Research Study

Intervertebral Disc Temperature Mapping During Disc Biacuplasty in the Human Cadaver

Mehul J. Desai, MD, MPH[1], Jeremy Ollerenshaw, PhD[2], Robert Harrison, MA[3], Laura Yu, PhD[3], Puneet Sayal, MD[4], Tyler Crone, MS[2], and Alan Dine, BSN[2]

From: [1]International Spine, Pain & Performance Center, Silver Springs, MD; [2]Kimberly-Clark Medicam, Roswell, GA; [3]Baylis Medical, Toronto, Ontario, Canada; [4]George Washington University Medical Center, Washington, DC

Address Correspondence:
Mehul J Desai, MD, MPH
Director, Spine, Pain Medicine & Research
International Spine, Pain & Performance Center
8401 Colesville Road #50
Silver Springs, MD 20910
E-mail:
mehuljdesaimd@gmail.com

Disclaimer: There was no external funding in the preparation of this manuscript.
Conflict of interest: Dr. Desai was previously a consultant for Kimberly-Clark Medical. No other authors report conflicts.

Manuscript received: 11-07-2014
Revised manuscript received: 11-21-2014
Accepted for publication:

Free full manuscript:
www.painphysicianjournal.com

Background: Intradiscal biacuplasty (IDB) is a novel heating therapy using cooled radiofrequency (RF), which may offer relief for discogenic pain. Effective neuroablation may be achieved intradiscally at higher lesion temperatures. The safety of intradiscal heating at elevated temperatures using cooled RF has never been reported.

Objective: The purpose of this study is to map the intradiscal and peridiscal temperatures when IDB is performed at increased temperature using a modified lesion approach. The resulting temperature profiles are used to assess the safety and theoretical efficacy of this approach to ablate nociceptors in the posterior annulus.

Study Design: Research article.

Methods: Eleven lumbar discs in a non-perfused human cadaver were treated by IDB. Temperature profiles in the disc during bipolar lesion at 50°C followed by 2 monopolar lesions at 60°C were mapped using custom thermocouples. Temperatures inside the disc, at the nerve roots, and in the midline ventral epidural space were monitored in real-time using a data-collection system with custom RF filters.

Setting: Human research laboratory.

Results: Higher maximum temperature was reached intradiscally, and a larger volume of tissue was exposed to neuroablative temperature (> 45°C). Temperature at the nerve roots and in the epidural space increased by 2.4°C ± 2.6°C and 4.9°C ± 1.9°C (mean ± SD), respectively, during bipolar lesion. Similarly, temperature increased by 2.2°C ± 1.9°C and 0.8°C ± 1.3°C at the nerve roots and in the epidural space, respectively, during monopolar lesion.

Limitations: Limitations include the *ex vivo* setting which lacks perfusion and may not reproduce in vivo conditions such as cerebrospinal fluid dynamics.

Conclusions: The modified treatment paradigm showed intradiscal heating is achieved and is concentrated in the posterior annulus, suggesting minimal risk of thermal damage to the neighboring neural structures. Clinical benefits should be evaluated.

Key words: Spine, biacuplasty, thermal, disc, intervertebral

Pain Physician 2015; 18:E217-E223

The lumbar intervertebral disc is commonly the source of back pain. Coupled with that, lumbar back pain is the most frequently reported musculoskeletal complaint (1). Of the possible sources, discogenic sites are the most likely source and the presentation of this condition is dynamic and typically nonspecific (2). The pathophysiology of discogenic pain is also not well understood; however, scientific evidence suggests that disc degeneration, delamination, and fissuring of the annulus; sensitization of nociceptors by the tracking of nuclear materials through the annular fissures; as well as ingrowth of unmyelinated nerve fibers into the annulus are plausible contributing factors to the development of discogenic pain (3-5). In normal, healthy intervertebral discs, the sensory nervous supply is located only in the outer third of the annulus fibrosus. In degenerated, pathological discs, the innervation extends centripetally. At the level of pathology, neoneuralisation accompanies the granulation tissue and neovascularization following the damage (4). The pain that follows this pattern of pathology is typically refractory to more conservative measures.

Intradiscal biacuplasty (IDB) using the TransDiscal (TD) system is a novel heating therapy that applies cooled-radiofrequency (cooled-RF) energy to ablate nerves in the posterior element of the disc, which may offer relief for discogenic pain (5,6). This ablation is accomplished using bipolar radiofrequency electrodes placed obliquely within the posterolateral aspect of the intervertebral annulus. This minimally invasive procedure, directed at lumbar pain of discogenic origin, theoretically ablates the pathological ingrowth of nerve fibers beyond the outer third of the annulus fibrosis of the lumbar intervertebral disc and targets annular tears via a mechanism involving collagen reformation. TD may be a suitable option for discogenic pain as it involves a percutaneous approach, therefore it is less invasive than other treatment options, likely ensuring a shorter recovery period (5,6).

The TD electrodes (Kimberly-Clark Corporation, Roswell, GA) are internally cooled to increase energy deposition and lesion size without causing undesirably high tissue temperatures around the electrodes. These internally cooled, RF electrodes have been applied in pain medicine to overcome the challenges of capturing diffuse or inconsistently located target structures through larger, more consistent lesion formation. Using these cooled RF probes, the user achieves a more predictable shape and size of the radiofrequency lesion in order to suit a therapeutic need. Under the current treatment protocol for IDB, 2 18G TD probes are inserted into the disc through 2 introducers at an oblique angle (~30°) to create a bipolar lesion at a set temperature of 45°C. During RF delivery, the active cooling of the electrode prevents tissue charring immediately adjacent to the electrode. This allows the user to extend the delivery of RF to heat a larger volume of tissue, while avoiding excessive heating of tissue close to the electrodes. Previous temperature monitoring studies in porcine and human cadaver discs demonstrated the safety and efficacy of bipolar lesion at 45°C (7,8).

Safety and outcomes data demonstrate similar or superior results to other minimally invasive procedures (5,6). Patient selection is the most important factor in treatment success. Kapural et al (6) describe the following considerations indicating a minimally invasive approach, like TD: persistent lower back pain of discogenic origin lasting at least 6 months, failure of a comprehensive conservative program (including exercises, physical therapy, at least one epidural corticosteroid injection) and a normal neurological examination, negative straight leg raise, lacking arthritis of an inflammatory nature, lack of surgery at the symptomatic vertebral disc, or other conditions that could imitate discogenic lower back pain. Improper patient selection is demonstrated to result in suboptimal outcomes (6).

The TD system offers patients further optimization of a device that has previously been used successfully in the treatment of chronic discogenic low-back pain as an alternative to invasive surgery. An internal analysis demonstrated the need for an improvement to the original treatment paradigm so that optimal heating across the posterior annulus particularly in patients with larger disc sizes (large males and for use at the L5-S1 level). The modified treatment paradigm functions by heating the target area of the disc to 50°C using bipolar RF energy in association with a short duration 60°C monopolar lesion in order to further coagulate the ingrowth of nerves and extend the heat lesion laterally. This may also function in fact to in effect "seal" the disc puncture from the introducer needles. It is thought that these heating effects will treat internally disrupted discs by reducing mechanically and chemically sensitized pain transmission, increasing stability of the disc around annulus fibrosus fissures, and promote the healing processes. The modified paradigm also uses a modified lesion approach that will theoretically account for variations in disc size while optimizing the heating profile across the posterior annulus of the intervertebral disc. Specifically, the needle angle is also modified to an entry angle of at 45° instead of 30°. This entry angle change is coupled with bipolar lesioning at 50°C instead of 45°C for 15 minutes and with 2 additional monopolar lesions at 60°C for 2.5 minutes.

The safety of intradiscal heating at elevated temperatures using cooled RF and a combination of bipolar and monopolar lesions has never been reported. The purpose of this study is to map the intra- and peri-discal temperatures when IDB is performed following the above treatment protocol. The resulting temperature profiles are used to assess the safety and theoretical efficacy of this approach to ablate nociceptors in the posterior annulus. Previous studies have been conducted using slightly different heating profiles. This study reports dose ranging data in a cadaveric model on thermal changes inside the disc and surrounding structures such as the epidural space, vertebral endplates, and spinal nerve roots when IDB is performed using an updated treatment protocol.

Methods

Intervertebral Disc Instrumentation and Treatment

Six lumbar discs from explanted human spines were used to study the effect of the new disc biacuplasty treatment protocol. The experimental set-up included an explanted spine with layers of surrounding soft tissue remaining intact, submerged in a thermostatic water bath set to 37°C, in an attempt to simulate physiological temperature (Fig. 1).

TD probes and thermocouple (TC) arrays were positioned in the desired locations in the intervertebral disc under fluoroscopic guidance. The TC arrays enable temperature measurements at targeted locations in and around the disc. For TD probe placement, the C-arm was rotated until the superior articular process (SAP) bisected the disc, which corresponded to 30° – 45° oblique angle depending on the lumbar level to be treated. The final depth of the probes was 1/3 to 1/2 of the disc depth. Custom TC arrays were used to measure intra- and peri-discal temperatures. The 4 TC arrays were similarly placed under fluoroscopic guidance around the safety zones (TC1 – 3) and in the center of the disc (TC4). Final probe and TC array placement was confirmed in the oblique, anterior-posterior (AP), and lateral fluoroscopic views (Fig. 2).

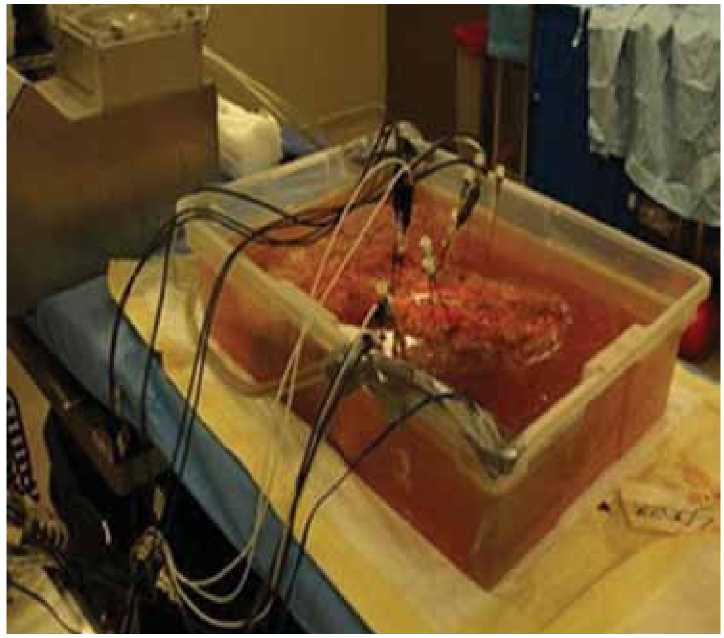

Fig. 1. *Experimental set-up where the explanted spine is equilibrated in a water bath.*

Temperatures of all the TC were allowed to equilibrate before the biacuplasty treatment. RF energy was delivered to the probes by the Pain Management Generator (Kimberly Clark Corporation Roswell, GA), peristaltic pump connected to the generator that continuously circulated water to cool the electrodes during RF delivery.

Data Acquisition and Analysis

Three explanted spines from human cadavers were used in this study, and 6 discs obtained from the L1 to L5 were treated using the above new treatment protocol. Temperature data, monitored by the TC arrays were collected at one second intervals using the Hotmux Data Acquisition System (DCC Corporation, Pennsauken, NJ). Output from the generator was recorded at 0.2 second intervals using the DataStream software (V 3.0.4, Baylis Medical Company).. After allowing the explanted spine specimens to reach thermal equilibrium, the tissue samples remained at temperatures between 28° and 31°C.

Intra- and peri-discal temperatures obtained from the lesions were normalized to 37°C before calculating the mean value at each TC location. The mean intra- and peri-discal temperatures were normalized (set to 37°C) to account for variation in initial starting temperature accumulated from both the water bath and residual heat from the creation of multiple lesions. The small variations between the initial starting temperature and 37°C were applied to the mean temperature of the lesions created. The

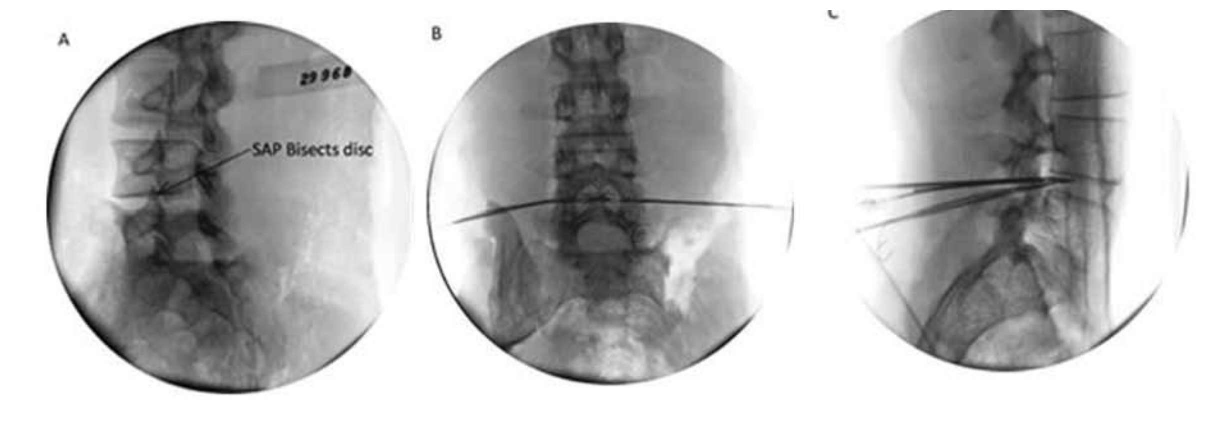

Fig. 2. *Fluoroscopic images showing (A) the oblique view for TD probe placement, (B, C) the anterior-posterior and lateral views showing the final placement of TD probes and TC arrays, respectively.*

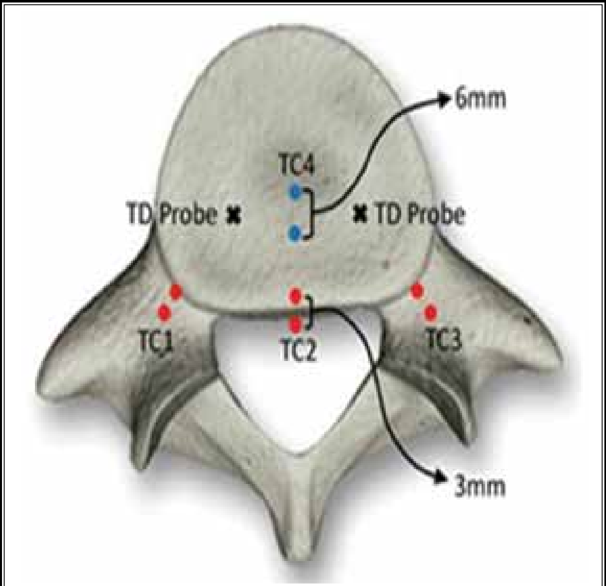

Fig. 3. *A schematic diagram of TD probes and TC arrays placement.*

radial distance between each TC and the TD probe was calculated by determining their respective locations in the sagittal plane. The x- and y-coordinates were assigned to each TC and probe from an analysis of the AP and lateral fluoroscopic images. The x-coordinate was calculated from the AP views using the Epsilon Ruler (where the radius and length of the center spoke corresponds to 10 mm) for scaling and the spinous process as the origin. Similarly, the y-coordinate was determined from the lateral views using the radiopaque band on the TD probe for scaling and the posterior edge of the disc as the origin.

Temperatures measured by TC3 and TC4 showed the greatest thermal distribution, as they are positioned in lateral and mid-disc structures, respectively (Fig. 3). A linear correlation was obtained between the normalized tissue temperatures and the calculated radial distances of TC3 and TC4. This linear correlation was then used to construct a thermal map for both bipolar and monopolar lesions with respect to the radial distance from the TD probe (Fig. 4).

Results

The mean intra- and peri-discal temperatures recorded during bipolar and monopolar lesions are shown in Fig. 5. Maximum intradiscal temperature measured during bipolar and monopolar lesion was 62.8°C and 61.4°C, respectively. The mean temperature around the safety zones remained below the neuroablative threshold (45°C) in all treated specimens.

Thermal maps of bipolar and monopolar lesions were constructed (Fig. 6) from the coordinates of the TC arrays and TD probes, and the real-time tissue temperatures recorded. From the calculated coordinates for the TD probes, the mean radial depth of insertion depth was 22.8 ± 5.3mm. At this mean insertion depth, the 45°C isotherm occurred 17.6 mm away from the TD probe in a bipolar lesion and 21.2 mm away in a monopolar lesion. The 65°C isotherm occurred 5.9 mm and 5.2 mm away from the TD probe in the bipolar and monopolar thermal maps, respectively, and is consistent with previously reported thermal profiles in bipolar annulus ablative technology (6).

Discussion

The current treatment protocol for IDB using the TD system heats the posterior annulus of the disc using a single bipolar lesion at 45°C utilizing a procedure in which the probes were introduced at a 20° – 30° angle to create a bipolar lesion in the disc. The treatment protocol included a gradual increase in temperature to 45° over 11 minutes (ramp rate of 2.0° C/min) and then maintenance at 45° C for 4 additional minutes.

Recently, a retrospective analysis of probe placement in fluoroscopic images from previously performed procedures indicated that a procedure modification was needed. The analyses revealed limitations in the treatment paradigm, specifically as it related to disc size and angle of entry of the probes. The change in the entry resulted in a slight shift in the location of the probes in the disc space, which had an effect on the size of the area affected by the lesion. To accommodate this change in probe location, the heating parameters were adjusted to maximize the lesion area. This modified lesion approach with TD 2.0 has TransDiscal probes inserted at a 35° – 45° angle and a bipolar lesion which is formed at 50°C for 15 minutes with the ramp rate of 2.0°C/min followed by sequential monopolar lesions at 60°C for 2.5 minutes. The temperature increase essentially increases the lesion size, and the additional monopolar lesions are included to fill in any areas that do not fully form.

Cadaver discs treated using the new biacuplasty protocol in this study demonstrated the following:

- Effective neuroablative temperatures reached intradiscally
- Minimal safety risk of heating sensitive neural structures (i.e., nerve root and epidural space)

From the thermal maps generated in this study the 65°C isotherm occurs about 5 mm away from the TD probe during both bipolar and monopolar lesions.

The 45°C isotherm was determined from the collected data to occur 17 – 21 mm away from the probe, which is at the posterior annular border when the radial probe insertion depth was about 22 mm deep. In an in vivo situation, the resulting tissue temperatures are expected to deviate slightly from the thermal maps obtained in this study, due to active cooling of the tissues by cerebrospinal fluid and blood flow in the vertebral canal. This means at a minimum probe insertion depth of 22 mm, plus circulation of bodily fluids in vivo, outcomes from these in vitro results suggest the new treatment protocol can be utilized safely in further clinical investigation.

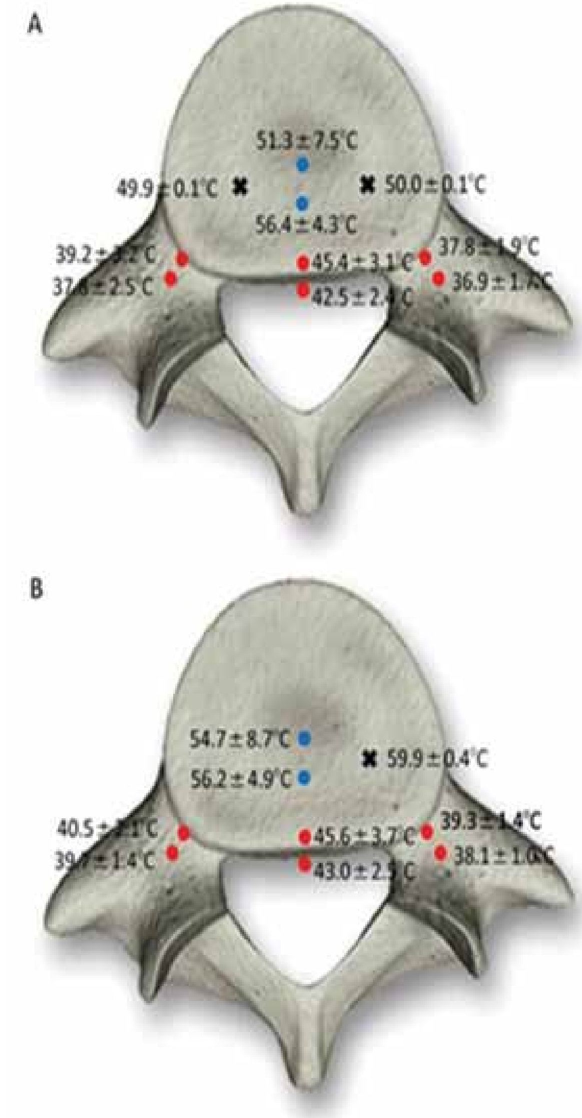

Fig. 4. *Intra- and peri-discal temperatures obtained during (A) bipolar and (B) monopolar lesions (mean ± S.D., N = 6).*

Limitations inherent in this study pertain to the fact that this was a small cadaveric study which did

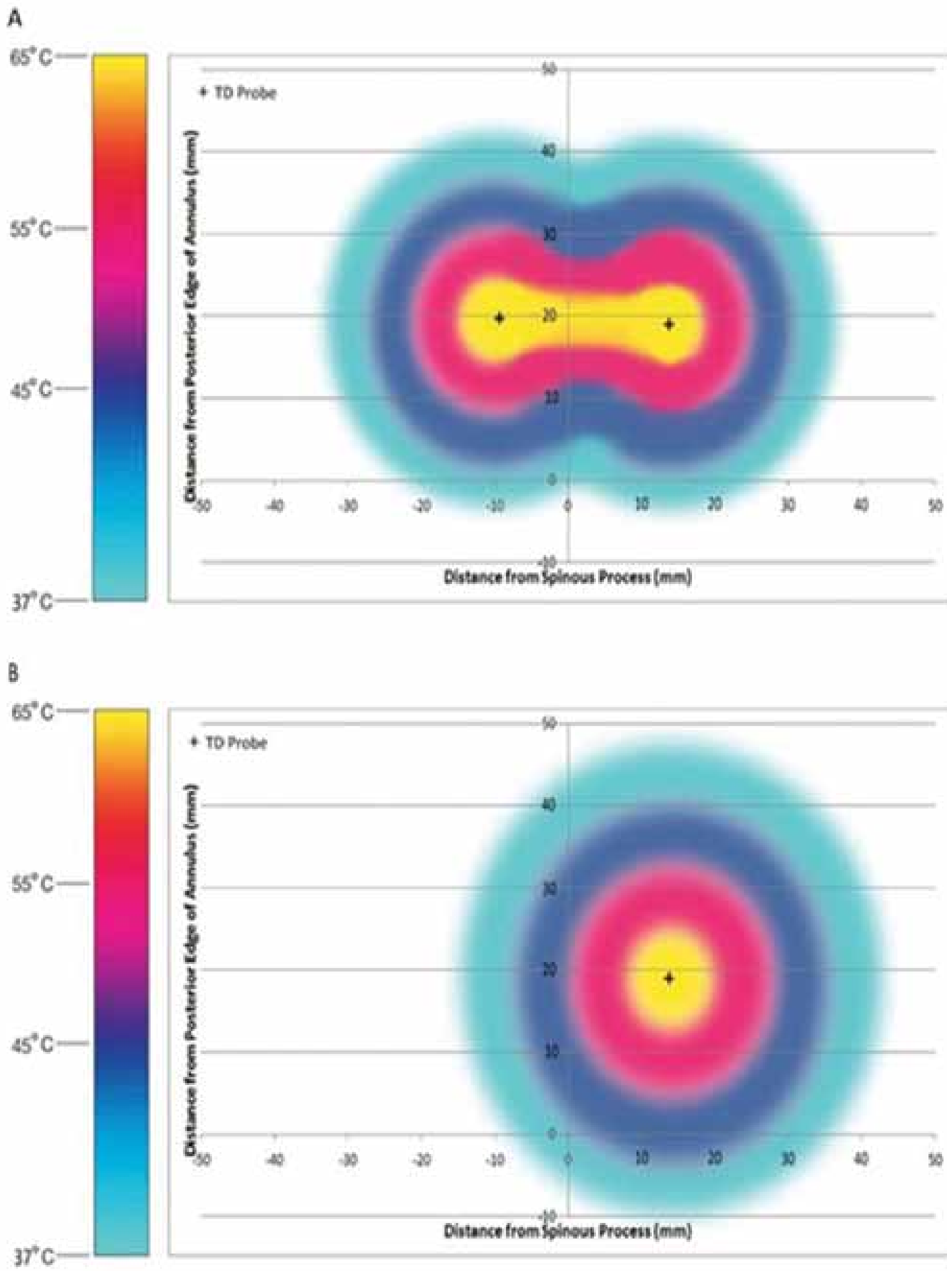

Fig. 5. Thermal maps constructed from the recorded tissue temperatures, and coordinates of the TD probes and TC arrays during (A) bipolar and (B) monopolar lesions.

not consider the effect of perfusion due to a lack of cerebral spinal fluid and blood flow. Histology was also not conducted, and thus, tissue damage was not measured. There was also difficulty in warming thawed tissue up to 37°C to simulate physiological temperature. Additionally, slight variations in exact locations of thermocouples were not specifically documented, but could have impacted temperatures recorded.

Conclusions

The modified treatment protocol demonstrated that intradiscal heating above the neuroablative threshold of 45°C is achieved and is concentrated in the posterior annulus at a minimum probe insertion depth of 22 mm. The thermal maps suggest minimal risk of thermal damage to the neighboring neural structures.

References

1. Schwartzer AC, Aprill CN, Derby R, Fortin J, Kine G, Bogduk N. The prevalence and clinical features of internal disc disruption in patients with chronic low back pain. *Spine* 1995; 20:1878-1883.
2. Goldberg SN, Gazelle GS, Mueller PR. Thermal ablation therapy for focal malignancy: A unified approach to underlying principles, techniques, and diagnostic imaging guidance. *AJR Am J Roentgenol* 2000; 174:323-331.
3. Fagan A, Moore R, Vernon Roberts B, Blumsberg P, Fraser R. ISSLS prize winner: The innervation of the intervertebral disc: A quantitative analysis. *Spine* 2003; 28:2570-2576.
4. Freemont AJ, Peacock TE, Goupille P, Hoyland JA, O'Brien J, Jayson MI. Nerve ingrowth into diseased intervertebral disc in chronic back pain. *Lancet* 1997; 350:178-181.
5. Kapural L, Mekhail N. Novel intradiscal biacuplasty (IDB) for the treatment of lumbar discogenic pain. *Pain Pract* 2007; 7:130-134.
6. Kapural L, Ng A, Dalton J, Mascha E, Kapural M, de la Garza M, Mekhail N.Intervertebral disc biacuplasty for the treatment of lumbar discogenic pain: Results of a six-month follow-up. *Pain Med* 2008; 9:60-67.
7. Petersohn JD, Conquergood LR, Leung M. Acute histologic effects and thermal distribution profile of disc biacuplasty using a novel water-cooled bipolar electrode system in an in vivo porcine model. *Pain Med* 2008; 9:26-32.
8. Pauza K. Cadaveric intervertebral disc temperature mapping during disc biacuplasty. *Pain Physician* 2008; 11:669-676.