

SPINE SECTION

Technical Report

An Assessment of a New Navigatable Percutaneous Disc Decompression Device (L'DISQ) Through Histologic Evaluation and Thermo-Mapping in Human Cadaveric Discs

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Abstract

Study Design. This is an *in vitro* experimental study of the technical capability and safety study of a navigatable percutaneous disc decompression device named L'DISQ.

Objectives. The objectives of this study were to determine if L'DISQ could adequately reach certain target zones in the disc and to measure the distri-

bution of rises in temperature in the surrounding tissue when the device was used to ablate the disc.

Methods. Placement of the wand of L'DISQ was attempted into the posterior annulus of the discs of four fresh human cadavers. During disc ablation, thermocouple probes were used to measure the temperature within the nucleus pulposus and annulus fibrosus, on the surface of the annulus, and on the posterior longitudinal ligament. Tissues harvested from around the disc were examined histologically.

Results. The tip of the wand could be successfully navigated to the posterolateral or posterocentral annulus at all levels above L5-S1 using a lateral approach. Rises in temperature did not exceed $13.25 \pm 0.84^\circ\text{C}$ within the disc, and did not exceed 1°C on the surface of the disc. Histology demonstrated no thermal damage to the surrounding neural tissues.

Conclusion. L'DISQ can be successfully navigated to the target zones, and disc tissue ablated without thermal or structural damage to the adjacent neural tissues.

Key Words. Spine; Disc Herniation

Introduction

L'DISQ (U&I Co., Uijeongbu, South Korea) is a device designed to ablate material within intervertebral discs [1]. It consists of a long flexible wand (electrode) attached to a handle. A wheel in the handle can change the curvature of the tip of the wand. This feature allows the wand to be introduced along a curved path to reach the base of a disc herniation in the posterior annulus fibrosus (Figure 1). Passing an electric current through the wand heats the tissues surrounding the tip, thereby ablating them.



Figure 1 Demonstration of the L'DISQ spine wand using an artificial intervertebral disc model. The wand is placed into disc via a 16-G 3.5 in. introducer needle (A,B). The tip of the wand is curved and advanced into the posterior annulus using the navigation system (C). After placement of the tip into the posterior annulus, plasma energy induced by radiofrequency can be generated to ablate and decompress the disc material (D).

The utility of L'DISQ depends on its ability to reach all sectors of the posterior annulus. Its safety depends on the extent to which heat from the wand affects the tissues beyond the immediate target zone. These two features were assessed in the present study.

Methods

Two fresh, adult human cadavers were used to assess the ability to navigate the wand.

From the other two cadavers, eight spinal motion segments were harvested and used to measure the temperature during disc ablation.

In the intact cadavers, five trained operators used either of the two approaches to the L1-2 through L5-S1 discs. For

the posterolateral approach, the entry point was approximately four fingerbreadths lateral to the midline; for the lateral approach, the entry point was approximately 15 cm lateral to the midline.

For the posterolateral approach at the L1 through L4 levels, the beam of a C-arm fluoroscope was aligned with the endplates of the target disc in the 90° anteroposterior view, and rotated 30°–35° laterally so that the superior articular process projected across, or just posterior to, the longitudinal midline of the vertebral bodies. For the lateral approach, the C-arm was rotated 15° posteriorly from an initial 0° lateral projection. At the L5-S1 level, when the ilium obstructed a direct posterolateral or lateral approach, the C-arm was additionally declined cephalad to use a puncture point 1 cm above the iliac crest.

Table 1 Success rates were higher in the lumbar discs above L5-S1 and were best when using the lateral approach

Approach Techniques	Target Points			
	L1/2 to L4/5		L5/S1	
	PC Annulus	PL Annulus	PC Annulus	PL Annulus
Posterolateral entry	75.0% (12/16)	87.5% (14/16)	0.0% (0/3)	0.0% (0/3)
Lateral entry	100.0% (16/16)	100.0% (16/16)	50.0% (2/4)	50.0% (2/4)

PC = postero-central; PL = posterolateral.

Note: the number of trials is indicated in parentheses.

We were unable to place the tip of the catheter into posterior positions in the L5-S1 disc using the posterolateral approach. Only 50% of trials were successful when using the lateral approach at the L5-S1 level. All trials were successful at the L1/2 through L4/5 intervertebral discs using the lateral approach.

Using these views, the guide-needle was introduced into the posterior annulus. To improve steerage, the distal 6–8 mm of the guide-needle was bent to 20°. Through the guide-needle, the operators inserted the wand and attempted to navigate it both to the posterior central annulus and to the contralateral, posterolateral annulus.

In the specimens of lumbar motion segments, once the wand was placed into position, the temperature probes (TM-7410; Tenmars, Taipei, Taiwan) were placed into the central nucleus pulposus and posterolateral annulus fibrosus. Temperatures were recorded 1–2 and 4–5 mm from the wand tip, at the posterolateral surface of the annulus, and at the central posterior longitudinal ligament and its lateral edge. Static ablation was performed both with and without saline infusion.

After ablation in two L4-5 and L5-S1 discs, the disc was inspected for charring and distortion. Samples were harvested of the posterolateral annulus fibrosus, the ipsilateral dorsal root ganglion, and ipsilateral spinal nerve roots. The samples were fixed in 10% buffered formalin and embedded in paraffin. Five micron sections were prepared and stained with hematoxylin and eosin.

Results

For discs above L5-S1, using the lateral approach, the operators succeeded in reaching both the posterior central annulus and the posterolateral annulus in all of 16 attempts, as shown in Table 1. Using the posterolateral entry, they successfully reached the posterior central annulus in 12 out of 16 attempts, and the posterolateral annulus in 14 out of 16 attempts.

Access into the L5-S1 disc proved more difficult. The operators reached the posterior central annulus and the posterolateral annulus each in only two out of four attempts using the lateral approach, and failed to reach either site in each of three attempts.

During ablations, temperatures within the nucleus pulposus and inner annulus fibrosus rose, as shown in

Table 2. In the outer annulus, and at the posterior longitudinal ligament, increases in temperature were all below 1°C.

On gross inspection, the treated discs exhibited a clean tissue defect where the nuclear material was ablated, but no evidence of charring or damage to the adjacent tissues.

Microscopy of the stained tissue samples showed that the posterolateral annulus, the dorsal ganglia, and the nerve roots were all intact.

Discussion

The thermal mapping data of the present study indicate that L'DISQ should be a safe procedure when used clinically. Although temperatures rise significantly within the

Table 2 Temperature changes in nucleus pulposus and annulus fibrosus during static ablation

Sites of Thermocouple Probe from the Tip of Wand	Ablation Sites of L'DSIQ	
	Center of NP	Inner Layer of AF
Without saline infusion		
Outer 1–2 mm	13.25 ± 0.84°C	8.25 ± 0.64°C
Outer 4–5 mm	11.35 ± 0.61°C	6.36 ± 0.51°C
With saline infusion		
Outer 1–2 mm	9.44 ± 0.53°C	6.24 ± 0.12°C
Outer 4–5 mm	8.36 ± 0.71°C	5.14 ± 0.08°C

NP = nucleus pulposus; AF = annulus fibrosus.

Statistically significant temperature increases were observed at outer 1–2 and 4–5 mm from the wand tip in both the annulus fibrosus and the nucleus pulposus (*P* < 0.01). However, the temperature change did not exceed 13.25 ± 0.84 above the initial temperature at any location.

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disc, in the vicinity of the wand, they do not rise at the surface of the disc.

Consequently, nerves or other structures outside the disc should be at no risk of thermal damage, provided that the wand remains within the disc.

With respect to navigation, the posterolateral approach was reasonably adequate above L5, but totally inadequate at L5-S1. The relatively acute angulation of this approach impedes access across the posterior annulus. In contrast, the lateral approach was consistently successful above L5, and successful half the time at L5-S1.

Therefore, the lateral approach is recommended for clinical trials.

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Reference

- 1 Lee SH, Derby R, Sul D, et al. Efficacy of a new navigable percutaneous disc decompression device (L'DISQ) in patients with herniated nucleus pulposus related to radicular pain. *Pain Med* 2011;12:370–6.