Cadaveric Study

# Changes in Temperature Following Radiofrequency Thermal Ablation of the Nucleus Pulposus and Annulus Fibrosus: A Cadaveric Study

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**Background:** Various minimally invasive procedures for treating discogenic pain have been reported in recent years. A Disc-FX® system can be used to perform nucleus pulposus (NP) removal, radiofrequency ablation, and annuloplasty under the guidance of x-ray fluoroscopy. However, when a probe tip with focused heat is placed on the intradiscal/subannular area to perform nucleo-annuloplasty using radiofrequency lesioning, thermal injury to the spinal cord or spinal nerves is a concern.

**Objectives:** To assess the thermal profile generated by the Disc-FX ablation and modulation system in intervertebral discs from human cadaveric spine sections and evaluate the safety of its thermal dispersion function.

**Study Design:** A cadaveric study.

**Methods:** NP ablation and annulus fibrosus modulation were performed on a fresh human cadaveric lumbar spine intervertebral disc in a 36.5°C circulating water bath using radiofrequency. The 4 points from the center of the disc to one-third, two-thirds and the outer layer of the annulus were divided into 4 points, A-D, respectively, and radiofrequency lesions were performed on the 4 points.

**Results:** The temperature was increased upon irradiation. It fell slowly with the cessation of irradiation. The temperature was not significantly different between Turbo and Hemo mode at each point. The temperature was not significantly different among the 4 points at each mode. The average temperature of the ventral side of the dura mater was kept below 37°C.

**Limitations:** The results of this study are limited due to the use of a cadaveric spine, which could not reflect the effect of soft tissue such as muscles and connective tissue around the disc. The position of the temperature measuring probe was relatively fixed. This cadaver demonstration was conducted at the L4-L5 level, which is mostly not restricted by the height of the iliac crest.

**Conclusions:** When performing NP ablation and annular modification, the epidural peripheral temperature should always be kept below 37°C. This preliminary in vitro research using human cadaveric discs showed that radiofrequency maintained the epidural space at a safe temperature during nucleo-annuloplasty.

**Key words:** Temperature, thermal, radiofrequency, nucleo-annuloplasty, spine

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Discogenic pain (DP) is primarily defined as a chronic pain induced by the activation of pain receptors in the intervertebral disc due to intervertebral disc degeneration, annular fissures, intervertebral discitis, or other intervertebral disc diseases (1,2). Most researchers believe that DP is mainly caused either by protruding or bulging nucleus pulposus (NP) tissue that compresses the nerve roots, internal disc derangement, ingrowth of nociceptive nerve fibers into the intervertebral disc, an annulus fibrosus (AF) tear, or various inflammatory mediators (3).

Treatment options for DP vary from nonsurgical therapies such as physiotherapy, to surgical operations such as disc replacement and spinal fusion (4). However, major operations are linked to a greater risk of surgical morbidity and complications (5). As a result, various minimally invasive procedures for treating DP have been reported in recent years. The majority of these treatments, such as nucleoplasty, seek to alleviate pressure on the neural tissue by decreasing intra-discal pressure and decompressing the disc (6,7).

Compared to nucleoplasty alone, a Disc-FX® system (Elliquence, LLC) can be used to perform NP removal, radiofrequency (RF) ablation, and annuloplasty under the guidance of x-ray fluoroscopy (8). The procedure decompresses the nerve through disc shrinkage and modulation of the NP while annuloplasty denervates nerve fibers of the AF and aids healing of an annular tear. The possible mechanism is the heating of disc tissue with RF to ablate hypersensitive nociceptors and aberrant neural in-growth inside the annulus fibrous (9). Several studies have reported that Disc-FX might be helpful in selected patients with DP as it can provide promising results (8,9).

However, when a probe tip with focused heat is placed on the intradiscal/subannular area to perform nucleo-annuloplasty using RF lesioning, thermal injury to the spinal cord or spinal nerves is a concern. Thus, the purpose of this study was to investigate the thermal profile generated by a Disc-FX ablation and modulation system in intervertebral discs from human cadaveric spine sections and to evaluate the safety of its thermal dispersion function.

## Methods

Two cadavers were selected to undergo NP ablation and AF modulation at the L4-L5 level using the Disc-FX system. Cadavers with severe degeneration such as fissuring, bridging osteophytes, a history of spine trauma, infection, tumor, or any other bony diseases were excluded as donors. A puncture needle was placed in the L4-L5 intervertebral space with the tip positioned at the center of the surgical disc on orthogonal fluoroscopy and at the midpoint of the intervertebral space no more than the posterior one-fourth of the vertebral body on lateral radiographs.

A small skin incision of 3 mm was made to accommodate the introduction of the access cannula and the soft tissue dilator into the AF. A steerable Trigger-Flex (Elliquence) probe was inserted through the cannula. NP ablation and AF modulation were then performed with a Surgi-Max (Elliquence) generator set at Bipolar Turbo mode and Bipolar Hemo mode. At each point, in Turbo and Hemo modes, lesioning was performed for 10 seconds with pausing for 3 seconds.

After confirming the position of the puncture needle, the working cannula and dilator was placed along the guide needle, with the access device only breaking through the AF. After connecting a bipolar RF kit, the RF head was bent to the ventral side. After fluoroscopically determining that the RF head was located in the contralateral AF, the NP was slowly pulled out to the operator's side for ablation in Bipolar Turbo mode (1.7 MHz) for 10 seconds. With a 3-second break, the ablation in Bipolar Turbo mode (1.7 MHz) for 10 seconds was repeated 3 times.

The RF head was then bent to the dorsal side. After fluoroscopically determining that the RF head was located in the contralateral AF, the AF was slowly pulled out to the operator's side for AF formation at 1.7 MHz (Bipolar Hemo mode) for 10 seconds. With a 3-second break, the AF formation at 1.7 MHz (Bipolar Hemo mode) for 10 seconds was repeated 3 times.

In order to correct the temperature of the disc affected by the cerebrospinal fluid and blood circulation, we made an artificial water bath. In an attempt to recreate physiological temperature, the cadaver was immersed in a thermostatic water bath at 36.0°C-36.5°C (Fig. 1). The 4 points from the center of the disc to one-third, two-thirds, and the outer layer of the AF were divided into 4 points, A-D (Fig. 2). Radiofrequency lesions were performed on the 4 points. An epidural catheter was inserted via the caudal hiatus to check the temperature for each RF lesioning.

The temperature at the ventral epidural space was simultaneously checked (Fig. 3). The temperature was recorded for each point under Turbo and Hemo modes separately. Temperature data were collected at one-second intervals using a Fiber Optic Temperature Sensor FOB104 (Omega Engineering Inc). Before computing the mean value at each point, the peridiscal temperatures acquired from lesions were standardized to 36.0°C -36.5°C. To account for heterogeneity in the initial temperature acquired from both the water bath and leftover heat from the development of numerous lesions, mean peridiscal temperatures were normalized (set to 36.0°C -36.5°C). We recorded and analyzed the temperature using a multichannel data acquisition system.

*Fig. 1. Experimental set-up. Cadaver, temperature measurement devices, and radiofrequency equipment (Disc-FX system).*

## Results

Average temperature recordings for the 4 points from 2 cadavers according to time are shown in Figs. 4 and 5. The temperature increased upon irradiation. It then decreased slowly with the cessation of irradiation.

In Turbo mode, the mean temperature ranged from 36.1°C to 36.4°C at point A, 36.1°C to 36.2°C at point B, 36.6°C to 36.7°C at point C, and 36.6°C to 36.7°C at point D (Fig. 4).

In Hemo mode, the mean temperature ranged from 36.1°C to 36.4°C at point A, 36.1°C to 36.3°C at point B, 36.5°C to 36.6°C at point C, and 36.1°C to 36.3°C at point D (Fig. 5).

The temperature was not significantly different between Turbo and Hemo modes at each point. It was not significantly different among the 4 points at each mode either. The average temperature of the ventral side of the dura mater was kept below 37°C.

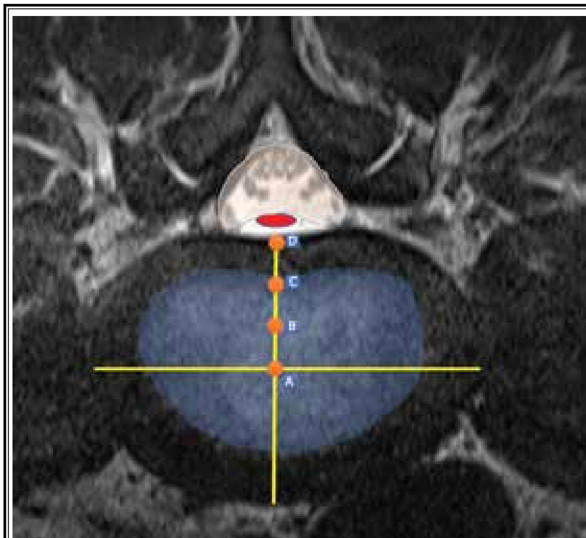


Fig. 2. *The 4 points from the center of the disc to one-third, two-thirds, and the outer layer of the annulus fibrosus were divided into 4 points, A-D, respectively.*

## Discussion

Although the physiopathology of DP remains unknown, many experts contend that disc degeneration, delamination, and AF fissure are primary causes of DP. According to previous studies (10,11), nerve infiltration can develop as a result of degenerative changes in the disc, in which capillaries and nerves grow into the ruptured ring fissure and progressively spread to the inner fibrous layer and even the NP. The majority of these nerves are unmyelinated fibers, which can be painful if they are compressed or stimulated.

Another source of DP is biochemical and biomechanical changes generated by intervertebral disc degeneration, which can lead to an increase in inter-

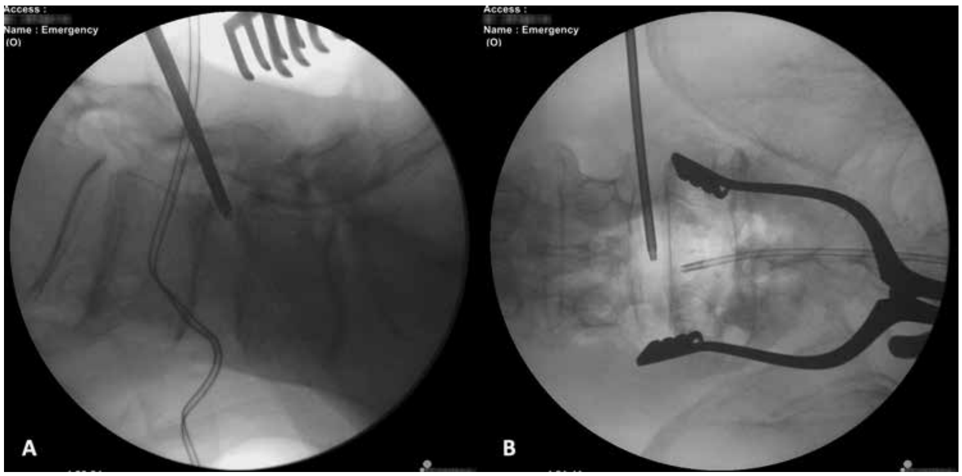


Fig. 3. *Fluoroscopic images showing the lateral (A) and anteroposterior (B) views showing the placement of the radiofrequency probe and fiber optic temperature sensor, respectively.*

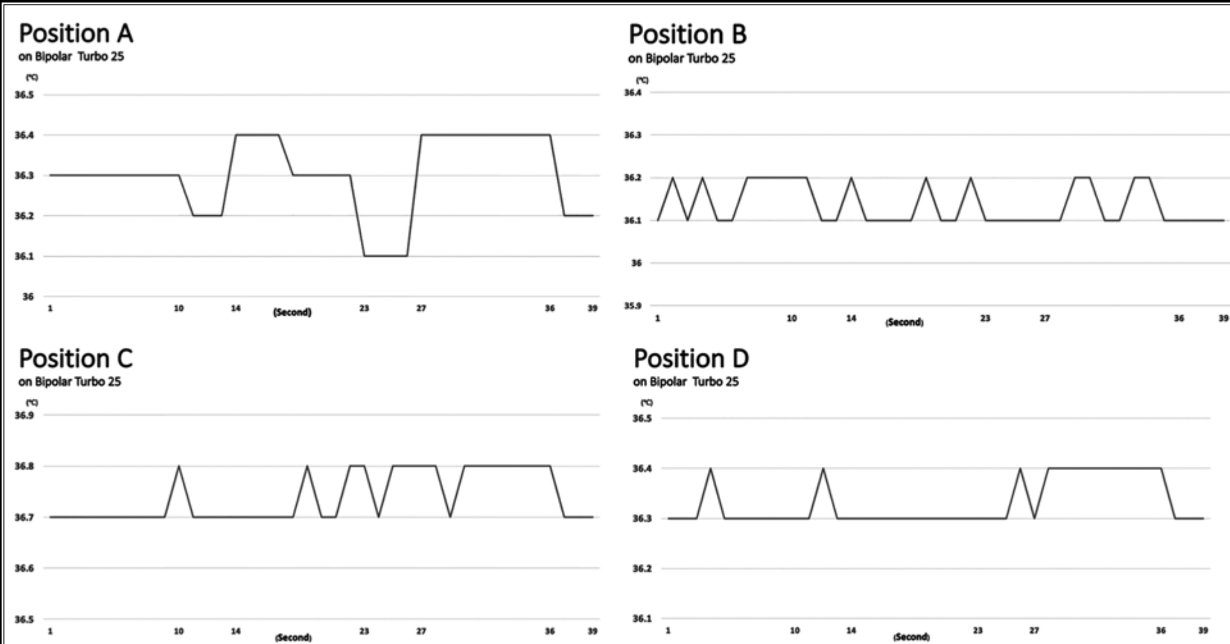


Fig. 4. *Average temperature recordings for the 4 points from the Bipolar Turbo mode according to time are shown.*

vertebral disc pressure (12,13). In addition, the deteriorated NP can be employed as an antigen to trigger an immunological response and create inflammatory mediators such as interleukins and tumor necrosis factor alpha (14). These inflammatory mediators can enter the outer AF through fissures of degenerative discs, sensitizing or directly stimulating outer nerve fibers, resulting in discomfort (14). A number of inflammatory variables can directly trigger or diminish the threshold of neuralgia by producing changes in the intervertebral disc's microenvironment, resulting in DP (15).

The principle of a Disc-FX system for the treatment of DP corresponds to the mechanism of its pathogenesis. A unique NP forceps can remove deteriorated NP and inflammatory tissues through working channels, relieving pressure on the disc, allowing the disc to contract, and reducing nerve irritation (8). RF ablation can further reduce the pressure in the intervertebral disc and ablate allergic nerve terminal receptors that grow into the intervertebral disc and the AF fissure, thereby effectively alleviating pain symptoms (16). Modulation of the dorsal AF can result in cauterization of inflamed

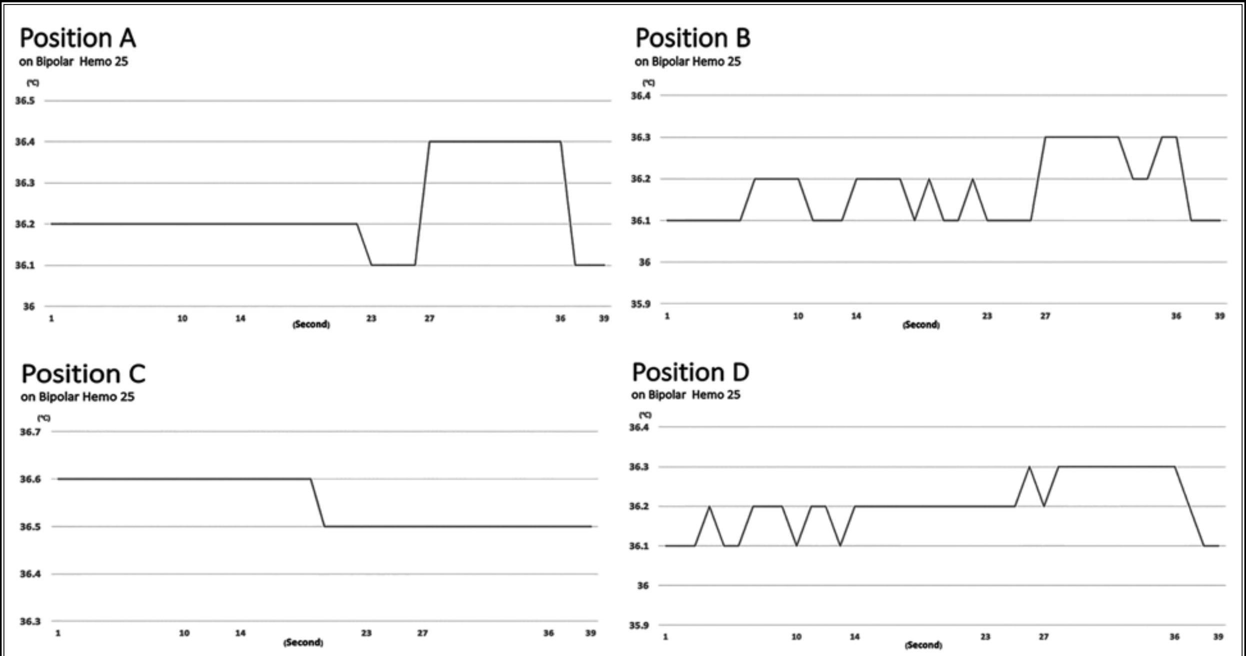


Fig. 5. *Average temperature recordings for the 4 points from the Bipolar Hemo mode according to time are shown.*

structures and shrinkage of the AF. The retracted AF can also reduce the compression and stimulation of the nerve root. It can relieve pain symptoms of lower limbs to a certain extent (17).

In addition, RF ablation can change the expression of cytokines in the intervertebral disc, significantly reduce interleukin-1 content but increase interleukin-8 content, thus playing a certain role in relieving pain and promoting the repair of the intervertebral disc (18). This technique utilizes the higher frequency of 1.7 MHz through the Elliquence Surgi-Max generator with 2 different modes -Bipolar Turbo and Bipolar Hemo modes. Turbo mode allows nuclear ablation, while Hemo mode allows annular modification with shrinkage. The function of RF energy is to create a plasma field in local tissues around electrodes and to generate a large number of highly ionized particles. The passage of these electron particles through the biological tissue can raise the temperature to a critical value and break intermolecular bonds. The heat generated can ablate the NP tissue, granulation tissue, and nerve fibers that grow into the intervertebral disc (9). A steerable delivery system using Trigger-Flex probes allows targeted applications in pathological areas.

Nucleoplasty depends mostly on indirect decompression because the thermal effect can induce disc contraction and a reduction in intradiscal pressure. However, conventional nucleoplasty produces less than ideal outcomes, particularly for ablation of sensitive nociceptors in the posterior or posterolateral AF and for nerve blocks of aberrant inward development (17). Therefore, the Disc-FX technique is added to the annuloplasty procedure using RF. RF energy is used for nucleus ablation and annular modification in Disc-FX. As RF technology advances, RF energy production and heat transfer will need to be addressed on a regular basis (19). The potential of accidental thermal damage to surrounding structures or the central nervous system exists as a result of this heat transfer. Reduced heat transfer and little tissue damage are 2 advantages of using Trigger-Flex RF (Elliquence). The use of irrigation throughout the operation aids in controlling heat levels at the probe's tip and limiting the region subjected to thermal coagulation.

In this study, we used RF to perform ablation and modification at 4 points in the disc space. The Turbo mode allows ablation, while the Hemo mode allows modification with shrinkage. At each point, there was no significant difference in temperature between Turbo and Hemo modes. Both temperatures were below 37°C. The temperature at point D (near the epidural space) was also below 37°C. In an in vivo porcine model, a study about histological effects and thermal distribution of disc biacuplasty has revealed that this method can achieve appropriate temperatures for neural ablation in the disc while causing no injury to adjacent nerve roots (20). Another publication described a cadaver investigation on disc biacuplasty temperature distribution, showing that temperatures are sufficient to ablate nerves in the disc while maintaining the epidural space and neural foramina at safe temperatures (21). Additionally, temperature monitoring experiments have shown that bipolar lesion is safe and effective at 45°C (20,21). In summary, bipolar RF ablation and modification are safe and effective.

### Limitation

The results of this study are limited due to the use of a cadaveric spine, which could not reflect the effect of soft tissue such as muscles and connective tissue around the disc. The position of the temperature measuring probe was relatively fixed. This cadaver demonstration was conducted at the L4-L5 level, which is mostly not restricted by the height of the iliac crest. However, it is difficult to perform annular modulation targeting the AF at the L5-S1 level due to a high iliac crest. Moreover, no tissue immunological examination was performed. Specific tissue reactions to thermal damage and the lack of blood flow make determining heat dissipation and injury more difficult. Furthermore, quantifying the level of harm caused by inflammatory edema is challenging.

## Conclusions

When performing NP ablation and annular modification, the epidural peripheral temperature should always be kept below 37°C. This preliminary in vitro research of human cadaveric discs shows that RF can maintain a safe temperature for the epidural space during nucleo-annuloplasty.

### Authors' contributions

Writing – original draft: Guang-Xun Lin; Investigation: Sagar Sharma; Methodology: Yanting Liu; interpreted of data: Hussam Jabri; Writing – review & editing: Jin-Sung Kim.

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