is ideal for the safety of the cauda equina. The temperature reached by the thermocouple in the anterior annulus was less than 45°C in all cases. In one case the temperature of the anterior annulus thermocouple reached 44.4 °C. In this case the TransDiscal probes were inserted further anterior in the disc than in other cases explaining why the anterior of the disc got slightly hotter. Painful discs are typically innervated in the posterior and if it is not necessary to heat the anterior then it is better not to subject it to thermal stress. Therefore these results are favorable. However, if anterior innervation is suspected in a patient, the probes can be advanced further anterior to heat the region.

Temperatures are in the 46° – 67°C range in the inner two-thirds of the annulus fibrosus across the posterior half of the disc, and above 45°C in the outer third. Additionally, temperature increases at a greater rate in the inner layers of the posterior annulus than in the outer layers, PLL and anterior disc. Thus, treatment time can be increased if a higher temperature is desired in the inner layers of the disc while safely maintaining lower temperatures in the outer layers, PLL, and anterior. Figure 4 is a plot of temperature vs.

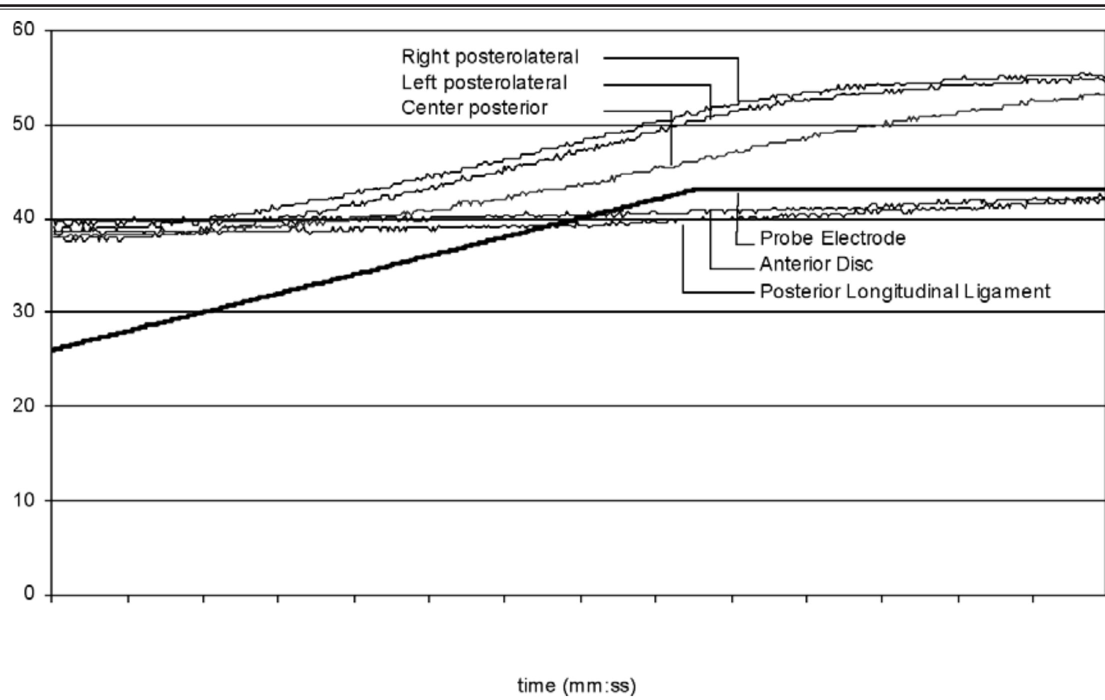

Fig. 4. *Temperature vx. time lot for disc 6.*

time for disc 6. It illustrates how temperature increases in different regions of the disc over time.

Conclusions

This study was conducted with investigational treatment parameters on human cadaver discs. The level of degeneration of the disc ranged from healthy to mildly degenerated including one disc with a 4 mm central protrusion. Temperatures measured in the discs were sufficient for neural tissue ablation while demonstrating safe temperatures in the anterior disc and border of the spinal canal. At the time of this cadaver study clinical studies were not started. This study was used to determine that it was safe to conduct clinical studies. This study is also important for practicing physicians to not only understand clinical results but also understand temperatures achieved in the disc at the level of detail shown in this cadaver study. Long-term randomized controlled trials with large populations are required for increased evidence of the efficacy of disc biacuplasty.

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