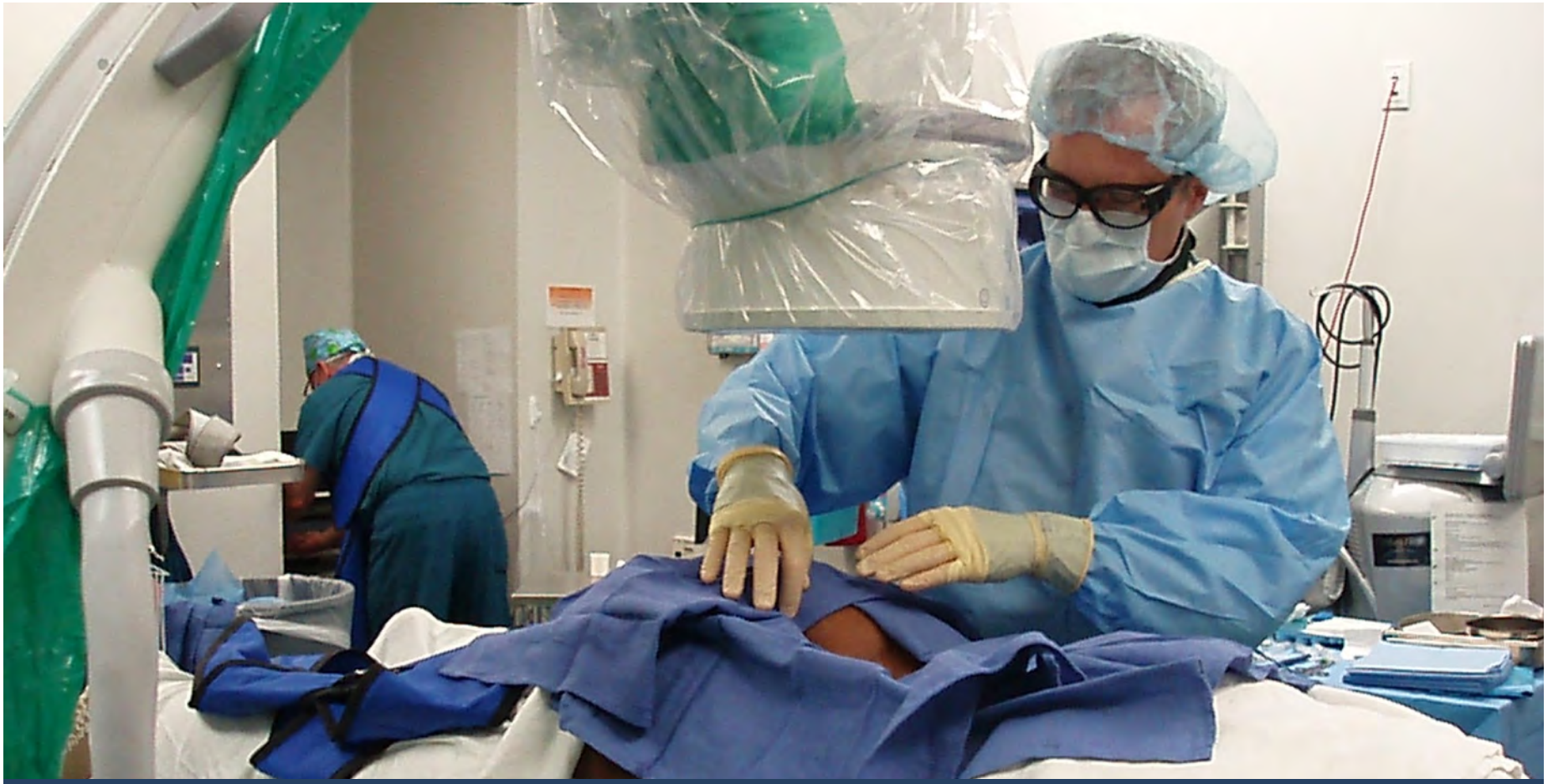

Brian Durkin, DO

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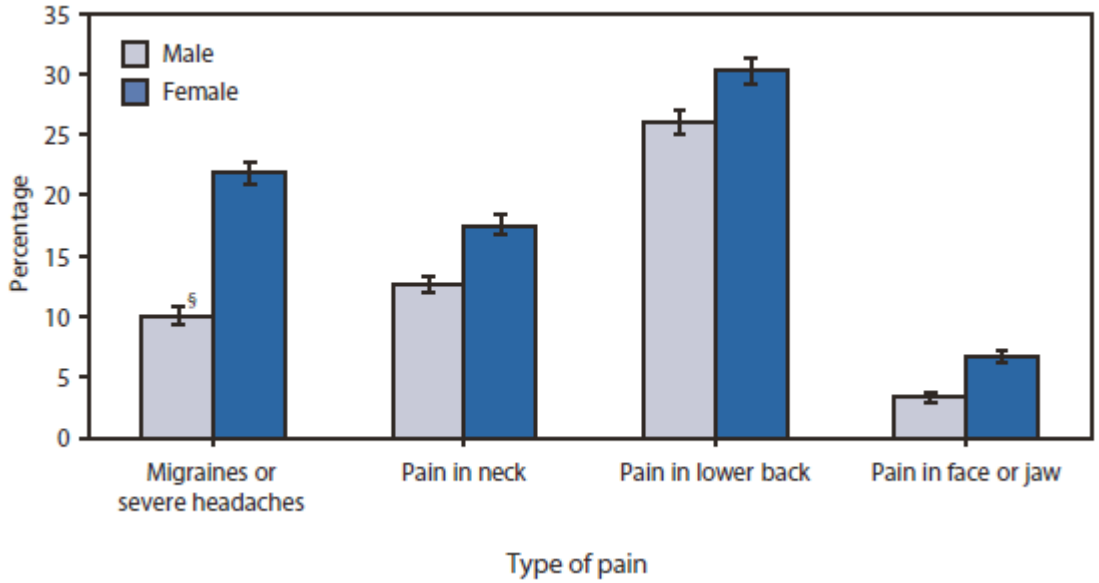
MILD® QA/QI Study TEAM

- Helene Benveniste, MD, PhD
- Laurie A. Shroyer, PhD (Surgery)
- Christopher Biel
- Jaimie Romeiser, MS
- Stacey Hildebrand, NP
- Laura Wahl
- Raphael Davis, MD (Neurosurgery)
- Robert Peyster, MD (Radiology)
- Sachin Jambawalikar, PhD (Radiology)

Epidemiology of chronic low back pain



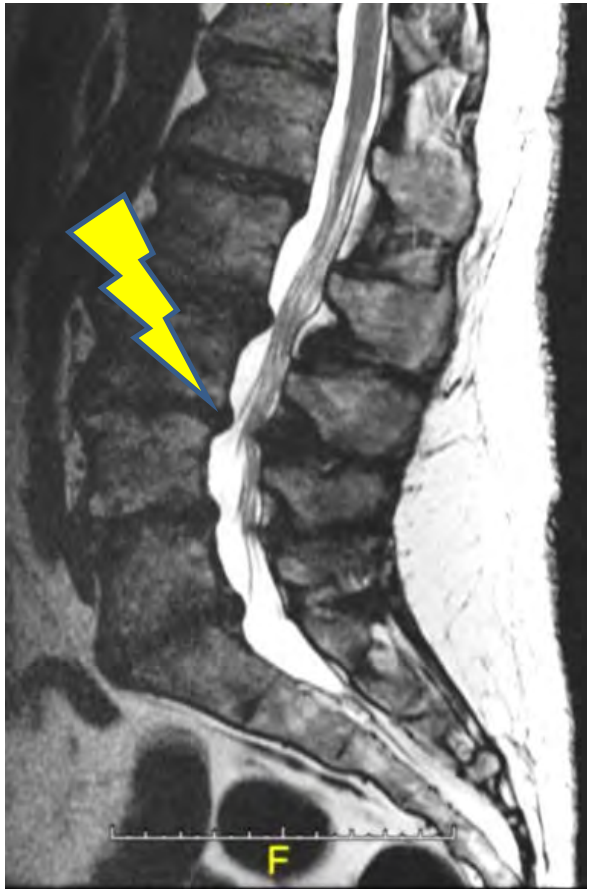
For each type of pain, respondents were asked, "During the past three months, did you have [type of pain]?" Respondents were instructed to report pain that had lasted a whole day or more , and conversely, not to report fleeting or minor aches or pains. Persons might be represented in more than one pain category

The percentage of adults who had migraines or severe headaches, pain in the neck, lower back, or face/jaw, by sex in 2009. Females were more likely than males to have experienced a migraine or severe headache (21.8% versus 10.0%), pain in the neck (17.5% versus 12.6%), ***pain in the lower back (30.2% versus 26.0%)****, and pain in the face or jaw (6.6% versus 3.3%). For both sexes, pain in the lower back was the most common of these four types of pain, and pain in the face or jaw was the least common*

Pleis JR, Ward BW, Lucas JW. Summary health statistics for U.S. adults: National Health Interview Survey, 2009 (provisional report). Vital Health Stat 2010;10(249).

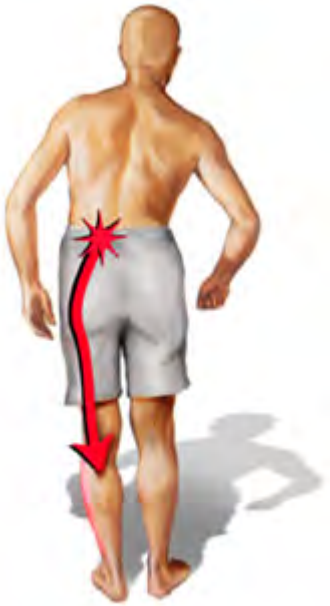
Symptomatic Lumbar Spinal Stenosis

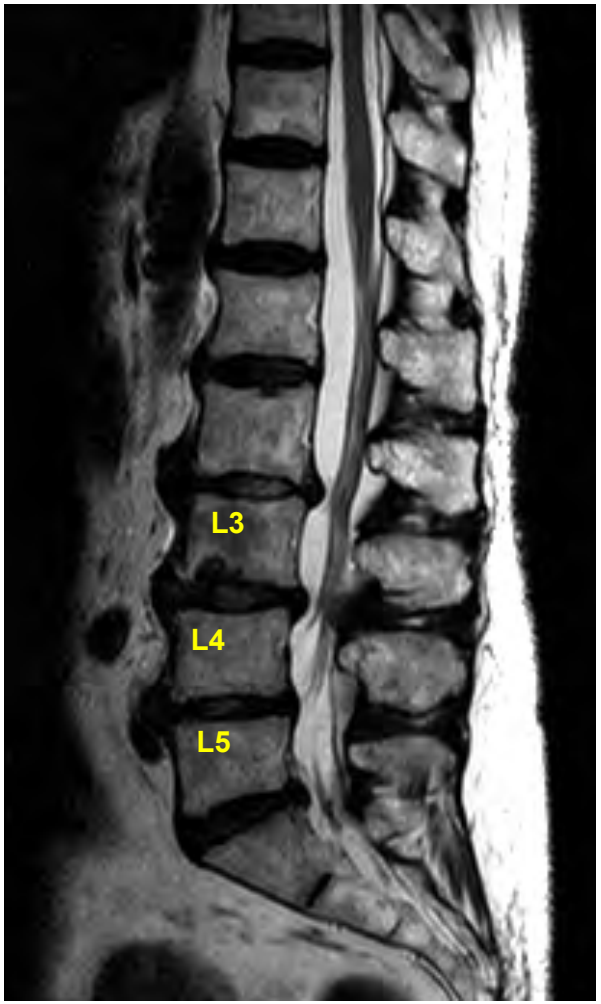
- The prevalence of lumbar spinal stenosis (LSS) in patients ranging from 60-69 years of age is estimated to be 47% for relative spinal stenosis and 20% for absolute stenosis
- 1.2 million physician office visits in the US are related to symptoms of LSS in elderly patients
- 125,000 laminectomy procedures were performed in 1995; and based on 2007 estimates this number will surge as life expectancy increases



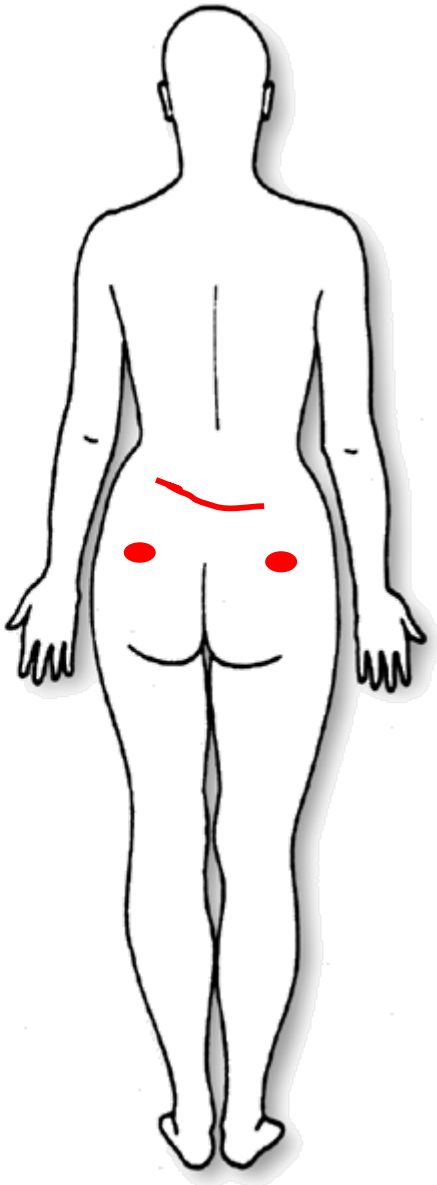
Clinical diagnosis of LSS

- Pain in the low back area, buttocks, and/or legs in combination with neurogenic claudication.
- Neurogenic claudication occurs with erect postures such as standing or walking

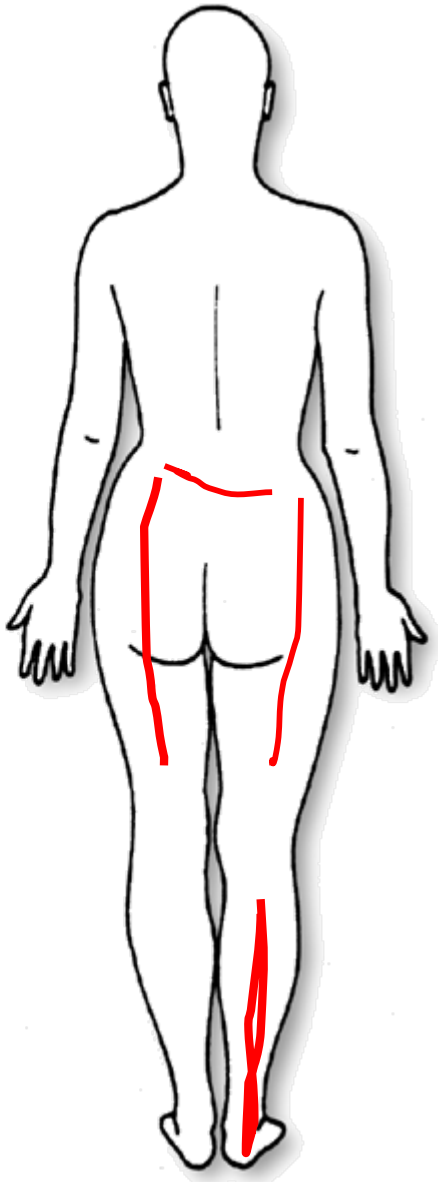




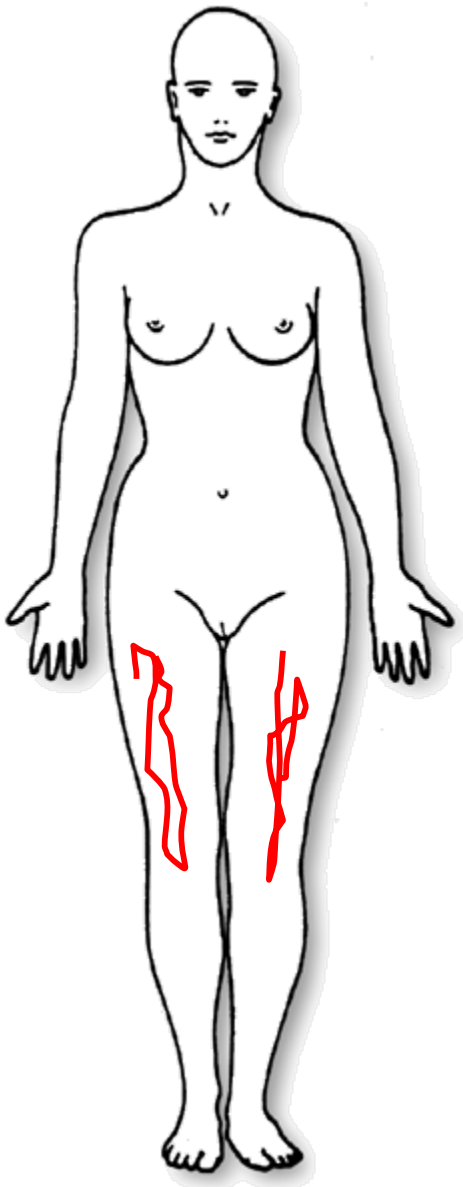
Example's of patient's pain patterns



VAS = 5/10



VAS = 8/10

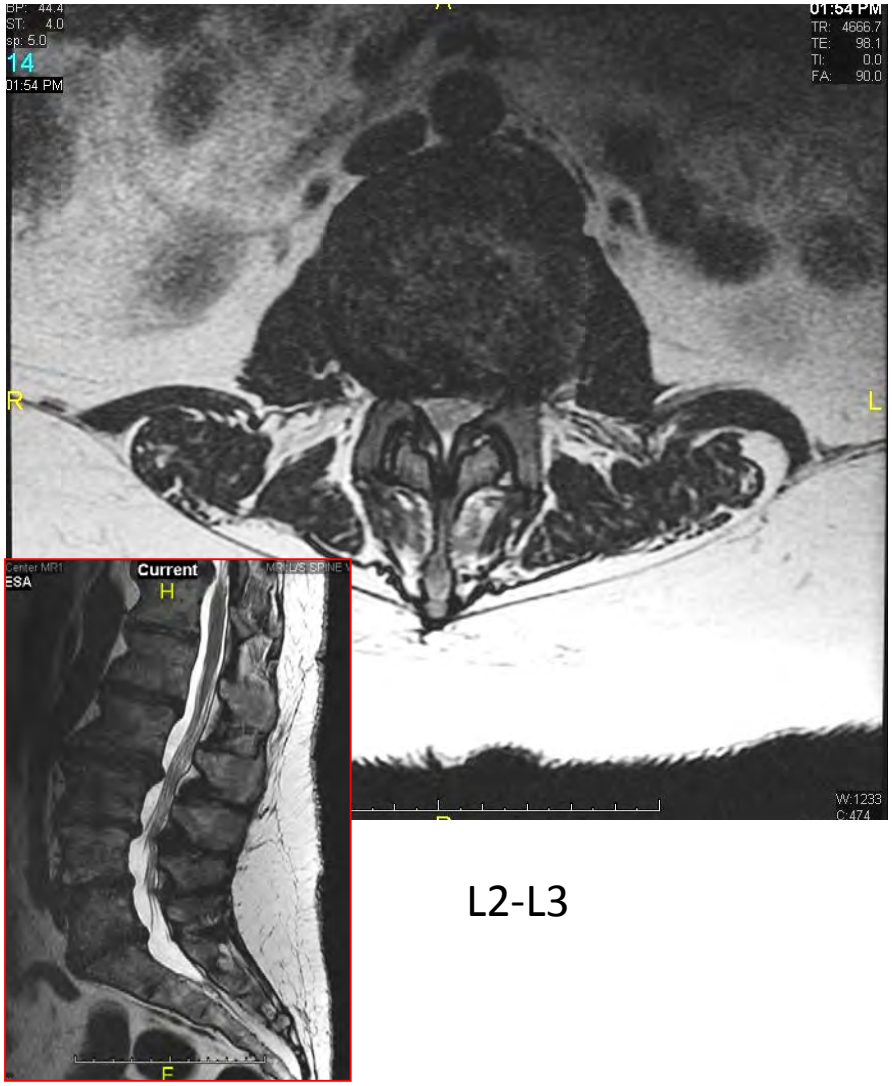


VAS = 9/10

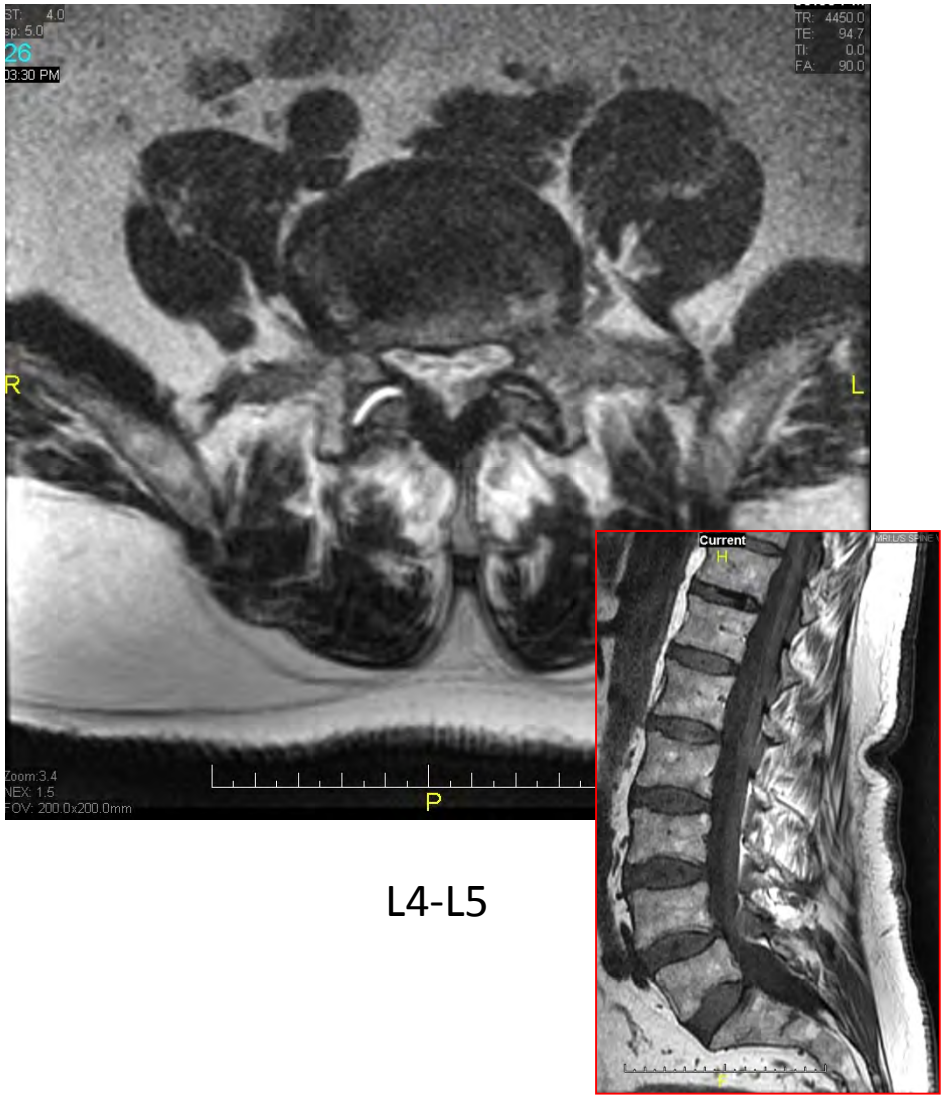
Causes of Symptomatic LSS

- Ligamentum Flavum (LF) hypertrophy
- Facet joint hypertrophy
- Vertebral body osteophytosis
- Herniated discs
- Spondylolisthesis
- LSS can occur at a single or multiple levels
- Concurrent pathologies (i.e. LF, Facet joint hypertrophy and/or herniated discs)

Ligamentum Flavum Hypertrophy

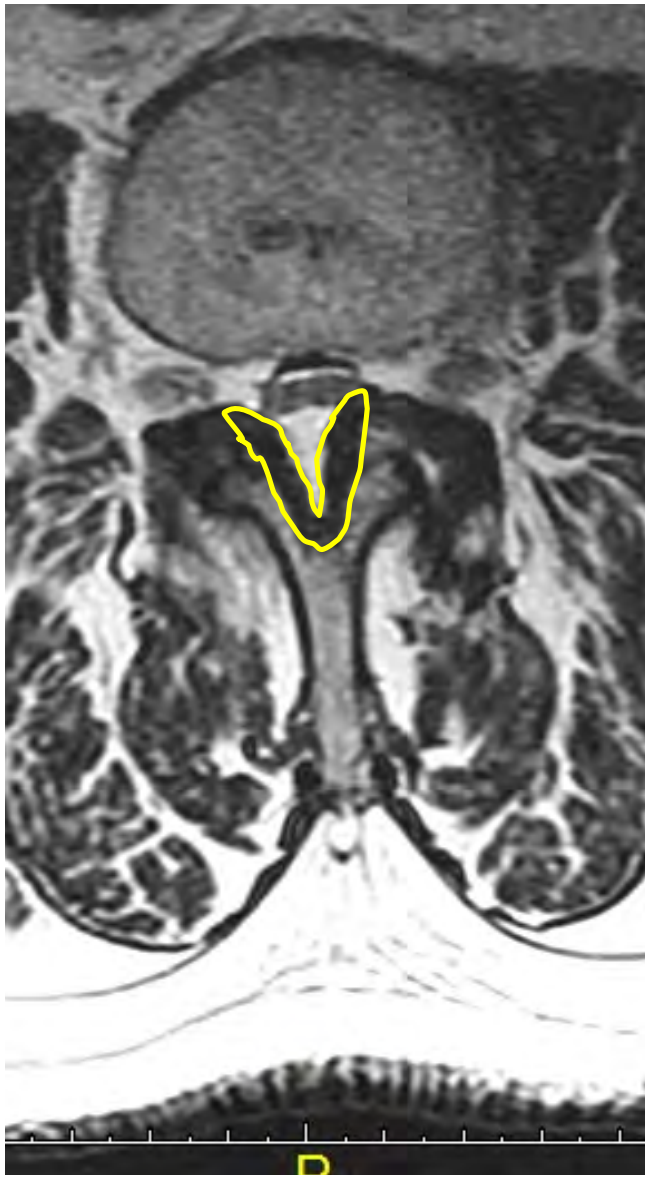


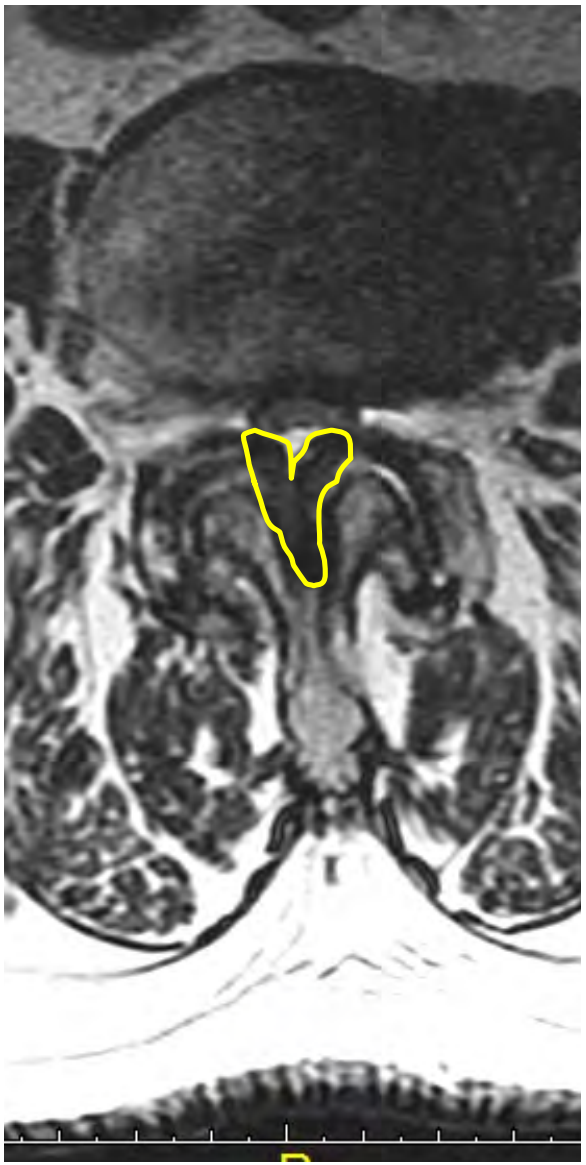
L2-L3



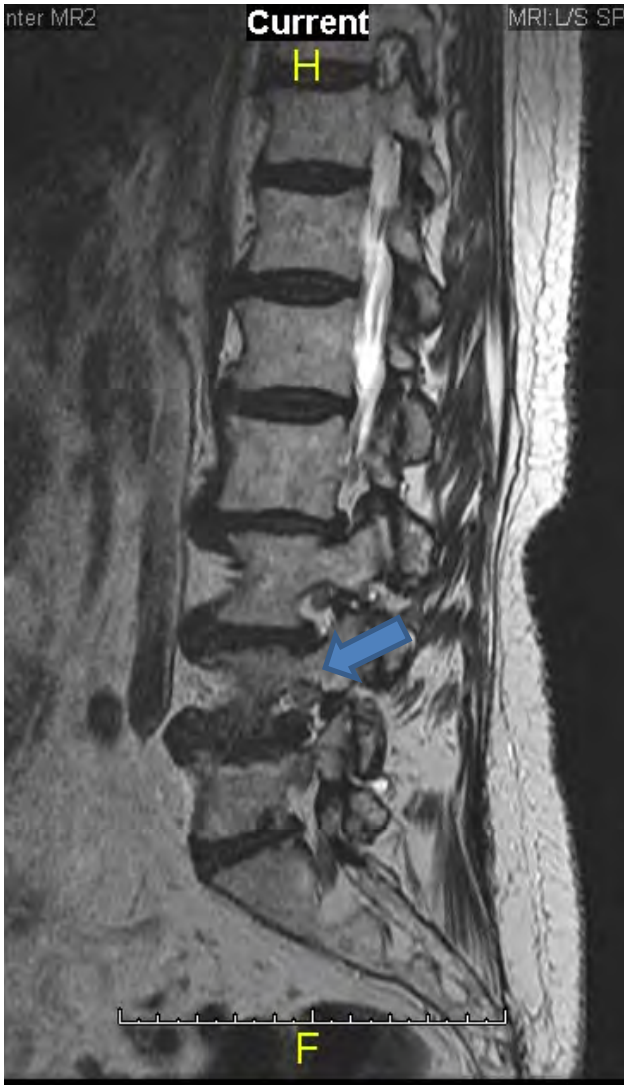
L4-L5

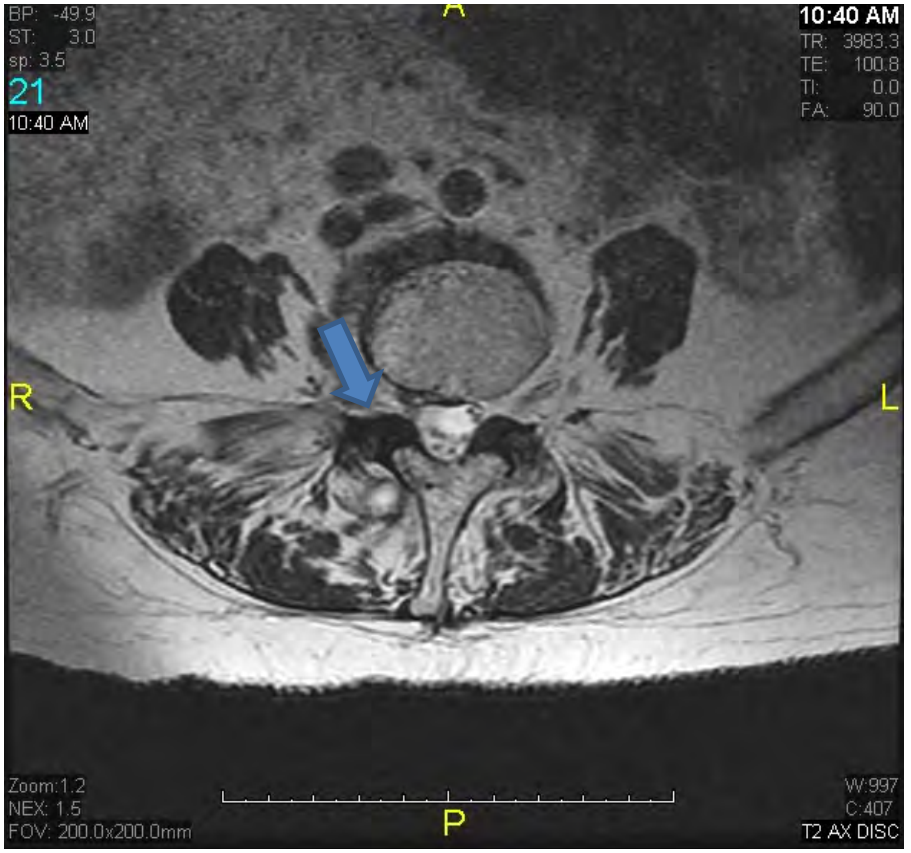
Ligamentum Flavum Hypertrophy





Other spine pathology can contribute to symptoms……





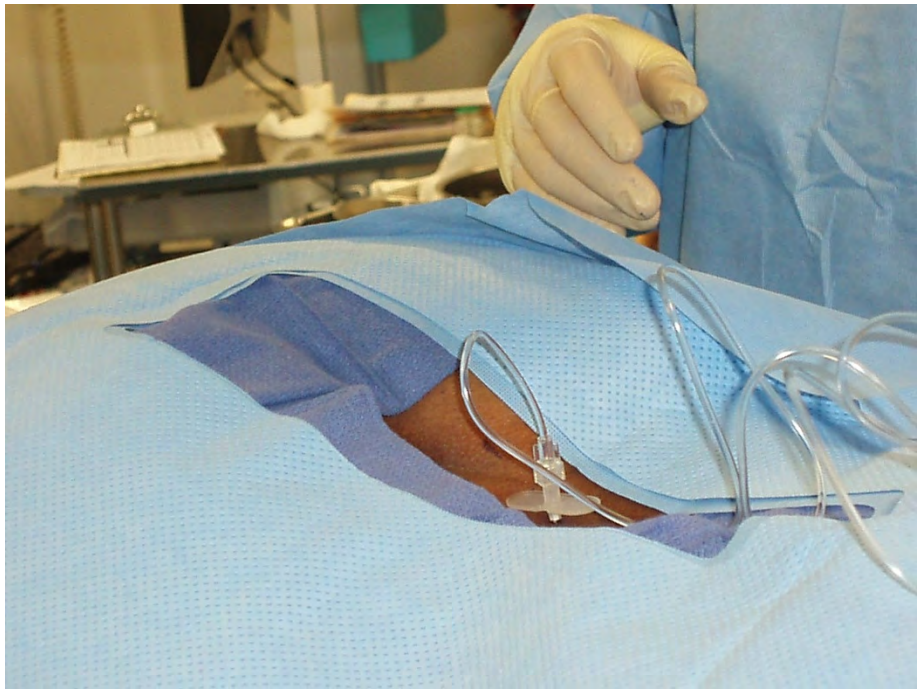
Surgical Approaches for Symptomatic LSS with radiculopathy

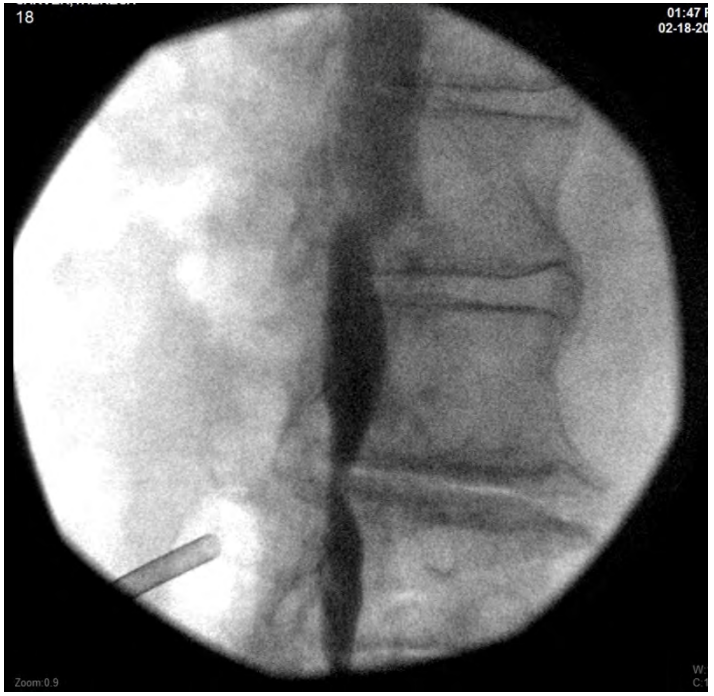
- Decompressive laminectomy (without fusion)
- Decompressive laminectomy with fusion
- X-Stop interspinous space
- (Standard open discectomy)

MILD®

Minimally Decompressive Lumbar Decompression (MILD®)

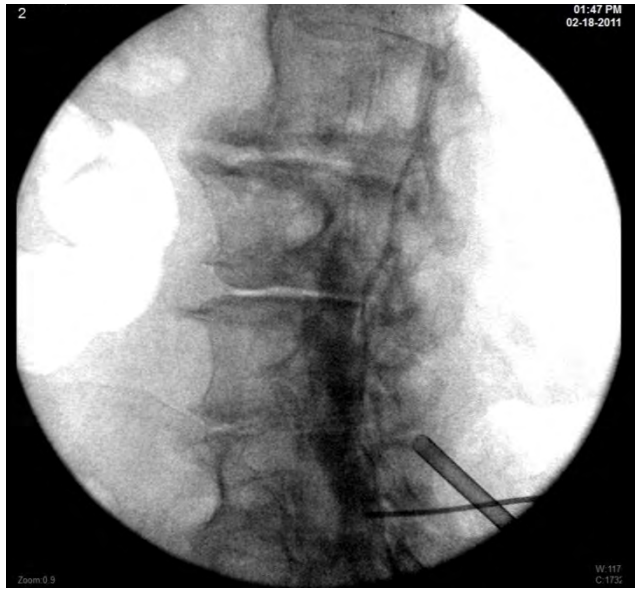
- The patient can undergo the procedure under local anesthesia & MAC.
- The patient is positioned in the prone position and an epidural needle is placed for contrast and visualization of the working space via fluoroscopy. central canal and requires 1-2 hours

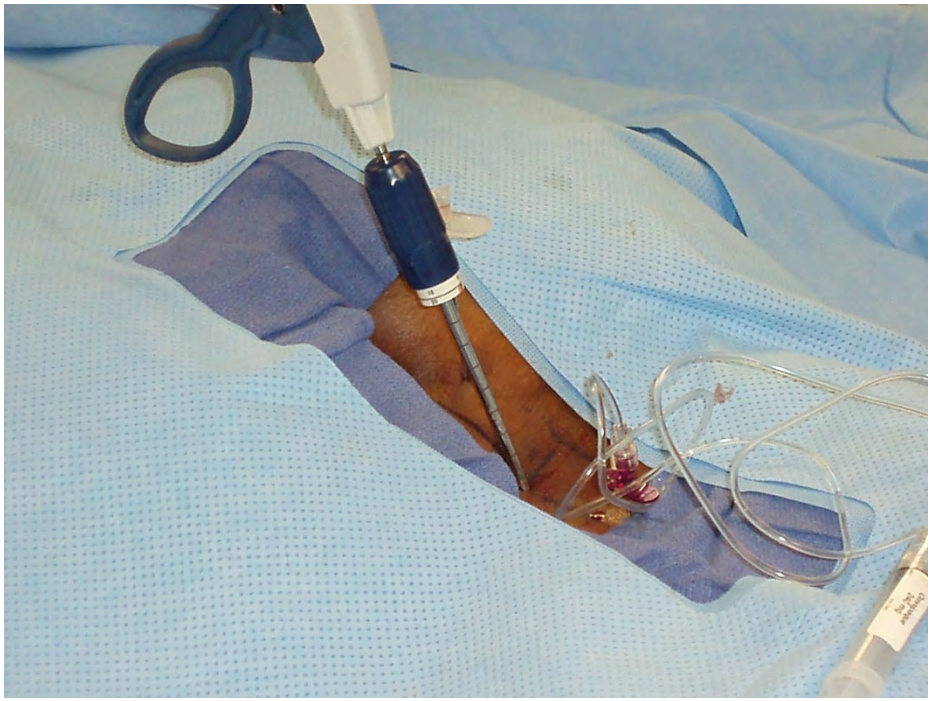




MILD®

- A 6-gauge portal cannula is positioned under fluoroscopy guidance adjacent to the intra-laminar space
- The trocar is used to direct the sculpting or shaving instruments directly into the area
- Decompression is confirmed via changes in epidural contrast distribution and contrast flow.
- The process can be performed at multiple levels and requires 1-2 hours





MILD® (Deer et al., 2009)

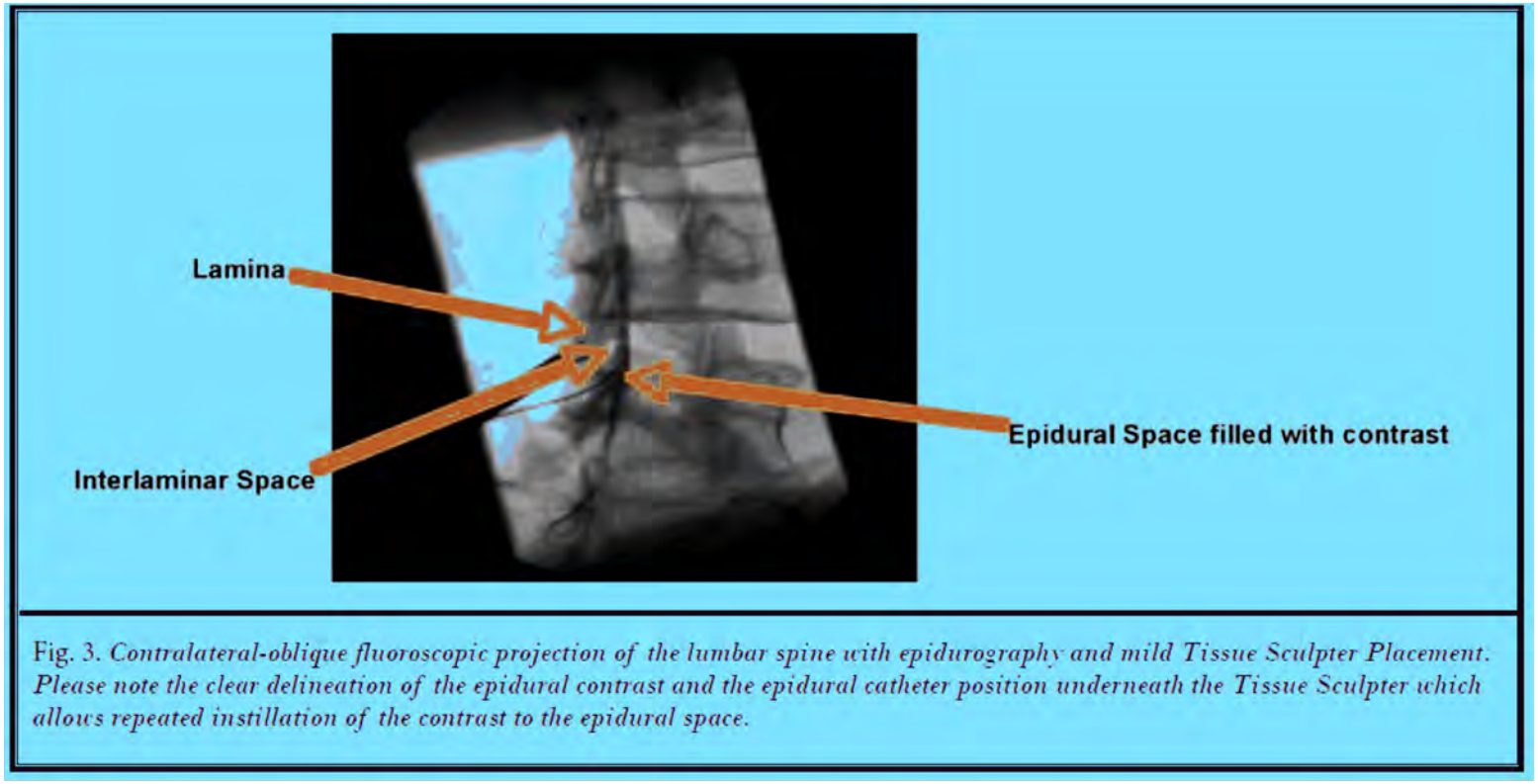
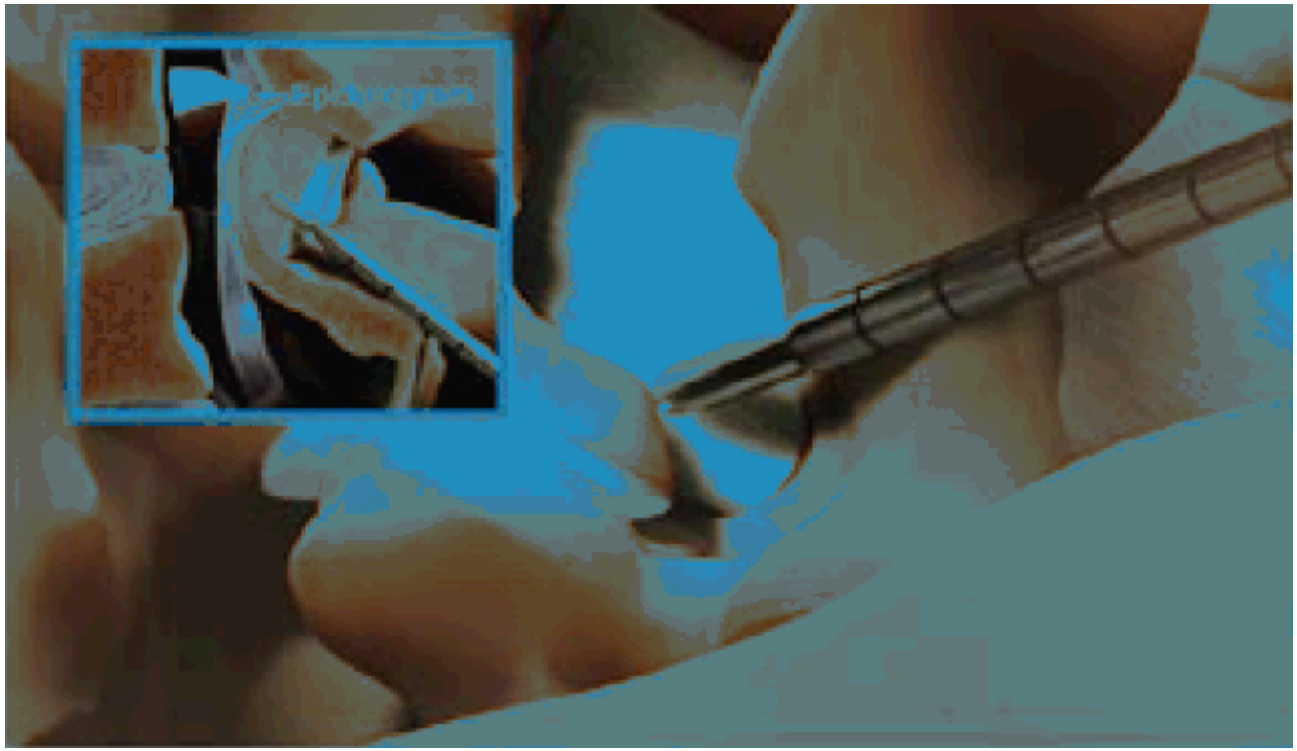


Fig. 3. *Contralateral-oblique fluoroscopic projection of the lumbar spine with epidurography and mild Tissue Sculpter Placement. Please note the clear delineation of the epidural contrast and the epidural catheter position underneath the Tissue Sculpter which allows repeated instillation of the contrast to the epidural space.*

Pain Physician: January/February 2010; 13:35-41

MILD®



Pain Physician: January/February 2010; 13:35-41

Retrospective review of 90 cases

Observational Study

New Image-Guided Ultra-Minimally Invasive Lumbar Decompression Method: The *mild*® Procedure

Timothy R. Deer, MD[1], and Leonardo Kapural, MD, PhD[2]

Results: Of 90 procedures reviewed, there were no major adverse events or complications related to the devices or procedure. No incidents of dural puncture or tear, blood transfusion, nerve injury, epidural bleeding, or hematoma were observed.

Pain Physician 2010; 13:35-41 • ISSN 1533-3159

QA MILD® Project Quality Plan

Inclusion/Exclusion

- **Inclusion criteria**
  - All patients with primary leg pain (leg pain > low back pain) associated with localized hypertrophy of ligamentum flavum and central canal stenosis on MRI or CT scan (neuro-radiologist's criteria)
  - All patients with low back pain and leg pain associated with localized hypertrophy of ligamentum flavum on MRI or CT scan (neuro-radiologist's criteria)
- **Exclusion criteria:**
  - Patients with low back pain associated with lumbar spine pathology not likely to improve by procedure (e.g. foraminal stenosis and/or disc bulge-herniation compressing exiting nerve roots as determined by Dr. Peyster & Durkin)
  - Patients unable to tolerate 1-3 hr procedure in prone position
  - Dementia or inability to understand procedure and answer questionnaires

PROJECT QUALITY PLAN

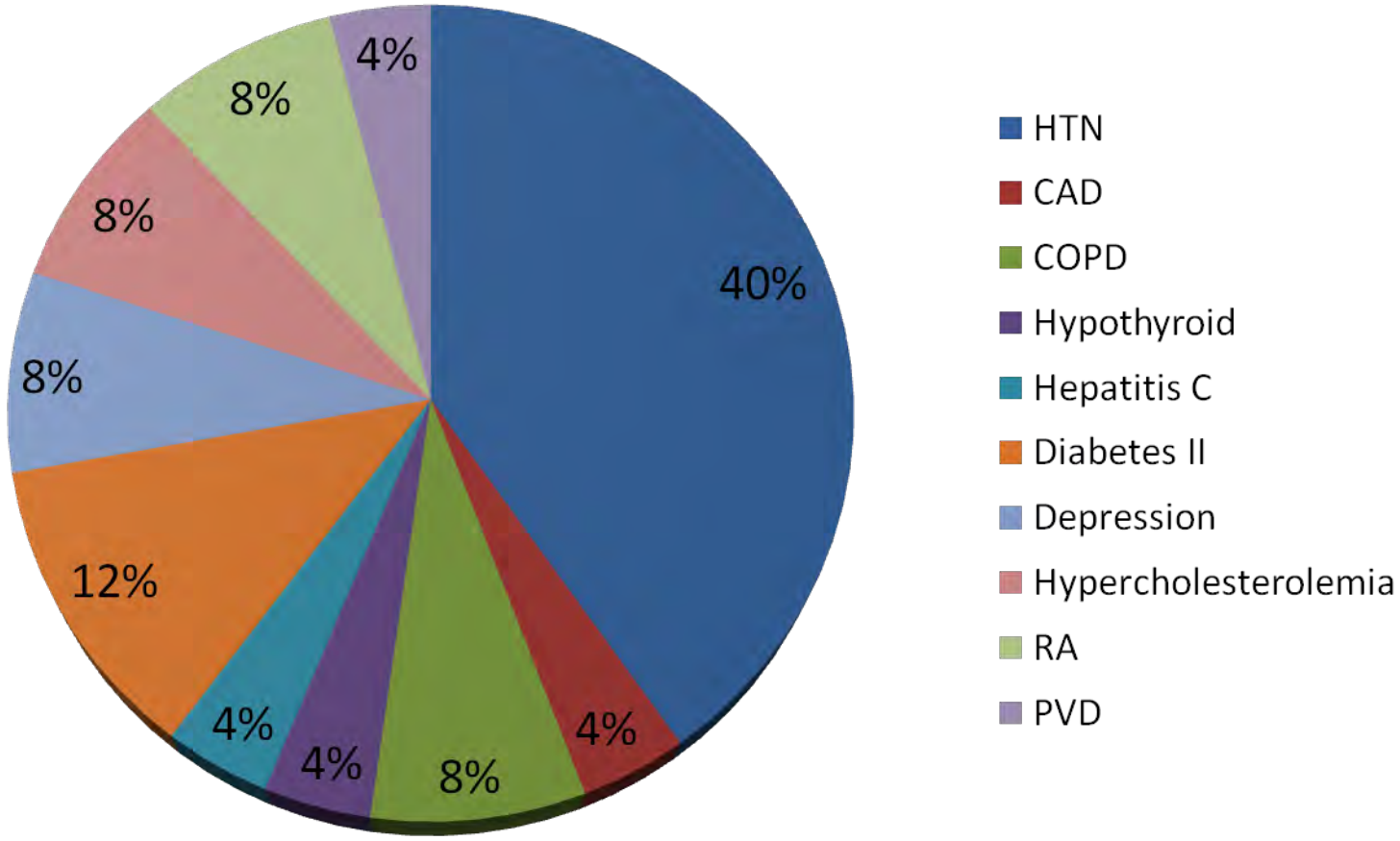
Purpose & outcome goals:

To assess pain scores and long-term functional status in patients with low back pain associated with ligamentum flavum hypertrophy and central canal stenosis before and after the MILD® procedure

Demographics of 11 MILD® Patients

- 5 Female; 6 male
- Average Age: 69.6 ± 11.5 years
- Average BMI: 31.3 ± 6.7
- Race: White: 10; African-American: 1
- Hx of tobacco use: 64% (active smokers: 9%)
- Opioids: 4 patients out of 11 (36%)

Co-morbidity in MILD® Patients (n=11)



ASA STATUS: ASA II – 5 patients; ASA III – 6 patients

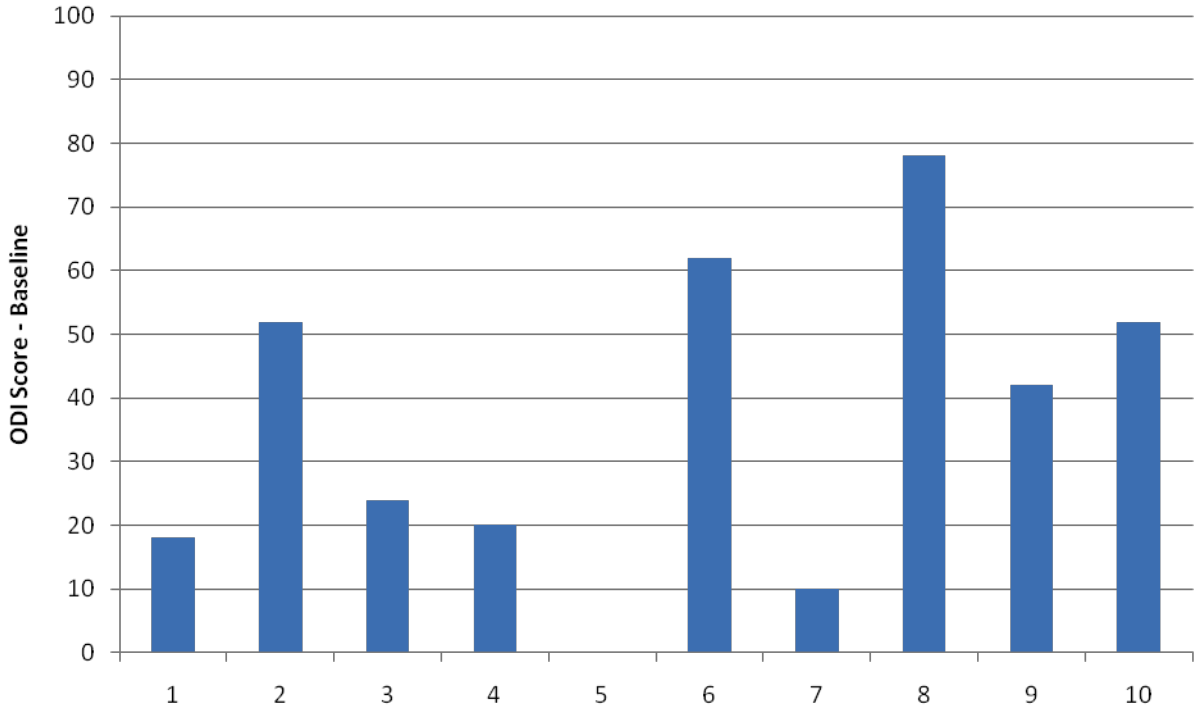
Low back pain descriptors

	Yes (%)	No (%)
Gait Instability	64%	34%
Use of Walking Assistance Device	45%	55%
Low back pain	100%	-
Leg pain at rest	81%	19%
Neurogenic Claudication	100%	-
Baseline VAS pain score (0-10)	8.3 ± 1.8	-

MRI Diagnosis (based on 9 patients with MRIs)

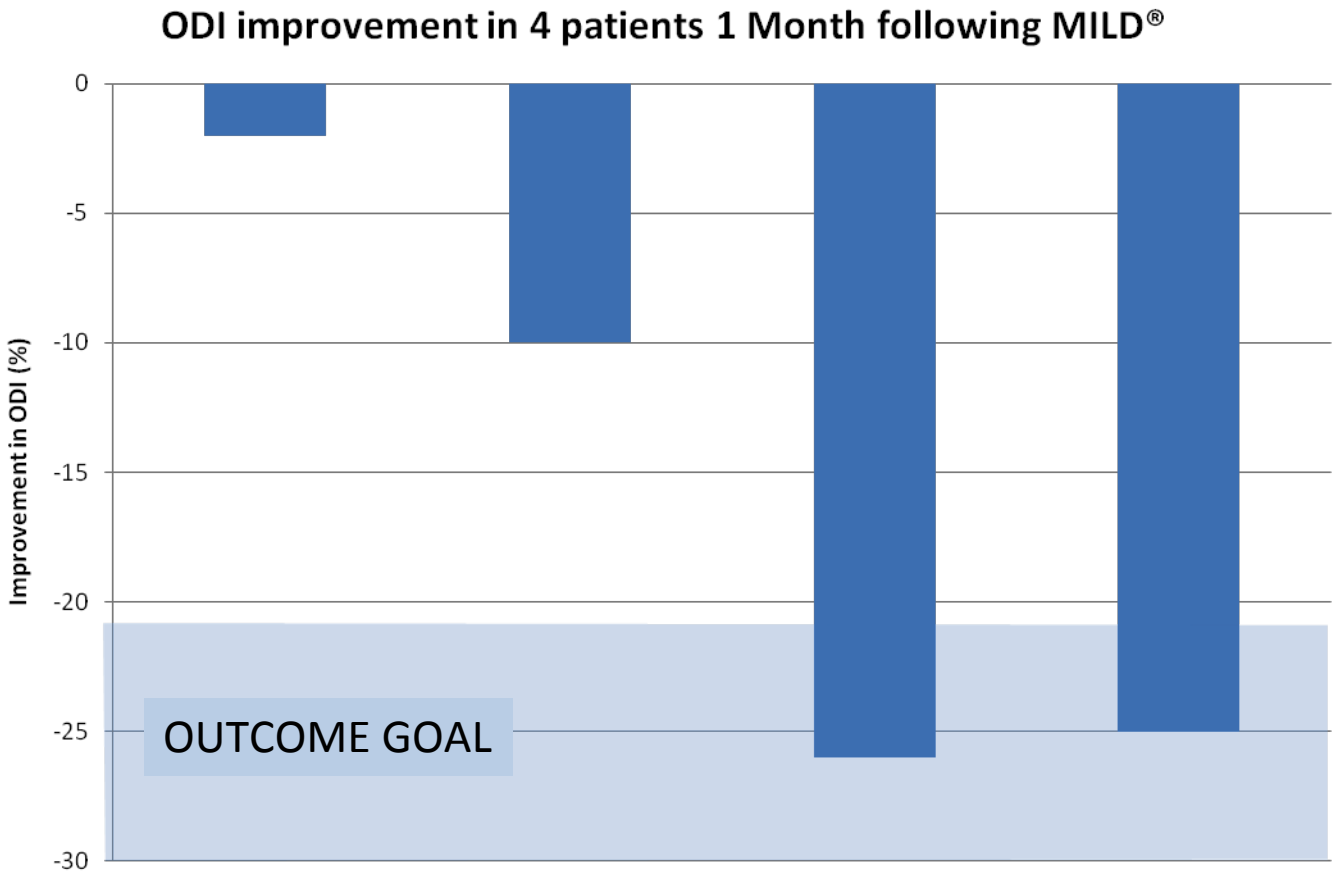
Level	Canal Stenosis & LF hypertrophy
L2-L3	Mild: 44% Moderate: 22% Severe: 34%
L3-L4	Mild: 12% Moderate: 44% Severe: 44%
L4-L5	Mild: 11% Moderate: 33% Severe: 56%
L5-S1	Mild: 77% Moderate: 11% Severe: 22%

ODI status of MILD® Patients Prior to Procedure: ODI variable and most patients are relatively functional

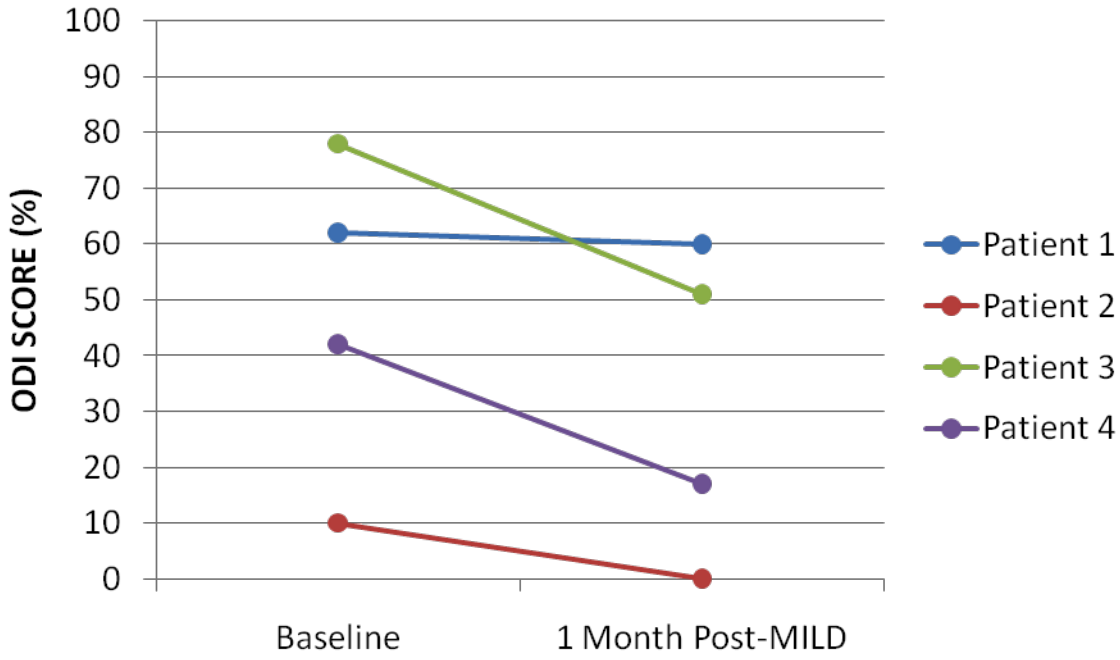


The Oswestry Disability Index (ODI) is a validated, patient-completed questionnaire used to assess 10 parameters: pain intensity, personal care, lifting, walking/walking aids, sitting, standing, sleeping, sex life, social life and travelling. Scores are from 0 to 100% with *higher scores meaning greater disability*.

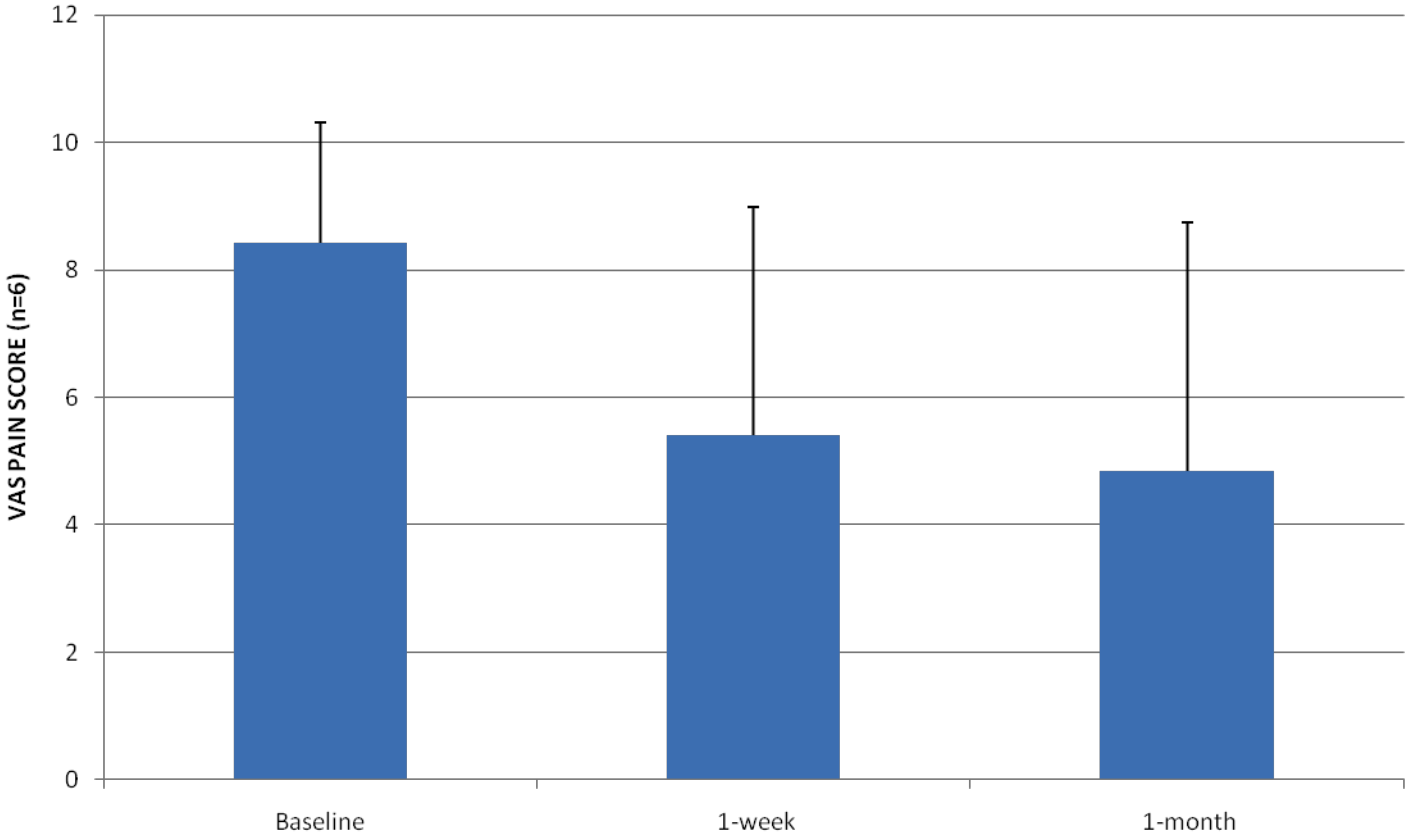
% ODI improvements in four patients before and 1-month following MILD®

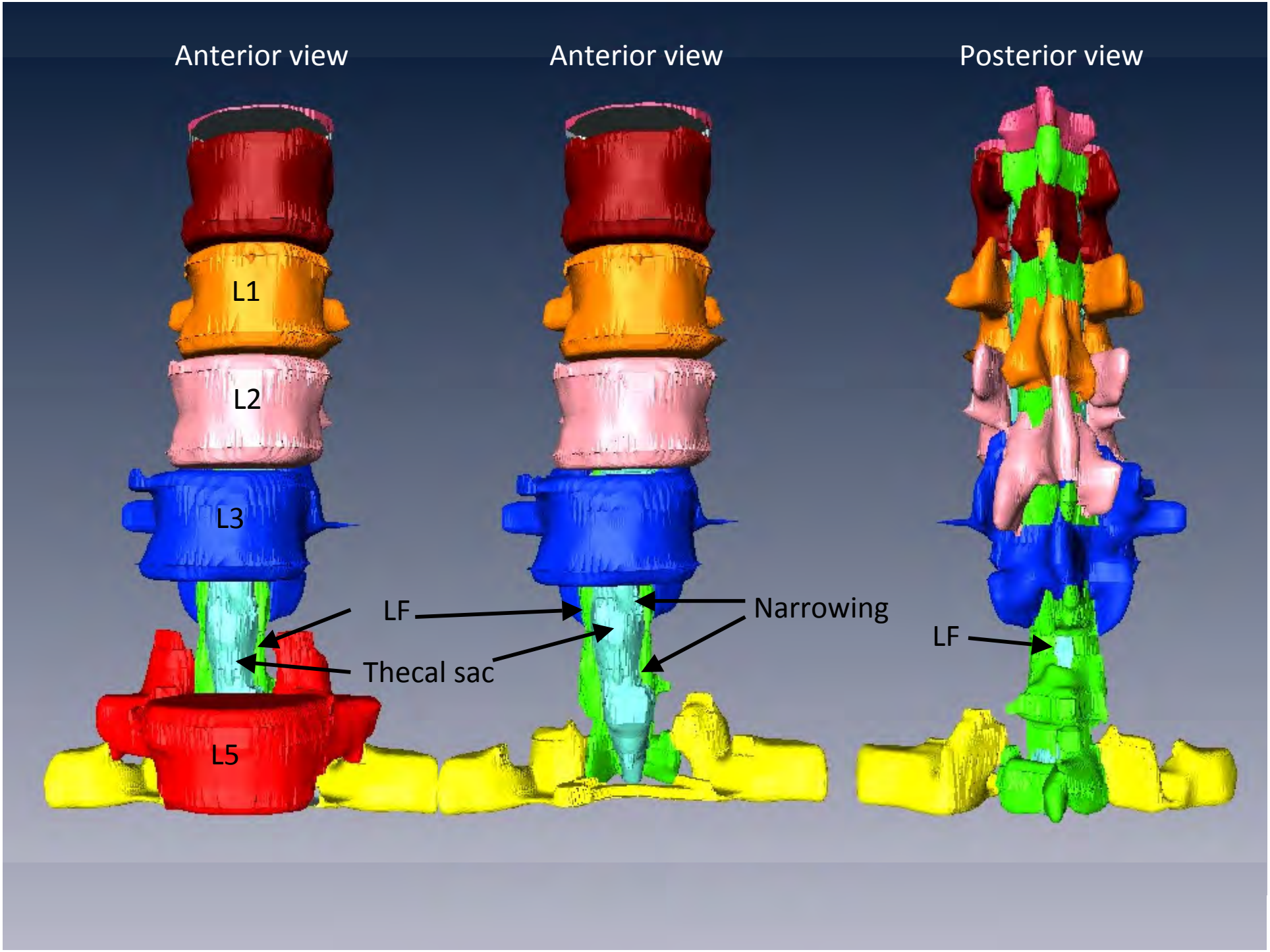


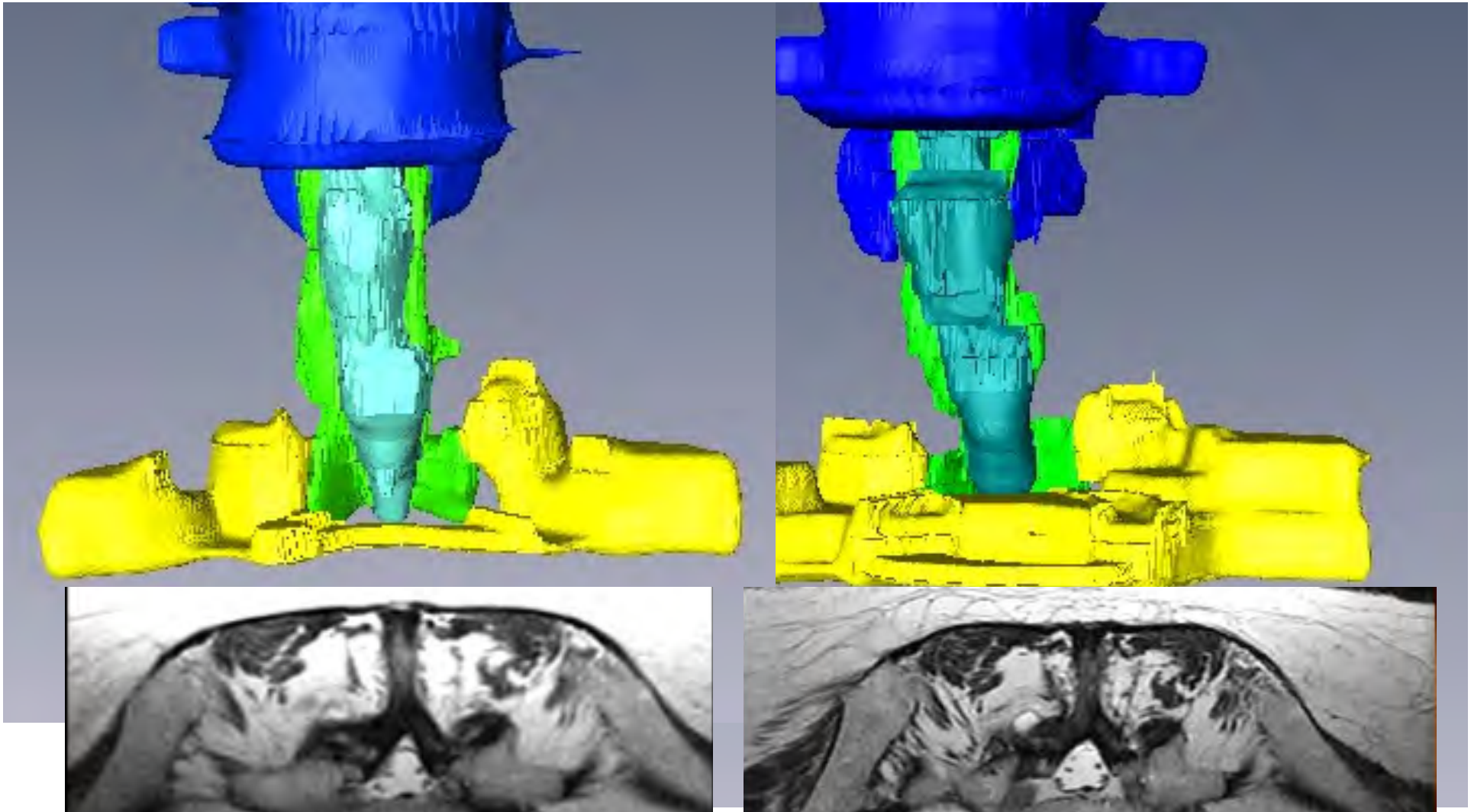
RAW ODI scores in the 4 patients before and 1-month following procedure

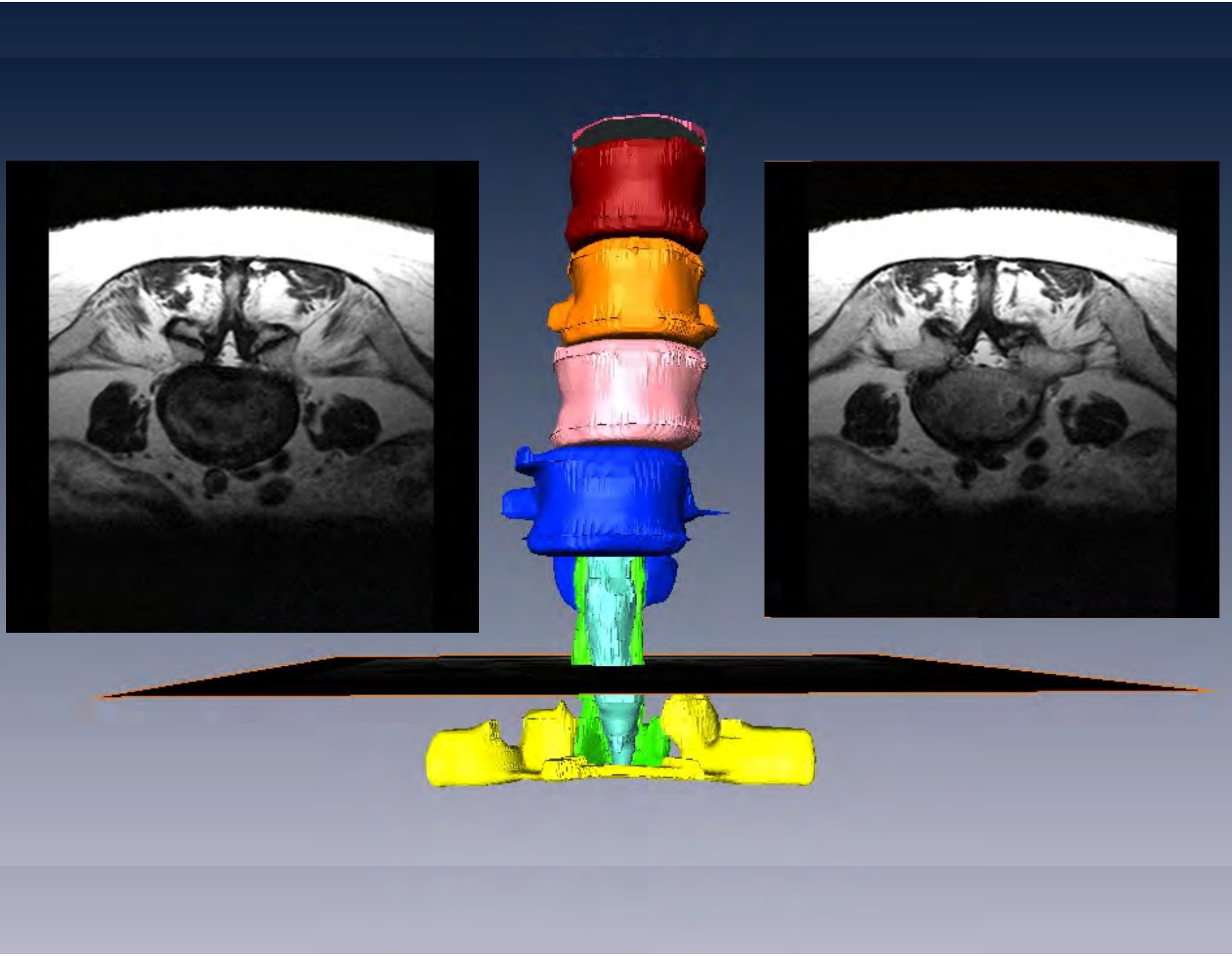


VAS pain scores over time following MILD®




Anterior view
Anterior view
Posterior view
L1
L2
L3
L5
LF
Thecal sac
Narrowing
LF





Specific Preoperative services points

- H&P
  - personal or family history of bleeding
  - Ability to lie flat(prone)
- Labs as per our guidelines.
- Creatinine (contrast used)
- Hold 'plavix' /aspirin 325mg (7-)10 days (confirm with cardiol or prescribing physician)
- NSAIDs and baby aspirin OK to continue
- Anesthesia consult if ASA 3 or 4
- Procedure is 1hr for 1st level/30min /additional level.
- Prone, fluoroscopy
- IV sedation
- Main OR if AICD/ home $O_{2/}$ bridging heparin needed