


Functional Anaesthetic Discography™ Procedure

Isolating Symptomatic Discs Amongst Abnormal Discs

Case Study

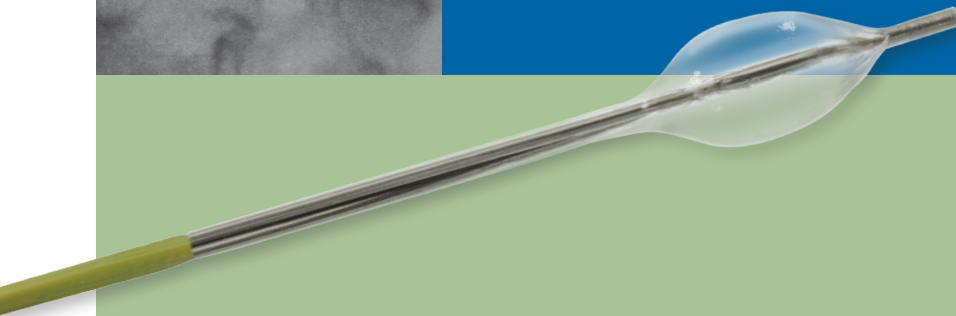
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Isolating
Symptomatic Discs amongst
Abnormal Discs

F.A.D.™



Product Used:
DISCYPHOR™ Catheter System

PATIENT HISTORY

A 45 year old female presented with a 14 month history of midline lumbosacral pain that she described as constant in duration, achy in character, and 7 out of 10 in severity on a Numerical Pain Rating Scale (NPRS). Her symptoms started acutely upon lifting an object and had not improved despite physical therapy, non-steroidal anti-inflammatory medications (NSAIDs), and other analgesics. She experienced short term improvement with bilateral S1 transforaminal epidural steroid injections. However, her symptoms were persistent and functionally limiting, exacerbated by prolonged sitting and alleviated somewhat by lying in the lateral decubitus position.

PHYSICAL EXAMINATION

Sustained hip flexion with knees extended and pelvic rock both reproduced her lumbosacral pain. Straight leg raising (SLR) at 50° reproduced her symptoms which were then exacerbated by passive ankle dorsiflexion and reduced by passive knee flexion bilaterally.

DIAGNOSTIC EVALUATION

MRI

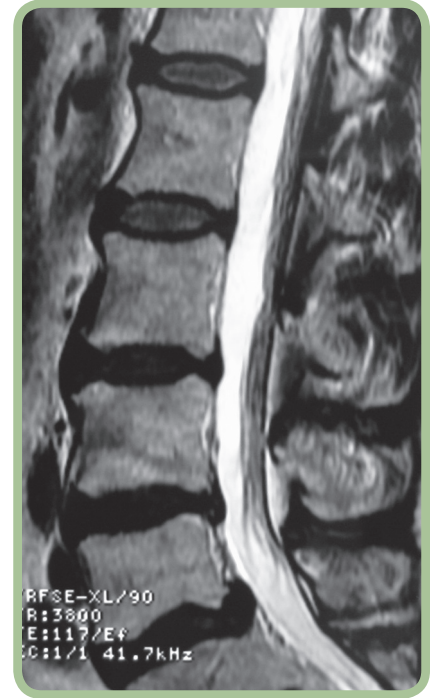
L1-2: Mild disc desiccation.

L2-3: Mild disc desiccation.

L3-4: Moderate disc desiccation.

L4-5: Moderate to severe disc desiccation. Small, broad-based central focal protrusion present.

L5-S1: Moderate to severe disc desiccation. Small, broad-based central focal extrusion present.



T2 weighted Sagittal l/s Spine MRI.

Provocative Discography

Level	Opening Pressure (psi)	Pressure at (Peak) Pain (psi)	Total Volume Injected (cc)	Pain (NPRS)	Type of Pain	Morphology	Conclusion
L4-5	Manometry not routinely used		2.0	9/10	Concordant	Contrast extension to posterior outer annular fibers	Positive
L5-S1			2.8	None	N/A	Contrast extension to the outer annular fibers	Negative
L3-4			1.8	None	N/A	Irregular nucleogram with no extension of dye beyond inner annular fibers	Negative
L2-3			1.8	None	N/A	Lobular nucleogram	Negative

“The patient reported experiencing mild pressure but no pain, confirming anesthetization of the L4-L5 intervertebral disc.”

—Michael J. DePalma, M.D.

Post Discography CT Scan

L4-5: Midline, posterior grade IV annular tear.

L5-S1: Right, posterolateral grade IV annular tear.

Functional Anaesthetic Discography™ Procedure

A DISCYPHOR™ Catheter was inserted into the disc at the L4-5 level. The patient was asked to recreate her typical low back pain by sitting, standing, and bending; and rate her pain level. The patient was then injected with 0.7 cc of 4% xylocaine into the L4-5 disc, and asked again to rate her pain level while performing the same activities.

During xylocaine injection, the patient reported exacerbation of her usual Low Back Pain (LBP). 10 minutes post-xylocaine injection, 0.7 cc's of sterile saline was injected. The patient reported experiencing mild pressure but no pain, confirming anesthetization of the L4-L5 intervertebral disc. After resuming the sitting position, her LBP score was a 2/10, and upon forward flexion, her score was a 3/10.

Functional Anaesthetic Discography™ Procedure Pain Score Results at L4-5

Range of Motion	Baseline Pain (NPRS)	Post Injection Pain* (NPRS)	% Pain Reduction	Interpretation
Lying fetal position	5/10	N/A	N/A	N/A
Straight Leg Raises (SLR)	50° Max	65° max and less painful than pre-xylocaine injection	N/A	Positive response to anesthetic
Sitting	8/10	2/10	75%	Positive response to anesthetic
Standing upright, arms extended with shoulders forward flexed @ 20° lumbar flexion	9/10	3/10	67%	Positive response to anesthetic
Forward flexion	Fingertips reach pre-tibial area of each leg	Fingertips reach distal legs bilaterally	N/A	Positive response to anesthetic

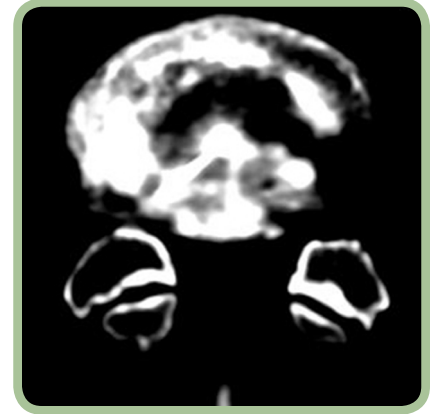
* Final NPRS pain is based on xylocaine injection followed by saline injection.

ASSESSMENT

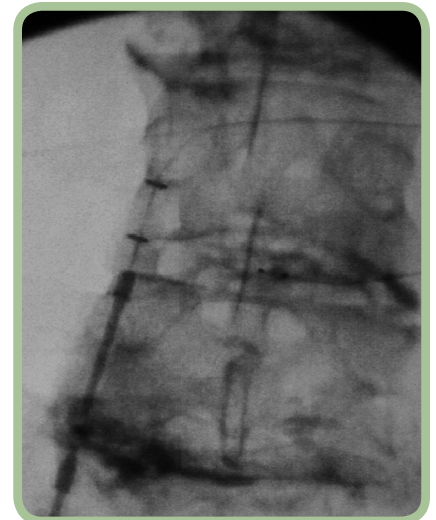
The patient underwent an instrumented, single-level L4-5 anterior-posterior fusion. At 6-months post-fusion, the patient had sustained improvement in her low back pain, and level of function.

KEY POINTS

1. The F.A.D.™ Procedure confirmed diagnosis of L4-5 as the primary pain generator.
2. Appropriate therapeutic recommendations were selected from the additional diagnostic confirmation.
3. The functional aspect of the F.A.D.™ Procedure allows for the real-time evaluation of the patient's typical low back pain.
4. The DISCYPHOR™ Catheter enables assessment of the disc's response to an anesthetic, and permits confirmation of the disc's anesthetization by evaluating the patient's response to a secondary saline injection.



Post-discography CT axial view through the L4-5 intervertebral disc.



A/P Fluoroscopic image of the DISCYPHOR™ Catheter with balloon inflated in L4-5.



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As with most interventional procedures, the Functional Anaesthetic Discography™ (F.A.D.™) Procedure has associated risks, including serious complications. For complete information regarding indications for use, contraindications, warnings, precautions, adverse events and methods of use, please reference the devices' Instructions for Use.

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