Presented by the
Departments of Orthopaedic Surgery and Neurological Surgery
University of California, San Francisco

15TH ANNUAL
UCSF SPINE SYMPOSIUM

PARC 55 SAN FRANCISCO, A HILTON HOTEL

COURSE DIRECTORS

Sigurd Berven, MD
Professor, Department of
Orthopaedic Surgery;
Chief of Orthopaedic Spine Service
University of California, San Francisco

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FRIDAY - SATURDAY
June 5-6, 2020

UCSF Spine Center

Departments of Orthopaedic Surgery and Neurological Surgery
University of California, San Francisco - School of Medicine

15th Annual UCSF SPINE SYMPOSIUM

June 5, 2020

San Francisco, California

Course Chairs
Sigurd Berven, MD
Praveen V. Mummaneni, MD
Conor O'Neill, MD
University of California, San Francisco

University of California, San Francisco School of Medicine

Acknowledgement of Commercial Support

This CME activity was supported in part by educational grants from the following:

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University of California, San Francisco School of Medicine Presents

15th Annual UCSF Spine Symposium

Overview

The UCSF Spine Symposium is an annual two-day event emphasizing pioneering trends in diagnostic and therapeutic strategies for patients suffering from spinal disorders. This course is designed to be interactive with talks given by leaders in the spine community. All lectures are followed by case discussions aimed at highlighting key issues in breakthrough treatments. The course is designed for neurosurgeons, orthopedists, nurses, physical therapists, physiatrists, anesthesiologist, pain specialists as well as primary care providers.

Educational Objectives

The purpose of this course is to increase competence and improve clinical practice in the management of patients with spinal pathologies. Attendees will be better equipped to:

- Evaluate and treat spinal pain in a cost-effective and reliable manner based on recently published guidelines;
- Identify appropriate indications for surgery of the painful, degenerated spine and identify the appropriate surgical approach in painful, degenerative spinal conditions based on recently published guidelines;
- Evaluate and treat lumbar degenerative disease and deformity in a cost-effective manner and avoid perioperative complications by identifying risk factors that may predispose to morbidity;
- Determine pain management strategies for patients with spine-related pain;
- Increase utilization and competence with NASS spinal stenosis guidelines and the AANS-CNS cervical spine guidelines;
- Provide physical exams that include a process to identify lower extremity pain that dissipates while sitting and exacerbates with standing or walking;
- Identify spinal instability related to spinal tumors and formulate surgical treatment plans to deal with neurological deficits and pain in spine oncology patients based on recently published guidelines.

Accreditation

The University of California, San Francisco School of Medicine (UCSF) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

UCSF designates this live activity for a maximum of **14.75** *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Pain Management and End-of-Life Care: The approved credits shown above include a maximum of **7.25** credits toward meeting the requirement under California Assembly Bill 487, Pain Management and End-of-Life Care.

Nurses: For the purposes of recertification, the American Nurses Credentialing Center accepts *AMA PRA Category 1 Credit*™ issued by organizations accredited by the ACCME.

Physician Assistants: AAPA accepts *category 1 credit* from AOACCME, Prescribed credit from AAFP, and *AMA PRA Category 1 credit*™ from organizations accredited by the ACCME.

General Information

Attendance Verification
In order to receive credit, you must log into the live virtual program on June 5th. Once you have logged on you can view the session in real time or review anything that you might have missed as the program will be recorded. Recorded presentations will be available for 90 days post course.

Speaker Survey- Electronic
In the early morning on Friday, June 5th, you should have received an email from sean.kirklen@ucsf.edu through the Qualtrics system with a personalized link via to access the Speaker Survey.
The Speaker Survey should be completed in real time during the course and is separate from the Evaluation/CME Certificate.

Evaluation / CME Certificates
After the end of the program on Friday, June 5th you will receive another email from sean.kirklen@ucsf.edu through the Qualtrics system to complete your online ***Course Evaluation/ CME Certificate***. The Qualtrics system will send you reminders to complete your Course Evaluation/ CME Certificate until you complete it.

Upon completing the Course Evaluation/ CME Certificate, your CME certificate will be automatically generated to print and/or email yourself a copy. For smartphone users, you may want to take a photo of your certificate as some settings prevent you from emailing the certificate.

The link will be available for 30 days after the last day of the course. However, after that date the link will expire and you will no longer be able to claim your credits online. You must then contact the Office of CME at RegEmail@ucsf.edu to receive your certificate and a $15 administrative fee may be applied.

Virtual Exhibit Hall
We invite you to join our supporting exhibitors in the virtual exhibit hall. You should have received a link to the exhibit hall in your pre-course materials. The course would like to thank all of our exhibitors for their continued support of the course especially during this unprecedented time.

Recorded Presentations
You should have received a link to the recorded presentations with your pre-course materials. These presentations as well as the recording of the live virtual program will be available for 90 days post course. In order to receive the full 14.75 AMA PRA Category 1™ credits, you must view all of the course content and complete the post-test.

Post-Test
The post-test will be posted on the Recorded Presentation webpage. Please be sure to complete the post-test to receive the full 14.75 AMA PRA Category 1™ credits the course provides.

Federal and State Law
Regarding Linguistic Access and Services for Limited English Proficient Persons

I. Purpose.

This document is intended to satisfy the requirements set forth in California Business and Professions code 2190.1. California law requires physicians to obtain training in cultural and linguistic competency as part of their continuing medical education programs. This document and the attachments are intended to provide physicians with an overview of federal and state laws regarding linguistic access and services for limited English proficient ("LEP") persons. Other federal and state laws not reviewed below also may govern the manner in which physicians and healthcare providers render services for disabled, hearing impaired or other protected categories

II. Federal Law – Federal Civil Rights Act of 1964, Executive Order 13166, August 11, 2000, and Department of Health and Human Services ("HHS") Regulations and LEP Guidance.

The Federal Civil Rights Act of 1964, as amended, and HHS regulations require recipients of federal financial assistance ("Recipients") to take reasonable steps to ensure that LEP persons have meaningful access to federally funded programs and services. Failure to provide LEP individuals with access to federally funded programs and services may constitute national origin discrimination, which may be remedied by federal agency enforcement action. Recipients may include physicians, hospitals, universities and academic medical centers who receive grants, training, equipment, surplus property and other assistance from the federal government.

HHS recently issued revised guidance documents for Recipients to ensure that they understand their obligations to provide language assistance services to LEP persons. A copy of HHS's summary document entitled "Guidance for Federal Financial Assistance Recipients Regarding Title VI and the Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons – Summary" is available at HHS's website at: http://www.hhs.gov/ocr/lep/

As noted above, Recipients generally must provide meaningful access to their programs and services for LEP persons. The rule, however, is a flexible one and HHS recognizes that "reasonable steps" may differ depending on the Recipient's size and scope of services. HHS advised that Recipients, in designing an LEP program, should conduct an individualized assessment balancing four factors, including: (i) the number or proportion of LEP persons eligible to be served or likely to be encountered by the Recipient; (ii) the frequency with which LEP individuals come into contact with the Recipient's program; (iii) the nature and importance of the program, activity or service provided by the Recipient to its beneficiaries; and (iv) the resources available to the Recipient and the costs of interpreting and translation services.

Based on the Recipient's analysis, the Recipient should then design an LEP plan based on five recommended steps, including: (i) identifying LEP individuals who may need assistance; (ii) identifying language assistance measures; (iii) training staff; (iv) providing notice to LEP persons; and (v) monitoring and updating the LEP plan.

A Recipient's LEP plan likely will include translating vital documents <u>and</u> providing either on-site interpreters or telephone interpreter services, or using shared interpreting services with other Recipients. Recipients may take other reasonable steps depending on the emergent or non-emergent needs of the LEP individual, such as hiring bilingual staff who are competent in the skills required for medical translation, hiring staff interpreters, or contracting with outside public or private agencies that provide interpreter services. HHS's guidance provides detailed examples of the mix of services that a Recipient should consider and implement. HHS's guidance also establishes a "safe harbor" that Recipients may elect to follow when determining whether vital documents must be translated into other languages. Compliance with the safe harbor will be strong evidence that the Recipient has satisfied its written translation obligations.

In addition to reviewing HHS guidance documents, Recipients may contact HHS's Office for Civil Rights for technical assistance in establishing a reasonable LEP plan.

III. California Law – Dymally-Alatorre Bilingual Services Act.

The California legislature enacted the California's Dymally-Alatorre Bilingual Services Act (Govt. Code 7290 *et seq.*) in order to ensure that California residents would appropriately receive services from public agencies regardless of the person's English language skills. California Government Code section 7291 recites this legislative intent as follows:

> "The Legislature hereby finds and declares that the effective maintenance and development of a free and democratic society depends on the right and ability of its citizens and residents to communicate with their government and the right and ability of the government to communicate with them.
>
> The Legislature further finds and declares that substantial numbers of persons who live, work and pay taxes in this state are unable, either because they do not speak or write English at all, or because their primary language is other than English, effectively to communicate with their government. The Legislature further finds and declares that state and local agency employees frequently are unable to communicate with persons requiring their services because of this language barrier. As a consequence, substantial numbers of persons presently are being denied rights and benefits to which they would otherwise be entitled.
>
> It is the intention of the Legislature in enacting this chapter to provide for effective communication between all levels of government in this state and the people of this state who are precluded from utilizing public services because of language barriers."

The Act generally requires state and local public agencies to provide interpreter and written document translation services in a manner that will ensure that LEP individuals have access to important government services. Agencies may employ bilingual staff, and translate documents into additional languages representing the clientele served by the agency. Public agencies also must conduct a needs assessment survey every two years documenting the items listed in Government Code section 7299.4, and develop an implementation plan every year that documents compliance with the Act. You may access a copy of this law at the following url: http://www.spb.ca.gov/bilingual/dymallyact.htm

FRIDAY, JUNE 5, 2020 – Live Presentations

I. Management of Spinal Pain

8:30-8:35 AM		**Guest Lecture Introduction**	Conor O'Neill, M.D
8:30-9:15 AM	**P**	**Spine Care Within the Multidisciplinary Pain Clinic**	Scott M. Fishman, MD
9:15-9:30 AM	**P**	**Panel Discussion**	Conor O'Neill, MD

II. Updates and Controversies in the Management of Common Spinal Pathologies

9:30-9:35 AM		**Guest Lecture Introduction**	Praveen Mummaneni, MD
9:35- 10:20 AM	**P**	**Dissecting Patient Experience After Lumbar and Cervical Spine Surgery**	Michael P. Steinmetz, MD
10:20-10:30 AM		**Discussion**	
10:30- 10:50 AM		*Break*	

III. Healthcare Reform- Economics of Managing Spinal Disorders

10:50-10:55 AM	**Guest Lecture Introduction**	Sigurd H. Berven, MD
10:55-11:50 AM	**Reimbursement for the Management of Spinal Disorders-Challenges and Reform: Procedures/New Technologies**	Jeffrey C. Wang, MD
11:50AM-12:00 PM	**Discussion**	

IV. Alternative Payment Models

12:00-12:05 PM	**Guest Lecture Introduction**	Sigurd H. Berven, MD
12:00- 12:45 PM	**ACO's and the Kaiser Experience**	Ravinder-Raj S Bains, MD
12:45-12:55 PM	**Panel Discussion on APM and Healthcare Reform**	
12:55-1:45 PM	**Lunch Break**	

V. Case Presentations

1:45-3:45 PM	**Case Discussion**	Sigurd H. Berven, MD Praveen V. Mummaneni, MD
3:30- 3:45 PM	*Break*	
3:45- 5:00 PM	**Case Discussion**	Sigurd H. Berven, MD Praveen V. Mummaneni, MD
5:00 PM	*Adjourn*	

P = Pain Credit

RECORDED PRESENTATIONS

	Lumbar Disc Herniation – Ambulatory versus Inpatient	Tarun Arora, MD
	Complex Spinal Deformity – Primary	Dean Chou, MD
	Intraoperative Strategies for Avoiding and Managing Neurological Complications in Spine Surgery	Aaron Clark, MD
P	**Clinical Tests**	Sibel Deviren, MD
	High Risk Spinal Trauma	Sanjay Dhall, MD
P	**Use of EMG in the Assessment of Pain**	John Engstrom, MD
P	**Neuromoduation**	Lines Jacques, MD
P	**Basic Science of Pain Generators**	Jeffrey Lotz, MD
	Impact of Complications on Outcome and Cost of Care, Classification of Complications, Strategies for Avoiding Complications, and Risk	Lionel Metz, MD
	Degenerative Spondylolisthesis	Catherine Miller, MD
P	**Treatment of Painful Spinal Tumors During the COVID-19 Pandemic**	Praveen Mummaneni, MD
P	**Radiology/Imaging**	Vinil Shah, MD
	When to Say No to Surgery	Lee Tan, MD
	High Risk Patient with Spinal Disorders	Alekos Theologis, MD
	Creating Distinct Access for Narrow Network	Kushagra Verma, MD
P	**Injections**	Patricia Zheng, MD
P	**Pharmacologic- Article and Questions**	Melanie Henry, MD

P = Pain Credit

Faculty List

Course Chairs

Sigurd Berven, MD
Professor of Orthopaedic Surgery; Chief of Spine Service
University of California, San Francisco

Praveen V. Mummaneni, MD
Joan O'Reilly Endowed Professor; Vice Chair, Department of Neurosurgery
Director, Cervical Spine Surgery; Director, Minimally Invasive Spine Surgery
Co-director, UCSF Spine Center
University of California, San Francisco

Conor O'Neill
Professor of Orthopaedic Surgery
University of California, San Francisco

Special Guest Faculty

Ravinder-Raj S. Bains, MD
Chief, Regional Spine Surgery Department, Kaiser Permanente, Oakland, CA

Scott M. Fishman, MD
Fullerton Endowed Chair in Pain Medicine
Professor of Anesthesiology and Pain Medicine
Professor of Psychiatry and Behavioral Sciences (secondary)
Vice Chair, Department of Anesthesiology and Pain Medicine
Director, Center for Advancing Pain Relief
University of California, Davis School of Medicine

Michael P. Steinmetz, MD
William P. and Amanda C. Madar Endowed Professor and Chair Department of Neurosurgery
Cleveland Clinic Lerner College of Medicine Neurological Institute, Cleveland, OH

Jeffrey C. Wang, MD
Professor of Clinical Orthopaedic Surgery and Neurosurgery; Chief, Orthopaedic Spine Service
Co-director, USC Spine Center, University of Southern California, Los Angeles, CA

Course Faculty (University of California, San Francisco unless indicated)

Tarun Arora, MD
Associate Professor of Neurological Surgery

Dean Chou, MD
Professor of Neurological Surgery

Sibel Demir Deviren, MD
Professor, Department of Orthopaedic Surgery

Sanjay Dhall, MD
Associate Professor of Neurological Surgery
Chief of Spine Surgery, Zuckerberg San Francisco General Hospital

Aaron J. Clark, MD, PhD
Assistant Professor of Neurological Surgery

John W. Engstrom, MD
Betty Anker Fife Distinguished Professor of Neurology; Vice Chair for Clinical Affairs, Department of Neurology

Course Faculty (University of California, San Francisco unless indicated)

Melanie Henry, MD
Professor of Anesthesia and Pain Management; Director, PMC Telehealth and Outreach

Line Jacques, MD
Professor of Neurological Surgery; Director of Peripheral Nerve and Pain

Jeffrey Lotz, MD
Professor of Orthopaedic Surgery

Lionel Metz, MD
Assistant Professor of Orthopaedic Surgery

Catherine Miller, MD
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Vinil Shah, MD
Assistant Professor of Radiology and Biomedical Imaging; Director, Neuroradiology Fellowship Program

Lee Tan, MD
Assistant Professor of Neurological Surgery

Alekos Theologis, MD
Assistant Professor in Residence, Department of Orthopaedic Surgery

Kushagra Verma, MD
Assistant Professor of Orthopaedics and Sports Medicine

Patricia Zheng, MD
Assistant Professor of Orthopaedic Surgery

Disclosures

The following faculty speakers, moderators, and planning committee members have disclosed they have no financial interest/arrangement or affiliation with any commercial companies who have provided products or services relating to their presentation(s) or commercial support for this continuing medical education activity:

Ravinder-Raj Bains, MD
Scott M. Fishman, MD
John W. Engstrom, MD
Melanie Henry, MD
Line Jacques, MD
Catherine Miller, MD
Vinil Shah, MD
Patricia Zheng, MD

The following faculty speakers have disclosed a financial interest/arrangement or affiliation with a commercial company who has provided products or services relating to their presentation(s) or commercial support for this continuing medical education activity. All conflicts of interest have been resolved in accordance with the ACCME Standards for Commercial Support:

Tarun Arora, MD	Mizuho OSI Spineart	Consultant Consultant
Sigurd Berven, MD	Medtronic Spine Stryker Spine Innovasis Medicrea Globus Medical Integrity Spine	Advisor or Reviewer Consultant Honorarium Recipient Royalties/Intellectual Property Rights Consultant Honorarium Recipient Royalties/Intellectual Property Rights Advisor or Reviewer Honorarium Recipient Consultant Board Member Honorarium Recipient Consultant Advisor or Reviewer Honorarium Recipient Consultant
Dean Chou, MD	Globus Medical	Consultant Royalties/Intellectual Property Rights
Aaron Clark, MD, PhD	NuVasive	Consultant Grant/Research Support
Sibel Demir Deviren, MD Vedat Deviren, MD** (spouse)	NuVasive** Biomet** Seaspine** Medicrea** ATEC (Alphatec) Spine**	Consultant Royalties/Intellectual Property Rights Consultant Consultant Consultant Consultant Royalties/Intellectual Property Rights
Sanjay Dhall, MD	Globus Medical DePuy Synthes	Honorarium Recipient Honorarium Recipient

This UCSF CME educational activity was planned and developed to: uphold academic standards to ensure balance, independence, objectivity, and scientific rigor; adhere to requirements to protect health information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA); and, include a mechanism to inform learners when unapproved or unlabeled uses of therapeutic products or agents are discussed or referenced.

This activity has been reviewed and approved by members of the UCSF CME Governing Board in accordance with UCSF CME accreditation policies. Office of CME staff, planners, reviewers, and all others in control of content have disclosed no relevant financial relationships.

Jeffrey Lotz, MD	Nocimed, LLC Relievant MedSystems Bioniks	Board Member Stock Shareholder Advisor or Reviewer Stock Shareholder Board Member Stock Shareholder
Lionel Metz, MD	Evolution Spine	Consultant Royalties/ Intellectual Property Rights
Praveen V. Mummaneni, MD	Depuy Synthes Globus Stryker Spinicity/ISD ISSG NREF Thieme Publishing Springer Publishing AO Spine	Consultant Royalties/ Intellectual Property Rights Consultant Consultant Stock Shareholder Grant/Research Support Grant/Research Support Royalties/ Intellectual Property Rights Royalties/ Intellectual Property Rights Grant/Research Support
Conor O'Neill, MD	Relievant Noicmed	Stock Shareholder Stock Shareholder
Michael P. Steinmetz, MD	ZimmerBiomet Stryker Globus Medical	Royalties/ Intellectual Property Rights Honorarium Recipient Honorarium Recipient
Lee Tan, MD	Stryker/K2M Medtronic Integrity Implants DePuy Synthes	Consultant Consultant Consultant Consultant
Alekos Theologis, MD	DePuy Synthes ATEC Spine Intuitive Surgical JBJS, Inc. Innovasis	Consultant Consultant Consultant Consultant Grant/Research Support
Kushagra Verma, MD	Aegis Spine Medtronic DePuy Synthes NuVasive Innovasis	Consultant Consultant Consultant Consultant Consultant
Jeffrey C. Wang, MD	ZimmerBiomet DePuySynthes Amedica Seaspine Bone Biologics Electrocore Pearl Diver Surgitech	Royalties/ Intellectual Property Rights Royalties/ Intellectual Property Rights Royalties/ Intellectual Property Rights Royalties/ Intellectual Property Rights Stock Shareholder Stock Shareholder Stock Shareholder Stock Shareholder

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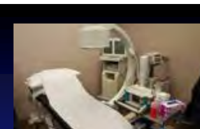
An Interdisciplinary Approach to the Management of Pain of Spinal Origin

Scott M. Fishman, MD
Professor
Fullerton Endowed Chair
Director: Center for Advancing Pain Relief
Chief: Division of Pain Medicine
Ex Vice Chair, Dept. of Anesth.
Univ. of California, Davis School of Medicine

Disclosures

- I have NO Direct Financial Relationships with drug companies
- I receive NO compensation from industry speakers or consultation programs
- I participate in official CME programs (and receive honorarium and travel reimbursement)
- I receive payment from publishers of books and journals I have authored /edited
- I authored *Responsible Opioid Prescribing* by The Federation of State Medical Boards
- I am…
  - Past President of The American Academy of Pain Medicine
  - Past Chair of Board for The American Pain Foundation
  - Past Chair and current member of the Pain Care Coalition
    - [ASA, APS, AAPM]
- I am not a lawyer and do not offer legal advice



Recognizing Pain

So Why is Treating Pain So Hard

"An unpleasant sensory and emotional experience arising from the actual or potential tissue damage or described in terms of such damage. Pain is always subjective. Each individual learns the application of the word through experiences related to injury in early life…. It is unquestionably in a part or parts of the body, but it is also always unpleasant and therefore an emotional experience"

» *International Assoc. for the Study of Pain*

PAIN

- Untestable Hypothesis
- Many Meanings
  - No two patients the same
- It's All in Your head
  - Mind always modulates pain
  - Its usually also in the body
- Mind & Body
  - Inextricably Linked

Objective Functional Outcomes

- Pain is Subjective
- Subjective reports of pain are untestable
- Pain impairs QOL by impairing function
- Function is essential for QOL
- Functional outcomes are testable

- Q1: What does pain keep you from doing?
- Q2: What can you do with pain treatment than without?

Objective Functional Outcomes

- Functional Outcomes
  - Do NOT determine the validity of pain
  - Helps [in large part] determine:
    - How much risk to take
    - How well treatment is working
  - Highly individual
    - Differs based on acute, chronic or EOL
    - No cookie cutter formula

Controversies

Controversies

Controversies

Controversies

- We are a chemically coping society

Controversies

- Some seek analgesia for dissociation
- Acceptable medical standards for taking risks with prescribed analgesics for chronic pain requires demonstrable improved QOL
  - (usually functional improvement or maintenance)

Terminology
Multidisciplinary Pain Management (MDPM)

- Evidence for MDPM
  - substantial evidence for the effectiveness of multidisciplinary treatment for chronic pain problems
- Multidisciplinary Pain Center
  - Broad clinical programs that typically has education, & research
- Multidisciplinary Pain Clinic
  - Broad clinical programs
- Pain Clinic
  - Focused or modestly broad clinical programs
- Pain Practice
  - Single orfFew clinicians of same profession/disciplines

Terminology

- Multidisciplinary
  - Clinicians from different specialties
    - Work together in the same space
    - Communication across professions and disciplines
    - Expertise in pain related to:
      - Biology
      - Psychology
      - Social/environmental

Terminology

- Multidisciplinary Team

- "Patient" (person with pain)
- Significant others (family, friends)
- Physicians
- PAs and NPs
- Nurses
- Psychologists
- Physical therapists
- Occupational therapists
- Recreational therapists
- Vocational counselors
- Pharmacists
- Nutritionists/dieticians
- Social workers
- Integrative Clinicians
- Support staff
- Volunteers
- Others

Terminology

- Specialty Pain Center
  - Spine Pain
  - Pediatric Pain
  - Pain Rehabilitation
  - Pain Psychology
  - Alternative Pain Management
  - Pain and Addiction/SUD

Referral from Spine to Pain

- Specialty Pain Center
  - Non-operative interventions and therapies
    - Medications
    - Procedures
      - Diagnostic & Therapeutic
    - Physical Rehabilitation
      - Targeted to injury
      - Targeted to deconditioning
    - Psychological Rehabilitation
      - Targeted to injury
      - Targeted to deconditioning
    - Alternatives

Drug Therapies for Pain

- Weak analgesics
- Strong analgesics
- Neuropathic analgesics
- Analgesic adjuvants
- Routes of Administration
  - Oral
  - Transdermal
  - Transmucosal
  - Rectal
  - Nasal
  - Intravenous / PCA or subcutaneous
  - Intrathecal or epidural
  - Intraventricular
  - Iontophoresis

Interventional Treatments for Pain

- Injection Therapies
  - Epidural space: LA, Steroid, Clonidine, etc
  - Nerves: nerve roots, peripheral n., sympathetic n.
  - Joints: Facet, SI, etc
  - Muscles: Piriformis (Botox)
- Implantable Therapies
  - IT Pumps (opioids, LA, clonidine)
  - Spinal Cord Stimulators

Annals of Internal Medicine
Established in 1927 by the American College of Physicians

From: Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society
Ann Intern Med. 2007;147(7):478-491. doi:10.7326/0003-4819-147-7-200710020-00006

Low Back Pain (LBP)

- 5th most common reason for all physician visits in US
- Approximately ¼ of U.S. adults reported having LBP lasting at least 1 whole day in the past 3 months
- 7.6% of US Adults reported at least 1 episode of severe acute low back pain within a 1-year period

Hart LG, Deyo RA, Cherkin DC. Physician office visits for low back pain. Frequency, clinical evaluation, and treatment patterns from a U.S. national survey. Spine. 1995; 20:11-9
Deyo RA, Mirza SK, Martin BI. Back pain prevalence and visit rates: estimates from U.S. national surveys, 2002. Spine. 2006; 31:2724-7.
Carey TS, Evans AT, Hadler NM, Lieberman G, Kalsbeek WD, Jackman AM. et al. Acute severe low back pain. A population-based study of prevalence and care-seeking. Spine. 1996; 21:339-44.

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Low Back Pain (LBP)

- *Acute low back pain:*
  - Low back pain present for fewer than 4 weeks
- Subacute low back
  - Pain as symptoms present for fewer than 3 months
- *Chronic low back pain:*
  - Low back pain present for more than 3 months

Hart LG, Deyo RA, Cherkin DC. Physician office visits for low back pain. Frequency, clinical evaluation, and treatment patterns from a U.S. national survey. Spine. 1995; 20:11-9
Deyo RA, Mirza SK, Martin BI. Back pain prevalence and visit rates: estimates from U.S. national surveys, 2002. Spine. 2006; 31:2724-7.
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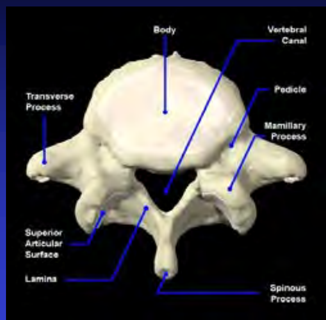
Low Back Pain (LBP)

- Many patients have self-limited episodes of acute LBP & do not seek medical care
  - Among those who do seek medical care, pain, disability, and return to work typically improve rapidly in 1st month
  - Up to 1/3 of patients report persistent back pain of at least moderate intensity 1 year after an acute episode
  - 1 in 5 report substantial limitations in activity
  - Approximately 5% of those with back pain disability account for 75% of costs associated with low back pain

Carey TS, Evans AT, Hadler NM, Lieberman G, Kalsbeek WD, Jackman AM. et al. Acute severe low back pain. A population-based study of prevalence and care-seeking. Spine. 1996; 21:339-44.
Pengel LH, Herbert RD, Maher CG, Refshauge KM. Acute low back pain: systematic review of its prognosis. BMJ. 2003; 327:323. **Von Korff M, Saunders K.** The course of back pain in primary care. Spine. 1996;21:2833-7; discussion 2838-9. [PMID: 9112707]
Frymoyer JW, Cats-Baril WL. An overview of the incidences and costs of low back pain. Orthop Clin North Am. 1991; 22:263-71.

Pain Producing Structures



- Dura
- Disc/Annulus
- Facet joint capsule
- Ligaments & Tendons
- Periosteum
- Muscle & Fascia
- Skin

Nerve Blocks / Percutaneous Injections

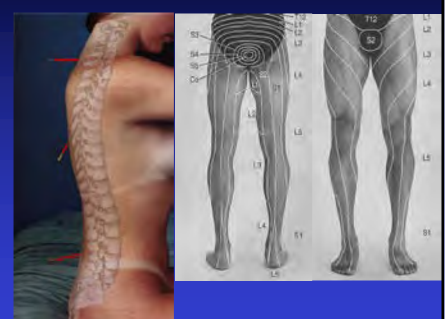
- Diagnostic
  - Clarify mechanism or simulate effects of therapy
  - Local anesthetic
- Therapeutic
  - Temporary Effect with Local Anesthetic
  - Prolonged Effect with Corticosteroid or Lysis
- Simultaneous Dx/Tx
  - Trigger-point injection
  - SNRB

Common Injections for Back Pain

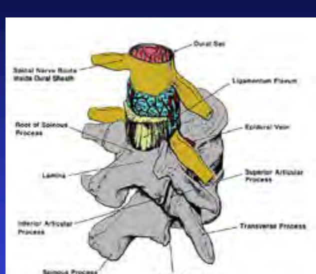
- Neuroaxial Epidural injection
- Trigger-point injection (TPI)
- Muscle Injection (piriformis, TPI)
- Peripheral nerve injection
  - Medial branch (Block & RFA)
- Intra-articular (eg, facet, SI)

Central Nervous System Access

- *Choice of Location*
  - Cervical
  - Thoracic
  - Lumbar
  - Sacral
- *Medication*
  - Local anesthetic
  - Opioid
  - Steroid
  - Other



Spinal Interventional Targets



- Epidural Space
  - Translaminar
  - Transforaminal
- Facet Joints
  - Medial Branch
- Nerve Roots
  - Transforaminal
- Sympathetic Chain
  - Paraspinal
- Discs


The NEW ENGLAND JOURNAL of MEDICINE

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ORIGINAL ARTICLE

A Correction Has Been Published

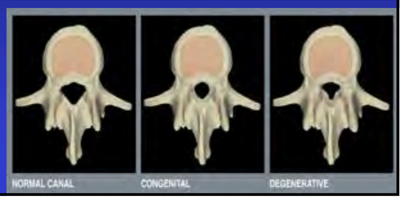
A Randomized Trial of Epidural Glucocorticoid Injections for Spinal Stenosis

Janna L. Friedly, M.D., Bryan A. Comstock, M.S., Judith A. Turner, Ph.D., Patrick J. Heagerty, Ph.D., Richard A. Deyo, M.D., M.P.H., Sean D. Sullivan, Ph.D., Zoya Bauer, M.D., Ph.D., Brian W. Bresnahan, Ph.D., Andrew L. Avins, M.D., M.P.H., Srdjan S. Nedeljkovic, M.D., David R. Nerenz, Ph.D., Christopher Standaert, M.D., Larry Kessler, Ph.D., Venu Akuthota, M.D., Thiru Annaswamy, M.D., Allen Chen, M.D., M.P.H., Felix Diehn, M.D., William Firtch, M.D., Frederic J. Gerges, M.D., Christopher Gilligan, M.D., Harley Goldberg, M.D., David J. Kennedy, M.D., Shlomo Mandel, M.D., Mark Tyburski, M.D., William Sanders, M.D., David Sibell, M.D., Matthew Smuck, M.D., Ajay Wasan, M.D., Lawrence Won, M.D., and Jeffrey G. Jarvik, M.D., M.P.H.

N Engl J Med 2014; 371:11-21 | July 3, 2014 | DOI: 10.1056/NEJMoa1313265

Spinal Stenosis

- 4 structures contribute to vertebral canal stenosis:
  - Ligamentum flavum
  - Facet joints
  - Disc space
  - Bony structures

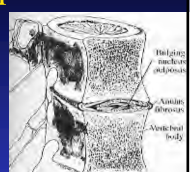


Disc Herniation

- Definitions
  - Bulge
  - Prolapse
  - Extrusion
  - Sequestration

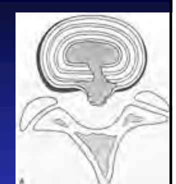
Disc Herniation

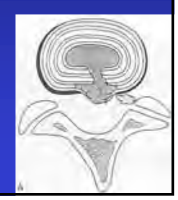
- Definitions
  - Bulge
    - Herniation beyond disc margin
    - Annulus is intact
  - Prolapse
    - Herniation through incomplete annular defect



Disc Herniation

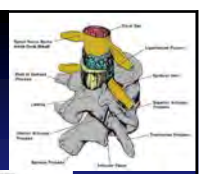
- Extrusion
  - Herniation through complete annular defect
- Sequestration
  - Portion of nucleus pulposus extruded through complete annular defect
  - Lost continuity with remaining part of nucleus pulposus.

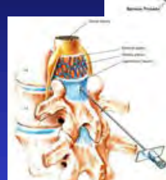




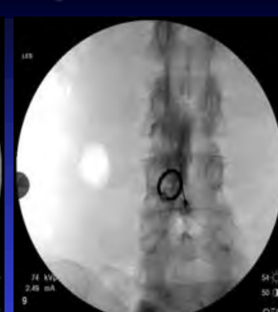
Epidural Injection

- Techniques
  - Glucocorticoid ± local anesthetic
  - Translaminar
    - Transligamentous
  - Transforaminal
  - Caudal
    - useful w/ prior lumbar surgery & scarring





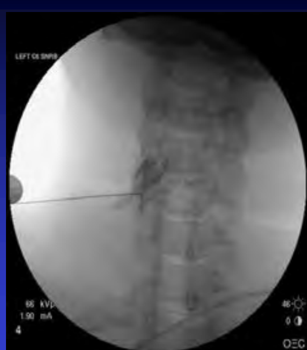
Inter-Laminar Injection



Covino BG, Scott DB. *Handbook of Epidural Anaesthesia and Analgesia.* New York, NY: Grune

Layering of Contrast in Epidural Space (C5-6 Epidural)

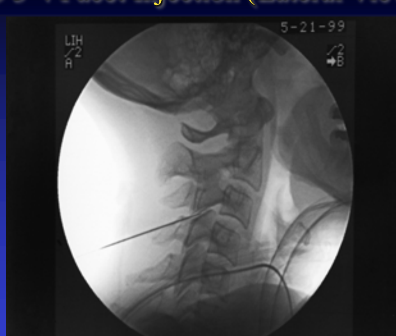
L5 Root SNRB



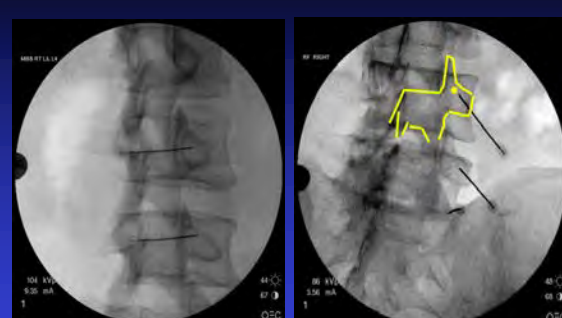
Facet Injections

- Intra-articular
- Medial Nerve Branch Blocks
- Radiofrequency Ablation

C 3-4 Facet Injection (Lateral View)

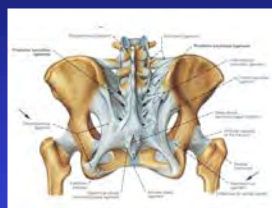


MBB Injection



Posterior Sacroiliac Ligament Pain as a Potential Source of Pain

- Posterior sacral ligaments = Functional stability

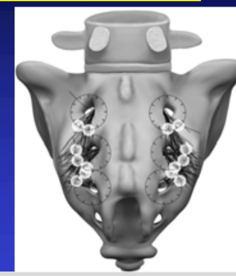


Maigne JY, Aivaliklis A, Pfefer F. Results of sacroiliac joint double block and value of sacroiliac pain provocation tests in 54 patients with low back pain. Spine. 1996;21(16):1889-1892.

Posterior Sacroiliac Ligament Pain as a Potential Source of Pain

Dreyfuss et al (2009)

- More recently, these targets have been altered to attain even higher capture rates



Stout A, Dreyfuss P, Swain N, Roberts S, Loh E, Agur A. Proposed optimal fluoroscopic targets for cooled radiofrequency neurotomy of the sacral lateral branches to improve clinical outcomes: an anatomical study. Pain Med. 2018;19(10):1916-1923.

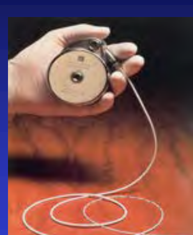
Myofascial Pain & Trigger Points

Spinal Cord Stimulation

- Indicated in a variety of pain problems
  - Complex Regional Pain Syndrome
  - Postlaminectomy syndrome
  - Arachnoiditis
  - Peripheral Neuropathies

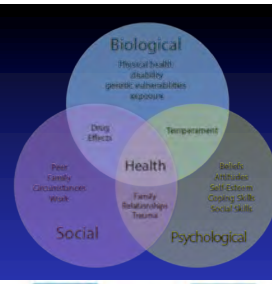
Drug Delivery Devices

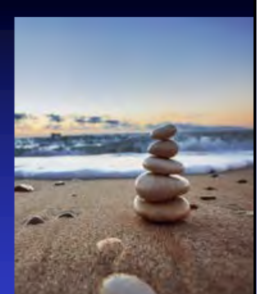
- Indicated in a variety of pain syndromes
- An alternative method of medication delivery if side effects or dosage needs are high
- Programmable or fixed rate devices available



Nonpharmacological Pain Treatment

- Physical Rehabilitation
  - PM&R component
  - Functional Restoration
- Psychological Rehabilitation
  - Cognitive Behavioral Psychology
  - Biofeedback, Hypnosis, relaxation
  - Group Therapy

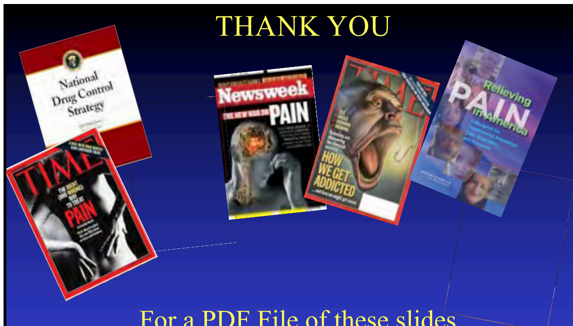




Wellness is Good Pain Management

TREATING SUFFERING: Improving Quality of Life

THANK YOU

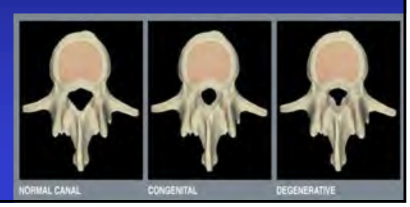


For a PDF File of these slides,

smfishman@ucdavis.edu

Spinal Stenosis

- 4 structures contribute to vertebral canal stenosis:
  - Ligamentum flavum
  - Facet joints
  - Disc space
  - Bony structures



Pain Relief

- Conventional Medicine
- Procedures and Surgery
- Psychology
- Physical Rehabilitation
- Alternative Medicine

Thank You

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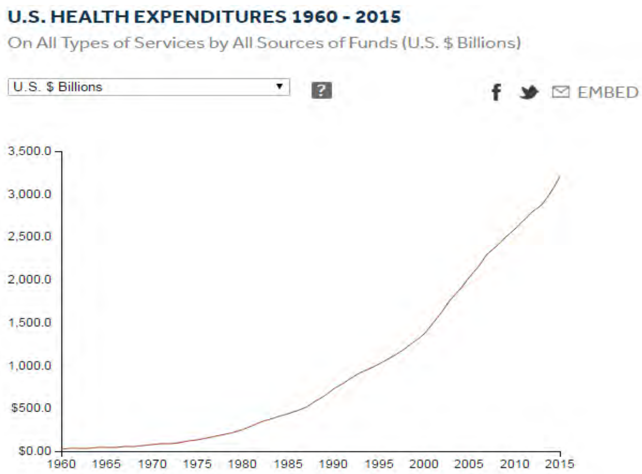
Dissecting the Patient Experience of Lumbar Spine Surgery

Michael P. Steinmetz, MD
William P. and Amanda C. Madar Endowed Professor and Chairman
Department of Neurologic Surgery
Cleveland Clinic Lerner College of Medicine
Director of Clinical Operations
Center for Spine Health
Neurologic Institute

Disclosures

- **Royalties**
  - Biomet Spine, Elsevier, Thieme
- **Consultant**
  - Globus
- **Honorarium**
  - Globus
  - Stryker
- **Board of Directors/Executive Committee**
  - NeuroPoint Alliance-BOD
  - Chair -AANS/CNS Section on Disorders of the Spine and Peripheral Nerves
  - Chair-Council of State Neurosurgical Societies

Consumerism in Medicine



Consumerism in Medicine

- **Two methods proposed to control costs (Fisher 2016)**
  - 1. Reduce patient utilization
    - Cost sharing reduced utilization but potential negative benefits for low income participants
  - 2. Reducing hospitals and providers payments
    - Reward quality over quantity

Consumerism in Medicine

- **Patients have seen a continued rise in healthcare costs (premiums and out of pocket expenses)**
  - In many cases the increase has exceeded the rate of wage increases
  - The average family premium rose 3% over the 2015 average premium
  - Workers wages increased 2.5% and inflation increased 1.1% over the same period

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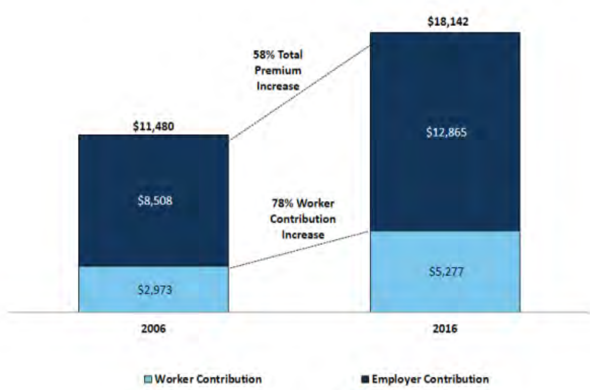
Exhibit D:
Average Annual Health Insurance Premiums and Worker Contributions for Family Coverage, 2006-2016



SOURCE: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2006-2016.

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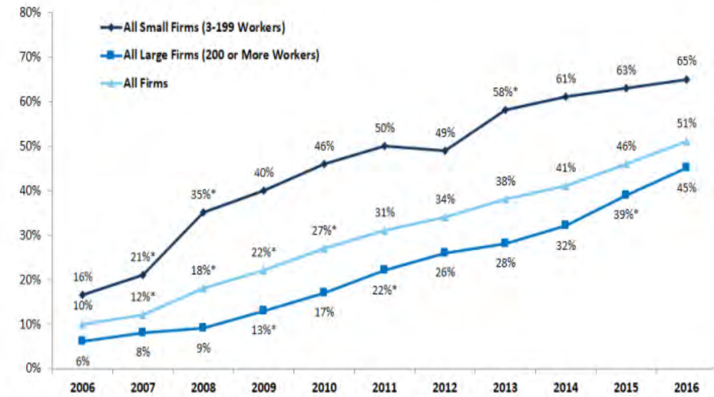
Exhibit F:
Percentage of Covered Workers Enrolled in a Plan with a General Annual Deductible of $1,000 or More for Single Coverage, By Firm Size, 2006-2016



* Estimate is statistically different from estimate for the previous year shown (p < .05).

NOTE: These estimates include workers enrolled in HDHP/SO and other plan types. Average general annual health plan deductibles for PPOs, POS plans, and HDHP/SOs are for in-network services.

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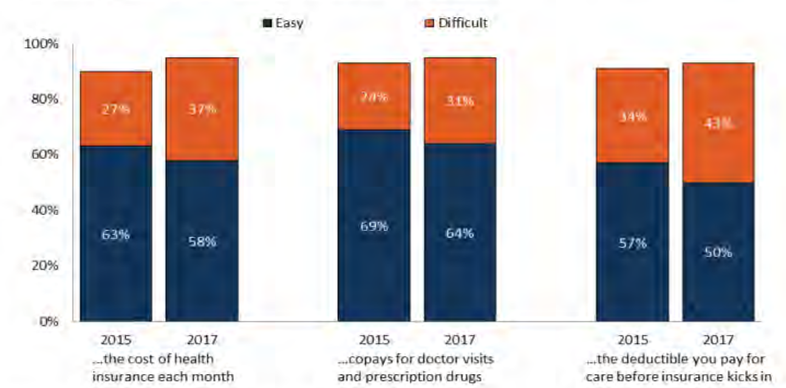
More Insured Americans Now Report Difficulty Affording Health Care

AMONG THE INSURED: In general, how easy or difficult is it for you to afford to pay...



NOTE: Don't have to pay (Vol.) and Don't know/Refused responses not shown.
SOURCE: Kaiser Family Foundation Health Tracking Polls

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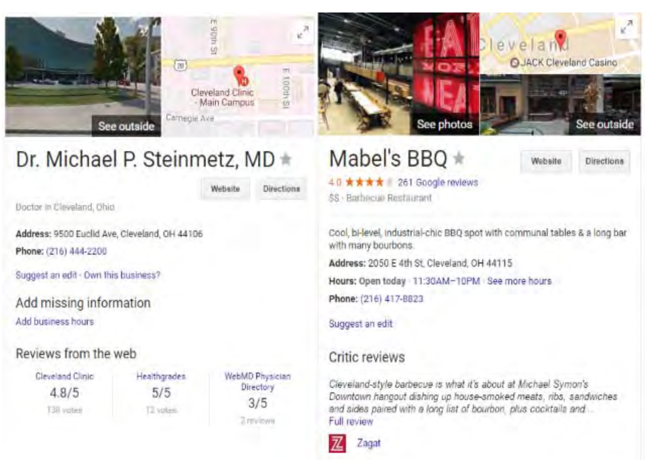
Consumerism in Medicine

- **These increasing costs (insurance premiums and increasing prevalence of higher deductible health plans**
  - Resulted in more cost conscious consumer (Huckman 2013)
- **More cost conscious consumer will look to get the most value for their healthcare dollar**
  - Increasing importance of doctor and hospital ratings
  - Consumer shopping for care may use as their main indicator a summary star rating system



Pros and Cons of Provider Rating Online

- **Pros**
  - Empowers patients to provide feedback of their interactions with their providers
  - Patients get incite to experience of their peers (find a doctor they are looking for)
- **Cons**
  - Patient may be reading reviews of other patients who have different ailments
  - Bias in whose reporting these scores
  - Unable to verify if the former patient actually received care from the provider

Focus on Patient Experience

- **Two fundamental changes in medicine**
  - Consumerism
  - Reimbursement shift from volume to value

- Fundamental change in focus
- Not just technical aspect of care but patients' satisfaction with that care

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Patient Satisfaction as Quality Measure is Controversial

- Patients ability to evaluate technical aspects of care has been questioned (Jaipul 2003)
- Patient satisfaction may be influence by factors not directly related to process of care
  - Desires/expectations
  - Background and inherent characteristics (culture, socioeconomic status, age, gender)

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Studies Support Patient Experience as a Quality Measure

- **Safran 1998**
  - When patients have a better experience, they are more likely to adhere to treatments, return for follow-up appointments, and engage with the healthcare system by seeking appropriate care
- **Jaipaul 2003**
  - Patient satisfaction inversely correlated with mortality
- **Druss 1999**
  - Fewer readmissions + fewer hospital days

ORIGINAL RESEARCH

Patient-Centered Care is Associated with Decreased Health Care Utilization

Klea D. Bertakis, MD, MPH, and Rahman Azari, PhD

Patient-Centered Care and Decreased Health Care Utilization

- **Study of 509 patients using patient-centered care**
- Eliciting understanding and validating the

Sounds like domains of the CG- and HCAPS surveys

making, power, and responsibility

- Higher average amount of patient-centered care recorded in visits throughout the 1-year study period was related to:
  - a significantly decreased annual number of visits for specialty care (P .0209)
  - less frequent hospitalizations (P .0033)
  - fewer laboratory and diagnostic tests (P .0027)

- Total medical charges for the 1-year study were also significantly reduced (P .0002)
- Total charges were reduced for specialty care clinic visits (P .0005)
- Authors concluded that patient-centered care was associated with decreased utilization of health care services and lower total annual charges

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OTHER STUDIES SUGGEST PATIENT EXPERIENCE MAY BE A POOR MEASURE OF QUALITY

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Is Satisfaction Linked to Outcome

ORIGINAL INVESTIGATION

ONLINE FIRST

The Cost of Satisfaction

A National Study of Patient Satisfaction, Health Care Utilization, Expenditures, and Mortality

Joshua J. Fenton, MD, MPH; Anthony F. Jerant, MD; Klea D. Bertakis, MD, MPH; Peter Franks, MD

Scan for Author Audio Interview

Arch Intern Med. 2012;172(5):405-411. Published online February 13, 2012. doi:10.1001/archinternmed.2011.1662

- **Prospective cohort study of 52K adult respondents**
- **1 year patient satisfaction based on 5 items form the CAHPS survey**
- **Assessed health care utilization (any ER visit, and any inpatient admission), health care expenditures (total and for prescription drugs) and mortality**
- **Follow-up 3.9 years**
- **Data adjusted for cofounders: socioeconomic status, chronic disease burden, health status, etc.**

Results

- **Respondents in the highest satisfaction quartile**

UNINTENDED CONSEQUENCES
Greater utilization
Greater expenditures
Higher mortailty

expenditures

– Higher mortality (26% more likely to die)

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- **Fenton and colleagues found a strong association with expenditures and satisfaction**
- **Utilization itself may drive satisfaction**
- **Unknown cofounders of satisfaction**
  - Location of care (dialysis center vs. ER), mental health, socioeconimics, cultural, personality
  - Impact of these differences are not measured
  - Huge in the spine and chronic pain populations

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Perverse Outcomes based on Satisfaction

- **Increased utilization of resources and tests**
  - MRI, antibiotics, etc.
- **Avoid or limit access to certain patient populations or situations**
  - Obesity
  - Chronic pain
  - Substance abuse

HOW DO WE MEASURE HOSPITAL PATIENT EXPERIENCE TODAY?

HCAHPS

- **Hospital Consumer Assessment of Healthcare Providers and Systems**
  - National
  - Standardized
  - Public reporting of patients perception (experience) of hospital care they received
  - Allows valid comparisons across hospitals locally, regionally and nationally

HCAHPS

- **Asks discharged patients 32 questions about their hospital stay**
- **7 composite dimensions**
  - Communication with nurses and doctors (3Q each)
  - Responsiveness of hospital staff (2Q)
  - Pain management (2Q)
  - Communication about medicines(2Q)
  - Discharge information (2Q)
  - Care Transition (3Q)

HCAHPS

- **2 single item questions**
  - Cleanliness of hospital environment
  - Quietness of hospital environment
- **2 global dimensions of satisfaction**
  - Hospital rating
  - Willingness to recommend hospital

HCAHPS

- **Administered to a random sample of adult patients across medical conditions**
- **48 hours and six weeks after discharge**
- **Not restricted to Medicare beneficiaries**
- **CMS implemented HCAHPS survey in Oct 2006 with first public reporting in March 2008**

HCAHPS

- **Measures patient EXPERIENCE and not SATISFACTION**
- **Questions about how often experienced specific process measures of care not how they felt about it**
- **Two proxy questions for satisfaction**
  - Rate overall experience
  - Would they recommend hospital to a family or friend

HCAHPS

- **Scores are adjusted at hospital level**
  - Try to achieve a fair comparison between hospitals with different patient mixes
  - Variables adjusted for:
    - Self reported health status
    - Education level
    - Age
    - Non-response rate
    - Service line (maternity, surgery, medical)
    - Language
    - Survey mode-telephone vs. mail

HCAHPS

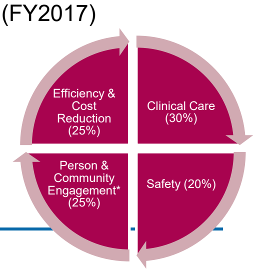
- **3 Goals**
  - 1. Produce data about patient's perspectives of care that allow objective and meaningful comparisons of hospitals on topics that are important to consumers
  - 2. Public reporting of results creates new incentives for hospitals to improve quality of care
  - 3. Enhance accountability in health care by increasing transparency of the quality of hospital care provided in return for the public investment

Public Reporting

- **Reports scores for 11 dimensions of patient experience**
  - Nurse and doctor communication, responsiveness of hospital staff, pain management, communication about medicines, discharge information, care transitions, cleanliness, quietness, hospital rating and willingness to recommend
- **Uses all scores in calculation of a dimensional value (not just top-box) and develop a linear mean score for each dimension**
- **Avg scores for 11 dimension used to calculate a summary star rating for hospital**

Value Based Purchasing (VBP) Program

- **Only Program that can earn money back FY2017: 2% of the Annual Payment Update initially withheld**
  - Can earn that, plus more, based on performance. Budget neutral program (some win, some lose!)
- **Comprised of 4 components equally weighted**
  - Outcomes (30%)
  - Safety (20%)
  - Patient Experience (25%)
    - Name changed to Person & Community Engagement (FY2017)
    - 8 dimensions from HCAHPS survey
    - All dimensions weighed equally
  - Efficiency and Cost Reduction (25%)



Argument for HCAHPS

- Patient-centeredness is one of the six domains that define quality care (IOM)
- Survey data is continuously collected, valid and reliable measure of patients experience
- Public reporting plus linkage to reimbursement compels hospital to assess and improve the patient experience (Tefera 2016)
- Survey is not an assessment of satisfaction rather an assessment of key process measures (i.e., communications) that only the patient can report on (Greaves 2014)

Argument Against HCAHPS

- Patient feedback is not credible b/c patients lack formal medical training (Manaray 2013)
  - Patients are unable to evaluate technical quality, particularly in the operating room (Lyu 2013)
- Experience measures could be confounded by factors not directly associated with the quality of processes (Manaray 2013)
  - "Sky-high patient experience may just be a marker of pandering to superficial expectations and inappropriate use of limited resources" (Greaves 2014)

Argument Against HCAHPS

- **Patient experience may reflect fulfillment of a patient's a priori desires/expectations**
  - If they decide they want drugs, they will be more satisfied if they receive drugs (Manaray 2013)
- **Patient may not be able to interpret publicly reported data or find the information very helpful (Huckman 2013)**

Some Research has Supported HCAHPS and Outcomes

- **Patient experience rating for avg hospital in US improving (Elliot 2015)**
  - Adoption is leading to improved patient experience
- **Higher pt satisfaction measured by HCAHPS**
  - Better surgical quality (SCIP measures, shorter stays, lower 30 day readmission) (Tsai 2015)
  - Greater adherence to care guidelines (HQA scores for AMI, CHF, Pneumonia) (Jha 2008, Glickman 2010)
  - Lower mortality (Surgery Tsai 2015, AMI patients Glickman 2010)

Research Does not Support HCAHPS as an Indicator of Quality

- **HCAHPS + VBP may enhance disparities in healthcare**
  - Safety net hospitals have lower performance on metrics of patient satisfaction (Chaterjee 2012)
  - Lower performing providers often care for larger share of racial or ethnic minority groups-HVBP could exacerbate this disparity (Ryan 2013)
  - Patient experience is less positive at hospitals serving a high proportion of minority patients (Goldstein 2009)

Research Does not Support HCAHPS as an Indicator of Quality

- **Patient characteristics are known to influence scores (other then those adjusted at the hospital level)**
  - Men more likely to report positive experience (Elliot 2012)
  - Predictors of less satisfied patients (Danforth 2014)
    - Female, younger, less ill, narcotic use, admitted via ER, un resected cancer

WHAT ABOUT SATISFACTION AND SPINE SURGERY

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ELSEVIER

The Spine Journal 13 (2013) 1006–1012

THE SPINE JOURNAL

Clinical Study

Determining the quality and effectiveness of surgical spine care: patient satisfaction is not a valid proxy

Saniya S. Godil, MD[a], Scott L. Parker, MD[a], Scott L. Zuckerman, BS[a], Stephen K. Mendenhall, BS[a], Clinton J. Devin, MD[b], Anthony L. Asher, MD, FACS[c], Matthew J. McGirt, MD[a,*]

[a]Department of Neurosurgery, Vanderbilt University, 1161 21st Ave S., T4224 MCN, Nashville, TN 37232, USA
[b]Department of Orthopedic Surgery, Vanderbilt University, Nashville, TN, USA
[c]Carolina Neurosurgery and Spine Associates, 225 Baldwin Ave, Charlotte, NC 28204, USA

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- **422 patients**
  - 287 lumbar surgery, 135 cervical surgery
- **Validated PROs and satisfaction with outcome and provider**
  - Recorded at baseline and at 3 months
- Receiver-operating characteristic (ROC) curve analysis was performed to determine whether extent of improvement in quality of life (SF-12 physical component summary [PCS]) and disability (ODI/NDI) accurately predicted patient satisfaction versus dissatisfaction

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Results

- **84.8% were satisfied with their provider,68.2% were satisfied with their outcome**
- **12.1% 90 day complications**
  - 5% readmissions, 2.8% return to the operating room

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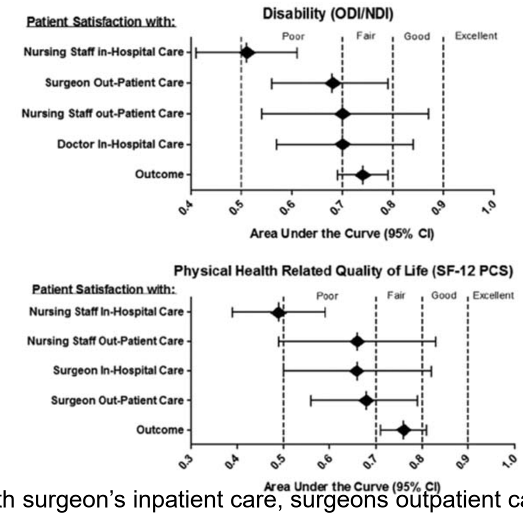

Satisfaction with surgeon's inpatient care, surgeons outpatient care, nursing staff inpatient care, and nursing staff outpatient care were all poor measures of effectiveness (improvement in disability and quality of life) of care. Patient satisfaction with outcome was also not a good measure of effectiveness.

Conclusion

- The evidence of a casual relationship of patient experience to outcomes is weak
- In most settings technical health care quality is simply invisible to patients and thus would not impact satisfaction
- Satisfaction is probably driven more by fulfilling patient expectations of care

Our Research Motivation

- **Patient-centered care is important, but we need to have a better understanding of what factors impact care**

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Our Research

- **It is well known that patient experience metrics will differ for different subgroups of patients**
  - Strikingly different patterns of assessment across patient subgroups + critical differences do exist
- **Our goal is to ID risk factors/areas for improvement that can be addressed in a spine population**

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WE FIRST WANTED TO KNOW IF PATIENT EXPERIENCE AS MEASURED BY HCAHPS IS ASSOCIATED WITH QUALITY OF LIFE OUTCOMES AT ONE YEAR FOLLOWING LUMBAR SURGERY

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THE SPINE JOURNAL

The Spine Journal 17 (2017) 1586–1593

Clinical Study

The association between the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey and real-world clinical outcomes in lumbar spine surgery

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Received 17 October 2016; revised 4 April 2017; accepted 2 May 2017

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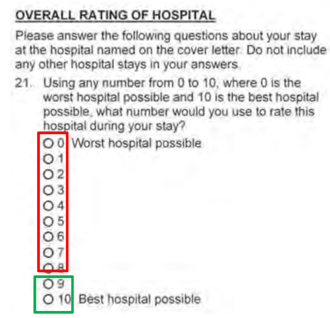
Methods

- 249 patients included:
  - ✓ Lumbar spine surgery at Cleveland Clinic (2013-2015)
  - ✓ Completed HCAHPS survey
  - ✓ 1-year follow-up
- Overall Rating of Hospital used to determine satisfaction with hospital experience
  - o 9 or 10 → "top-box" → Satisfied
  - o 8 or less → Unsatisfied
- Primary outcomes: preoperative and 1-year postoperative patient-reported health status measures - EQ-5D, PDQ, and VAS-BP



OVERALL RATING OF HOSPITAL

Please answer the following questions about your stay at the hospital named on the cover letter. Do not include any other hospital stays in your answers.

21. Using any number from 0 to 10, where 0 is the worst hospital possible and 10 is the best hospital possible, what number would you use to rate this hospital during your stay?

O 0 Worst hospital possible
O 1
O 2
O 3
O 4
O 5
O 6
O 7
O 8
O 9
O 10 Best hospital possible

Demographics

- No difference between both groups before surgery including baseline EQ5D, PDQ and VAS-BP
- 79% selected an OHR of 9 or 10 and were in the satisfied group

After using a multivariable linear regression analysis to assess the association between patient satisfaction and pre- to one-year postoperative changes in health status measures, selecting a top-box OHR was not found to be associated with change in either EQ-5D, PDQ, or VAS-BP

These results suggest that high satisfaction with the overall hospital experience does not correlate with favorable clinical outcomes

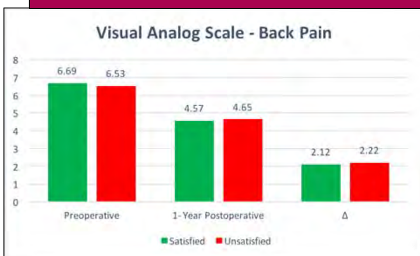


Table 1 – Linear regression models: The association between satisfaction and pre- to 1-year postoperative change in health status measures

	Δ EQ-5D		Δ PDQ		Δ VAS-BP	
	Unadjusted	Adjusted*	Unadjusted	Adjusted	Unadjusted	Adjusted
Top-box overall satisfaction	-0.009 (-0.091 – 0.073)	0.055 (-0.035 – 0.145)	2.555 (-11.192 – 16.302)	-9.013 (-23.782 – 5.755)	0.105 (-0.987 – 1.196)	-0.849 (-2.125 – 0.426)

*Adjusted estimates were obtained from a multivariable linear regression model developed for each health status measure and included the following covariates: age, gender, ethnicity, prior lumbar surgery, lumbar degenerative disc disease, history of chronic renal failure, history of stroke, heavy preoperative narcotic use and preoperative EQ-5D.

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Multivariable Logistic Regression Model

Table 5– Predictors of a top-box (9 or 10 out of 10) Overall Hospital Rating on HCAHPS

	Odds Ratio (95% Confidence Interval)	P value
Female gender	0.306 (0.126 – 0.745)	0.009*
Prior lumbar surgery	0.356 (0.153 – 0.830)	0.017*
Degenerative disc disease	0.158 (0.032 – 0.785)	0.024*
History of chronic renal failure	0.118 (0.012 – 1.199)	0.071
History of stroke	0.254 (0.056 – 1.164)	0.078
Heavy preoperative narcotic use[1]	0.470 (0.179 – 1.233)	0.125
White Ethnicity	0.268 (0.025 – 2.826)	0.273
Age	1.009 (0.973 – 1.046)	0.632
Preoperative EQ-5D[2]	1.477 (0.203 – 10.727)	0.700

[1]*Heavy preoperative narcotic use* defined as > 1000 morphine equivalent doses prescribed to a patient within the three months prior to their spine surgery admission date.
[2]*EQ-5D* EuroQol 5 Dimensions
*All P values less than 0.05 were considered statistically significant

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Conclusion

- **Both the satisfied and unsatisfied groups made similar improvements in EQ-5D, PDQ and VAS-BP measured one year postoperatively**
- **Satisfying hospital experience (HCAHPS) may not be a reliable indicator of quality care in lumbar spine surgery**
- **Gender, surgical history and spinal pathology were significant negative predictors of a top box OHR**
  - These are not controlled by the treating physician and argue, HCAHPS should not be used as a measure of surgical quality

WE NEXT WANTED TO UNDERSTAND WHAT DRIVES PATIENT SATISFACTION IN LUMBAR SPINE SURGERY

JNS SPINE CLINICAL ARTICLE

Key drivers of patient satisfaction in lumbar spine surgery

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Methods

- 460 patients included:
  - ✓ Lumbar spine surgery at Cleveland Clinic (2013-2015)
  - ✓ Completed HCAHPS survey
  - ✓ 1-year follow-up
- Overall Rating of Hospital used to determine satisfaction with hospital experience
  - o 9 or 10 → “top-box” → Satisfied
  - o 8 or less → Unsatisfied

OVERALL RATING OF HOSPITAL

Please answer the following questions about your stay at the hospital named on the cover letter. Do not include any other hospital stays in your answers.

21. Using any number from 0 to 10, where 0 is the worst hospital possible and 10 is the best hospital possible, what number would you use to rate this hospital during your stay?

O 0 Worst hospital possible
O 1
O 2
O 3
O 4
O 5
O 6
O 7
O 8
O 9
O 10 Best hospital possible

Overall top box hospital rating was 79.8%

Variables	Unsatisfied (n=92, 20.0%)	Satisfied (n=368, 79.8%)	P value
Age	62.94 +/- 12.17	63.92 +/- 11.13	0.447
Gender			0.423
Male	49/92 (53.3%)	213/368 (57.9%)	
Female	43/92 (46.7%)	155/368	
Race			0.198
White	89/92 (96.7%)	339/364 (93.1%)	
Other	3/92 (3.3%)	25/364 (6.9%)	
Overall Health			0.039*
Excellent	2/85 (2.4%)	37/356 (10.4%)	
Very Good	28/86 (32.6%)	137/356 (38.5%)	
Good	38/86 (44.2%)	142/356 (39.9%)	
Fair	16/86 (18.6%)	38/356 (10.7%)	
Poor	1/86 (1.2%)	2/356 (0.6%)	

Mental Health			0.149
Excellent	21/84 (25.0%)	133/358 (37.2%)	
Very Good	40/84 (47.6%)	130/358 (36.3%)	
Good	16/84 (19.0%)	74/358 (20.7%)	
Fair	7/84 (8.3%)	19/358 (5.3%)	
Poor	0/84 (0.0%)	2/358 (0.6%)	
Education Level			0.369
College+	20/85 (23.5%)	89/357 (24.9%)	
College	19/85 (22.4%)	63/357 (17.6%)	
Some College	26/85 (30.6%)	104/357 (29.1%)	
High School	17/85 (20.0%)	93/357 (26.1%)	
Some High School	3/85 (3.5%)	4/357 (1.1%)	

Prior Surgery	42/92 (45.7%)	127/368 (34.5%)	0.047*
Primary Diagnosis			0.558
Stenosis	42/92 (45.7%)	155/368 (42.1%)	
DDD[1] or Spondylosis	21/92 (22.8%)	84/368 (22.8%)	
Spondylolisthesis	18/92 (19.6%)	60/368 (16.3%)	
HNP[2]	11/92 (12.0%)	66/368 (17.9%)	
Spondylolysis	0/92 (0.0%)	3/368 (0.8%)	
Comorbidities			
Cancer	24/80 (30.0%)	70/342 (20.5%)	0.065
Chronic renal failure	3/80 (3.8%)	4/342 (1.2%)	0.129
Diabetes	21/80 (26.3%)	73/342 (21.3%)	0.343
Coronary artery disease	10/80 (12.5%)	46/342 (13.5%)	0.822
Hypertension	44/80 (55.0%)	166/342 (48.5%)	0.298
Stroke	6/80 (7.5%)	14/342 (4.1%)	0.197

Median BMI[3] (IQR[4])	29.80 (26.11 – 34.00)	29.00 (25.93 – 32.85)	0.374
Median Income (IQR)	$54,904 ($45,996 – 65,816)	$53,899 ($44,144 – 68,310)	0.761
Median Length of Hospital Stay (IQR)	3.00 (2.00 – 4.00)	3.00 (2.00 – 4.00)	0.101
Median Survey Response Time (IQR)	25.50 (17.00 – 37.00)	21.00 (16.00 – 35.00)	0.063
EQ5D[5]	0.542 +/- 0.221	0.562 +/- 0.205	0.440
PHQ9[6]	7.80 +/- 5.87	7.12 +/- 5.76	0.343
PDQ[7]	76.94 +/- 28.71	73.45 +/- 28.67	0.334

[1]DDD: Degenerative disc disease

Table 3 – Baseline multivariable logistic regression model predicting a top-box Overall Hospital Rating (OHR)		
Variable	**Odds Ratio (95% Confidence Interval)**	**P value**
Overall health	1.59 (1.09 – 2.32)	0.016*
Prior lumbar spine surgery	0.549 (0.323 – 0.934)	0.027*
History of chronic renal failure	0.217 (0.038 – 1.245)	0.086
White race	0.191 (0.024 – 1.523)	0.118
History of cancer	0.620 (0.340 – 1.129)	0.118
History of stroke	0.528 (0.185 – 1.505)	0.232
Survey response time	1.051 (0.923 – 1.198)	0.452
Length of hospital stay	0.997 (0.981 – 1.013)	0.710
Mental health	0.987 (0.708 – 1.375)	0.936
*All p values < 0.05 were considered statistically significant		

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Table 4 – Individual HCAHPS items and their association with top-box Overall Hospital Rating (OHR)		
Survey Item Response	**Top-Box Overall Rating**	
	Adjusted OR (CI)	Adjusted P value
The hospital staff always did everything they could to help you with your pain	12.60 (6.67 – 23.79)	<0.001*
Nurses always treated you with courtesy and respect	11.66 (5.70 – 23.84)	<0.001*
Nurses always listened carefully to you	8.88 (4.90 – 16.10)	<0.001*
Before giving you any new medicine, hospital staff always described possible side effects in a way you could understand	8.44 (3.56 – 20.02)	<0.001*
Staff took your preferences and those of your family into account in deciding what your health care needs would be	8.21 (4.25 – 15.87)	<0.001*
Doctors always treated you with courtesy and respect	6.67 (3.30 – 13.51)	<0.001*
Your room and bathroom were always kept clean	6.20 (3.43 – 11.22)	<0.001*
You had a good understanding of the things you were responsible for in managing your health	6.06 (3.40 – 10.81)	<0.001*
Your pain was always well controlled	5.72 (3.11 – 10.53)	<0.001*

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You always got help in getting to the bathroom or using a bedpan as soon as you wanted it	5.55 (2.88 – 10.69)	<0.001*
Doctors always listened carefully to you	5.54 (2.97 – 10.34)	<0.001*
Doctors always explained things in a way you could understand	5.06 (2.77 – 9.23)	<0.001*
The area around your room was always quiet at night	4.42 (2.42 – 8.06)	<0.001*
Nurses always explained things in a way you could understand	4.10 (2.29 – 7.34)	<0.001*
Before giving you any new medicine, hospital staff always told you what the medicine was for	3.53 (1.79 – 6.97)	0.002*
After you pressed the call button, you always got help as soon as you wanted it	3.08 (1.74 – 5.45)	<0.001*

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You clearly understood the purpose for taking each of your medications	2.57 (1.49 – 4.42)	0.004*
Patient needed help from staff in using bathroom/bedpan	0.50 (0.26 – 0.96)	0.152
Hospital staff talked with you about whether you would have the help you needed when you left the hospital	2.68 (0.95 – 7.6)	0.184
You got information in writing about what symptoms or health problems to look out for after you left the hospital	3.10 (1.11 – 8.62)	0.152
You needed pain medication during your hospital stay	0.35 (0.04 – 3.54)	0.752
After leaving the hospital, you went directly to your own home	1.37 (0.642 – 2.93)	0.752
*All p values < 0.05 were considered statistically significant		

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Perception of Effort for Pain Control

- In a surgical population of 4,349

Communication improves inpatient pain management
Patient satisfaction CAN improve without increased utilization of opiod medicaitons

and found that the perception of providers addressing pain control outranked actual pain control in terms of impact on global patient satisfaction

- Perceiving nursing care as courteous and respectful is the second strongest predictor of top box OHR
- Many other studies have also demonstrated patient satisfaction being tied to nursing care
- Doctor communication also found to be a significant predictor for all three measures

Foundations of Healthcare Communication Course

- **Well established that preoperative depression is associated with worse clinical outcomes in spine surgery**
- **Adogwa et al found that independent of postoperative improvement in pain and disability, increasing Zung depression score was significantly associated with patient dissatisfaction 2 years after surgery**
  - Measure of satisfaction with clinical outcome
  - Depression influences satisfaction independent of surgical effectiveness

ARE DEPRESSED PATIENTS MORE LIKELY TO HAVE A LOWER SCORES ON HCAHPS

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Methods

- **217 patients included:**
  - ✓ Lumbar fusion at Cleveland Clinic (2013-2015)
  - ✓ Completed HCAHPS survey
  - ✓ Had preoperative PHQ-9 scores
- **Preoperative PHQ-9 scores defined our two study groups**
  - o PHQ-9 ≥ 10 (moderate to severe depression) = **depressed**
  - o PHQ-9 < 10 = **non-depressed**
- **Pearson chi-square was used to compare the two groups; Multivariable logistic regression used to determine independent predictors of select top-box HCAHPS scores**

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- **57 patients depressed, 160 non-depressed**
- **2 groups different in a number of demographic factors**
  - Depressed
    - Younger
    - Higher proportion of females
    - Higher proportion not working and receiving full compensation
    - Greater number of smokers
    - Lower preoperative quality of life and significantly higher preoperative pain and disability

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Results

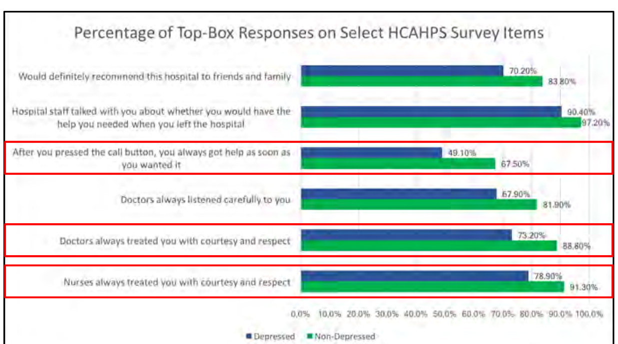

Table 1 – Multivariable Logistic Regression Results for Predicting Response Help[1]

Characteristic	Odds Ratio (95% Confidence Interval)	P value
Depression	0.376 (0.176 - 0.805)	0.012*
PDQ[2] score	1.008 (0.994 - 1.022)	0.260
EQ-5D[3] score	1.917 (0.333 - 11.046)	0.467

[1]Response Help = "During this hospital stay, after you pressed the call button, how often did you get help as soon as you wanted it?" Top-box response = "Always"
[2]Pain Disability Questionnaire
[3]EuroQol-five dimensions
*All P values <0.05 were considered statistically significant

Table 2 – Multivariable Logistic Regression Results for Predicting Doctor Respect[1]

Characteristic	Odds Ratio (95% Confidence Interval)	P value
		03*
		24*
		15
		16

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Since our two patient groups differed in important preoperative characteristics, multivariate logistic regression analysis was performed to determine whether depression was independently associated with the worse satisfaction, or if some other variable could better explain this association

- **In our study all items on the HCAHPS survey significantly associated with depression involved measures of interpersonal relations between patients and providers**
- **Patients with a major depressive disorder**
  - Suffer from impairments in social functioning
  - Heightened sensitivity to social rejection

- **Could our depressed patients have an overly sensitive impression that their health care providers were not as respectful and responsive to their needs as they should be?**

Conclusion

- In patients undergoing lumbar fusion, preoperative depression was shown to have a negative association with patient experience measured by the HCAHPS survey.
- These results suggest that depression may be a modifiable risk factor for poor hospital experience.
- Future work should investigate whether preoperative, multidisciplinary interventions may mitigate depression's negative impact on the patient experience, and thus improve HCAHPS scores.

There are conflicting data detailing whether early readmission or other post-discharge complications are associated with negative patient responses on the HCAHPS survey. Currently, the association between post-discharge ED visits and HCAHPS scores following lumbar spine surgery is unknown

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The Spine Journal 18 (2018) 226–233

THE SPINE JOURNAL

Clinical Study

Emergency department visits after lumbar spine surgery are associated with lower Hospital Consumer Assessment of Healthcare Providers and Systems scores

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- We sought to investigate whether experiencing an ED visit within thirty days of hospital discharge is associated with patients' ratings of their inpatient experience of care on HCAHPS
- We hypothesize that ED visits within 30 days after discharge following lumbar spine surgery are associated with a poorer perceived inpatient hospital experience, and therefore result in lower HCAHPS scores for these patients
- Post-operative ED visits are commonly associated with high costs, long waiting times and low satisfaction, and represent a significant burden on both patients and the healthcare system

Methods

- 453 lumbar spine surgery patients
- Surgery between 2013-2015 at CCF
- Patients who had an ED visit at our institution within 30 days of discharge were included in the ED visit cohort

Table 1– Reasons for ED visits within 30 days of discharge

Diagnosis	Number of Patients
Back pain +/- leg pain	5 (21.7%)
Urinary tract infection	5 (21.7%)
Gastrointestinal symptoms	3 (13.0%)
Pulmonary embolism/Deep vein thrombosis	2 (8.7%)
Other musculoskeletal pain	2 (8.7%)
Generalized symptoms (fever, dizziness)	2 (8.7%)
Wound drainage	1 (4.3%)
Cardiovascular event	1 (4.3%)
Pneumonia	1 (4.3%)
Staple removal	1 (4.3%)

Table 3 – Percentages of top-box HCAHPS responses for control patients versus patients seen in emergency department (ED) within 30 days of discharge	No ED	ED[1]	P Value
Communication with Nurses			
Nurses always treated you with courtesy and respect	381/429 (88.8%)	21/23 (91.3%)	0.710
Nurses always listened carefully to you	333/430 (77.4%)	18/23 (78.3%)	0.927
Nurses always explained things in a way you could understand	333/427 (78.0%)	16/23 (78.3%)	0.975
Communication with Doctors			
Doctors always treated you with courtesy and respect	384/428 (89.7%)	16/23 (69.6%)	0.003•
Doctors always listened carefully to you	359/428 (83.9%)	15/23 (65.2%)	0.021•
Doctors always explained things in a way you could understand	337/428 (78.7%)	17/23 (73.9%)	0.583
Cleanliness and Quietness of the Hospital Environment			
Your room and bathroom were always kept clean	344/427 (80.6%)	16/23 (69.6%)	0.199
The area around your room was always quiet at night	223/425 (52.5%)	16/22 (72.7%)	0.063
Responsiveness of hospital staff			
You always got help in getting to the bathroom or using a bedpan as soon as you wanted it	213/305 (69.8%)	14/19 (73.7%)	0.722
After you pressed the call button, you always got help as soon as you wanted it	263/398 (66.1%)	16/21 (76.2%)	0.338
Pain Management			
Your pain was always well controlled	248/420 (59.0%)	15/23 (65.2%)	0.557
The hospital staff always did everything they could to help you with your pain	336/418 (80.4%)	19/23 (82.6%)	0.793
Communication about Medicines			
Before giving you any new medicine, hospital staff always described possible side effects in a way you could understand	149/314 (47.5%)	10/16 (62.5%)	0.240
Before giving you any new medicine, hospital staff always told you what the medicine was for	258/320 (80.6%)	12/17 (70.6%)	0.312
Discharge Information			
Hospital staff talked with you about whether you would have the help you needed when you left the hospital	373/392 (95.2%)	19/21 (90.5%)	0.342
You got information in writing about what symptoms or health problems to look out for after you left the hospital	370/391 (94.6%)	20/21 (95.2%)	0.904
Staff took your preferences and those of your family into account in deciding what your health care needs would be when you left the hospital	244/427 (57.1%)	8/23 (34.8%)	0.035•
Transition of Care			
You had a good understanding of the things you were responsible for in managing your health	[illegible]	[illegible]	[illegible]
You clearly understood the purpose for taking each of your medications	288/429 (67.1%)	16/23 (69.6%)	0.809
Overall Rating of a Hospital			
Rated this hospital as a 9 or 10 out of 10 overall	350/430 (81.4%)	13/23 (56.5%)	0.004•
Would definitely recommend this hospital to friends and family	361/430 (84.0%)	15/23 (65.2%)	0.020•

[1] Emergency Department visit < 30 days post-discharge
•All P values <0.05 were considered statistically significant

Table 4 – Multivariable logistic regression models used to determine the association between emergency department (ED) visit within 30 days after discharge and individual Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey items

	Doctor Respect[1]	Doctor Listen[2]	Family Preferences[3]	Overall Rating[4]	Definitely Recommend[5]
Characteristic	Adjusted OR (95% CI)	Adjusted OR (95% CI)	Adjusted OR (95% CI)	Adjusted OR (95% CI)	Adjusted OR (95% CI)
ED visit	0.122 (0.039 – 0.381)**	0.239 (0.084 – 0.678)*	0.323 (0.115 – 0.909)*	0.318 (0.115 – 0.879)*	0.285 (0.098 – 0.826)*
Prior lumbar surgery	1.199 (0.597 – 2.409)	0.853 (0.488 – 1.491)	0.695 (0.453 – 1.067)	0.660 (0.391 – 1.111)	0.820 (0.467 – 1.440)
History of coronary artery disease	2.081 (0.651 – 6.649)	1.587 (0.651 – 3.867)	1.039 (0.566 – 1.905)	1.224 (0.556 – 2.694)	1.737 (0.688 – 4.387)
Length of hospital stay	0.954 (0.828 – 1.099)	0.928 (0.826 – 1.042)	1.028 (0.929 – 1.137)	1.010 (0.894 – 1.141)	0.989 (0.872 – 1.122)
Survey response time	1.007 (0.985 – 1.029)	0.998 (0.982 – 1.015)	0.996 (0.983 – 1.010)	0.996 (0.980 – 1.013)	0.990 (0.974 – 1.006)
Preoperative EQ-5D[6]	0.811 (0.128 – 5.139)	0.993 (0.210 – 4.698)	0.504 (0.147 – 1.730)	0.928 (0.208 – 4.142)	0.631 (0.130 – 3.072)
Preoperative PDQ[7]	0.981 (0.968 – 0.995)*	0.989 (0.977 – 1.000)	0.996 (0.987 – 1.005)	0.995 (0.984 – 1.005)	0.989 (0.977 – 1.000)

[1] Doctors always treated you with courtesy and respect
[2] Doctors always listened carefully to you
[3] Staff took your preferences and those of your family into account in deciding what your health care needs would be
[4] Rated this hospital as a 9 or 10 out of 10 overall
[5] Would definitely recommend this hospital to friends and family
[6] EQ-5D: EuroQol 5-Dimensions index score
[7] PDQ: Pain Disability Questionnaire
*Denotes P values <0.05, which were considered statistically significant

DOES THE TYPE OF SURGERY IMPACT PATIENT HCAHPS SCORES?

Cleveland Clinic

HCAHPS Survey Scores in Fusion vs. Decompression Surgery

Methods

- **438 patients who underwent lumbar surgery from 2013-2015**
- **HCAHPS data, demographics, operative history**
- **Two groups according to type of index surgery – fusion vs. decompression**
- **Pearson's chi-square test used to assess differences in "top-box" percentages between groups**
- **Logistic regression modeling of top-box outcome to assess impact of surgery in relation to CMS adjustment variables**

Fusion patients were found to have lower scores across the board (19 of 21 questions on HCAHPS), but were found to have statistically significant lower scores for…

Staff to Pain	[illegible]	[illegible]	**p = 0.04**
Staff Responsiveness When Help Needed	60.5%	70.7%	0.63 (0.42-0.96) **p = 0.03**
Reason for Meds	74.3%	84.2%	0.54 (0.31-0.94) **p = 0.03**

- **Logistic regression models for each of these questions demonstrated that the type of index surgery (fusion vs. decompression) remained a significant predictor of top-box satisfaction even after controlling for variables used by CMS to adjust HCAHPS scores (i.e. Patient Reported Health Status, Level of Education, and Age)**

Conclusions + Future Directions

- Fusion = significant predictor of lower scores after controlling for CMS adjustment variables
- Fusion surgery was associated with significantly lower scores in 4 of 21 domains of HCAHPS survey for lumbar surgery patients.
- The association of lower HCAHPS scores with fusion surgery was observed to persist after controlling for variables that CMS uses to adjust these scores. This finding suggests that fusion surgery may be an additional independent predictor of lower HCAHPS scores in spine patients.

Conclusion

- Since CMS does not account for specific procedure level information in their adjustments of scores, providers/institutions who perform a larger proportion of fusion surgeries compared to other providers may have lower HCAHPS scores, which could impact reimbursement (provider = worse performance evaluations, hospitals = lower patient experience scores in hospital value based purchasing).

Cleveland Clinic

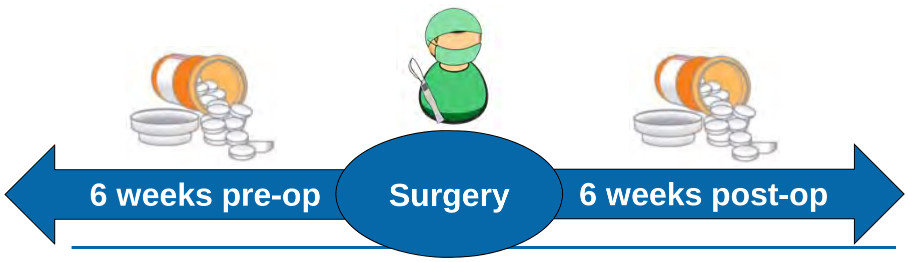
The Association of Opioids and Pain Management Scores on the HCAHPS Survey in Lumbar Spine Surgery Patients.

Patient Experience as Healthcare Quality Metric

- **There is considerable concern these scores are incentivizing providers to prescribe more opioids**
- **Research question: What is the association of post-operative opioids and Pain Management scores on the HCAHPS survey?**

Methods

- **Subjects: 170 pts w/ lumbar spine surgery + completed HCAHPS survey between 2013-2015**
- **Data: HCAHPS survey responses + demographics and opioids from EMR**
  - Opioid data: average daily dose 6 weeks after discharge ***AND*** 6 weeks prior to admission



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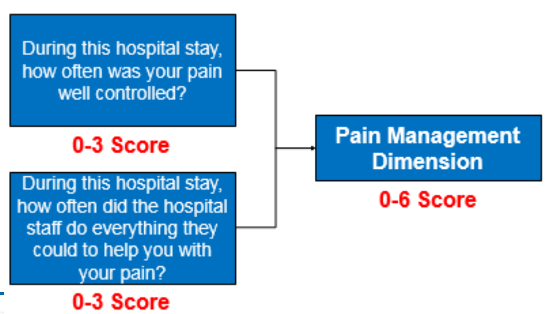
Methods

- **Analysis: Negative binomial regression model to investigate the assoc bw our opioid variable and pain mgmt score**
  - Outcome: Pain Management (PM) Score on HCAHPS
  - Predictor: 6 wk Average Dose of Post-op Opioids
    - Co-variates: Age, Gender, Type of Surgery, Health Status, Level of Education, 6wk Average Dose of Pre-op Opioids



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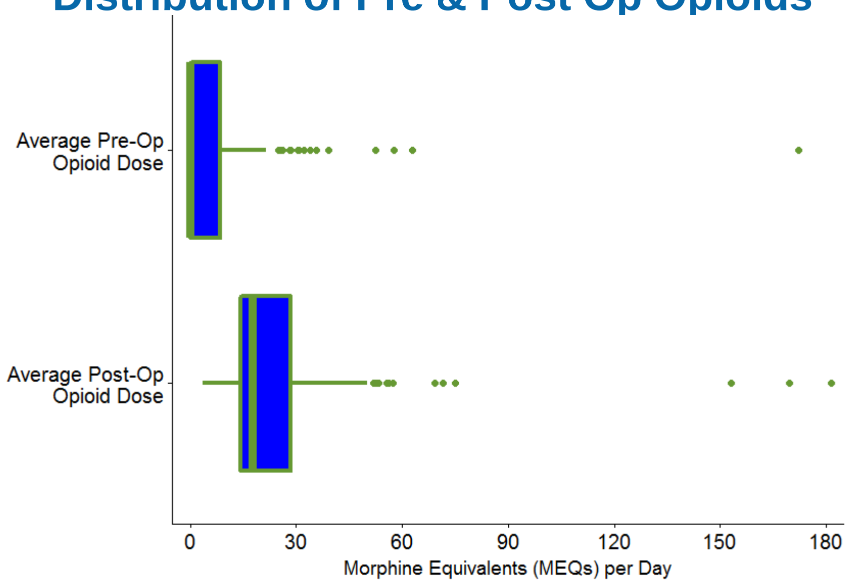
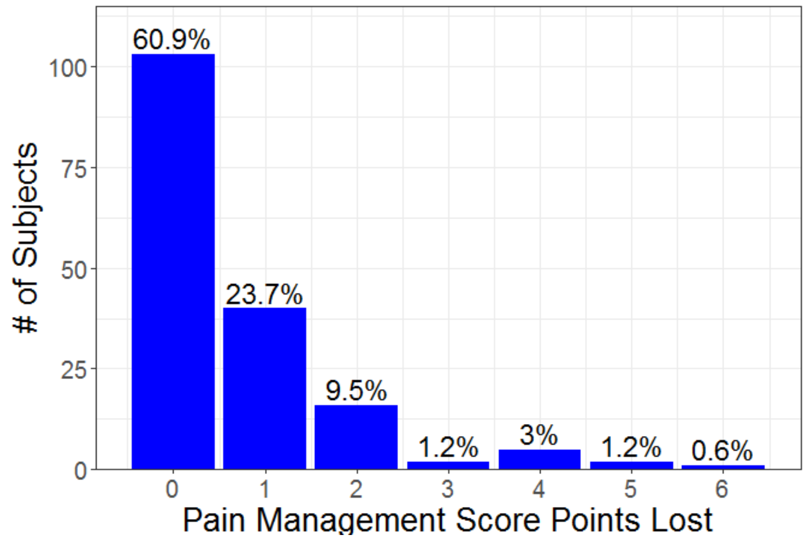
Demographics

	n=170
Age (mean (sd))	64.3 (11)
Sex = Male	54.4%
Primary Diagnosis	
Degenerative Disc Disease	23.1%
Disc Displacement	11.8%
Spondylolisthesis	13.6%
Stenosis	51.5%
Education Score (mean (sd))	4.39 (1.16)
Ov. Health Score (mean (sd))	2.59 (0.79)
Fusion Surgery	46.2%
Total Levels (median [IQR])	2.00 [1.00, 3.00]
Length of Stay (median [IQR])	3.00 [2.00, 4.00]

Distribution of Pre & Post Op Opioids



Distribution of Outcome: PM Score



Regression Model Coefficients

	Multiplicative Effects (95% CI)	p
Average Pre-Op Opioid Dose (15 MEQs)	0.99 (0.85-1.17)	0.94
Average Post-Op Opioid Dose (15 MEQs)	**1.26 (1.12-1.42)**	**<0.01**
Surgery? (Fusion)	1.27 (0.80-2.02)	0.31
Age	1.01 (0.99-1.03)	0.61
Sex (Female)	**1.62 (1.03-2.57)**	**0.04**
Overall Health Score	1.29 (0.98-1.71)	0.08
Education Score	**1.23 (1.01-1.50)**	**0.04**

Conclusions

- **Larger doses of post-op opioids are associated with lower PM scores on the HCAHPS survey**
- **Larger doses of post-op opioids may be a surrogate for psych. distress + poor coping skills (Nota et al. 2015)**
- **Opioid therapy alone likely insufficient – spine surgeons should consider a multifaceted approach to optimize post-op pain management**

Summary

- **We are uncovering patient and procedural factors that significantly impact patient experience post lumbar surgery**
  – Prior lumbar surgery, degenerative pathology, moderately to severely depressed, fusion, ED visit within 30 days, post operative opioids
- **We are currently assessing patient expectations, specific diagnoses/procedures, among others as to influence on HCAHPS surveys**

Summary

- **This data may be used at the provider, department and hospital level to understand patient and procedure factors which drive experience and satisfaction**
- **It remains unclear if mitigating treating these factors will alter experience**
  - Study interventions at at risk groups

Take Away Points

- **Patient experience and satisfaction IS important**
- **Measuring and reporting has improved experience across most hospitals**
- **HVBP encourages hospitals to create programs and pathways to improve overall patient (consumer) experience**

Take Away Points

- **Significant emphasis on satisfaction may have perverse ramifications**
  - Increased resource utilization
  - Increased cost
  - Under treatment or avoidance of difficult patient populations
  - This must be understood and mitigated
- **HCAPHS is validated for hospital to hospital comparisons**
  - Not validated for doctor to doctor or department to department comparisons

Key Take Away Points

- **HCAHPS does not account for patient or procedure factors that have significant influence on experience**
  - Understanding these factors and incorporating this knowledge into experience and clinical programs will influence overall scores
  - Some factors may be mitigated or treated prior to hospitalization and impact scores
    - Yet to be determined

Cleveland Clinic

Cleveland Clinic

Every life deserves world class care.

Reimbursement for the Management of Spinal Disorders: Challenges and Reform - New Technologies/Procedures

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Co-Director, USC Spine Center
Professor of Orthopaedic Surgery and Neurosurgery
USC School of Medicine
Los Angeles, CA

Disclosures

- Royalties –
  - Biomet, Seaspine, Amedica, Synthes
- Investments/Options –
  - Bone Biologics, Pearldiver, Electrocore, Surgitech
- Board of Directors:
  - Past-President North American Spine Society
  - 2nd Past-President Cervical Spine Research Society
  - Past-President Society for Brain Mapping and Therapeutics
  - AO Foundation
- Fellowship Funding: AO Foundation
- Editorial Boards
  - Spine, JAAOS, The Spine Journal, Clinical Spine Surgery, Global Spine Journal

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Disclaimer

- My own opinions
- Not based on science
- May differ from your own thoughts
- I may not be right
- This is what has worked for me in my experiences
- Self-conscious of the audience
  - Expert sitting in front of me
  - University setting

Managing Spinal Disorders: New Technologies/Procedures

- How are we doing to pay for the treatment of spinal disorders?
- How are we going to continue to advance the care of these patients?
  - Novel technology
  - Novel procedures
- Identify Barriers/Requirements for the future?

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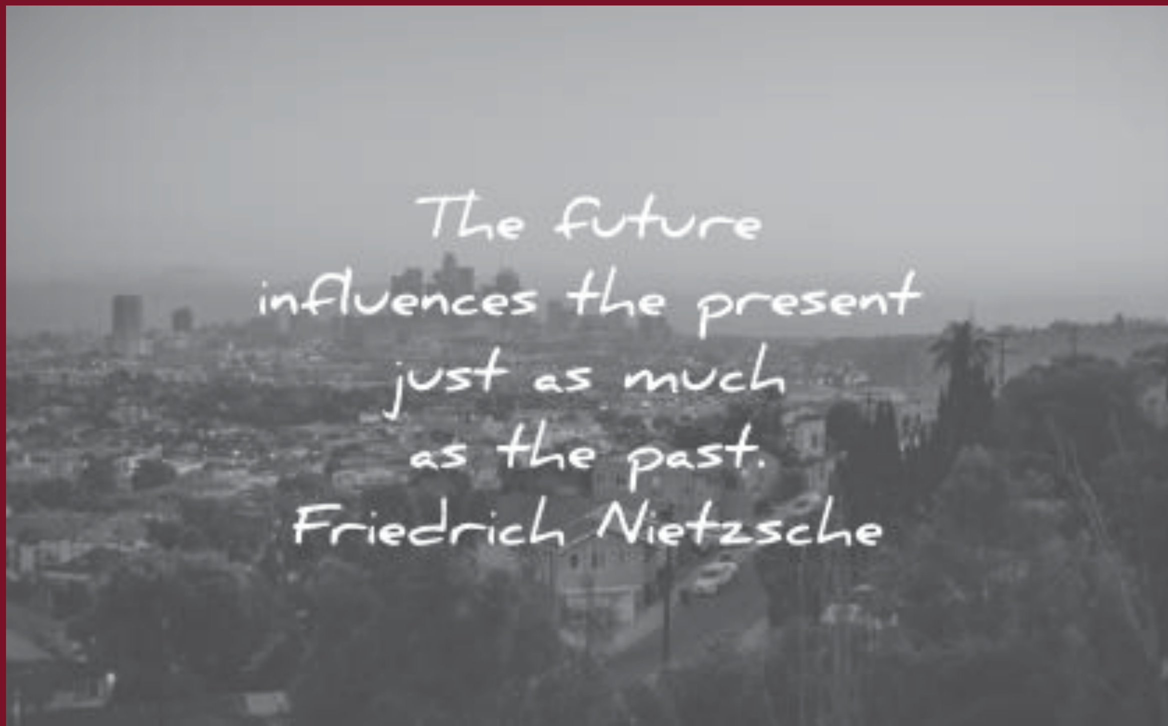
Requires Us to Predict the Future



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Forecast reality Check 1982-2020	Our reality is on the spot or ahead	Our reality is behind, the movie is off
Video messaging	The 1982 movie actually under-predicted current smartphone based - communication tools like Facetime etc.	
Home technology	With voice activated personal assistants and smart homes becoming the new norm for households the movie completely underpredicted	
Lie detector		Blade runner lie detectors were more comprehensive, but the general principles are still used
Weather		LA weather was famously rainy and foggy due to environmental changes. Sadly, overheating, droughts and forest fires have become the LA reality
Flying cars		They are way ahead in cool flying cars
Hairdryers		Ahead – it takes seconds, but they look quite simnilar
Photography	Our digital photography is way ahead of the analog prints used in the movie	
Robot sophistication		Their robots and underlying AI are way ahead of reality
Medical care	Concierge care and remote vitals are reality	

Overview

- Development of New Technologies
  - Timeline
  - Patents
  - FDA Approval
  - CPT Coding
  - Valuation
  - Reimbursement
- Future of Spine
- Novel Technology

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In the Past….

- See patient
- Bills for services
- Surgery
- Use implant
- Discharge patient
- Isolated events

- Insurance plan
- Payment model
- Advocate for procedure
- New technology
- Implant approved?
- Discharge - rated
- Reimbursement
- Events related

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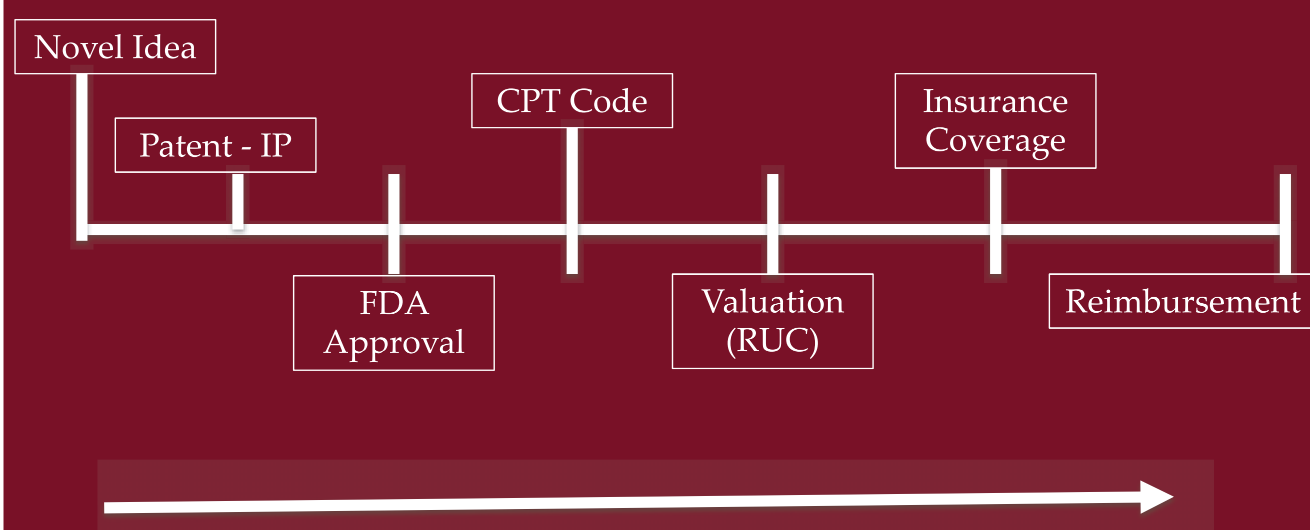

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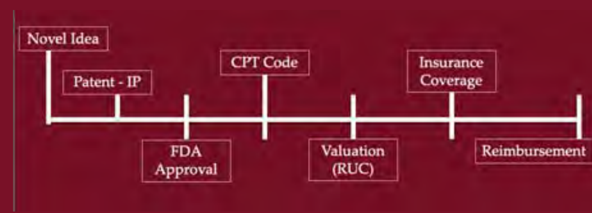
Timeline

- Novel idea to use of new technology in surgery and getting reimbursed
- Explain process in steps
- Discuss barriers and how to optimize this for the future (reform)
- Develop understanding of process and relationship of actions



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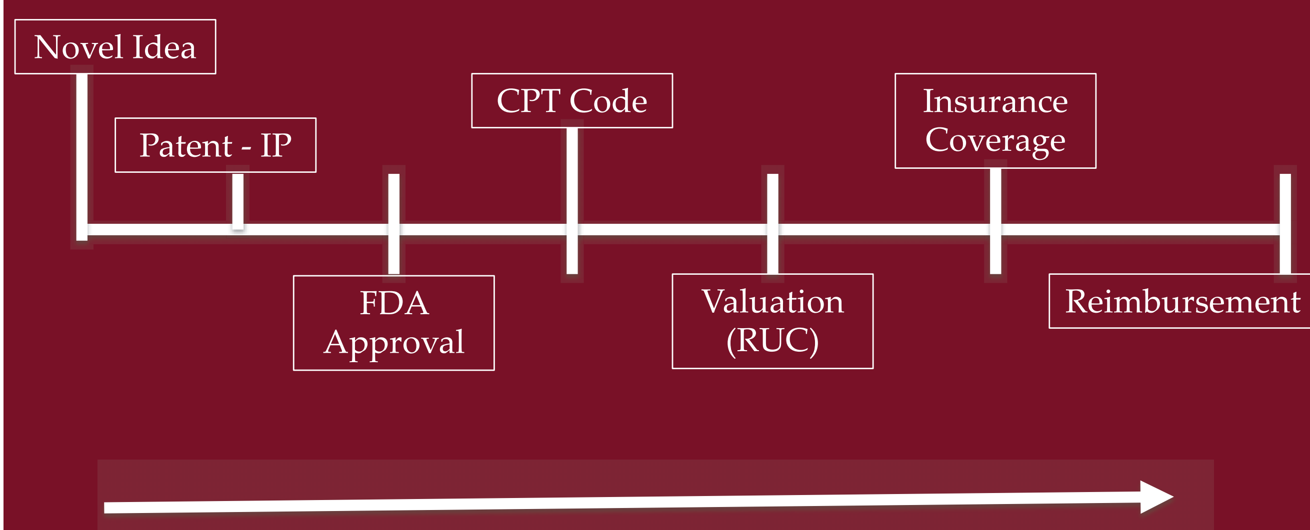
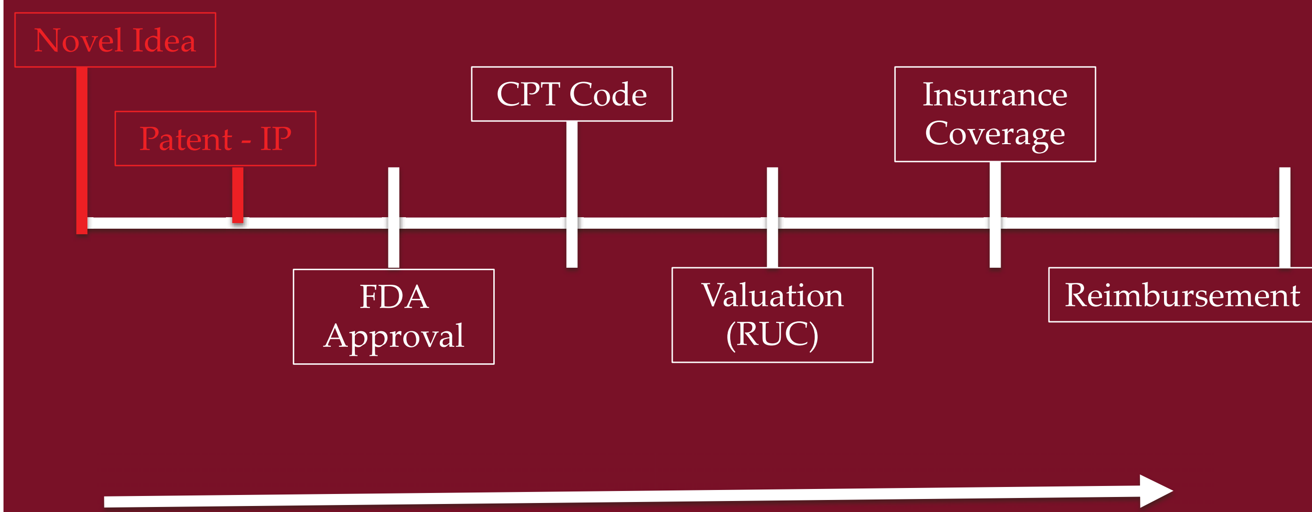
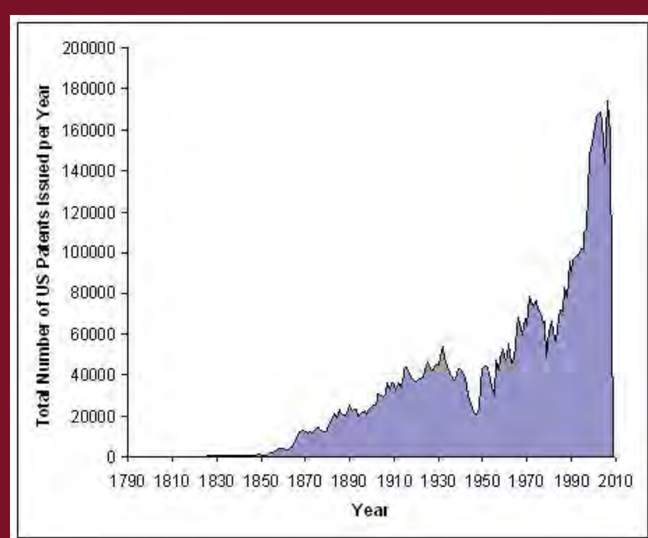


Timeline



Novel Idea

- Novel idea – new technology
- Develop it into new treatment/device/medication
- Patents
  - More difficult
  - 1180 – 634 applications
  - 1950 – 74,003 applications
  - 1963 – 90,982 applications
  - 2019 - 669,434 applications



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Patent

- Patent Granted
- Utility patent granted for 20 years
- Design patent granted for 14 years
- Filing date of patent
- Speed of patent issue can significantly affect the patent term
- Public domain
- Limited amount of time to develop the entire process

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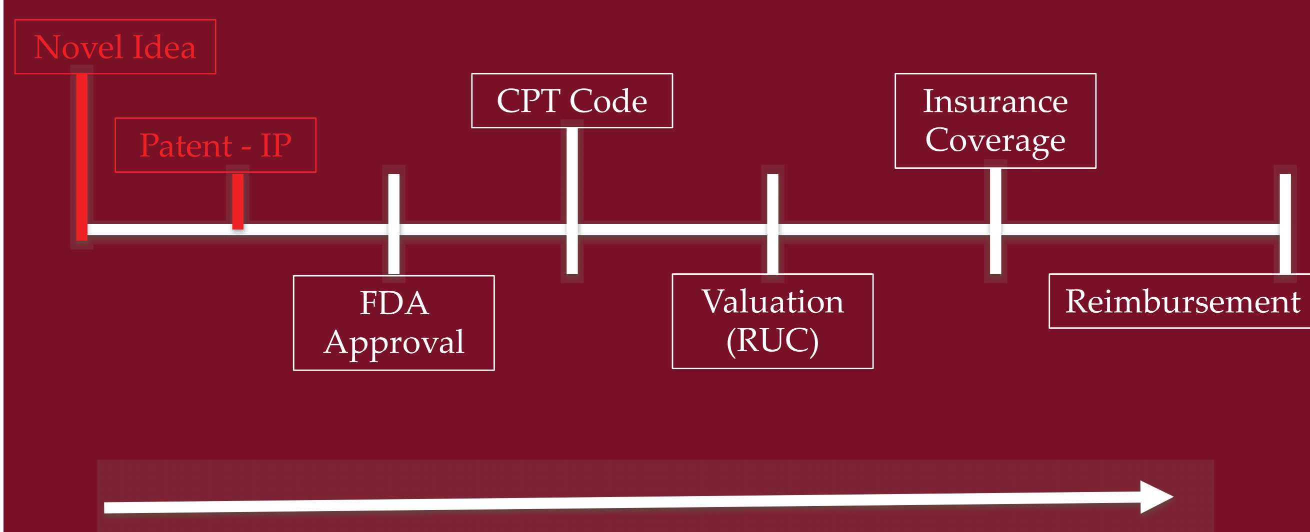

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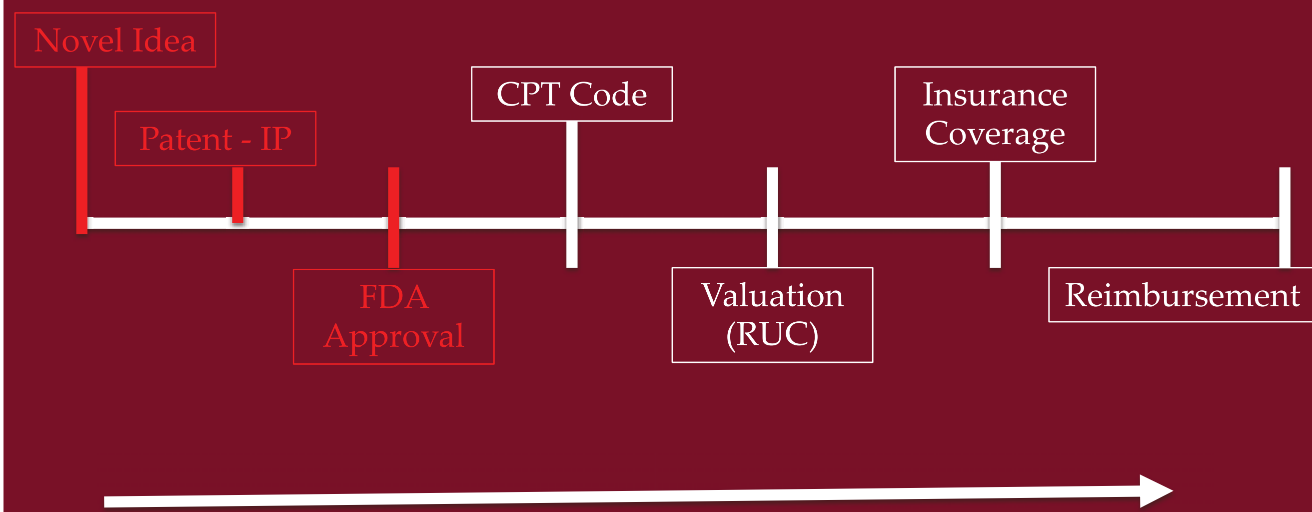
Timeline

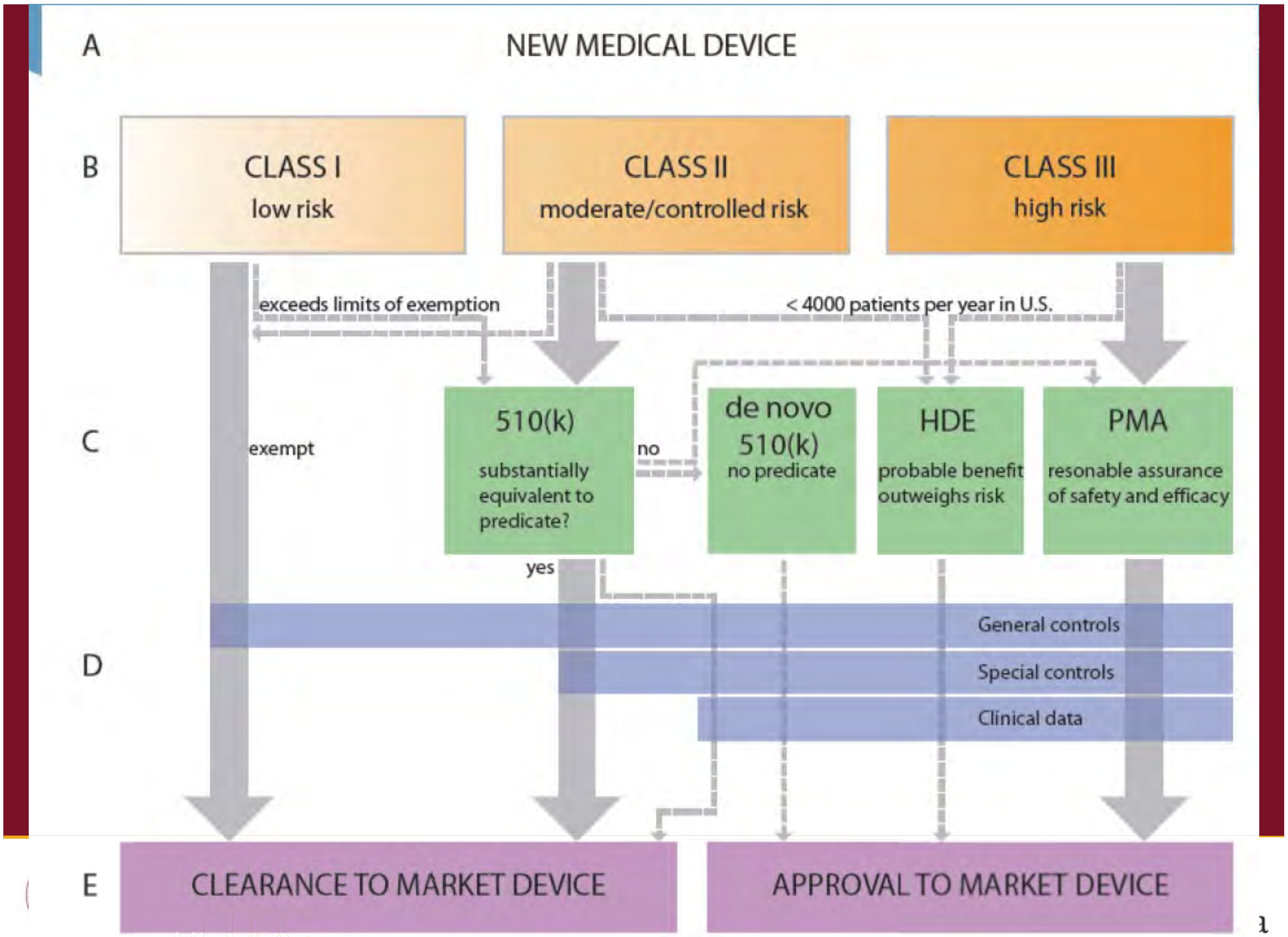


FDA Benefit-Risk Considerations

Assessment of Benefits:
- Type
- Magnitude and duration
- Probability of patient experiencing benefit

Assessment of Risks:
- Severity, type, number and rates of harmful events
- Probability of harmful event
- Duration of harmful event

Additional Factors:
- Type of submission: IDE, 510(k), HDE, PMA
- Type of study: EFS/FIH, feasibility, pivotal
- Uncertainty
- Characterization of Disease
- Patient tolerance for risk
- Availability of alternative treatments
- Risk Mitigation
- Novel technology addressing unmet need



Basic IDE Submission Elements

- Cover Letter
- Report of Prior Investigations
  - » prior clinical, animal, and laboratory testing of the device
- Detailed Device Description
- Investigational Plan
  - » Purpose (Proposed Indications for Use and objectives)
  - » Protocol
  - » Risk Analysis (description and analysis of all increased risks and how these risks will be minimized)
  - » Monitoring Procedures

Basic IDE Submission Elements

- Informed Consent
- Investigator Agreement & List of Investigators
  - » Certification that all investigators have signed the agreement, that the list of investigators includes all investigators participating in the study, and that new investigators will sign the agreement before being added to the study
- List of IRBs that have or will be asked to review the investigation
- Copies of all labeling for the device

FDA Decisions on IDEs

- **Approval**
  - » Approves the trial for a specified number of patients and investigational centers
  - » Subjects not exposed to unacceptable risks, even if study is not adequately designed to demonstrate the device is safe and effective
- **Conditional Approval**
  - » Trial may begin if conditions (deficiencies) are addressed within 45 days.
  - » Generally due to non-clinical testing issues, minor issues w/ informed consent, other clarifications, corrections, or modifications

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

FDA Decisions on IDEs

- **Disapproval**

The risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, the investigation is scientifically unsound, or there is reason to believe that the device as used is ineffective

» Trial may not start until deficiencies are adequately addressed
» Primarily related to subject protection (e.g., critical preclinical testing and study design concerns related to subject safety)

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FDA Additional Comments on IDEs

- **Study Design Considerations**
  » Additional modifications that FDA believes are needed in order for the study design to support a marketing approval or clearance (Pivotal Trial) or a future study (Feasibility Study)
  » Recommended (not required) modifications to the investigational plan
- **Future Considerations**

Additional considerations which FDA considers important for the support of a future submission, e.g., non-clinical testing not required for IDE but at the time of marketing application

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IDE Study Types

- **Early Feasibility Study (EFS):**
  - a limited clinical investigation (<15)
  - early in development, typically before the device design has been finalized, for a specific indication (e.g., innovative device for a new or established intended use, marketed device for a novel clinical application)
  - intended to provide proof of principle and initial clinical safety data
- **First in Human (FIH) Study:** a device for a specific indication is evaluated for the first time in human subjects.

A FIH can be a EFS, but not all FIH studies would be considered EFSs.

IDE Study Types (cont.)

- **Traditional Feasibility Study:**
  - to capture preliminary safety and effectiveness information on a near-final or final device design
  - to adequately plan an appropriate pivotal study.
  - does not necessarily need to be preceded by an early feasibility study
- **Pivotal Study:**
  - to collect definitive evidence of the safety and effectiveness of a device for a specified intended use, typically in a statistically justified number of subjects.
  - may or may not be preceded by an early and/or a traditional feasibility study.

Different Stages of Development

- Supporting evidence may vary for different stages of development
- EFS→Feasibility→Pivotal→PMKT
- Subject safety critical at each level
- Increasing emphasis placed on collecting effectiveness data and completion of additional testing (e.g. bench) needed to premarket submission

FDA Approval

- Long and complicated process
- It can fail
- Lose your investment
- 510k pathway – average cost $31 million
  - 4,000 applications each year
- PMA pathway - average cost $94 million
  - Less than 100 PMA applications each year

Managing Spinal Disorders: New Technologies/Procedures

- How are we doing to pay for the treatment of spinal disorders?
- Cost of development of new technology
- Certain requirements
  - No change
  - Safety/efficacy
- Barriers
  - Past failures – learn some lessons

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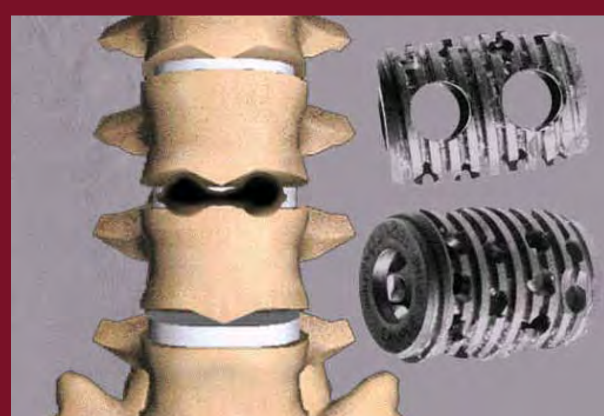
Managing Spinal Disorders: New Technologies/Procedures

- Barriers - reluctance to try
- Certain devices have failed
  - Sold outside of US
  - Indications have failed/discontinued
- Some devices with limited lifespans
- Some devices with complications
- IP may only last 20 years



Managing Spinal Disorders: New Technologies/Procedures

- More scrutiny on new technologies
- Support the ones that advance science and patient outcomes
- Eliminate the ones that likely to fail or lead to complications
- Do not want to stunt the growth of novel technology
- Consider the total number – competing studies

Managing Spinal Disorders: New Technologies/Procedures

- Limited funding – focus on some technologies
- Some vetting process – requires some coordination
- Innovations coming from companies
- Some working backwards from the need or potential market
- Base choices on science not the amount of money – greater success

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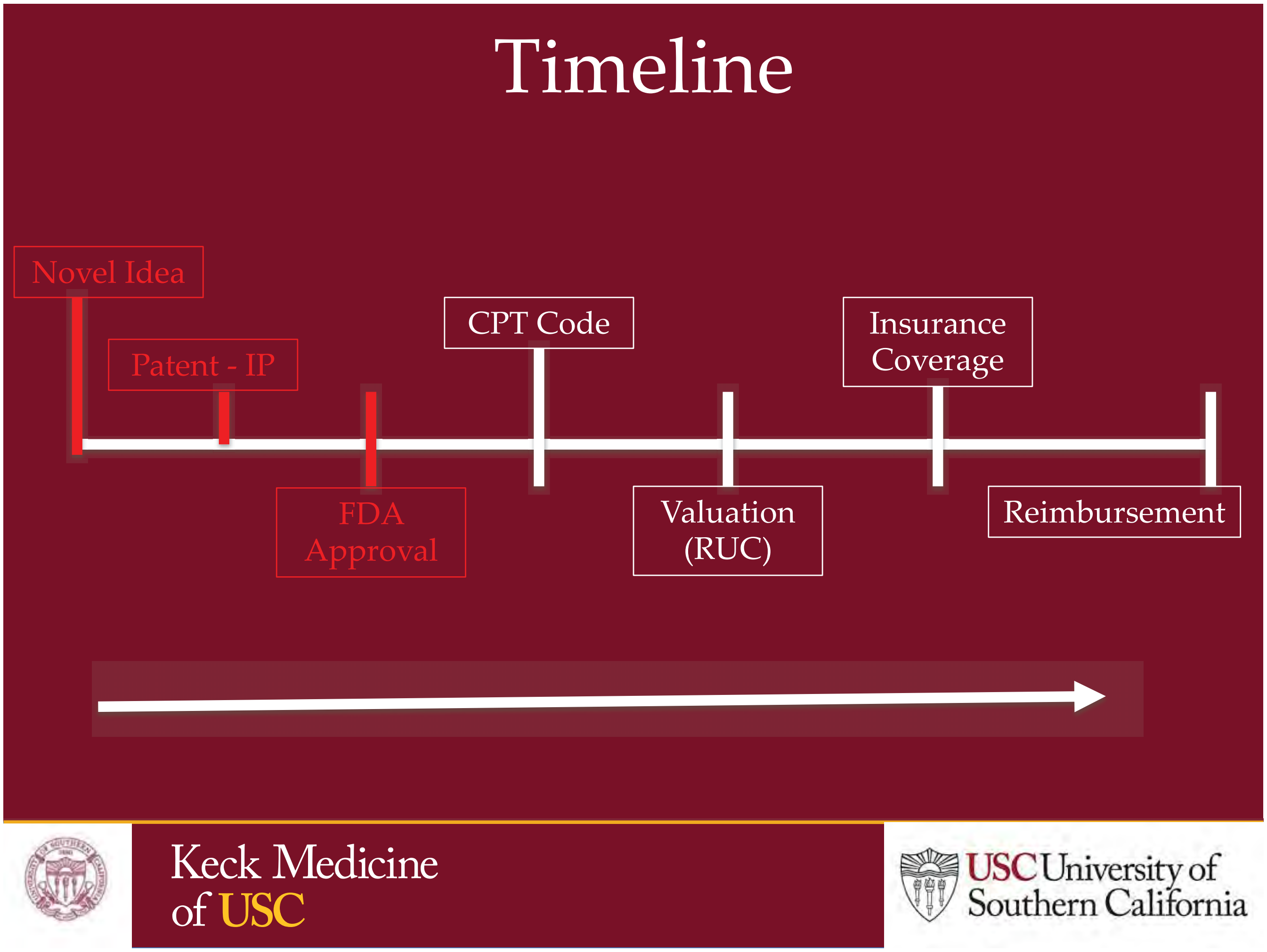
Timeline
Novel Idea
Patent - IP
CPT Code
Insurance Coverage
FDA Approval
Valuation (RUC)
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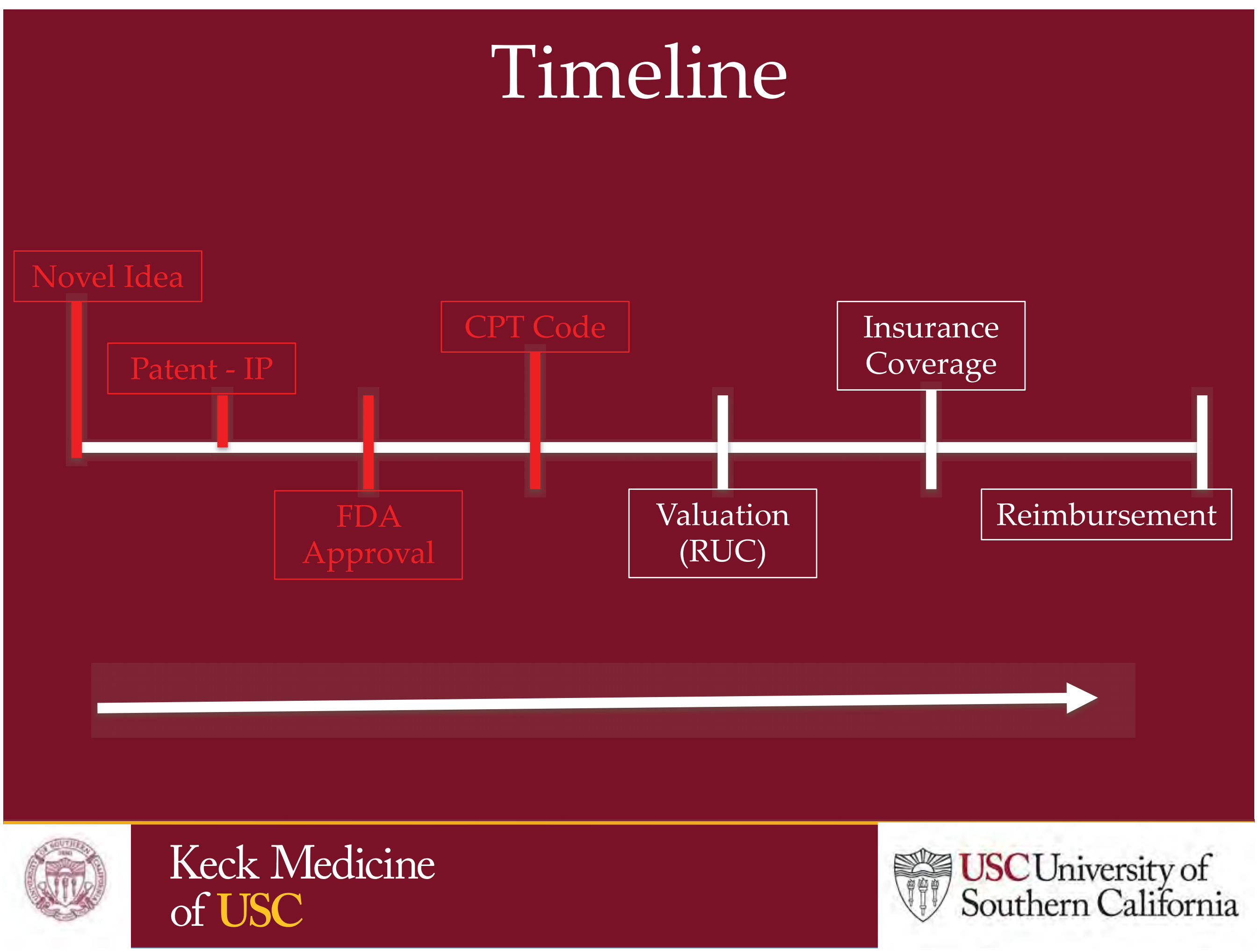
Timeline
Novel Idea
Patent - IP
CPT Code
Insurance Coverage
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Reimbursement For Novel Technology

- FDA approval
- How to be able to integrate and use this novel idea?
- Practitioners interested in new technology
- “advertise” and market studies in efforts to attract interest

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Reimbursement For Novel Technology

- Need CPT code for new procedures
- Category I code
- Category II code
  - Tracking code
  - Performance measures
- Category III code
  - New and emerging technologies

● ▲	CPT Code	Description
●	99453	Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment
●	99454	Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days
●	99457	Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month

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CPT Code Workflow

1. A new procedure, technology, or performance measurement is introduced.
2. The new item does not fit into an existing code
3. A coding request form is submitted
4. AMA staff review the coding suggestion
5. If it is a new request the CPT Advisory Committee reviews it
6. If the CPT Advisory Committee decides a new code is NOT needed the AMA staff inform the requestor and inform them on how to use existing codes to report the procedure.
7. If the CPT Advisory Committee agrees a change should be made it is then referred to the CPT Editorial Panel
8. The CPT Editorial Panel can result in three outcomes; 1. Add new code or revise existing nomenclature, 2. Postpone/table an item to obtain further information, 3. Reject an item.
9. If the request is rejected the requestor could appeal the rule.
10. To appeal the AMA must receive a written request that contains the reasons why the CPT Editorial Panel's decision was incorrect. This must be done within one year of the initial request.
11. When the appeal is submitted it goes to the CPT Executive Committee for review

Reimbursement For Novel Technology

- CPT code process complicated
- Time-consuming
- Not always successful
- Try to use existing codes
- Unlisted code and negotiate with carriers
- Lobby spine societies on CPT advisory panel – timing of revisit
- Lobby CMS to use existing codes
- Lobby insurance companies to pay for unlisted codes
- Lobby surgeons to utilize technology to show patterns of usage which are part of the tracking codes

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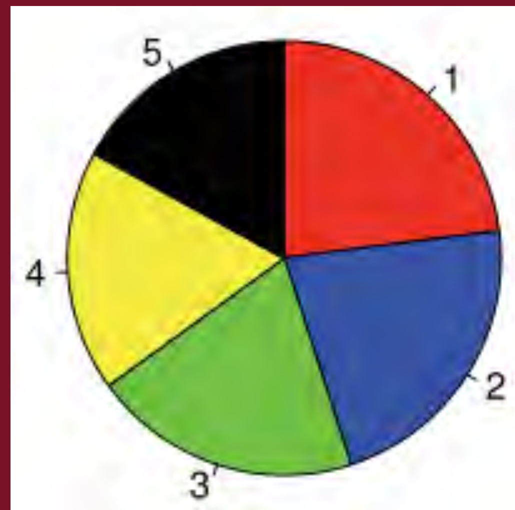
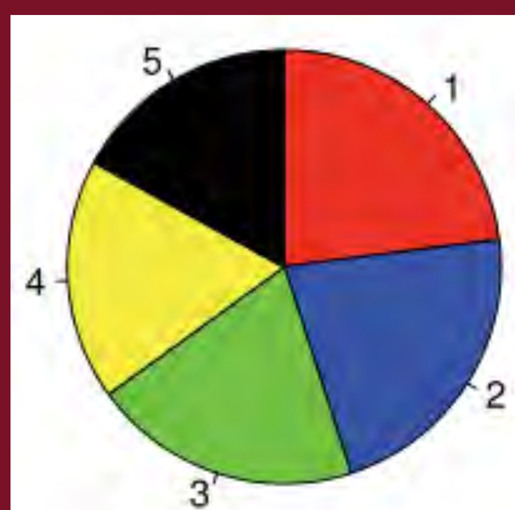
Managing Spinal Disorders: New Technologies/Procedures

- More scrutiny on new technologies – CPT codes
- Support the ones that advance science and patient outcomes
- Eliminate the ones that likely to fail or lead to complications
- Do not want to stunt the growth of novel technology
- Consider the total number



Managing Spinal Disorders: New Technologies/Procedures

- Each new technology seeking CPT code
- Leads to examination of current procedures
- Any code relating to aspect of new code (decompression)
- Devalues what current procedures
- Need new technology that advances patient care
- Will lead to decreased reimbursement



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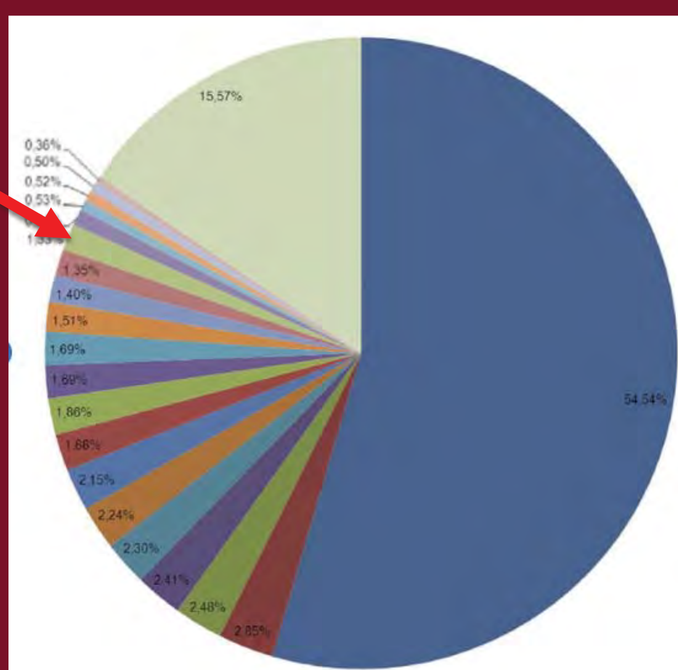
Managing Spinal Disorders: New Technologies/Procedures

Lumbar Surgery

New Device or Procedure



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Reimbursement For Novel Technology

- Limit new technology
- Vetting process
- AMA House of Delegates spine societies need to be aligned
- CPT Panel has advisors – societies in the house of delegates
- If the spine societies are not aligned, will have less influence
- CPT panel – multispecialty – makes decisions
- Not always aligned - right large issue affecting TLIF surgeries in contention right now

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Reimbursement For Novel Technology

- Alignment
- AMA House of Delegates
- NASS
- AANS
- AAOS
- Other spine societies
- Very knowledgeable volunteers on all sides
- No right or wrong answer
- Need to work together - Alignment

Overview

- Development of New Technologies
  - Timeline
  - Patents
  - FDA Approval
  - CPT Coding
  - Valuation
  - Reimbursement
- Future of Spine
- Novel Technology

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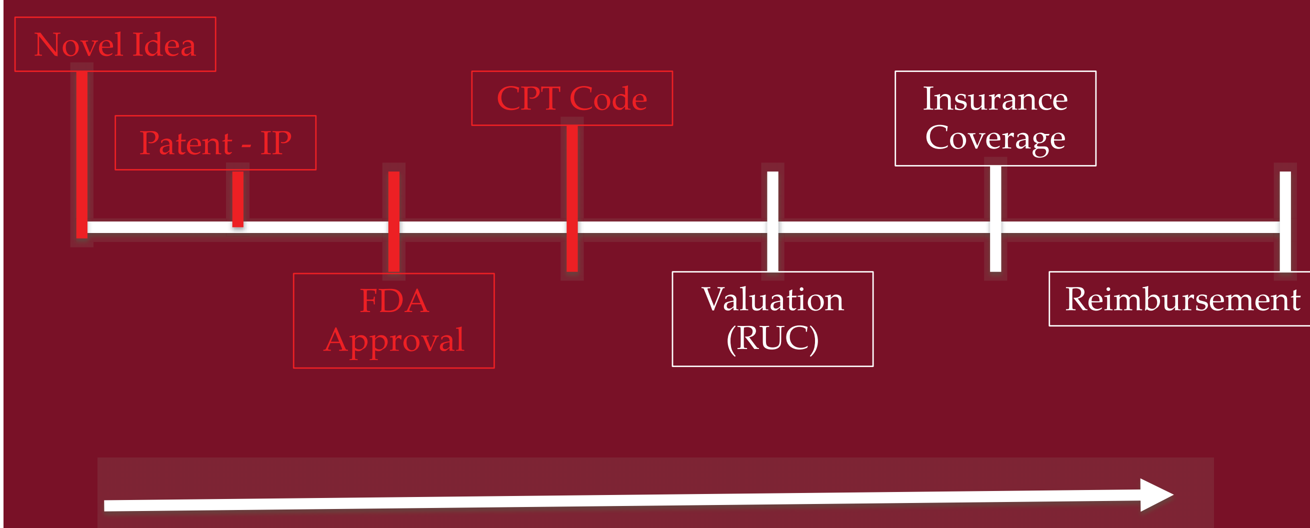
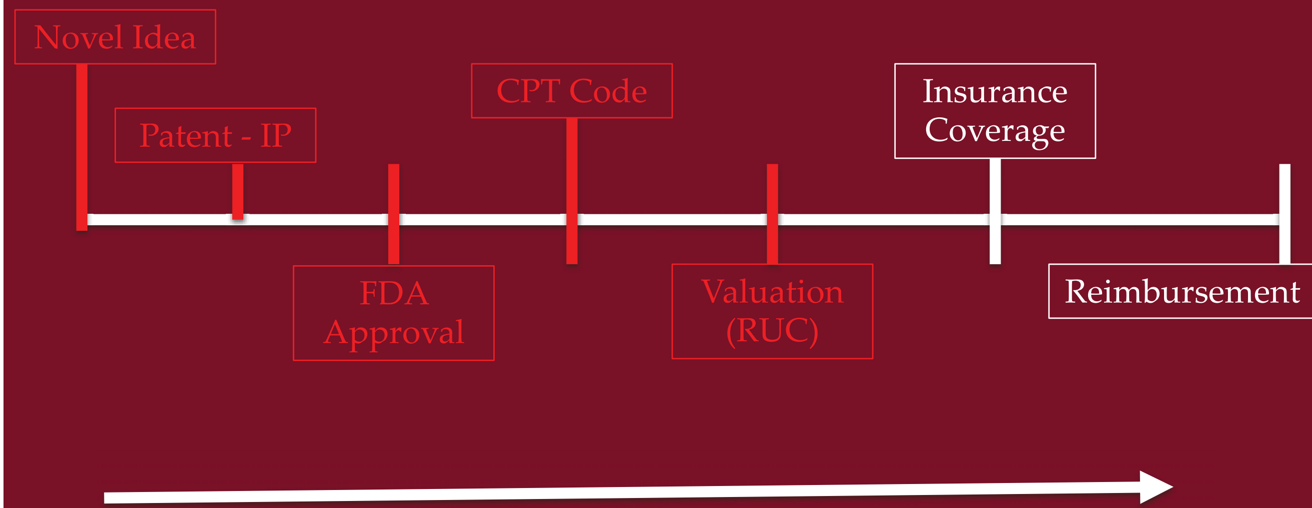
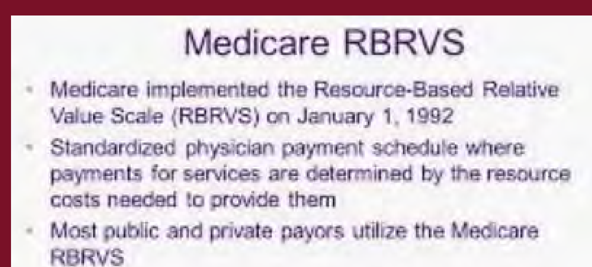


Timeline



Reimbursement For Novel Technology

- CPT panel makes recommendation to CMS for code
- Valuation of code
- AMA Relative Value Scale Update Committee (RUC)
- Makes CPT code value recommendations to the government


Medicare RBRVS

- Medicare implemented the Resource-Based Relative Value Scale (RBRVS) on January 1, 1992
- Standardized physician payment schedule where payments for services are determined by the resource costs needed to provide them
- Most public and private payors utilize the Medicare RBRVS

RUC Panel – Value of Procedure

- How to determine value of procedure?
- Vignette of procedure – time
- Intensity of procedure
- Risk involved
- Malpractice implications
- Regional variations for cost of living
- RUC Panel – advisors from organizations

Managing Spinal Disorders: New Technologies/Procedures

- Barriers – similar
- New technologies devalue current reimbursements
- Time
  - New time surveys on existing comparative procedures
  - PEEK cages for fusion
- Other aspects of valuations
  - Ease, intensity, risk involved
  - All lead to less value of procedure
  - Re-examine similar parts of current procedures

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Managing Spinal Disorders: New Technologies/Procedures

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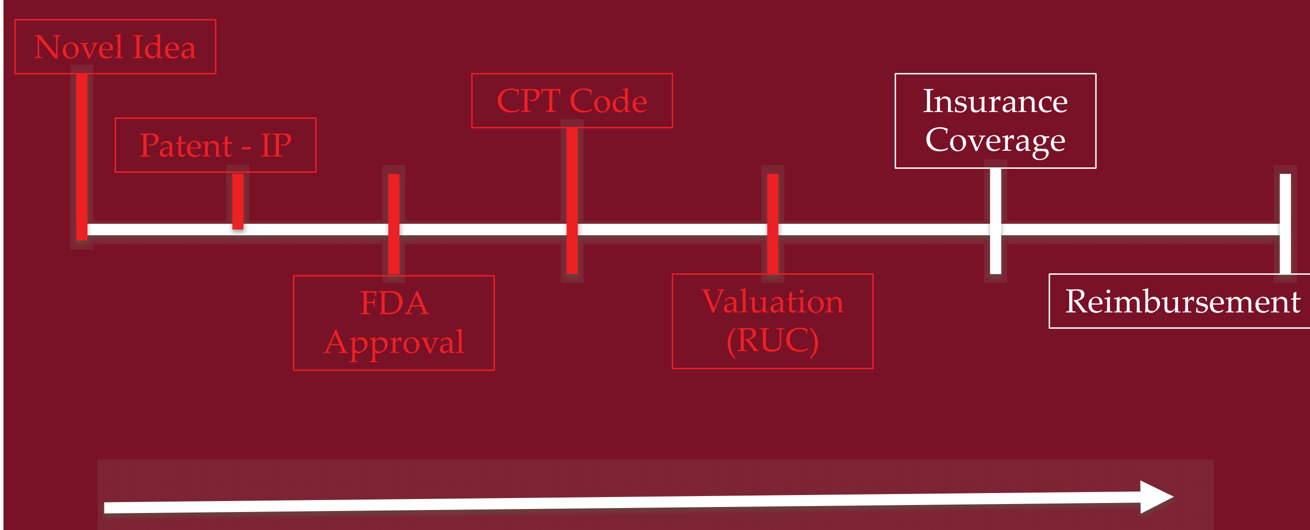

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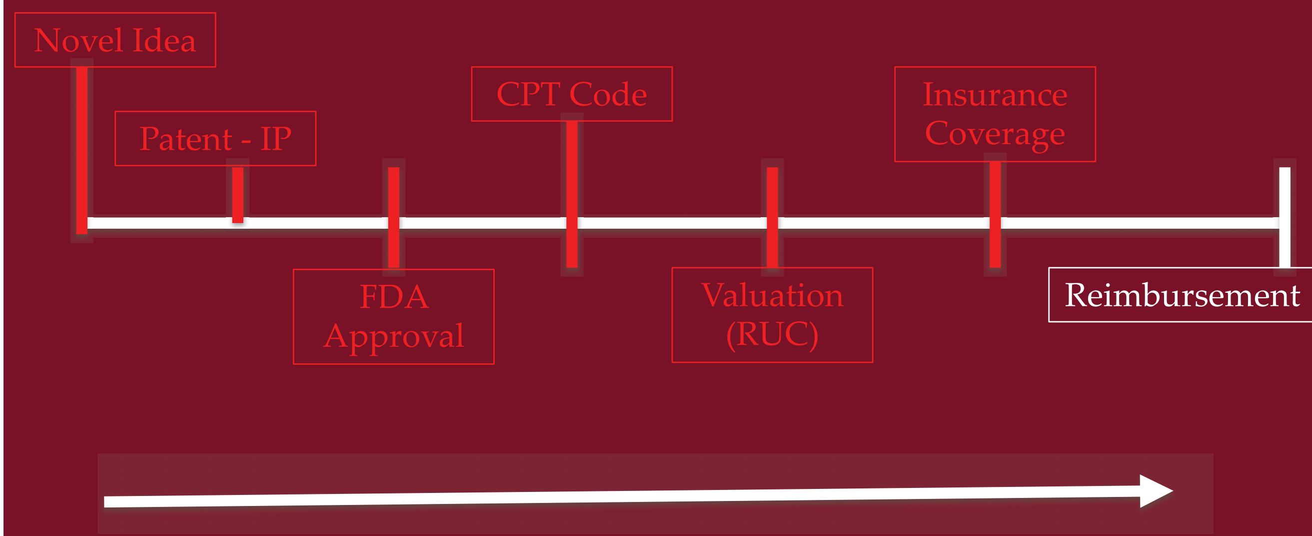

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Payment

- Novel technology with CPT code and defined reimbursement
- Insurance companies
- Coverage policies
- Allow the procedure – will reimburse for procedure
- Significant problem with the increasing costs of healthcare

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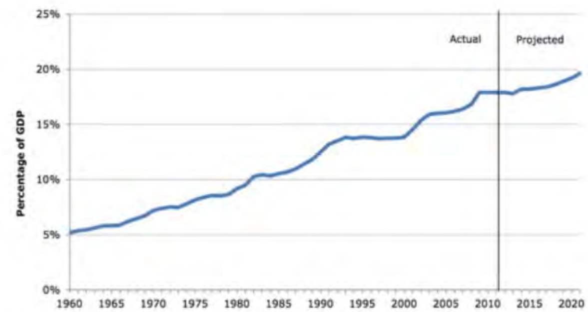
Payment

- Barriers
- Increased costs with novel technology
- Recoup costs of development/investment
- Reluctance to pay for each new procedure
- Need evidence that the procedure works
- Does the procedure improve patient care beyond the current available solutions?
- Less costly solutions?

Figure 2: U.S. National Health Expenditures as a Share of GDP, 1960-2021



Source: Centers for Medicare and Medicaid Services.

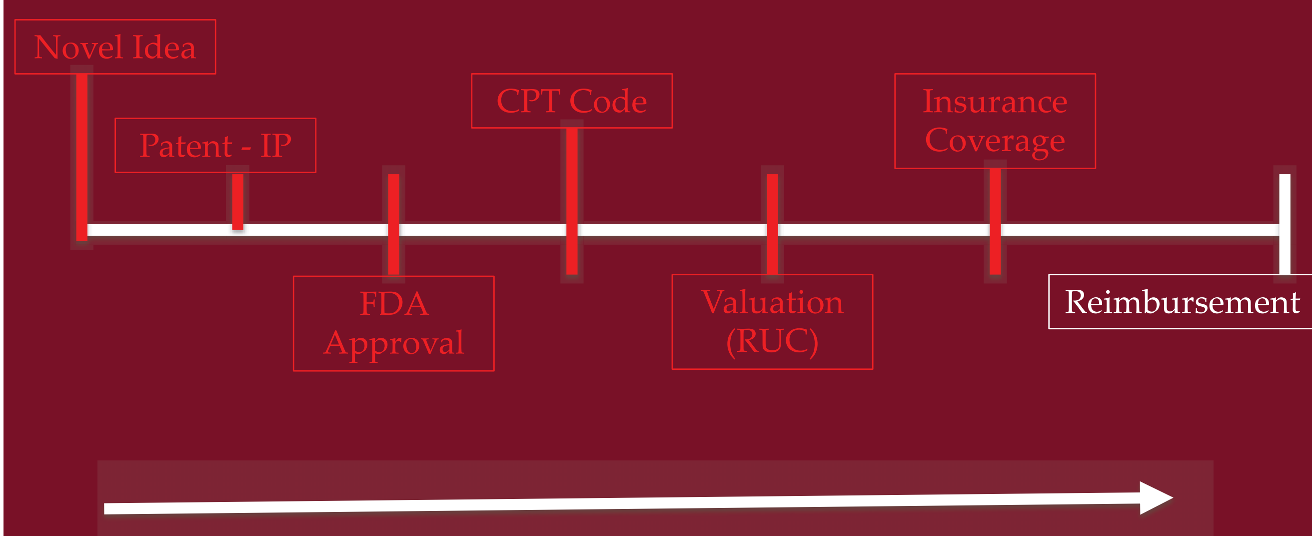
Payment

- Lumbar disc arthroplasty
- Had surgery at outside hospital
- Paid for surgical implant with cash
- Years later needed revision
- Insurance refused to cover costs of procedures

Payment

- Coverage policies
- Spine societies involved
  - Guidelines
  - Help in emergent situations
- Evidence-based coverage recommendations
- Need alignment
- Need evidence
- Novel Technologies
  - Companies pushing societies
  - Overwhelming number - volunteers

Timeline



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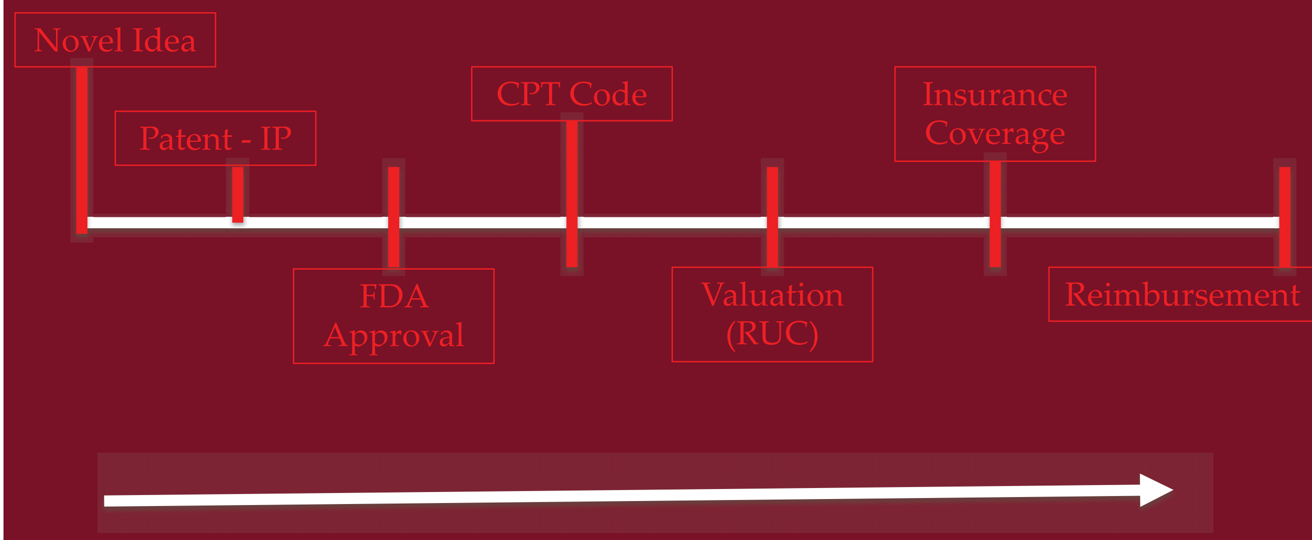
Timeline

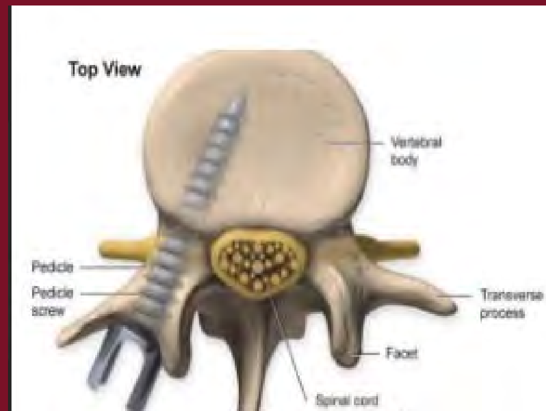


Reasons for Health Care Reform

- **Health care costs are increasing** at an alarming rate.
  - 2012: **$2.8 Trillion**, or 17.2% GDP
  - 2011 → 2012 1.4% Increase hospital expenditures → **$882 Billion**
- **Cost** of surgical procedures has increased.
  - 1985 Spinal Fusion : $9,915
  - 2003 Spinal Fusion : $63,555
- **Number** of fusions has **increased 137% in 10 yrs.**
  - 2008: 238,948 fusions
  - vs. Laminectomy (11.3%), hip replacement (49%), angioplasty (38%)

Reasons for Health Care Reform

- Current national expenditures are **UNSUSTAINABLE.**
- Known heterogeneity in delivery of spine care nationally.
  - Common pathologies
  - Spine Surgery is an easy target
  - Burden on Surgeons/Hospital/Government
  - How Does Novel Technology Fit?
    - Game-changing
    - New pedicle screw



Changes at the Ground Level

All stakeholders (payors, institutions, physicians) are maneuvering

Increased Denials

Drastically Competitive Implant Contracts

Decreased Reimbursements

Alternative Payment Models

Novel Technology?

Tighter Institutional Financial Margins

See more pts With less Resources

Lower Incomes

Better Patient Outcomes ?

Less Surgery?

Principles of Value Based Care

The Treatment with the Most Value will be the most effective at the lowest cost to society and the patient.

3 Main Economic Analyses

TABLE 2. Components of Decision Analysis Methods

	Cost	Outcome
CBA	Monetary value	Monetary value (dollars gained or saved)
CEA	Monetary value	Disease or condition-specific units of outcome
CUA	Monetary value	Health status preference (utility) quality-adjusted life years

CBA indicates cost-benefit analysis; CEA, cost-effectiveness analysis; CUA, cost-utility analysis.

From Angevine et al, Spine, 2014

Cost Utility Analysis - CUA

- **The most commonly accepted model for measuring patient reported *HEALTH STATUS.***

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Quality Adjusted Life Year (QALY)

- The most-used effectiveness measure that *combines* ***quality*** *of life and* ***length*** *of life in a single number.*

- QALY is estimated by multiplying the time spent in each health state by that health states utility and then summing up.

- Example:
  - 5 yrs perfect health (1), 3 yrs limited mobility (.85), 2 yrs moderate pain (.7)
  - (5 x 1) + (3 x 0.85) + (2 x 0.7) = 8.95 QALY

et al. Spine 2014

CUA Example: Surgery vs. NonOp for Lumbar HNP

TABLE 1. Results of Example Cost-Utility Analysis Shown in the Figures

	EV Cost ($)	EV Outcome	C/E Ratio ($/QALY)	Δ Cost ($)	Δ Outcome (QALY)	ICER ($/QALY)
No surgery	500	0.86	581	—	—	—
Surgery	5100	0.96	5312	$4600	0.1	46,000

Δ Cost = (cost of surgery) − (cost of no surgery).
Δ Outcome = (outcome with surgery) − (outcome with no surgery).
EV indicates expected value; C/E, cost-effectiveness; QALY, quality-adjusted life year; ICER, incremental cost-effectiveness ratio.

In general in the U.S., $60,000-$100,000 is an acceptable cost per QALY gained. Note, this is a SOCIETAL judgment, not a MEDICAL one.

Example: Surgery provides a clinical benefit over non-operative care at a cost below society's willingness to pay threshold.

Angevine et al, Spine, 2014

The Future of Spine Surgery

- Health Economic Analysis integrate cost and clinical outcomes data to determine economic impact for any clinical gain between treatments.
- CBA, CEA, CUA are all examples.
- ***CUA will have a major role in shaping the future of what we do as spine surgeons.***

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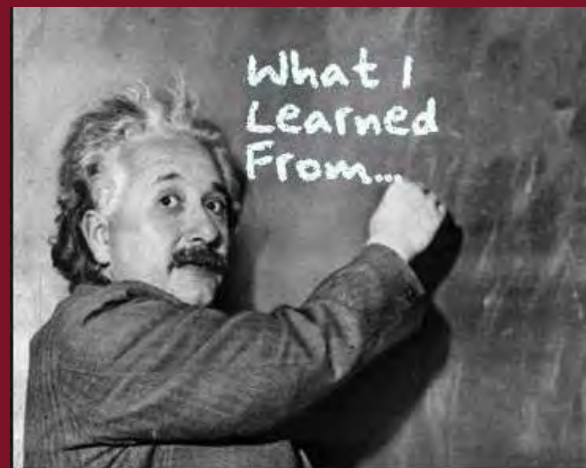
- CDR more cost-effective than ACDF for single-level cervical radiculopathy or myeleopathy
- Anterior surgery more cost-effective than posterior surgery for CSM at 1 year
- PCF more cost-effective than ACDF for radiculopathy at 2 years
- Future – cannot make decisions based on costs alone



Value Driven Healthcare

- US Healthcare is different – no national plan
- Medicare for those over age 65
- Insurance companies follow Medicare rates when in their best interests
- Rationing healthcare is less common
- Strategies
  - More value-driven initiatives
  - Cutting costs
  - Penalties for poor evaluations
  - Limiting new technologies based on lack of evidence

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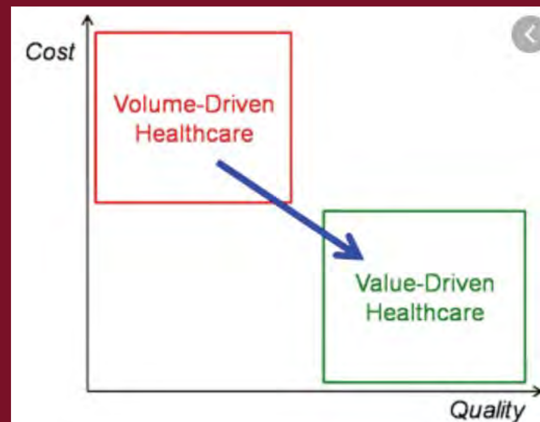
  - Limiting new technologies based on lack of evidence

Value Driven Healthcare

- Huge administrative burden
- Entire departments to meet requirements
- Look at coding/hospital stay/proper classification of patients
- Complications/re-admissions/re-classifications
- Proper coding of procedures/education of physicians
- Proper documentation – faculty meetings to discuss ongoing processes
- New Technology?

Value Driven Healthcare

- Strategies to decrease costs and payments
- Bundled payments for episode of care
  - Knee replacement/lumbar discectomy/ACDF
- Bundled coding for individual procedures
  - Lumbar interbody fusion – no decompression codes
  - Cervical disc arthroplasty – cervical fusion
- Novel Technology?



Value Driven Healthcare

- Try to maintain value of what we do now – preserve "traditional technology"
- TLIF – classified as an outpatient procedure
  - Inpatient requires justification
  - Re-look at coding reimbursements
  - Reimbursement based on time
  - MIS TLIF more than traditional TLIF
  - Not all patients can be done as an outpatient
  - What if this becomes the standard?
  - Sets the stage for policy on all patients having that procedure

Outpatient Minimally Invasive Lumbar Fusion

Minimally invasive spine surgery in an outpatient setting

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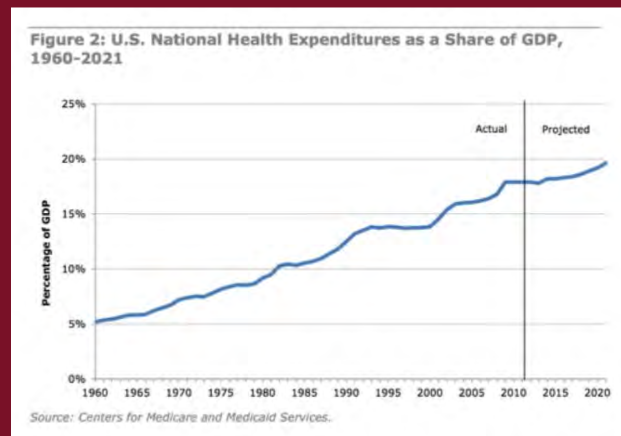
- **Cost** of surgical procedures has increased.
- **Number** of fusions has **increased 137% in 10 yrs**
- **UNSUSTAINABLE**
- **Novel Technology?**



Value Driven Healthcare

- Does novel technology typically save money?
- Soegaard et al. Spine 2007
  - Cost Utility Analysis that circumferential fusion dominant over posterolateral fusion
  - Significantly cheaper, better in long-term
  - For each QALY gained incremental savings estimated at $49,306
- Soegaard et al. Eur Spine J 2007
  - Significant increase in operative costs for anteroposterior group
  - rhBMP-2

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What is the Future – Spine Issues and Novel Technology?

Every American has a

1 in 4

Chance of Becoming Disabled

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25%

of All US Citizens
Will Become Disabled
Between the Ages of 20 - 65

Spinal Impairment

is the Leading Cause

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Back and Neck Pain

Cause More Disability World-Wide Than Any Other Disease or Disorder

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Spine Related Disability

Increased by 300%

In The Past 50 years

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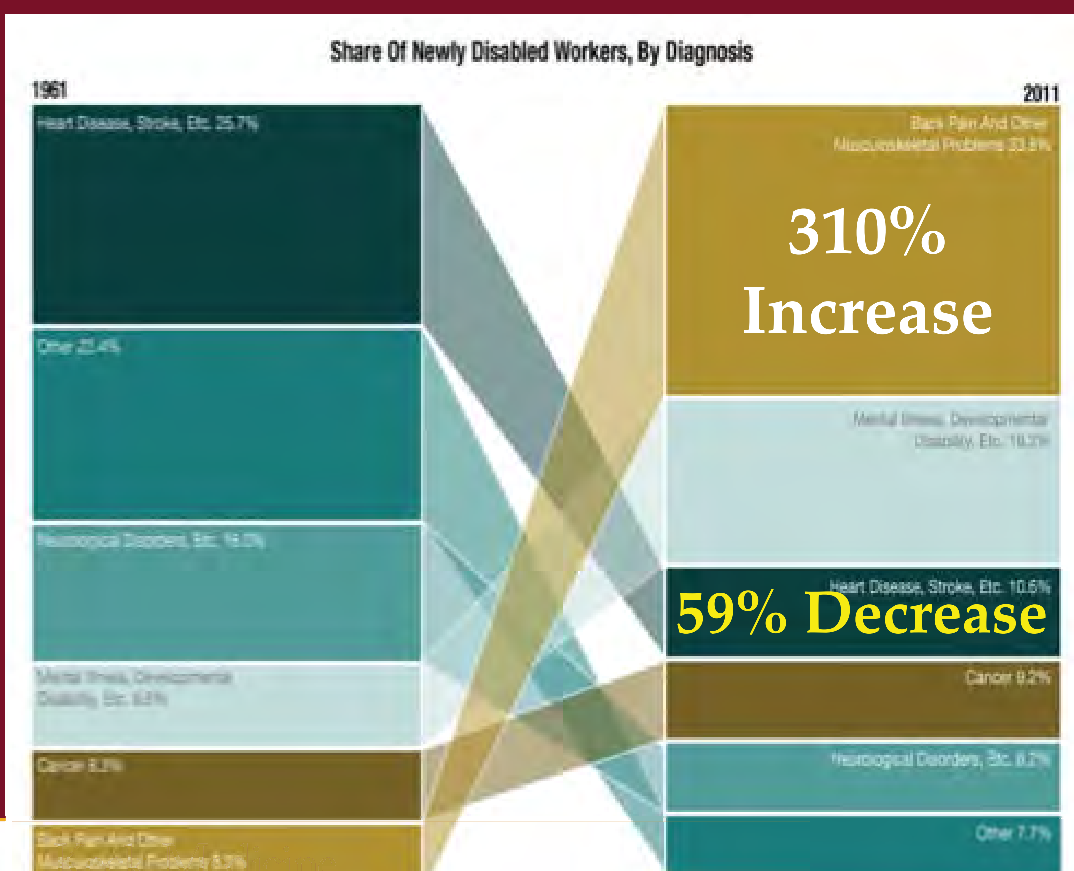
Global Burden of Disease
Bill & Melinda Gates Foundation

- Spinal impairment is NOW the leading disease burden in the world
  - Greater impact on health than ANY other disease or disorder:
    - Diabetes
    - Lung Cancer
    - Tuberculosis
    - Malaria

- > $600B spent annually in U.S. on spinal disorders



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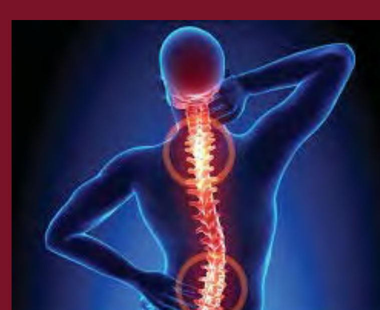
Why Should We Care?

- 85% of the population will experience a significant episode of spine-related pain during life span
- U.S. children have a 25% risk of becoming disabled during their working years (21 – 65)
  - Most common cause is spine impairment
- Disability = 23% ↓ in your annual earnings
  - 71% more likely to reach poverty level

Opiate Abuse

Future of Spine

- We will always have patients
- They will need care for their spine
- Need to determine how to manage it
- Novel technology
- Try to be responsible
- Growing problem



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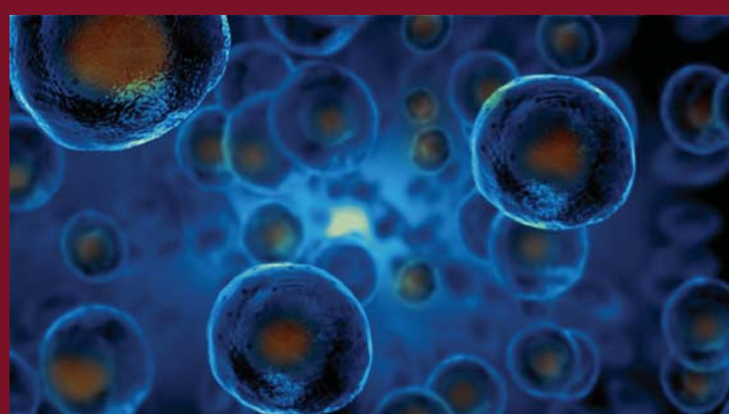
Managing Spinal Disorders: New Technologies/Procedures

- You now understand the process of the development/integration of new technology
- You understand the barriers and perhaps how to optimize things for the future
- You understand the costs of healthcare/spine are unsustainable – growing
- Solutions – reform
  - Government reform – lobby efforts (minimal)
  - What can we do?

How We Do It Today

- This is how we do this today
- Look at the other point of view
  - Patient
  - Payors
  - Government agencies
- Stem Cells
- Disclaimer
  - I do not know your fine print
  - I am comparing the generalized class together



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Center for Regenerative Medicine

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- Neurologic
- Autoimmune
- Age-Related Inflammation
- Immune Restoration
- Lyme Disease
- Chronic Wounds
- Urologic Conditions

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SEARCH

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Stem Cell Therapy Reviews & Testimonials for Back Pain

We love feedback about the results of your stem cell therapy for back pain

ThriveMD is excited to be receiving reviews about stem cell treatment for back pain on social media, along with testimonials during patient follow-ups at our premier stem cell clinics in Vail & Denver, CO. Patients often write about their stem cell therapy experience for low back pain, which is commonly due to degenerative discs, herniated discs; and for facet pain. Both chronic or acute.

We also regularly update our stem cell patient case studies, where you can find detailed descriptions of the patients' paths to back pain relief and results. Timing of the stem cell procedure is one of the key factors.

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Last Name (required)

- Regenerative Treatments Help Your Body Heal Faster and More Complete.
- Patented Procedures - 100% Focused on Orthopedic Conditions.
- Backed by Extensive Research.
- Published Patient Outcome Data.
- Precision Image Guided Injections Ensure Top Results.

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Stem Cell Treatments Provide Hope for Easing Back Pain

Stem cell surgery relieved golfer Jack Nicklaus of a lifetime of back pain. But experts say it's too early to tell whether this treatment is for everybody.

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alifornia

Hall of Fame golfer Jack Nicklaus used stem cell treatment for his back pain.

Personal Experience

- Stem Cells for spinal disorders
- Kobe Bryant injection
- One of many stem cell treatments available
- Research as a medical student
- Wanted to develop this at USC
  - Study outcomes
  - Legal issues control of the data
  - Why would they want to collect data?
  - Taiwan Orthopaedic Surgeon

Managing Spinal Disorders: New Technologies/Procedures

- Stem Cells
- Too many types/treatments
- Patients paying cash
- Patients are being told this is the latest treatment
- Marketing – advantages over competitors
- Some companies do not want public studies
- Several studies – do not know preliminary data – industry driven

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Managing Spinal Disorders: New Technologies/Procedures

- What if you invented a stem cell treatment that worked?
- Market is flooded with claims of stem cell treatments that work
- Development will be crowded
  - Patents
  - Studies – competing
  - Insurers – codes – valuation
  - Spine societies

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- Too many types/treatments
- Patients paying cash
- Patients are being told this is the latest treatment
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- Some companies do not want public studies
- Several studies – do not know preliminary data – industry driven

Personal Experience

- Disc Cure
- UCLA Medical Plaza
- Patented injection of Enbrel
- Advertised as alternative to spine surgery
- Patients are desperate for this alternative
- Cash payments
- Class-action lawsuit
  - Money donated to spine research
  - NASS

Etanercept

Etanercept is a biopharmaceutical that treats autoimmune diseases by interfering with tumor necrosis factor by acting as a TNF inhibitor. It has U.S. F.D.A. approval to treat rheumatoid arthritis, juvenile idiopathic arthritis and psoriatic arthritis, plaque psoriasis and ankylosing spondylitis. Wikipedia

Formula: $C_{2224}H_{3475}N_{621}O_{698}S_{36}$

Molar mass: 51234.9 g/mol g·mol^{-1}

Trade name: Enbrel, Benepali

Elimination half-life: 70–132 hours

Metabolism: Reticuloendothelial system (speculative)

People also search for: Adalimumab, Infliximab, Methotrexate, MORE

Manufacturer: Immunex Corporation, a wholly owned subsidiary of Amgen, manufactures ENBREL.

amgen.com

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Managing Spinal Disorders: New Technologies/Procedures

- NASS – guidelines
- Evidence-Based clinical guidelines
- Evidence does not support some of the currently available treatments for the treatment of chronic low back pain
- Affects entire groups of practitioners
  - Groups/specialties participated
  - End-results unfavorable
  - Dropped out of authorship
  - Lack of evidence – need to be willing to create the evidence for support

PERSPECTIVE

NASS releases guidelines for diagnosis, treatment of low back pain

The North American Spine Society announced the release of evidence-based clinical guidelines for multidisciplinary spine care for the diagnosis and treatment of low back pain.

The guidelines can help practitioners treat adult patients with non-specific low back pain above the knee, according to a press release issued by the North American Spine Society.

SEE ALSO

Several clinician characteristics predict low-value imaging

Significant site, regional influence seen in prevalence of seeking medical care, lost time due to low back pain

MRIs not always necessary for low back pain

"This is the largest clinical guideline NASS has ever undertaken," **D. Scott Kreiner, MD**, an Arizona physiatrist, co-chair of NASS' Evidence-Based Guideline Development Committee, and NASS Research Council Director, said in the release.

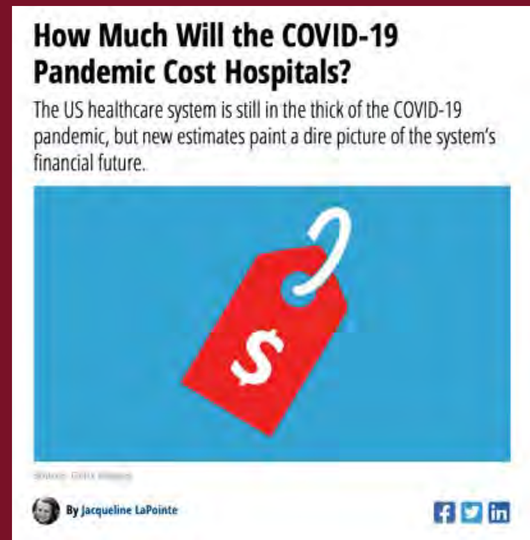
Eleven societies that offered stakeholder representatives to help develop the document and comment during its review. The Diagnosis and Treatment of Low Back Pain guideline document included over 45,000 literature search results and 82 clinical questions with more than 100 recommendation statements.

Need Reform in Reimbursement

- Covid-19 pandemic
- Importance of healthcare
  - Workers
  - Physicians
  - Equipment
- Must maintain treatments for Global problems
- Spine is important for the future
  - Novel Technology

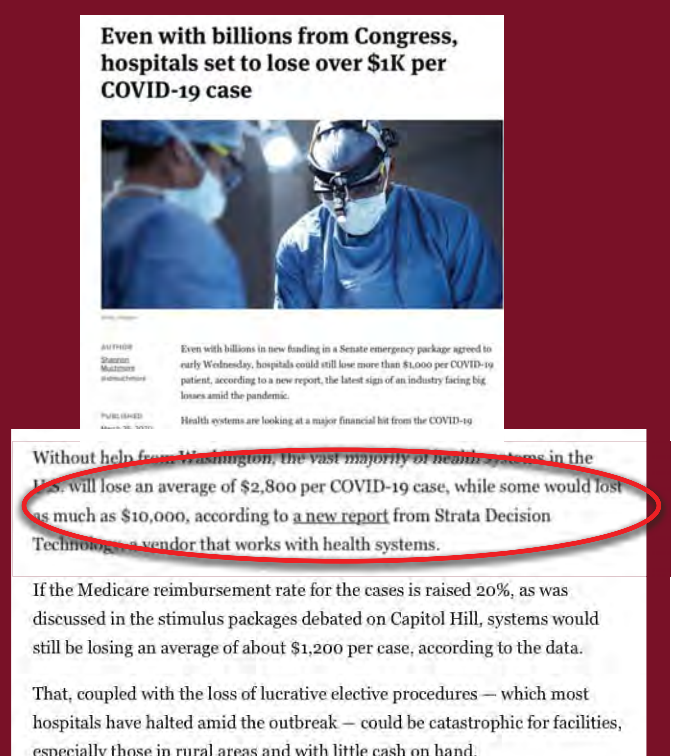
Need Reform in Reimbursement

- Covid-19 pandemic
- Hospital are so important
- Some are closing
- Some physicians retiring or closing practice
- May say they are not essential in this pandemic



Need Reform in Reimbursement

- If you sold lamps
- Everyone needed lamps
- You were so busy selling lamps, you were overwhelmed with selling lamps
- Business was great
- Losing money



Even with billions from Congress, hospitals set to lose over $1K per COVID-19 case

Even with billions in new funding in a Senate emergency package agreed to early Wednesday, hospitals could still lose more than $1,000 per COVID-19 patient, according to a new report, the latest sign of an industry facing big losses amid the pandemic.

Health systems are looking at a major financial hit from the COVID-19

Without help from Washington, the vast majority of health systems in the U.S. will lose an average of $2,800 per COVID-19 case, while some would lost as much as $10,000, according to a new report from Strata Decision Technology, a vendor that works with health systems.

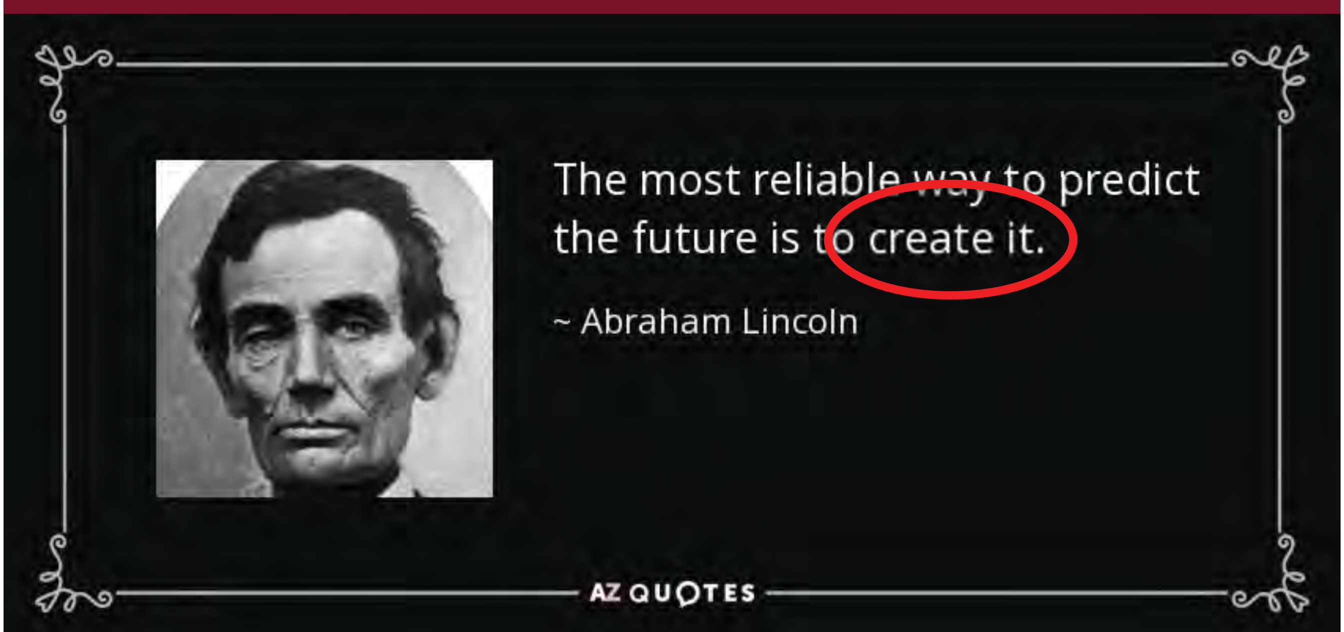
If the Medicare reimbursement rate for the cases is raised 20%, as was discussed in the stimulus packages debated on Capitol Hill, systems would still be losing an average of about $1,200 per case, according to the data.

That, coupled with the loss of lucrative elective procedures — which most hospitals have halted amid the outbreak — could be catastrophic for facilities, especially those in rural areas and with little cash on hand.

Keck Medicine of USC
USC University of Southern California

Managing Spinal Disorders: New Technologies/Procedures

- How are we doing to pay for the treatment of spinal disorders?
- How are we going to continue to advance the care of these patients?
  - Novel technology
  - Novel procedures
- Identify Barriers/Requirements for the future?



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Thank You

Lumbar Disc Herniation: Ambulatory vs. Inpatient

Tarun Arora, MD, MSPT, FAANS
Associate Professor, UCSF Neurosurgery

Disclosures

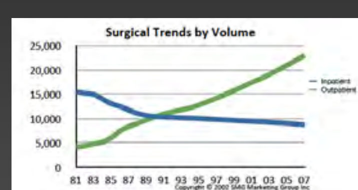
- Mizuho OSI-Consultant
- Spineart-Consultant

History and Evolution

- LBP is the NUMBER ONE cause of global disability
- Lumbar decompression with microdiscectomy is the most common spinal surgery
- Spine care costs: $100 Billion/year
- Short case, fitting for outpatient management

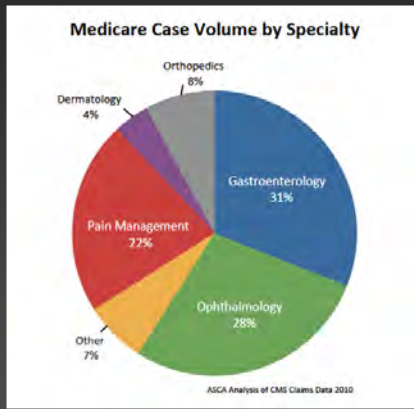
History and Evolution

- First outpatient lumbar microdiscectomy reported in 1987.
- Parallel rise in other outpatient procedures (eg. Endoscopy)
  - Patient and provider satisfaction.
  - Barrier: Perceived safety concerns



Ambulatory Surgery Centers

- First one opened in Phoenix, AZ in 1970
- Owned and operated by two physicians
  - Control over schedule
  - Control over quality
  - Specialized "teams"
  - Autonomy



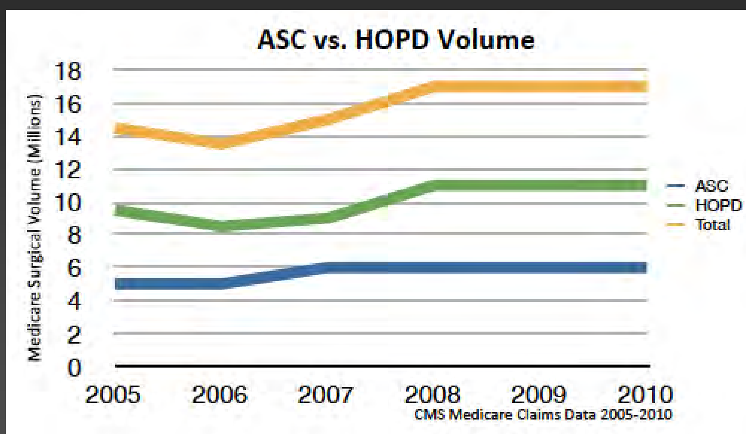
Who doesn't want a "good deal"?

- Value = Quality / Cost
- QUALITY of care
  - Clinical outcomes
  - Patient perception
  - Convenience
  - Expertise and Efficiency
- Can we decrease cost while maintaining or IMPROVING Quality?

“Inpatient vs. Ambulatory”

- Inpatient = Full service acute care hospital with > 24 hour Elective admission
- Hospital Outpatient Department (HOPD)
  - Division of acute care hospital
  - Can be discharged the same day OR up to 23 hrs observation
- Ambulatory Surgery Center (ASC)
  - Free standing, state licensed, federally reg
  - Up to 23 hour stay in Most states, BUT same calendar day discharge

Market Behavior

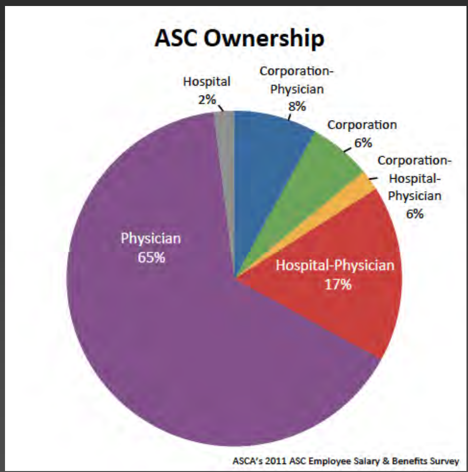


Push for Ambulatory

- Driver
  - COST
  - Physician control and efficiency (ASC)
- Enablers
  - Anesthesia/pain control
  - Technology→less invasive, faster, safer
- Derived Benefits
  - Efficiency
    - Smaller structure, less staff/overhead, no emergencies
    - Specialization-less case variety
    - Physician ownership→quick and focused changes
  - Value to payors and patients

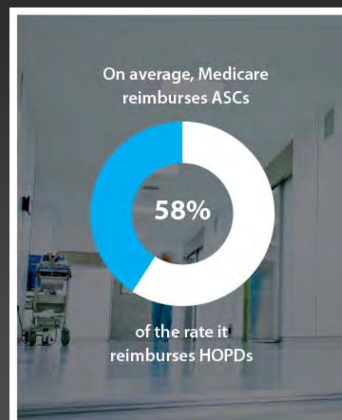
The ASC-Physician Relationship

- 90% of ASCs still have some physician ownership
  - Hospital
  - 21% of ASCs with Hospital co-ownership, 3% hospital only ownership



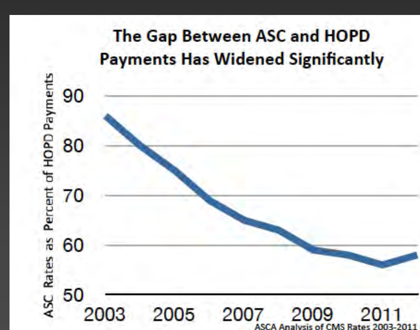
What drives cost difference?

- HOPD is part of an acute care hospital
  - Additional overhead
  - Reimbursement based on Hospital Market rate.
- ASC
  - Consumer price index urban consumer (CPI-U)
  - Lower rate of inflation, lower reimbursement



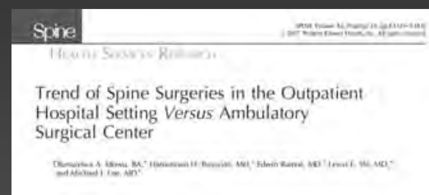
Reimbursement Gap

- Hospital bargaining power
  - More services available
  - 2003: 16% higher reimbursement
  - 2011: 72% higher reimbursement
- Hospitals converting ASCs to HOPDs



Trends in different settings

- Compare volumes of cases done at HOPD vs. "True" ASC with d/c same calendar day.
- FL, ME, MD, NE, RI, SC-States that specify d/c same


Spine

Trend of Spine Surgeries in the Outpatient Hospital Setting *Versus* Ambulatory Surgical Center

Trend of Spine Surgeries in the Outpatient Hospital Setting Versus Ambulatory Surgical Center

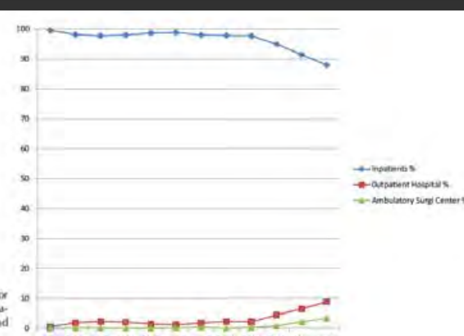


Figure 1. Percentage of lumbar fusion posterior interbody fusion first level (22630) in the outpatient hospital, ambulatory surgical center, and inpatient settings over the years 2003 to 2014.

Trend of Spine Surgeries in the Outpatient Hospital Setting Versus Ambulatory Surgical Center

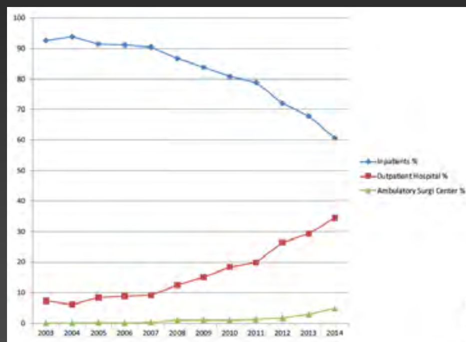


Figure 3. Percentage of lumbar decompression laminectomy first level (63047) in the outpatient hospital, ambulatory surgical center, and inpatient settings over the years 2003 to 2014.

Trend of Spine Surgeries in the Outpatient Hospital Setting Versus Ambulatory Surgical Center

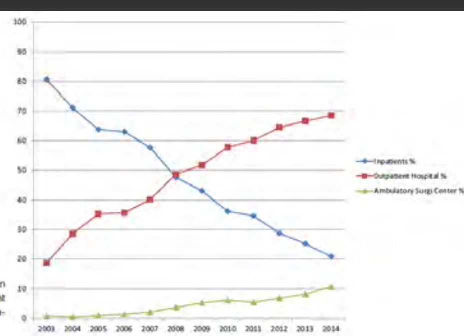


Figure 2. Percentage of lumbar decompression laminotomy first level (63030) in the outpatient hospital, ambulatory surgical center, and inpatient settings over the years 2003 to 2014.

Trend of Spine Surgeries in the Outpatient Hospital Setting Versus Ambulatory Surgical Center

- Increased proportion of cases in Outpatient setting
  - Dampened increase in the “True” ASC setting
- Possibly due to physician fear of complications AND difficulty with transitioning to inpatient care

Spine Surgery in the Ambulatory Surgery Center Setting: Value-Based Advancement or Safety Liability?

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Here, we systematically review clinical studies that report morbidity and outcomes data for cervical and lumbar surgeries performed in ambulatory surgery centers (ASCs). We focus on anterior cervical discectomy and fusion (ACDF), posterior cervical foraminotomy, cervical arthroplasty, lumbar microdiscectomy, lumbar laminectomy, and minimally invasive transforaminal interbody fusion (TLIF) and lateral lumbar interbody fusion, as these are prevalent and surgical spine procedures that are becoming more commonly performed in ASC settings.

A systematic search of PubMed was conducted, using combinations of the following phrases: "outpatient," "ambulatory," or "ASC" with "anterior cervical discectomy fusion," "ACDF," "cervical arthroplasty," "lumbar," "microdiscectomy," "laminectomy," "transforaminal lumbar interbody fusion," "spine surgery," or "TLIF."

In reviewing the available literature to date, there is ample level 3 (retrospective comparisons) and level 4 (case series) evidence to support both the safety and effectiveness of outpatient cervical and lumbar surgery. While no level 1 or 2 (randomized clinical trials) evidence currently exists, the plethora of real-world clinical data creates a formidable argument for serious investments in ASCs for multiple spine procedures.

KEY WORDS: Outpatient, Ambulatory surgery center, Spine surgery, Review, ACDF, TLIF

Neurosurgery 83:159–165, 2018 DOI:10.1093/neuros/nyy057 www.neurosurgery-online.com

Safety and Efficacy Outpatient Lumbar Discectomy

- High frequency case with high success rate, low rate of complications, minimal blood loss, short surgery and anesthetic.
- Most severe complications occur within 4-6 hours of surgery completion
- Early adoption to outpatient setting
- Supported in a variety of medico-economic settings (US, England, France…)

British Journal of Neurosurgery (1994) 8, 47–49

ORIGINAL ARTICLE

Results of day-case surgery for lumbar disc prolapse

ANDREW KELLY, HUW GRIFFITH & ABDULHAKIM JAMJOOM

Frenchay Hospital, Bristol, UK

Abstract
Microdiscectomy for lumbar disc prolapse on a day-patient basis was introduced by our department in 1985 and first reported in 1987, but has not been generally adopted in the United Kingdom. We now report our experience of the first 100 patients with lumbar disc prolapse treated by day-case microdiscectomy. Post-operative assessment was in the out-patient clinic and by subsequent postal questionnaire (average follow-up 37 months, range 3–64 months). Complications were few and are described. Only three patients developed a recurrent disc prolapse. Patient feedback was favourable and the majority (85%) said that, if necessary, they would be prepared to have the operation again on a day-case basis. For selected patients, lumbar microdiscectomy is a suitable procedure for day-case surgery.

Key words: *Disc prolapse, microdiscectomy, day-case surgery.*

World Neurosurg. 2017 Oct;106:891-897. doi: 10.1016/j.wneu.2017.07.065. Epub 2017 Jul 20.

Outpatient Lumbar Microdiscectomy in France: From an Economic Imperative to a Clinical Standard-An Observational Study of 201 Cases.

Debono B[1], Sabatier P[2], Garnault V[3], Hamel O[2], Bousquet P[2], Lescure JP[2], Plas JY[2].

⊕ Author information

Abstract

PURPOSE: The outpatient lumbar discectomy procedures have been established for more than 2 decades. However, especially in Europe, there are still obstacles to the development of these procedures, which may be related to medicoeconomic imperatives, and to several factors concerning both surgeons and patients. We describe our initial experience in introducing this method in our institution.

METHODS: During a 3-year period, 201 patients met the criteria for ambulatory lumbar microdiscectomy. A dedicated fast-tracking unit provided preoperative patient education and immediate postoperative follow-up. A surgical consultation was organized 6 weeks after surgery, and a late satisfaction phone survey concerning ambulatory management was carried out after 6 months.

RESULTS: The average total inpatient time was 10 hours and 12 minutes. One patient (0.5%) remained overnight because of an anxiety attack. No patients contacted the FT unit during the first night, and no complications occurred. All patients were reviewed in consultation around day 45: the average visual analog scale score was significantly reduced. At this early postoperative follow-up, 87.5% of patients were (very) satisfied with this procedure. At the day 180 survey, average visual analog scale scores were not significantly different from the day 45 data. In terms of return to normal activities of daily living, 120 patients (60%) had no limitation, 72 patients (36%) had minor or major limitations, and 8 (4%) were incapacitated. At this final evaluation, 8% of patients (n = 16) were very satisfied, 73% were satisfied (n = 146), 11% (n = 22) were partly satisfied, and 8% (n = 16) were not satisfied with the outpatient procedure.

CONCLUSIONS: Reducing hospitalization for lumbar discectomies to a few hours is not a reduction in the quality of care. It is not necessarily simple to overcome the resistances of all protagonists, but placing the patient as the main actor of an integrated management plan is the key to transforming a medicoeconomic incentive into a clinical success.

Success and Safety in Outpatient Microlumbar Discectomy

Natalie M. Best, BS and Rick C. Sasso, MD

Abstract: Currently, many spine surgeons perform microlumbar discectomies on an outpatient basis. Yet, it is often customary for patients to have a 1-night stay in the hospital. Many studies have shown the efficacy of microlumbar discectomy (MLD) and its preference among surgeons for the treatment of lumbar disc herniation. It has also been shown to be safe, successful, and cost-effective. However, a large comprehensive study of this magnitude, gauging safety, success, and patient satisfaction for these procedures on an outpatient basis has not yet been done. One thousand three hundred seventy-seven MLD procedures have been done from 1992 to 2001 by 1 surgeon. A retrospective chart review was done on all procedures. Patients were then contacted by either telephone or mail to complete an outcome questionnaire. Seven hundred thirteen patients (53.9%) completed the questionnaire. Follow-up questionnaires were not completed due to deaths, incorrect contact information, and refused responses. Out of all MLD procedures, 55 (4.0%) were done with a hospital stay—only 24 of these (1.7%) were originally intended outpatient procedures. Of those that were done on an outpatient basis, 8.6% had a complication, including 6.4% who had a recurrent disc herniation. When asked, 81.6% said they would undergo the procedure again as an outpatient. In 82.1% the surgery's outcome was good, very good, or excellent. MLD is a routine procedure that can be performed on an outpatient basis safely, successfully, and with high patient satisfaction.

Key Words: outpatient surgery, lumbar spine, microlumbar discectomy, complications

(*J Spinal Disord Tech* 2006;19:334–337)

informa healthcare

ORIGINAL ARTICLE

Day case lumbar discectomy – Viable option in the UK?

Ahmed Abou-Zeid[1,3], James Palmer[2] & Kanna Gnanalingham[1,4]

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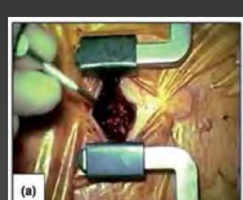
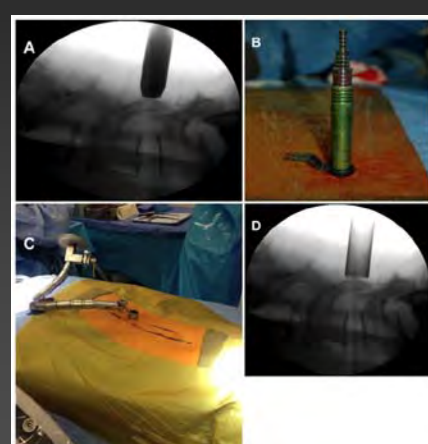
Abstract

Introduction. The inpatient length of stay for lumbar discectomy has been steadily declining, since its original description over 80 years ago. The operation was first described as a day case procedure in 1987, but only sporadically since then, especially in the UK. We describe our initial experience in introducing this service in Manchester. *Methods.* Over a 2-year period, 50 of 80 patients undergoing lumbar discectomy met the inclusion criteria for day case surgery, using standard microscopic techniques and admission via a day case unit. *Results.* Majority (N = 48) were single level, unilateral discectomies and 36 (72%) were discharged home the same day. The remainder (28%) were discharged after an overnight stay and within 24 h. Reasons for this included post-operative back pain and hypotension. Majority (N = 47), reported improvement or resolution of pre-operative back and leg pain, which was quantified using Visual analogue scores ($p < 0.01$). *Conclusions.* Lumbar microdiscectomy as a day case procedure remains a feasible and safe option in selected patients and can help free up in patient beds with a significant economic benefit also.

Keywords: day case surgery; lumbar discectomy

Open vs. MIS/MAS





Pros and Cons

Advantages

- Muscle sparing-Multifidus
- Fascial connection to bone
- Smaller incision
- Decreased infection
- Less blood loss
- Decreased LOS, pain
- Less pseudomeningocele if CSF leak
- Psychological
- ?Improved outcomes?

Disadvantages

- Up front cost
- Learning curve

Outcomes

Perioperative results following lumbar discectomy: comparison of minimally invasive discectomy and standard microdiscectomy

JOHN W. GERMAN, M.D.,[1] MATHEW A. ADAMO, M.D.,[1] REGIS G. HOPPENOT, M.D.,[2] JESSIN H. BLOSSOM, B.S., M.S.,[1] AND HENRY A. NAGLE, B.A., M.A.[1]

[1]Division of Neurosurgery, Albany Medical College, Albany, New York; and [2]Department of Neurosurgery, University at Buffalo Neurosurgery, Inc., Buffalo, New York

Results. Forty-nine patients underwent minimally invasive discectomy, and 123 patients underwent open microsurgical discectomy. At baseline the groups did differ significantly with respect to age, but did not differ with respect to height, weight, sex, body mass index, level of radiculopathy, side of radiculopathy, insurance status, or type of preoperative analgesic use. No statistically significant differences were identified in operative time, rate of cerebrospinal fluid leak, or need for a physical therapy consultation. Statistically significant differences were identified in length of stay, estimated blood loss, postanesthesia care unit narcotic use, and need for admission to the hospital.

Conclusions. In this retrospective study, patients who underwent minimally invasive discectomy were found to have similiar perioperative results as those who underwent open microsurgical discectomy. The differences, although statistically significant, are of modest clinical significance. *(DOI: 10.3171/FOC/2008/25/8/E20)*

Cost Effectiveness

Spine

ASSESSING VALUE OF SPECIFIC SPINE CONDITIONS

Is Minimal Access Spine Surgery More Cost-effective Than Conventional Spine Surgery?

Conclusion. Overall, the included cost-effectiveness studies generally supported no significant differences between open surgery and MAS lumbar approaches. However, these conclusions are preliminary because there was a paucity of high-quality evidence. Much of the evidence lacked details on methodology for modeling, related assumptions, justification of economic model chosen, and sources and types of included costs and consequences. The follow-up periods were highly variable, indirect costs were not frequently analyzed or reported, and many of the studies were conducted by a single group, thereby limiting generalizability. Prospective studies are needed to define differences and optimal treatment algorithms.

Economic Value in Minimally Invasive Spine Surgery

Benjamin Hopkins[1] • Aditya Mazmudar[2] • Kartik Kesavabhotla[1] • Alpesh A Patel[2]

Published online: 24 June 2019

Summary In the past 5 years, there has been increasing research interest in defining economic value in MIS surgery. However, a significant amount of heterogeneity in research quality and methodology persists. Therefore, MIS surgery has the potential to be of high economic value, though this is not yet definitive. Future research should continue to focus on high-quality cost-effectiveness studies with clear methodologies to further elucidate economic value in MIS surgery.

Complications Leading to Admission

- CSF leak PONV
- Retention
- LBP/incisional pain
- Hematoma
- Medical complications

Patient Selection=Selection Bias

- ASA grade/comorbidities
- Help at home
- Distance from hospital
- Age
- BMI
- Revision
- Cognitive
- Ease of transitioning care setting
- Patient choice

Lumbar microdiscectomy as a day-case procedure: Scope for improvement?

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Conclusions: Day-case lumbar microdiscectomy is viable when patients are carefully selected. Younger, fit patients living close to the hospital and operated on in the morning are more likely to be discharged on the same day. Knowledge of these factors while planning elective lists can help optimise bed space and improve spinal services.

Future endeavors in ambulatory spine surgery

Avani S. Vaishnav[1], Steven J. McAnany[1,2]

[1]Hospital for Special Surgery, New York, NY, USA; [2]Weill Cornell Medical College, New York, NY, USA

- Patient selection criteria
  - Patient selection guidelines, expert opinion
  - Eases surgeon and patient anxiety
- Perioperative care and pain control
  - TIVA, Lipophilic bupivacaine, epidural anesthesia
- Discharge criteria
  - 4-6 hours, voiding, taking PO, pain controlled, ambulatory

Future endeavors in ambulatory spine surgery

Avani S. Vaishnav[1], Steven J. McAnany[1,2]

[1]Hospital for Special Surgery, New York, NY, USA; [2]Weill Cornell Medical College, New York, NY, USA

- E-Health tools
  - Symptom alerts transmitted to physician
  - Avoids ER, patient satisfaction
- Expanding indications for outpatient surgery?
  - ASA 2-3, elderly
  - More complex procedures? More levels?
- Increased accessibility
  - Larger outpatient centers, specialized team
  - Minority populations
- Process improvement
  - Optimizing efficiency, timing of surgery

Conclusions

- Ambulatory lumbar microdiscectomy is safe, effective, less costly, and has high provider and patient satisfaction
- Different settings may serve the role of providing outpatient surgery. Opportunities for cost savings.
- MIS/MAS-potential to improve ambulatory spine surgery of all types
- Need for better guidelines for patient selection for optimizing the setting of care.

Question 1

- True / False
- To qualify as a Hospital Outpatient Department based ambulatory surgery, the patient must leave before the end of the SAME calendar day as the day of admission

Question 1 Answer

- FALSE
- Rationale:
  - ALL HOPDs in all states allow for up to 23 hours of observation, and thus can stay till the next calendar day.
  - MOST ASCs also allow for 23 hour observations crossing calendar days
  - Certain states MANDATE that patients in ASCs MUST leave on the same calendar day.

Question 2

- What percent of microdiscectomies/microdecompression surgeries are currently done as ambulatory cases
  A. 30%
  B. 50%
  C. 80%
  D. 95%

Question 2 Answer

A. 30%
B. 50%
C. 80%
D. 95%

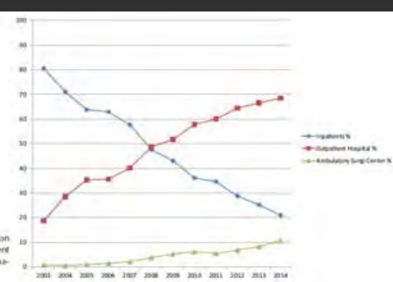

Figure 2. Percentage of lumbar decompression laminotomy first level (63030) in the outpatient hospital, ambulatory surgical center, and inpatient settings over the years 2003 to 2014.

References

- Rogers, L. A. (1987). "Outpatient microsurgical management of ruptured lumbar discs." N C Med J **48**(3): 117-120.
- Bookwalter, J. W., M. D. Busch and D. Nicely (1994). "Ambulatory surgery is safe and effective in radicular disc disease." Spine (Phila Pa 1976) **19**(5): 526-530.
- Kelly, A., H. Griffith and A. Jamjoom (1994). "Results of day-case surgery for lumbar disc prolapse." Br J Neurosurg **8**(1): 47-49.
- Zahrawi, F. (1994). "Microlumbar discectomy. Is it safe as an outpatient procedure?" Spine (Phila Pa 1976) **19**(9): 1070-1074.
- Silvers, H. R., P. J. Lewis, H. L. Asch and D. Clabeaux (1997). "Lumbar microdiscectomy in the elderly patient." Br J Neurosurg **11**(1): 16-24.
- Lorish, T. R., C. T. Tanabe, F. T. Waller, M. R. London and D. J. Lansky (1998). "Correlation between health outcome and length of hospital stay in lumbar microdiscectomy." Spine (Phila Pa 1976) **23**(20): 2195-2200.
- Bednar, D. A. (1999). "Analysis of factors affecting successful discharge in patients undergoing lumbar discectomy for sciatica performed on a day-surgical basis: a prospective study of sequential cohorts." J Spinal Disord **12**(5): 359-362.
- Asch, H. L., P. J. Lewis, D. B. Moreland, J. G. Egnatchik, Y. J. Yu, D. E. Clabeaux and A. H. Hyland (2002). "Prospective multiple outcomes study of outpatient lumbar microdiscectomy: should 75 to 80% success rates be the norm?" J Neurosurg **96**(1 Suppl): 34-44.
- Singhal, A. and M. Bernstein (2002). "Outpatient lumbar microdiscectomy: a prospective study in 122 patients." Can J Neurol Sci **29**(3): 249-252.
- Best, N. M. and R. C. Sasso (2006). "Success and safety in outpatient microlumbar discectomy." J Spinal Disord Tech **19**(5): 334-337.
- Best, N. M. and R. C. Sasso (2007). "Outpatient lumbar spine decompression in 233 patients 65 years of age or older." Spine (Phila Pa 1976) **32**(10): 1135-1139; discussion 1140.
- Hersht, M., E. M. Massicotte and M. Bernstein (2007). "Patient satisfaction with outpatient lumbar microsurgical discectomy: a qualitative study." Can J Surg **50**(6): 445-449.
- German, J. W., M. A. Adamo, R. G. Hoppenot, J. H. Blossom and H. A. Nagle (2008). "Perioperative results following lumbar discectomy: comparison of minimally invasive discectomy and standard microdiscectomy." Neurosurg Focus **25**(2): E20.
- Harrington, J. F. and P. French (2008). "Open versus minimally invasive lumbar microdiscectomy: comparison of operative times, length of hospital stay, narcotic use and complications." Minim Invasive Neurosurg **51**(1): 30-35.
- Liu, J. T., R. P. Briner and J. A. Friedman (2009). "Comparison of inpatient vs. outpatient anterior cervical discectomy and fusion: a retrospective case series." BMC Surg **9**: 3.
- Fallah, A., E. M. Massicotte, M. G. Fehlings, S. J. Lewis, Y. R. Rampersaud, S. Ebrahim and M. Bernstein (2010). "Admission and acute complication rate for outpatient lumbar microdiscectomy." Can J Neurol Sci **37**(1): 49-53.

References

- Lubelski, D., K. E. Mihalovich, A. C. Skelly, M. G. Fehlings, J. S. Harrop, P. V. Mummaneni, M. Y. Wang and M. P. Steinmetz (2014). "Is minimal access spine surgery more cost-effective than conventional spine surgery?" Spine (Phila Pa 1976) **39**(22 Suppl 1): S65-74.
- Debono, B., P. Bousquet, P. Sabatier, J. Y. Plas, J. P. Lescure and O. Hamel (2016). "Postoperative monitoring with a mobile application after ambulatory lumbar discectomy: an effective tool for spine surgeons." Eur Spine J **25**(11): 3536-3542.
- Clark, A. J., M. M. Safaee, N. R. Khan, M. T. Brown and K. T. Foley (2017). "Tubular microdiscectomy: techniques, complication avoidance, and review of the literature." Neurosurg Focus **43**(2): E7.
- Debono, B., P. Sabatier, V. Garnault, O. Hamel, P. Bousquet, J. P. Lescure and J. Y. Plas (2017). "Outpatient Lumbar Microdiscectomy in France: From an Economic Imperative to a Clinical Standard-An Observational Study of 201 Cases." World Neurosurg **106**: 891-897.
- Debono, B., P. Sabatier, V. Garnault, O. Hamel, P. Bousquet, J. P. Lescure and J. Y. Plas (2017). "Outpatient Lumbar Microdiscectomy in France: From an Economic Imperative to a Clinical Standard-An Observational Study of 201 Cases." World Neurosurg **106**: 891-897.
- Idowu, O. A., H. H. Boyajian, E. Ramos, L. L. Shi and M. J. Lee (2017). "Trend of Spine Surgeries in the Outpatient Hospital Setting Versus Ambulatory Surgical Center." Spine (Phila Pa 1976) **42**(24): E1429-E1436.
- Mohandas, A., C. Summa, W. B. Worthington, J. Lerner, K. T. Foley, R. J. Bohinski, G. B. Lanford, C. Holden and R. N. W. Wohns (2017). "Best Practices for Outpatient Anterior Cervical Surgery: Results From a Delphi Panel." Spine (Phila Pa 1976) **42**(11): E648-E659.
- Ahuja, N. and H. Sharma (2018). "Lumbar microdiscectomy as a day-case procedure: Scope for improvement?" Surgeon **16**(3): 146-150.
- Alvi, M. A., P. Kerezoudis, W. Wahood, A. Goyal and M. Bydon (2018). "Operative Approaches for Lumbar Disc Herniation: A Systematic Review and Multiple Treatment Meta-Analysis of Conventional and Minimally Invasive Surgeries." World Neurosurg **114**: 391-407.e392.
- Daly, C. D., K. Z. Lim, P. Ghosh and T. Goldschlager (2018). "Perioperative care for lumbar microdiscectomy: a survey of Australasian neurosurgeons." J Spine Surg **4**(1): 1-8.
- Lewandrowski, K. U. (2018). "Readmissions After Outpatient Transforaminal Decompression for Lumbar Foraminal and Lateral Recess Stenosis." Int J Spine Surg **12**(3): 342-351.
- Rushton, A., K. Zoulas, A. Powell and J. B. Staal (2018). "Physical prognostic factors predicting outcome following lumbar discectomy surgery: systematic review and narrative synthesis." BMC Musculoskelet Disord **19**(1): 326.
- Sivaganesan, A., B. Hirsch, F. M. Phillips and M. J. McGirt (2018). "Spine Surgery in the Ambulatory Surgery Center Setting: Value-Based Advancement or Safety Liability?" Neurosurgery **83**(2): 159-165.
- Choi, K. C., H. K. Shim, J. S. Kim, K. H. Cha, D. C. Lee, E. R. Kim, M. J. Kim and C. K. Park (2019). "Cost-effectiveness of microdiscectomy versus endoscopic discectomy for lumbar disc herniation." Spine J **19**(7): 1162-1169.
- Hoggett, L., M. J. Anderton and M. Khatri (2019). "30-day complication rates and patient-reported outcomes following day case primary lumbar microdiscectomy in a regional NHS spinal centre." Ann R Coll Surg Engl **101**(1): 50-54.
- Hopkins, B., A. Mazmudar, K. Kesavabhotla and A. A. Patel (2019). "Economic Value in Minimally Invasive Spine Surgery." Curr Rev Musculoskelet Med: 300-304.

References

- Nataraj, A. (2010). "Admission and acute complication rate for outpatient lumbar microdiscectomy." Can J Neurol Sci **37**(1): 1.
- Walid, M. S. and J. S. Robinson (2011). "Economic impact of comorbidities in spine surgery." J Neurosurg Spine **14**(3): 318-321.
- Chung, S. B., S. H. Lee, E. S. Kim and W. Eoh (2012). "Implementation and outcomes of a critical pathway for lumbar laminectomy or microdiscectomy." J Korean Neurosurg Soc **51**(6): 338-342.
- Abou-Zeid, A., J. Palmer and K. Gnanalingham (2014). "Day case lumbar discectomy--viable option in the UK?" Br J Neurosurg **28**(3): 320-323.
- https://www.ascassociation.org/home

Adult Spinal Deformity: How Much to Fuse?

UCSF Spine Day
June 2020

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Professor of Neurosurgery and Orthopedics
University of California San Francisco

Disclosure

- Globus—Consultant, Royalty

Introduction

- Patients with adult scoliosis can manage the back pain for many years.
- When the spine becomes unbalanced or radiculopathy ensues, patients may seek surgery.
- But many surgical options exist for adult spinal deformity management

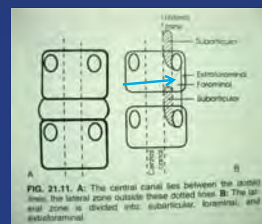
When does the pain become unbearable?

- Severe sagittal decompensation
- Severe coronal decompensation
- Severe radiculopathy

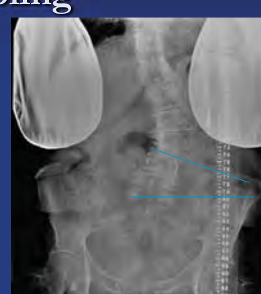
- Usually, scoliosis in and of itself is not disabling, as long as the spine is balanced and there is no radiculopathy

Fractional curve/concavity—how is it painful?

- Central stenosis
- Lateral recess Stenosis
- Foraminal stenosis (up down stenosis from concavity)



Fractional curve radiculopathy may be disabling. Scoliosis pain may not be disabling



What is the fractional curve?

- The minor curve below the major curve a the lumbosacral junction

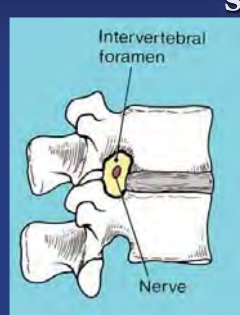
What is fractional curve?

- The minor curve below the major curve a the lumbosacral junction
- Usually L4 to S1
- Sometimes L5-S1 only

Why is the fractional curve important?

- Usually the cause of radiculopathy in scoliosis patient
- The radiculopathy is often times disabling, the scoliosis itself may not be

Concavity causes radiculopathy Up-down stenosis/foraminal stenosis

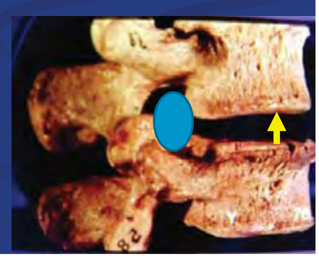


Why up-down stenosis is so painful

- Mechanical from body weight: up-down compression instead of ventral-dorsal compression
- Pinches the dorsal root ganglion, the most sensitive part of the nerve

Up-down foraminal stenosis

- Laminectomy usually not effective
- Need to separate vertebral bodies



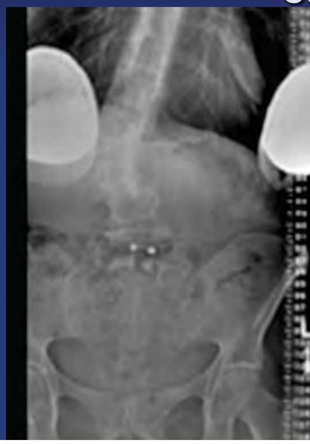
Where does painful radiculopathy occur?

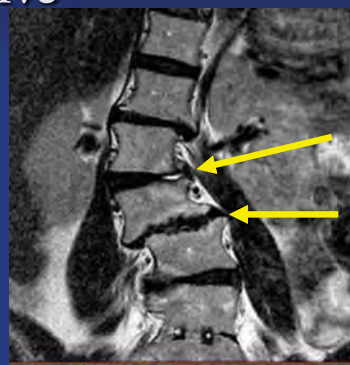
- Fractional curve
- Major curve concavity
- Lateral listhesis

Use the parsagittal MRI to evaluate up-down stenosis

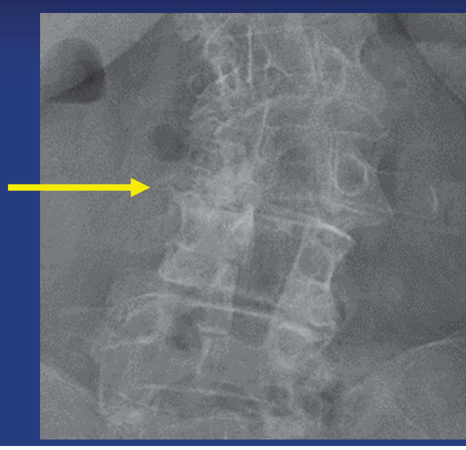
- Look closely at extra-foraminal component
- T1 parasagittal
- Can compress the dorsal root ganglion, the most sensitive part of the nerve.

Painful radiculopathy from concavity/lateral isthesis of major curve





Lateral listhesis causing radiculopathy and pain



Does lateral listhesis cause disability?
Schwab et al classification

- Apical level
- Lordosis modifier
- Subluxation modifier

Table 2. Outline: Classification of Scoliosis in the Adult

Classification	Radiographic Criteria
Type	
I	Thoracic-only curve (no other curves)
II	Upper thoracic major, apex T4–T8
III	Lower thoracic major, apex T9–T10
IV	Thoracolumbar major curve, apex T11–L1
V	Lumbar major curve, apex L2–L4
Lumbar lordosis modifier	
A	Marked lordosis (>40°)
B	Moderate lordosis (0°–40°)
C	No lordosis present (Cobb >0°)
Subluxation modifier	
0	No intervertebral subluxation any level
+	Maximal measured subluxation 1–6 mm
++	Maximal subluxation >7 mm

7mm or more of lateral listehsis is associated with increased disability

Table 5. Summary of Significant Radiographic–Clinical Correlations*

Curve Type	Lordosis Modifier	Subluxation Modifier	*P*
I, II, and III	A, B, and C	—	Not significant
IV and V	A *versus* C	—	≤0.007†‡§
I, II, and III	—	0 *versus* ++	Not significant
IV and V	—	0 *versus* ++	<0.001†‡§

*Comparison of mean, †SRS pain, ‡SRS function, and §ODI scores (*t* test).

Questions:

1) Can we just fuse the source of the severe pain (fractional curve/ listhesis levels only)?

2) How do outcomes of limited fusion of the fractional curve (FC) only compare vs long fusion of entire deformity?

Treatment of Fractional Curve Only versus T10-Pelvis or T3 to Pelvis

- Dominic Amara BA[1], Sigurd H. Berven MD[2], Christopher P. Ames MD[1], Bobby Tay MD[2], Vedat Deviren MD[2], Shane Burch MD[2], Praveen V. Mummaneni MD[1], Dean Chou MD[1]

University of California San Francisco Retrospective Study

- Inclusion: Scoliosis patients by 8 spine surgeons (ortho and neuro)
- Fractional > 10 degrees with concordant radiculopathy

Radiculopathy only: L4-S1, T10-S1, T3-S1

Methods

- Surgeries:
- 99 patients
  - Fractional curve only (FC, n=27)
  - Lower thoracic (T10) to sacrum (LT, n=46),
  - Upper thoracic (T3/T4) to sacrum (UT, n=26).
- Outcomes:
  - Blood loss, length of stay, spinal-pelvic parameters, revision surgery, extension surgery, complications

Results, n=99 patients

	Total (n=99)	FC (n=27)	LT (n=46)	UT (n=26)	p-value
Procedure duration (min)	426	421	454	383	0.26
Estimated blood loss (cc)	1753	592	1950	2634	**<0.001**
Length of Stay (days)	7.5	5.5	8.3	8.3	**<0.001**

Results

Factor, no. of patients (%)	Total (n=99)	FC (n=27)	LT (n=46)	UT (n=26)	p-value
Complications	47 (47.5)	6 (22.2)	26 (56.5)	15 (57.7)	**0.0086**
Extension surgery	14 (14.1)	7 (25.9)	6 (13)	1 (3.8)	**0.068**
Time to extension (days)	662	765	462	1147	0.66
Non-extension revision surgery	23 (23.2)	0 (0)	14 (30.4)	9 (34.6)	**<0.001**
Discharge Destination	51 (51.5)	8 (29.6)	21 (45.7)	22 (84.6)	**<0.001**
Postoperative spine imaging characteristics (degrees)					
Fractional curve	5.9	7.1	5.8	5.0	0.11
Pelvic tilt	23.6	23.7	24.2	22.6	0.77
Lumbar lordosis	43.8	42.3	44.3	44.6	0.78
Pelvic incidence-Lumbar lordosis mismatch	11.8	17.9	7.7	12.7	**0.037**
Sagittal vertical axis	4.6	4.4	5.5	3.4	0.18
Coronal balance magnitude	2.0	1.6	2.1	2.5	0.25
Scoliosis major curve	16.6	26.1	11.6	15.4	**<0.001**
Double curve, no. of patients (degrees)	18 (23.4)	4 (33.5)	3 (29.0)	11 (18.3)	0.089

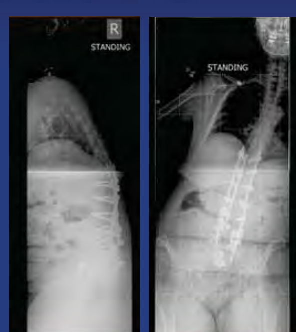
Limitations

- Only patients with FC >10 degrees
- Primarily coronal deformities, not necessarily sagittal plane deformities
- Selection bias when choosing shorter surgeries (healthier patients and severe sagittal plane patients will get UT and LT fusions)

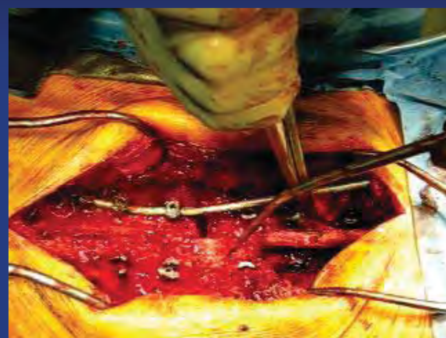
Case examples—Not good for limited fusion

- These types of patients are *not* candidates for limited fusion:
- Severe sagittal imbalance
- Severe coronal imbalance

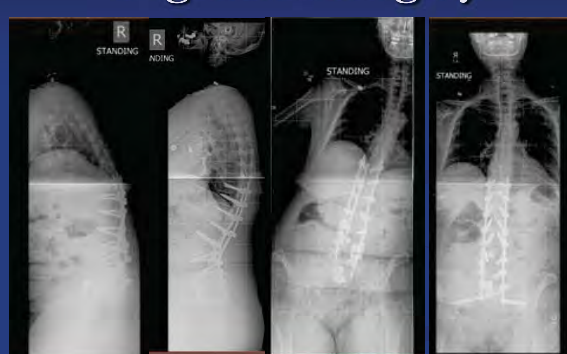
50 yo female can't stand up straight—no leg pain



Cantilever closure of PSO



After asymmetric PSO and revision ALIF—Needs re-alignment surgery

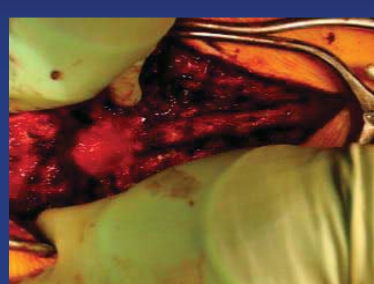


Nor this type of patient

51 yo with prior fusion—cannot stand up straight. No leg pain

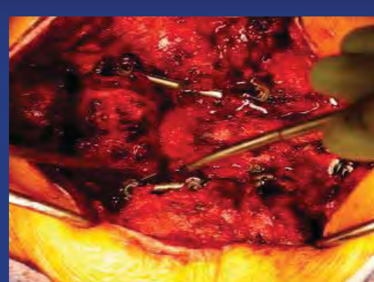
4-rod technique—release temporary rod

Manual compression



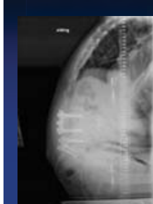
Further compression over PSO site with short rod only

Inspect super-foramen



T10 to pelvis with PSO—4 rod technique

Post op—limited fusion would be simply be inadequate

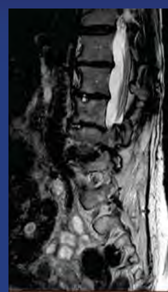


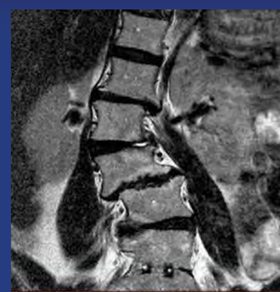
Types of cases for limited fusion

55 yo female with back and leg pain

- Prior laminectomy and fusion
- Right leg pain
- Leg pain worse than back pain, however.

L3-4, L4-5 foraminal stenosis
L4 lateral listhesis



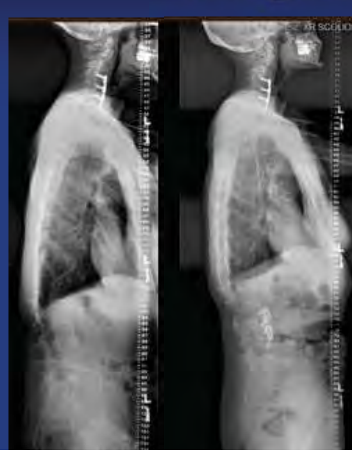


Main complaint

- Back pain for years, but mangeable.
- Leg pain now is disabling
- She would be happy to eliminate the leg pain, even if back pain persisted

Post op long films. Same coronal imbalance but very happy because leg pain is gone

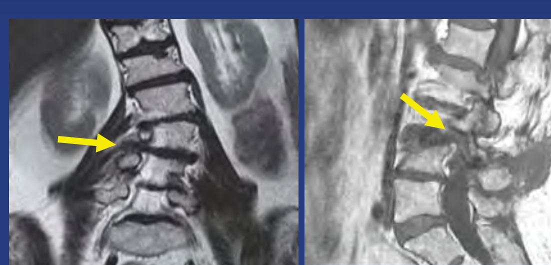
Postop sagittal films. "I can stand straighter"



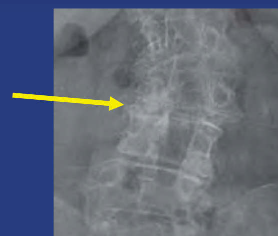
70 yo female with right anterior thigh pain

- Exhausted conservative care

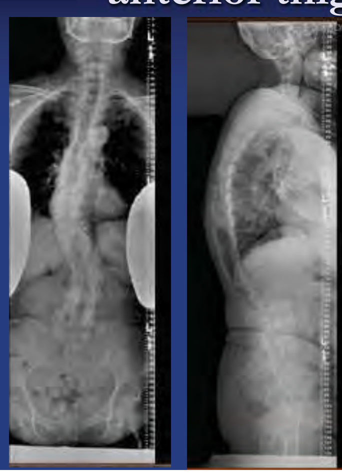
L3 compression



L3-4 lateral listhesis

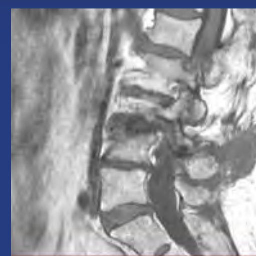


She has no back pain at all, only anterior thigh pain.



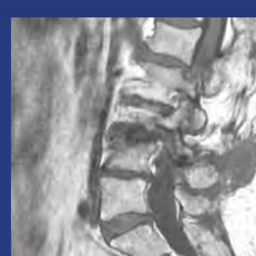
Laminectomy #1

- "I don't want fusion"
- Laminetomy: No benefit

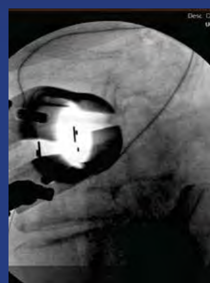


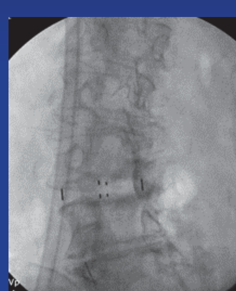
Laminectomy #2

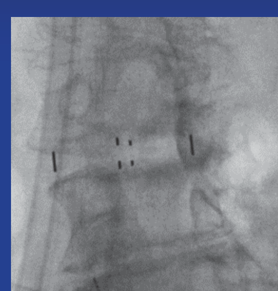
- No benefit
- Continues to have pain
- Disabling
- "I will consider fusion"



L3-4 OLIF

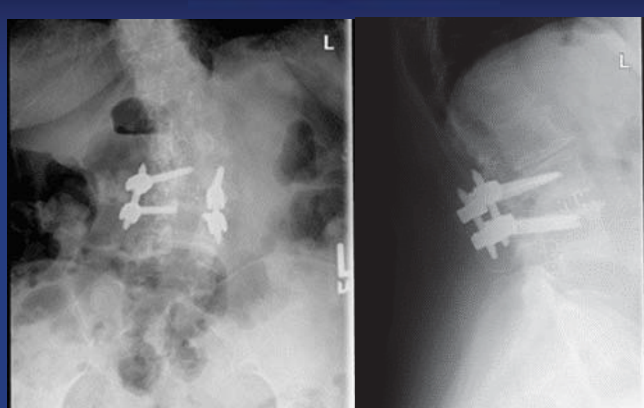






MIS screws

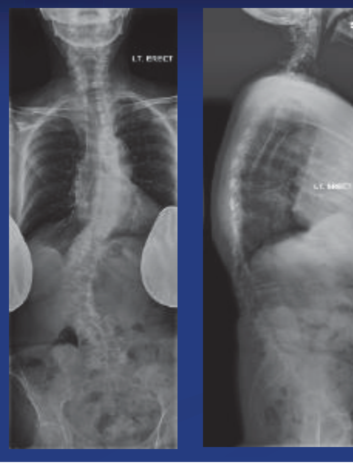
Postop films



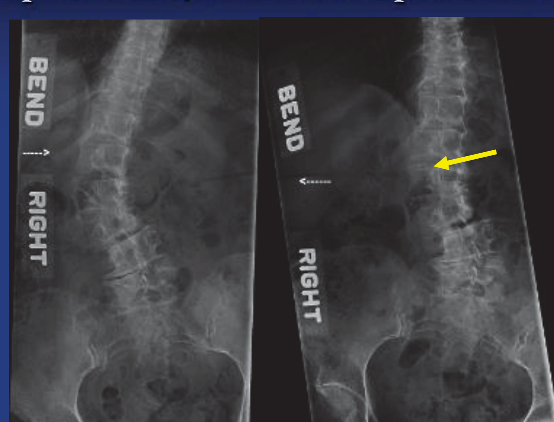
L3-4 up-down stenosis treated
Lateral listhesis stabilized
Pain completely gone with 1 level fusion

VAS=0. “ALL (yes ALL) her symptoms have vanished, completely.”
--Pt’s husband email.

69 yo female with leg pain and back pain---Scoliosis since teenager

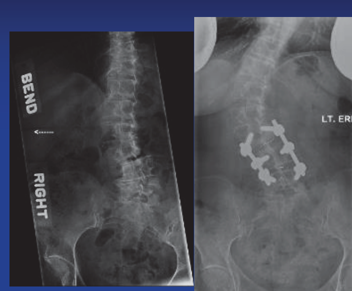


Leg pain is disabling.
Back pain is bad, but has been present for years

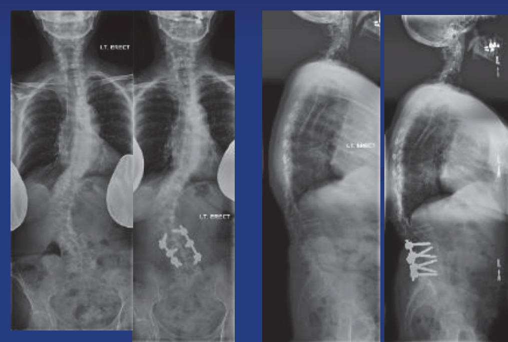


Limited decompression with TLIF

- L3-4 and L4-5.
- Pt understood that entire scoliosis not addressed



Lateral listhesis treated. Sagittal plan okay pre-op



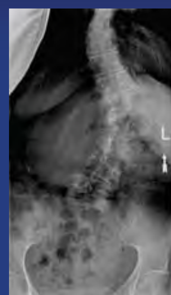
63 yo female with disabling right leg pain. Back pain minimal

L3-4, L4-5 fusion
Pain gone. Very happy.

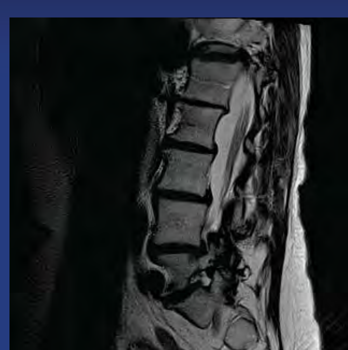
The fractional curve

- 64 yo female
- s/p 2 decompressions
- Left leg pain
- Scoliosis diagnosed as adolescent
- Back pain manageable

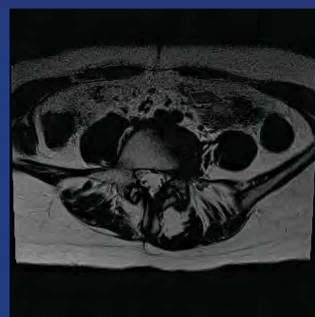
Side bending films



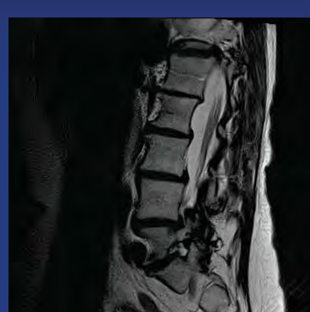
MRI

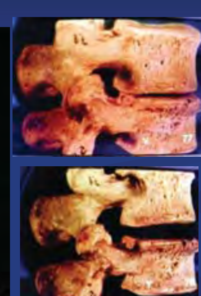


Left leg/buttock pain (L4-5)



Failed 2 laminectomies





Candidate for fractional curve treatment only

- Does not want entire scoliosis addressed
- More leg pain than back pain
- Pt aware back pain may still be there

- L4-S1 ALIF to induce lordosis
- L4-S1 lami/fusion
- Leg pain completely gone

Outcomes of Study

- Limited fusion is associated with:
  - Lower complication rate
  - Lower overall revision surgery rate
  - Shorter hospital stays
- However:
  - Higher rate of extension surgery compared to UT and LT fusions

Other studies

- **The Impact of Lower Thoracic vs. Upper Lumbar UIV in Minimally Invasive Correction of Adult Spinal Deformity**
- Robert Eastlack, Pierce Nunley, Juan Uribe, Paul Park, Stacie Tran, Michael Wang, Khoi Than, David Okonkwo, Adam Kanter, Neel Anand, Richard Fessler, Kai-Ming Fu, Dean Chou, Praveen Mummaneni, Gregory M. Mundis, Jr., International Spine Study Group

Upper Instrumented Vertebra (UIV)

- 112 patients
- Multi-center
- Levels divided by UIV location of L1-2 (UL) or T10-12 (LT).

Re-operation rates

- Reoperation rates were lower in the UL group (17.4% vs. 36.8%; p=0.025),
- Fewer radiographic failures (UL=10.9% vs. LT=26.5%; p=0.042)

Intraoperative morbidity

- shorter operative times
- less EBL

Total OR Time (min)	**587.0 (234, 1235)**	**460.0 (180, 772)**	**0.011**
Total EBL (cc)	1293.3 (50, 8020)	594.0 (75, 2750)	0.001

What about the scoliosis?

- Radiographic cobb correction was better in LT, but not associated with clinical outcomes

Δ Cobb(°)	**-22.9 (-25.6, -20.3)**	**-10.1 (-13.5, -6.7)**	**<0.001**

Why high extension rates for fractional curve only fusions?

- PI-LL mismatch was higher in FC patients postop
- Selection bias with more frail patients getting FC only
- FC technically stops in the major curve.

Minimally Invasive Scoliosis Surgery

Original Article

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SAGE

Treatment of the Fractional Curve of Adult Scoliosis With Circumferential Minimally Invasive Surgery Versus Traditional, Open Surgery: An Analysis of Surgical Outcomes

Dean Chou, MD[1], Praveen Mummaneni, MD[1], Neel Anand, MD[2], Pierce Nunley, MD[3], Frank La Marca, MD[4], Kai-Ming Fu, MD, PhD[5], Richard Fessler, MD[6], Paul Park, MD[4], Michael Wang, MD[7], Khoi Than, MD[8], Stacie Nguyen, MPH[9], Juan Uribe, MD[10], Joseph Zavatsky, MD[11], Vedat Deviren, MD[1], Adam Kanter, MD[12], David Okonkwo, MD[12], Robert Eastlack, MD[13], Gregory Mundis, MD[13], and the International Spine Study Group

Original Article

Treatment of the Fractional Curve of Adult Scoliosis With Circumferential Minimally Invasive Surgery Versus Traditional, Open Surgery: An Analysis of Surgical Outcomes

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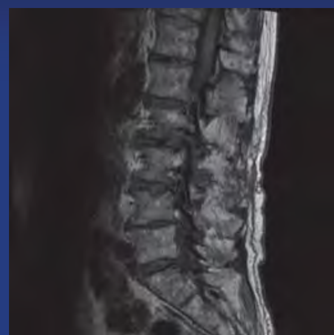
- 118 patients
- MIS vs open fractional curve treatment had equal results in terms of pain relief.
- Significantly fewer MIS patients needed laminectomy compared to open patients (indirect decompression with interbody alleviated pain)

2 surgeries done, no standing xrays ever taken

- 80 yo male with left leg pain
- Injections—failed
- PT—failed
- Laminotomies—failed
- Repeat laminotomies—failed
- On high-dose narcotics for left leg radiculopathy

Left parasagittal MRI



Standing xrays show the reason for laminectomy failure

Mild scoliosis, but severe pain

- Pre-psoas approach
- Lateral interbody fusion
- Percutaneous screws
- No revision laminectomy

Pain completely gone.
No approach-related symptoms.
Home POD #2

Stereotactic navigation for the prepsoas oblique lateral lumbar interbody fusion: technical note and case series.

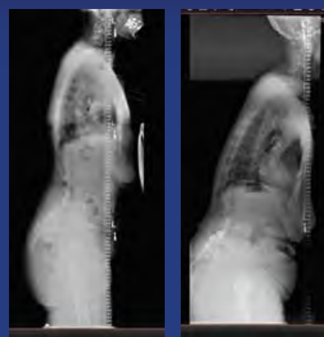
Neurosurg Focus. 2017 Aug;43(2):E14.

DiGiorgio AM, Edwards CS, Virk MS, Mummaneni PV, and Chou D.

What about standard degenerative cases and degenerative "flat backs"?

- Do they all get T10-pelvis because of PI-LL mismatch?

After an L4-5 fusion
Can't stand up. Falling forward.

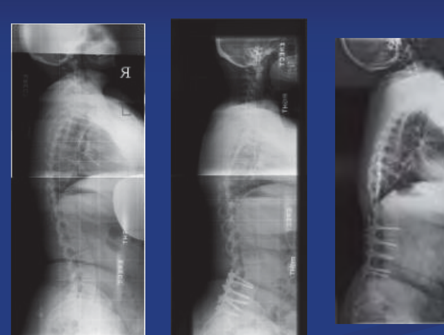


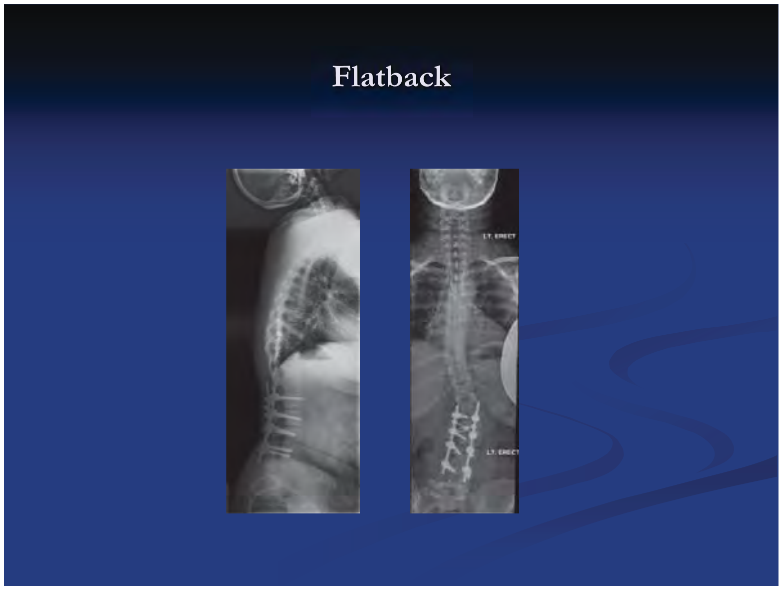
Degenerative case turned into a deformity one

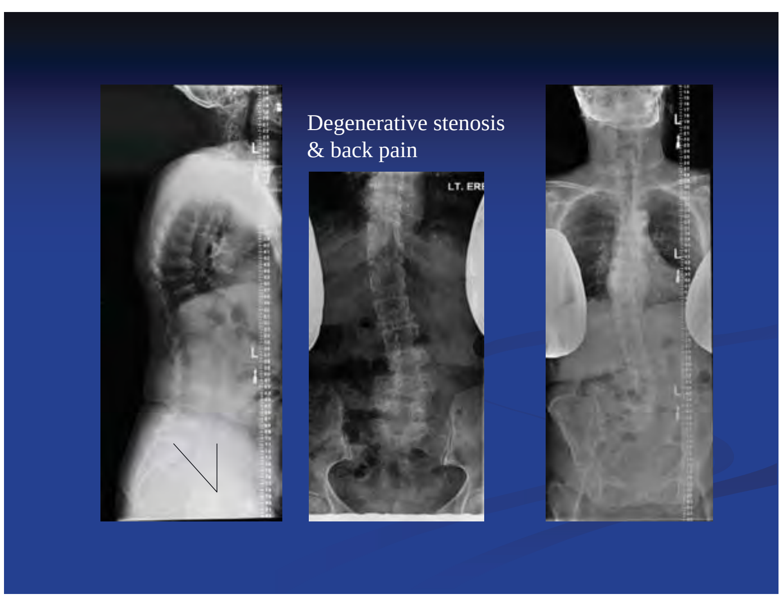
- 38 yo female
- s/p multiple surgeries with interbody fusion

Fixed sagittal imbalance

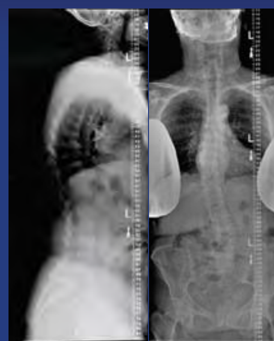
2004, 2007, 2009




Flatback
LT. ERECT
LT. ERECT


Degenerative stenosis
& back pain
LT. ERE

Treatment?



- Needs L2-S1 laminectomy
- What if we fuse in this position?
- What if we do not fuse?

L2 to ilium.

Posterior PCOs
to
Induce lordosis

If you must
fuse multiple
levels, don't
fuse flat

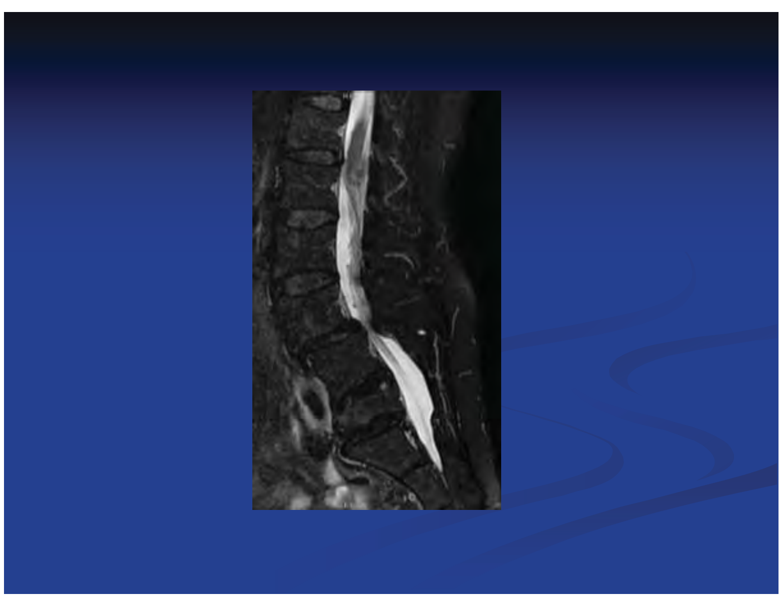
One level fusion--revisted

- 63 yo female with leg pain
- Patient ambulates cautiously, with a modified gait, in a flexed forward posture.
- s/p L4-5 fusion in 1974 at an OSH, who presents to the UCSF Spine Center with complaints of leg pain

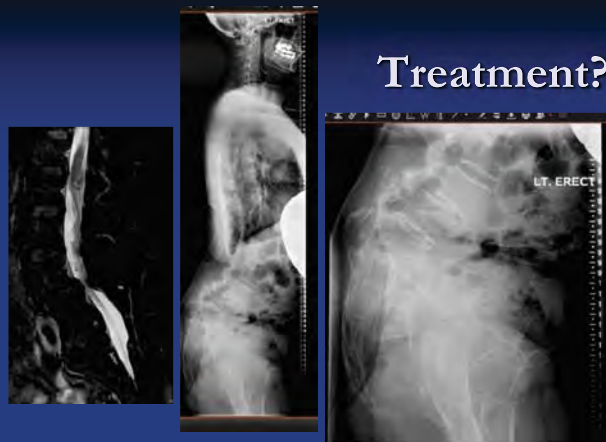
- The patient has AP and lateral standing scoliosis x-rays which demonstrate that the patient has a pelvic incidence of 50°, and lumbar lordosis of 20°, a pelvic tilt of 46°, and positive sagittal balance of 11 cm.

Further questioning

- She has no back pain
- She can stand "fairly straight"
- Clinical examination shows knees and hips are straight



Treatment?

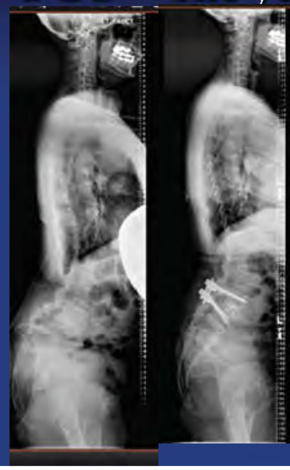


Treatment plan

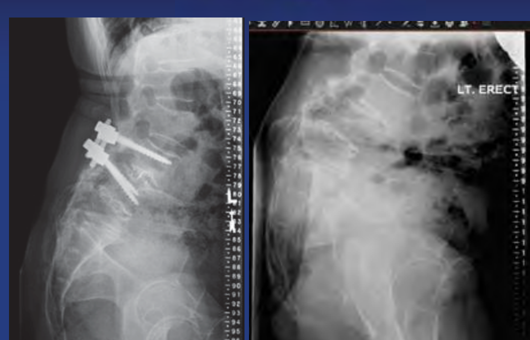
- Pt does not want multi-level fusion
- Key points are:
  - Fully release segment to correct the slip angle, aka lordosis
  - Do not fuse in the kyphotic position—flat back
  - Even though it's one segment, get as much as you can
  - Adding on top of prior fusion with kyphosis may tip patient over edge

Single-level posterior column osteotomy (PCO)

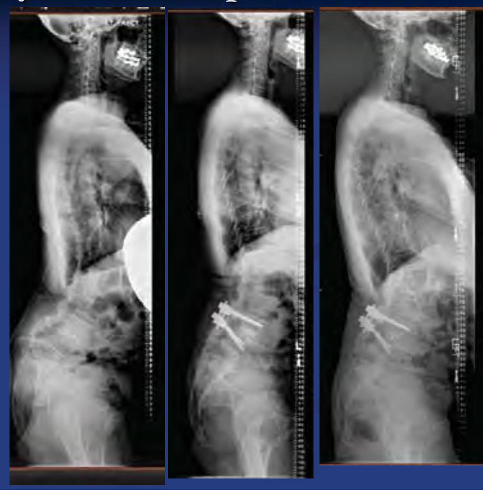
Single-level OLIF fusion with PCO—one year f/u



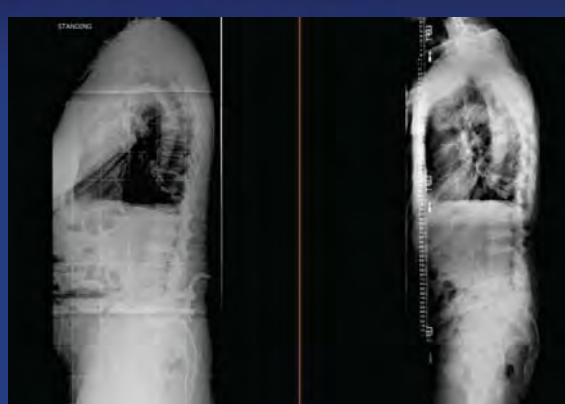
Pt ODI down, "I can stand up straight".



1 & 2 year follow up—one level fusion



L5-S1 front-back with single level ALIF and PCO—no PSO needed



How far can MIS go in deformity surgery?

OXFORD ACADEMIC

OPERATIVE NEUROSURGERY

THE SURGEON'S ARMAMENTARIUM

The Mini-Open Pedicle Subtraction Osteotomy for Flat-Back Syndrome and Kyphosis Correction: Operative Technique

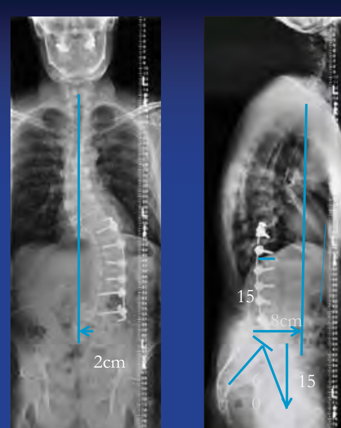
Dean Chou, MD, Darryl Lau, MD

Operative Neurosurgery, Volume 12, Issue 4, 1 December 2016, Pages 309–316,
https://doi.org/10.1227/NEU.0000000000001167
Published: 28 November 2015 **Article history** ▾

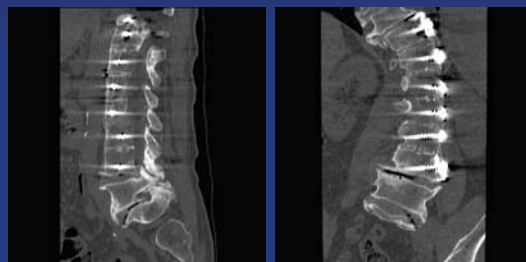
Cite Permissions Share ▾

Case

- 52 yo male s/p anterior-only fusion 30 years ago
- Now with severe back pain
- Inability to stand erect
- No leg pain
- Neuro intact
- Healthy

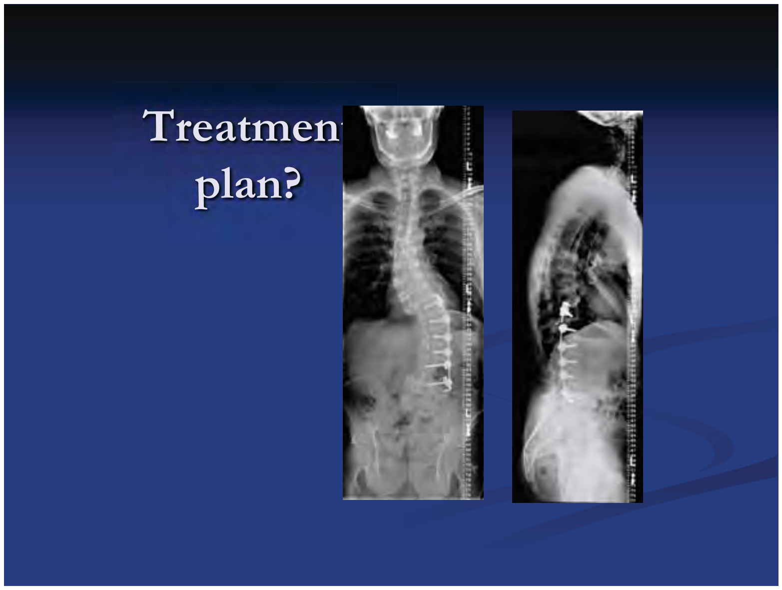


Preop CT: solid fusion T11 to L4



MRI

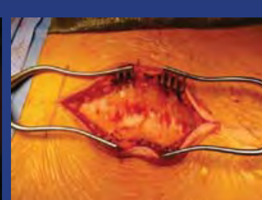
- No severe stenosis at any level.


Treatmen
plan?


He says, “
want MIS
surgery.”

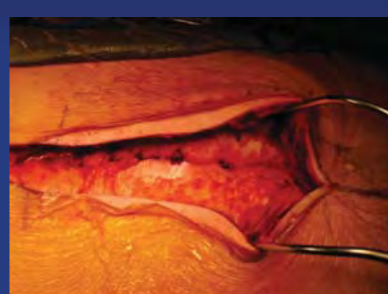
ALIF L4-S1
Mini-open
L3 PSO
T11 to
pelvis
percutaneo
us fixation

Single skin incision; fascia intact



Place reference arc for navigation

Open skin to desired level



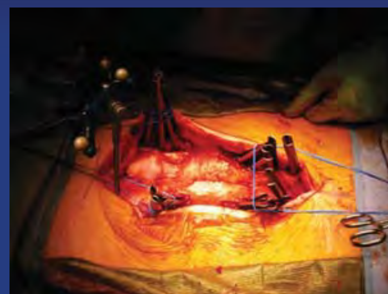
Navigation arc placed; proximal screws in

Navigating Pelvic Fixation

Placing pelvic fixation

Placing iliac screw

Distal screws in; Screw towers held apart



Fascia opened over PSO site only

Fascia opened

Exposing like open PSO

Assess mobility of spine

Mobility of spine

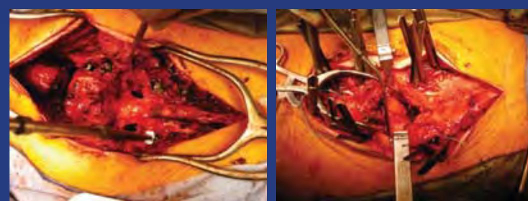
Cantilever closure

Further compression can be applied

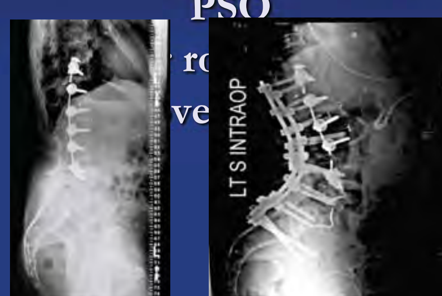
Cantilever 2 rods, compress over domino connector

Single skin incision closure

Same skin incision, but less muscle dissection



Correction with Mini-Open PSO



2 year postop

2 year postop

Conclusion

- Ask the chief complaint.
- If radiculopathy, claudication, leg pain, then identify the focal compression
- Consider smaller surgery if primarily leg pain, not back pain—AND the patient is well-balanced
- If complaint is "I can't stand up straight" after prior fusion, then larger surgery should be undertaken

Conclusion

- Need to make sure sagittal and coronal balance is okay
- Limited fusion for leg pain if you identify the cause—lateral listhesis, stenosis
- Long-standing scoliosis may be painful, but not disabling.
- If purely back pain from scoliosis without radiculopathy, long-segment fusion may be beneficial

Thank you!

Intraoperative Strategies for Avoiding and Managing Neurological Complications in Spine Surgery

15th Annual UCSF Spine Symposium
June 6, 2020

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Assistant Professor
Department of Neurological Surgery
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Department of NEUROLOGICAL SURGERY at UCSF

Disclosures

- Nuvasive – consultant, grant support

UCSF

Introduction

- New neurologic deficits are inherent risks of spine surgery
- Hamilton et al., 2011
  - 108,419 spinal procedures (SRS membership)
  - 1064 (1%) new neurological deficits

Parameter	N	Total (%)	P*
Spinal fusion performed			
Yes	72,534	1.17 (851)	<0.001
No	35,877	0.50 (178)	
Not recorded	8	0 (0)	
Type of fusion			
Posterior-anterior-posterior	271	3.32 (9)	0.0009
Anterior-posterior	7887	1.76 (139)	<0.001
TLIF/PLIF	12,267	1.54 (189)	<0.001
Posterolateral	19,710	1.28 (252)	0.12
All fusion cases	72,534	1.17 (851)	
Interlaminar/facet	16,192	0.99 (161)	0.017
Anterior only	15,336	0.66 (101)	<0.001
Not recorded	871	0 (0)	
Implants			
Yes	74,114	1.15 (850)	<0.001
No	34,305	0.52 (179)	
Revision surgery			
Yes	16,503	1.25 (207)	<0.001
No	91,916	0.89 (822)	
Minimally invasive approach			
Yes	14,301	0.42 (60)	<0.001
No	94,115	1.03 (969)	
Not recorded	3	0 (0)	
Membership status			
Active member	76,748	0.82 (632)	<0.001
Candidate member	24,901	1.24 (310)	
International	6534	1.33 (87)	
Other/not recorded	236	0 (0)	

*P values are based on statistical comparisons of tota

- Increasing complexity
  - Fusion
  - Anterior-posterior
  - Implants
  - Revision
- More invasive
- Less experience

Case 1 - history

- 76 year old male
- Neck pain
- Fall at the gym
- Second fall from gurney at local ER
- Ankylosing spondylitis

Case 1 - exam

- Motor 5/5
- Sensation intact
- Reflexes normal
- Neurologically intact

Case 1 – bony imaging

Case 1 – neural imaging

Case 1

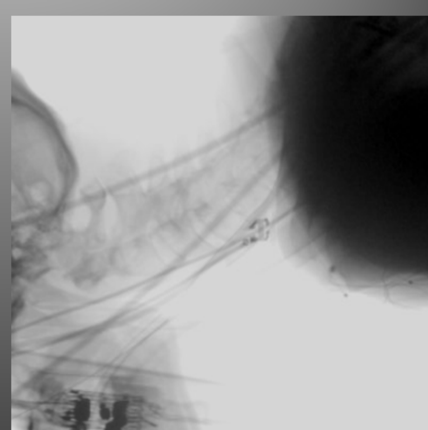
Case 1 - plan

- C4-T2 posterior spinal fusion
- Adjuncts
  - Intraoperative 3D imaging
  - Navigation
  - Neuromonitoring

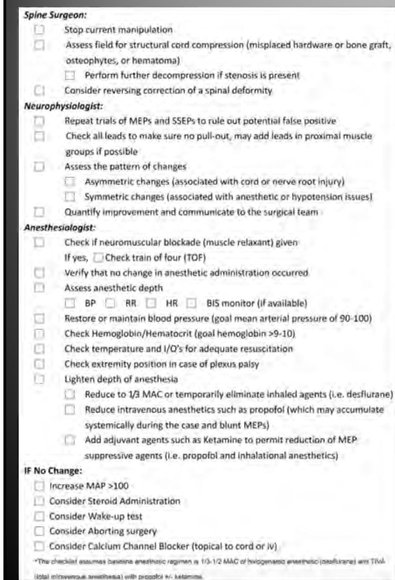
Case 1

Case 1 – intraoperative details

- Positioning
- Exposure, spin, navigation, instrumentation
- Locking down the rod
  - Acute complete loss of MEP and SSEP from C6 down



UCSF Neuromonitoring checklist



Spine Surgeon:

- ☐ Stop current manipulation
- ☐ Assess field for structural cord compression (misplaced hardware or bone graft, osteophytes, or hematoma)
  - ☐ Perform further decompression if stenosis is present
- ☐ Consider reversing correction of a spinal deformity

Neurophysiologist:

- ☐ Repeat trials of MEPs and SSEPs to rule out potential false positive
- ☐ Check all leads to make sure no pull-out, may add leads in proximal muscle groups if possible
- ☐ Assess the pattern of changes
  - ☐ Asymmetric changes (associated with cord or nerve root injury)
  - ☐ Symmetric changes (associated with anesthetic or hypotension issues)
- ☐ Quantify improvement and communicate to the surgical team

Anesthesiologist:

- ☐ Check if neuromuscular blockade (muscle relaxant) given
  If yes, ☐ Check train of four (TOF)
- ☐ Verify that no change in anesthetic administration occurred
- ☐ Assess anesthetic depth
  - ☐ BP ☐ RR ☐ HR ☐ BIS monitor (if available)
- ☐ Restore or maintain blood pressure (goal mean arterial pressure of 90-100)
- ☐ Check Hemoglobin/Hematocrit (goal hemoglobin >9-10)
- ☐ Check temperature and I/O's for adequate resuscitation
- ☐ Check extremity position in case of plexus palsy
- ☐ Lighten depth of anesthesia
  - ☐ Reduce to 1/3 MAC or temporarily eliminate inhaled agents (i.e. desflurane)
  - ☐ Reduce intravenous anesthetics such as propofol (which may accumulate systemically during the case and blunt MEPs)
  - ☐ Add adjuvant agents such as Ketamine to permit reduction of MEP suppressive agents (i.e. propofol and inhalational anesthetics)

IF No Change:

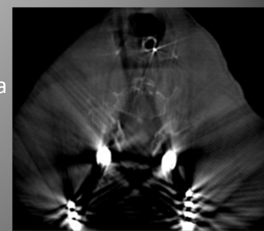
- ☐ Increase MAP >100
- ☐ Consider Steroid Administration
- ☐ Consider Wake-up test
- ☐ Consider Aborting surgery
- ☐ Consider Calcium Channel Blocker (topical to cord or iv)

Explore C6/7
Large hematoma

No technical problems

No anesthetic changes
No paralytics
Labs ok

Increase MAP



Ziewacz et al., 2012

Case 1 - outcome

- After decompression – MEP returned to 70%
  - Sensitive to changes in MAP
- ICU postop for pressors
- Immediate
  - Motor exam 4+/5 in arms and legs
- Follow-up
  - Neurologically intact

Case 1 – follow-up

Neuromonitoring can detect deficits during cervical spine surgery

TABLE 3: Contingency table describing the association between IONM MEP alerts that persisted until completion of the operation and new postoperative neurological deficits*

Variable	MEP Alert	No Alert
no. of cases	8	132
new motor deficit		
yes (%)	6 (75)	2 (1.5)
no (%)	2 (25)	130 (98.5)

* Significant association between MEP alert and new deficit (p < 0.001).

Clark et al., 2013

- Sensitivity 75%
- Specificity 98%

- PPV 75%
- NPV 98%

Case 1

Neuromonitoring has lower sensitivity and specificity in nondegenerative pathologies

Table 3 Association between intraoperative MEP alerts and new postoperative neurologic deficits in patients with nondegenerative causes of myelopathy

	MEP alert ($n = 11$), n (%)	No alert ($n = 31$), n (%)
New motor deficit		
Yes	1 (9)	2 (6)
No	10 (91)	29 (94)

Abbreviation: MEP, motor evoked potential.
Note: $p > 0.99$; sensitivity 33%; specificity 74%.

Clark et al., 2016

- Nondegenerative
  - Tumor
  - Infection
  - Fracture
- Degen; AUC 0.83
- Nondegen; AUC 0.54

Case 2

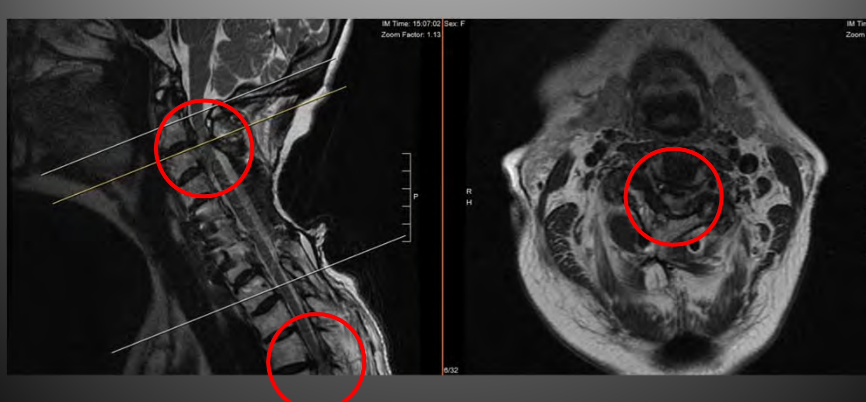
Case 2 - history

- 78 year old female
- Neck pain
- Numbness in the arms
- Difficulty with gait → wheelchair
- C5-7 ACDF, C3-T1 PSF
- L4-S1 TLIF

Case 2 - exam

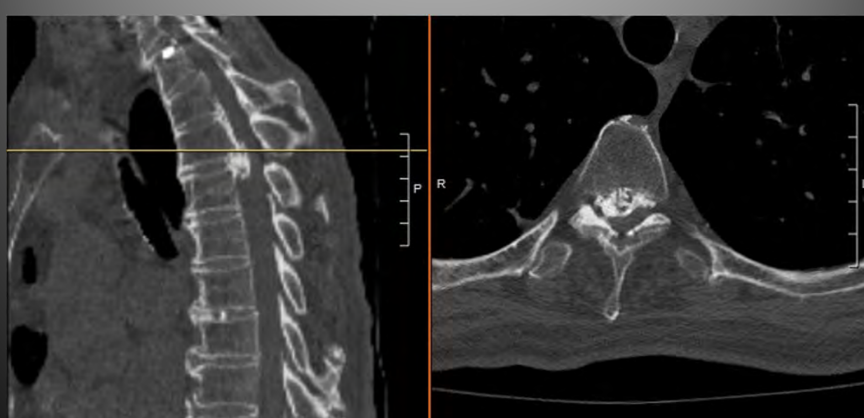
- Motor – 4-/5 uppers, 4+/5 lowers
- Intact sensation
- Hyperreflexia in legs
- 2 beats of clonus
- Positive Hoffman sign

Case 2 - MRI



Case 2 – total spine MRI

Case 2 - CT



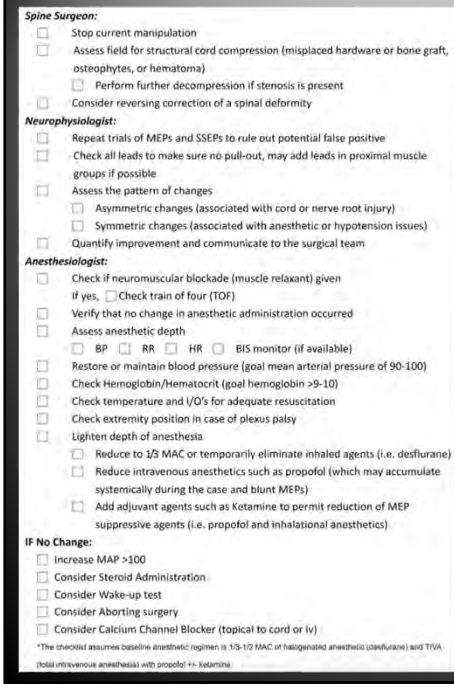
Case 2 - plan

- C2-T9 PSF, C2/3 laminectomy, T3-4 VCR
- Adjuncts
  - O-arm
  - Navigation
  - Neuromonitoring

Case 2 – intraoperative details

- Positioning, exposure, hardware removal, instrumentation, C2/3 laminectomy
- While dissecting calcified disc from ventral dura
  - Acute loss of MEPs in lowers

Case 2



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- ☐ Increase MAP >100
- ☐ Consider Steroid Administration
- ☐ Consider Wake-up test
- ☐ Consider Aborting surgery
- ☐ Consider Calcium Channel Blocker (topical to cord or iv)

*The checklist assumes baseline anesthetic regimen is 1/3-1/2 MAC of halogenated anesthetic (desflurane) and TIVA (total intravenous anesthesia) with propofol +/- Ketamine

Ventral spinal cord compressed
Completed ventral decompression
Shortening of spine

No technical problems

No anesthetic changes
No paralytics
PRBC and FFP transfused

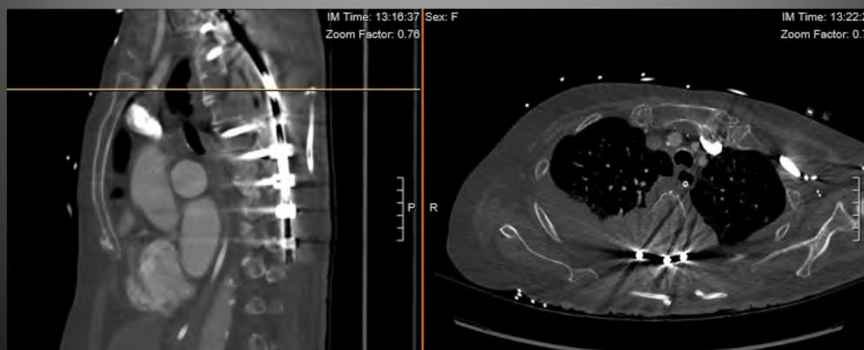
Increase MAP
Steroids

Case 2

Case 2 – outcome

- After VCR completed, left leg MEP improved to baseline, right leg improving
- ICU postop
- Immediate
  - Uppers and left leg 4+/5
  - Right leg proximally 2-3/5
- Follow-up
  - Motors 4+/5

Case 2 - outcome



Thoracic calcified discs are very high risk

Table IV: Postoperative Complications in Anterior and Posterior Groups

Complications	Anterior Group (n=68)	Posterior Group (n=18)	p	ODDS (95% CI)
Neurological Deterioration	1 (1.5%)	4 (22.2%)	**0.006**	19.143

Otulu et al., 2019

- Almost 20x high rate of neurologic deterioration after posterior vs anterior
- Pre-existing cord dysfunction
- Diminished blood supply

Risk factors

Table 3. Associated factors and their significances of complications

Factors	Grouping	Complication Yes	Complication No	Odds ratio (CI)	*p*-value
Gender	Female	54	67	1.16	0.678
	Male	46	66	(0.69–1.94)	
Age (yr)	>35	55	50	2.03	0.012
	≤35	45	83	(1.20–3.44)	
Diagnosis	Postuberculous	23	16	2.18	0.041
	Others	77	117	(1.08–4.40)	
Kyphosis	Yes	89	89	3.91	0.0002
	No	11	43	(1.89–8.07)	
Scoliosis	Yes	45	72	0.70	0.273
	No	54	61	(0.42–1.19)	
Preop. neurologic deficit	Yes	25	8	5.21	0.0001
	No	75	125	(2.23–12.14)	
Surgical technique	Decancellation osteotomy	37	44	1.19	0.629
	PVCR	63	89	(0.69–2.05)	
Resection level	Thoracic spine	49	46	1.82	0.037
	Lumbar spine	51	87	(1.07–3.09)	
No. of fusion extent (segments)	>6	57	46	2.51	0.001
	≤5	43	87	(1.47–4.27)	
No. of vertebrae resected (segments)	≥2	29	19	2.45	0.010
	1	71	114	(1.28–4.69)	
Usage of mesh	Yes	35	31	1.77	0.070
	No	65	102	(0.997–3.15)	
Operation time (min)	≥200	80	85	2.26	0.012
	<200	20	48	(1.23–4.13)	
Blood loss (ml)	≥3,000	61	52	2.44	0.001
	<3,000	39	81	(1.43–4.15)	
Kyphosis correction (°)	≥40	59	51	1.47	0.28
	<40	30	38	(0.80–2.69)	

Current patient

Older age

Preop deficit

Longer fusion

Longer surgery

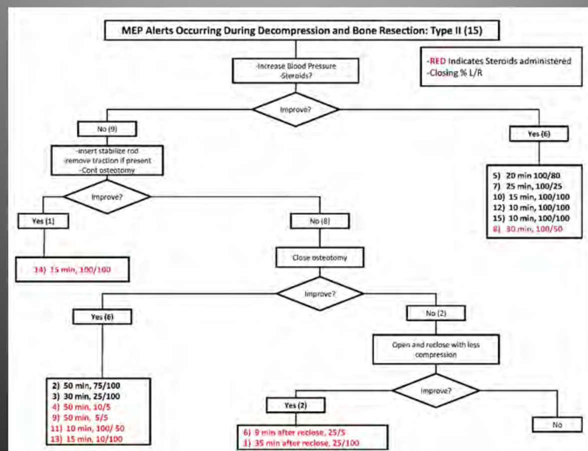
Higher EBL

Kim et al., 2012

Techniques to avoid neurologic complications

- Temporary rod
  - Minimizes translation
- Costotransversectomy
  - Minimizes spinal cord manipulation
- Spinal shortening
  - As long as dura is not kinked
  - Increase in spinal cord blood flow

Responding to MEP loss during 3 column osteotomy surgery



Jarvis et al., 2013

Case 3 - history

- 62 year old female

- Mechanical back pain
- Neurogenic claudication

- Leg weakness and numbness
- Uses a 4 point cane

- Tried PT, ESI, NSAIDs, opioids

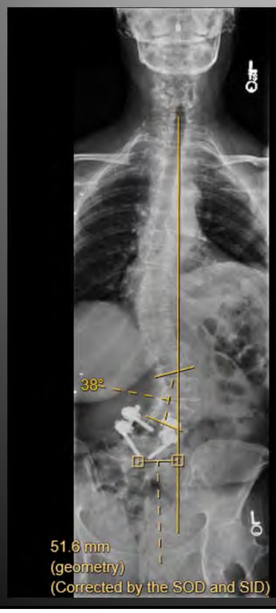
- Prior L4-5 fusion

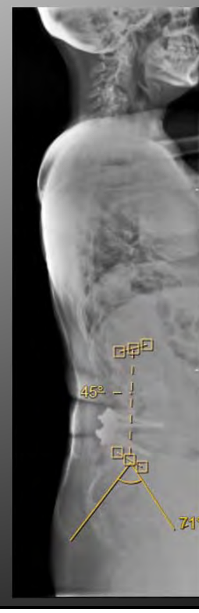
Case 3 -exam

- Motor 5/5
- Decreased sensation in L5 and S1 bilaterally
- Sagittal and coronal imbalance

Case 3

Case 3





Case 3 -plan

- L5/S1 ALIF, hardware removal, T10-pelvis PSF, L1-S1 SPO, L3/4 laminectomy, T9-10 vertebroplasty
- Adjuncts
  - 2 surgeons
  - Intraoperative 3D imaging
  - Navigation
  - Neuromonitoring

2 surgeon rationale

Spine Deformity
www.spine-deformity.org

Spine Deformity 1 (2013) 51–58

Perioperative Outcomes and Complications of Pedicle Subtraction Osteotomy in Cases With Single Versus Two Attending Surgeons

Christopher P. Ames, MD[a,*], Jeffrey J. Barry, MD[b], Sassan Keshavarzi, MD[a], Ozgur Dede, MD[b], Michael H. Weber, MD[b], Vedat Deviren, MD[b]
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	Single surgeon	2 surgeons	p value
%EBV (%)			
Mean	109.1	35.0	<.0001
Standard error of mean	15.2	4.11	
Range	12.5–411	3–109	
EBL (mL)			
Mean	5,278.6	2,002.5	<.0001
Standard error of mean	649.3	256.5	
Range	500–16,000	200–8,000	
Operative time (minutes)			
Mean	453.7	297.1	<.0001
Standard error of mean	23.9	12.0	
Range	239–1,018	198–465	

Case 3 –intraoperative details

- ALIF – day 1
- Day 2 – exposure, hardware removal, instrumentation, cement augmentation, decompression, osteotomies
- Deformity correction with rod
  - Loss of MEPs in right leg

Spine Surgeon:

- ☐ Stop current manipulation
- ☐ Assess field for structural cord compression (misplaced hardware or bone graft, osteophytes, or hematoma)
  - ☐ Perform further decompression if stenosis is present
- ☐ Consider reversing correction of a spinal deformity

Neurophysiologist:

- ☐ Repeat trials of MEPs and SSEPs to rule out potential false positive
- ☐ Check all leads to make sure no pull-out, may add leads in proximal muscle groups if possible
- ☐ Assess the pattern of changes
  - ☐ Asymmetric changes (associated with cord or nerve root injury)
  - ☐ Symmetric changes (associated with anesthetic or hypotension issues)
- ☐ Quantify improvement and communicate to the surgical team

Anesthesiologist:

- ☐ Check if neuromuscular blockade (muscle relaxant) given
  If yes, ☐ Check train of four (TOF)
- ☐ Verify that no change in anesthetic administration occurred
- ☐ Assess anesthetic depth
  ☐ BP ☐ RR ☐ HR ☐ BIS monitor (if available)
- ☐ Restore or maintain blood pressure (goal mean arterial pressure of 90-100)
- ☐ Check Hemoglobin/Hematocrit (goal hemoglobin >9-10)
- ☐ Check temperature and I/O's for adequate resuscitation
- ☐ Check extremity position in case of plexus palsy
- ☐ Lighten depth of anesthesia
  - ☐ Reduce to 1/3 MAC or temporarily eliminate inhaled agents (i.e. desflurane)
  - ☐ Reduce intravenous anesthetics such as propofol (which may accumulate systemically during the case and blunt MEPs)
  - ☐ Add adjuvant agents such as Ketamine to permit reduction of MEP suppressive agents (i.e. propofol and inhalational anesthetics)

IF No Change:

- ☐ Increase MAP >100
- ☐ Consider Steroid Administration
- ☐ Consider Wake-up test
- ☐ Consider Aborting surgery
- ☐ Consider Calcium Channel Blocker (topical to cord or iv)

*The checklist assumes baseline anesthetic regimen is 1/3-1/2 MAC of halogenated anesthetic (desflurane) and TIVA (total intravenous anesthesia) with propofol +/- Ketamine

Released some of correction

No technical problems

No anesthetic changes
No paralytics
Low hct → transfusion

Increase MAP

MEP loss after osteotomy closure

MEP loss after osteotomy closure

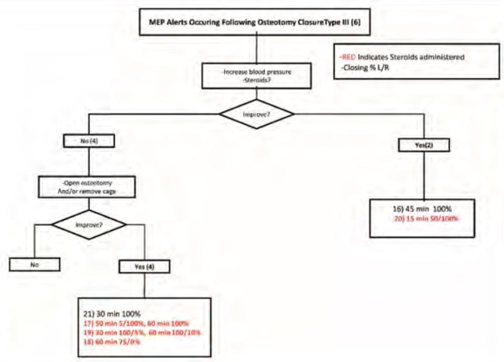


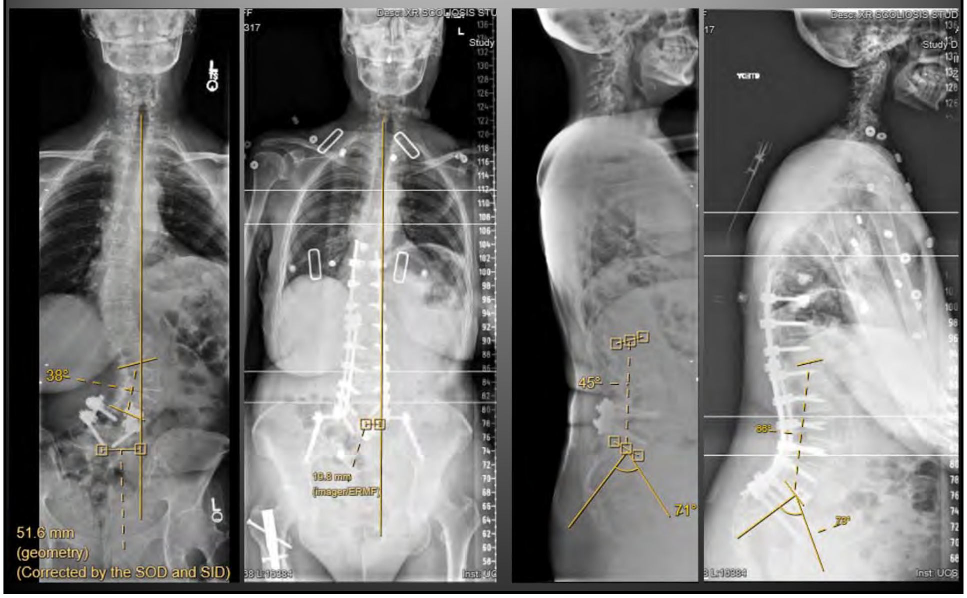
Figure 6. Management algorithm of motor evoked potential changes occurring after osteotomy closure (type III alerts).

Jarvis et al., 2013

Case 3 –outcome

- ICU postop
- Immediate postop check
  – Right leg 4/5
- Follow-up
  – Motor 5/5

Case 3



Conclusion

- Risk of neurologic complications increases with complexity
- It is important to understand the risks at each stage of the operation
- Neuromonitoring can identify neurologic compromise
- Implementation of specific maneuvers during a neuromonitoring change may decrease risk of deficit

Thank you!

- My team
  - Tiffany Pong, PA
  - Diego Esquivel
  - Omar Flamenco
- UCSF Neurosurgery
  - Mitchel Berger, MD
  - Chris Ames, MD
  - Michael Safaee, MD
- UCSF Orthopedic Surgery
  - Alekos Theologis, MD
  - Vedat Deviren, MD

UCSF

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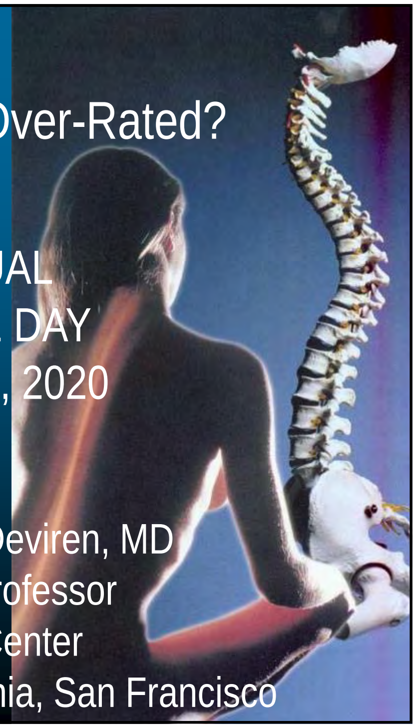
Are Clinical Tests Over-Rated?

15TH ANNUAL
UCSF SPINE DAY
San Francisco, 2020

Sibel Demir-Deviren, MD
Clinical Professor
Spine Center
University of California, San Francisco



UCSF Orthopaedics

DISCLOSURE

Vedat Deviren, MD Sibel Deviren, MD	Nuvasive Royalties Alphatec Consultant, Royalties Biomet Consultant Medicrea Consultant Seaspine Consultant

Sacroiliac joint

- Frequent source of low back and referred leg pain
- Pain source in 15 - 30% patients with chronic LBP
- Absorbs vertical forces from the spine and transmit them to the pelvis and lower extremities
- Transmit forces from the extremities to the spine
- During activities, the joint motion is small
  - 2-3 degrees
- Sports that require unilateral loading as in kicking and throwing
- Cross-country skiers and rowers
- History of trauma
- Increased lordosis

Predictive value

- Positive predictive value
  - how frequently those who have a positive test will have the condition
- Negative predictive value
  - how frequently those with a negative test do not have the condition

Predictive Value

- 2 out of 4 tests positive PPV: 67% NPV: 93%
  - Distraction
  - Thigh thrust
  - Compression
  - Midsacral thrust
- 1 or more positive tests PPV: 47% NPV: 100%
- 2 or more positive tests PPV: 58% NPV: 96%
- 3 or more positive tests PPV: 68% NPV: 96%
- 4 or more positive tests PPV: 60% NPV: 81%
- 5 or more positive tests PPV: 50% NPV: 72%
  - Gaenslen's

Sensitivity

- The proportion of people with a positive test who have the disorder
- True positives

Sensitivity

Thigh thrust	36% - 88%
Gillet test	43%
Midsacral thrust	53% - 63%
Gaenslen's	53% - 71%
Distraction	60%
Resistive abduction of the hip	65% - 87%
Patrick's	69%
Compression	69%
Spring	75%
Sacral sulcus tenderness	95%

Sensitivity

- 2 out of 4 tests positive 88%
  - Distraction
  - Thigh thrust
  - Compression over iliac crest
  - Midsacral thrust
- 3 out of 5 tests positive 91%
  - Gaenslen's
- Sensitivity decreases as the number of tests required to be positive increases

Specificity

- The proportion of people with a negative test who do not have the disorder
- True negatives

Specificity

Sacral sulcus tenderness	9%
Patrick's	16%
Gaenslen's	26% - 74%
Midsacral thrust	29% - 75%
Spring	35%
Thigh thrust	50% - 69%
Gillet test	68%
Compression	69%
Distraction	81%
Resistive abduction of the hip	100%

Specificity

- 2 out of 4 tests positive 78%
  - Distraction
  - Thigh thrust
  - Compression
  - Midsacral thrust
- 3 out of 5 tests positive 87%
  - Gaenslen's
- Specificity increases as the number of positive tests increase

Inter-tester Reliability

- The degree of agreement among testers
- Inter-rater reliability

Inter-tester Reliability

- The inter-tester reliability for assessments of SIJ alignment is poor
- The inter-tester reliability for the movement of bony landmarks is poor
  - Gillet
  - Spring test
- Movements of bony landmarks associated with the SIJs are too small to detect with palpation or visual assessment.

Inter-tester Reliability of Pain Provocation Tests

- Distraction: high inter-tester reliability
- Compression: high inter-tester reliability
- Thigh thrust: high inter-tester reliability
- Midsacral thrust
- Resistive abduction of the hip: moderate - high inter-tester reliability

Conclusion

- Tests designed to assess the symmetry and movement of bony landmarks associated with the SIJ are invalid

- Pain provocation tests for determining the presence of dysfunction of the SIJ are valid

Conclusion

- No test has proven to be superior to the others

- Combining several tests may allow for more accurate results
  - 3 positive tests out of 5
- Include tests with higher sensitivity and specificity
  - distraction
  - compression
  - thigh thrust
  - midsacral thrust
  - resistive abduction of the hip

Tests with Higher Sensitivity and Specificity

- Distraction test
  - Pressure is applied to anterior and superior iliac spines directed posteriorly and laterally
- Compression over iliac crest
  - With the patient lying on his/her side, pressure is applied to the lateral iliac crest and directed toward the opposite iliac crest
- Thigh thrust
  - With the patient in the spine position and the tested leg's hip is flexed 90 degrees, the examiner provides steady pressure through the axis of the femur

Tests with Higher Sensitivity and Specificity

- Midsacral thrust
  - With the patient in the prone position, the examiner gives a rapid, short amplitude vertical thrust to the sacrum with the palm of the hand
- Resistive abduction of the hip
  - With the patient in the spine position and the tested leg is abducted 30 degrees, the examiner resists abduction

REFERENCES

1. Cornelis W.J. van Tilburg, Johannes G. Groeneweg, Dirk L. Stronks and Frank J.P.M. Huygen. Inter-rater reliability of diagnostic criteria for sacroiliac joint-, disc- and facet joint pain. Journal of Back and Musculoskeletal Rehabilitation 30 (2017) 551–557
2. Kent Jason Stuber. Specificity, sensitivity, and predictive values of clinical tests of the sacroiliac joint: a systematic review of the literature. J Can Chiropr Assoc 2007; 51(1) 30-41
3. Freburger JK, Riddle DL. Using Published Evidence to Guide the Examination of the Sacroiliac Joint Region. Phys Ther. 2001;81:1135–1143
4. Mark Laslett, , Charles N. Aprill, Barry McDonald, Sharon B. Young. Diagnosis of Sacroiliac Joint Pain: Validity of individual provocation tests and composites of tests. Manual Therapy 10 (2005) 207–218
5. Amir Massoud Arab, Iraj Abdollahi, Mohammad Taghi Joghataei, Zahra Golafshani, Anoshirvan Kazemnejad. Inter- and intra-examiner reliability of single and composites of selected motion palpation and pain provocation tests for sacroiliac joint. Manual Therapy 14 (2009) 213-221
6. Markku Paatelma, Eira Karvonen & Ari Heinonen. Inter- and intra-tester reliability of selected clinical tests in examining patients with early phase lumbar spine and sacroiliac joint pain and dysfunction. Advances in Physiotherapy, 12:2, 74-80
7. Foley BS, Buschbacher RM. Sacroiliac joint pain: anatomy, biomechanics, diag- nosis, and treatment. Am J Phys Med Rehabil 2006;85:997–1006
8. Maigne JY, Aivaliklis M, Pfefer F. Results of sacroiliac joint double block and value of sacroiliac pain provocation tests in 54 patients with low back pain. Spine. 1996;21:1889–1892
9. Slipman CW, Sterenfeld EB, Chou LH, et al. The predictive value of provocative sacroiliac joint stress maneuvers in the diagnosis of sacro- iliac joint syndrome. Arch Phys Med Rehabil. 1998;79:288–292
10. Broadhurst NA, Bond MJ. Pain provocation tests for the assessment of sacroiliac joint dysfunction. J Spinal Disord. 1998;11:341–345
11. Dreyfuss P, Dreyer S, Griffin J, et al. Positive sacroiliac screening tests in asymptomatic adults. *Spine*. 1994;19:1138–1143
12. Broadhurst NA, Bond MJ. Pain provocation tests for the assessment of sacroiliac joint dysfunction. *J Spinal Disord.* 1998;11:341–345
13. Laslett M, Williams M. The reliability of selected pain provocation tests for sacroiliac joint pathology. *Spine*. 1994;19:1243–1249
14. Potter NA, Rothstein JM. Intertester reliability for selected clinical tests of the sacroiliac joint. *Phys Ther.* 1985;65:1671–1675
15. LaslettM,YoungSB,AprillCN,McDonaldB.Diagnosing painful sacroiliac joints: a validity study of McKenzie evaluation and sacroiliac provocation tests. Aust J Physiother 2003; 49:89–97
16. DreyfussP,MichaelsenM,PauzaK,McLartyJ,BogdukN. The value of medical history and physical examination in diagnosing sacroiliac joint pain. Spine 1996; 21(22):2594–2602

University of California, San Francisco Medical Center

TRACK-SCI
TRANSFORMING RESEARCH AND CLINICAL KNOWLEDGE IN SPINAL CORD INJURY

Spinal Cord Injury
Early-surgery and future directions

2020 UCSF SPINE SYMPOSIUM

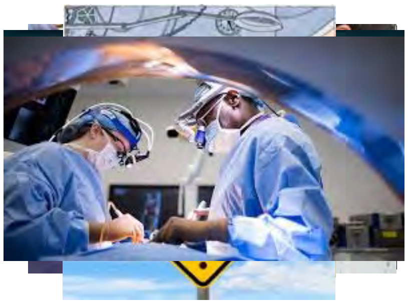
Sanjay S. Dhall, MD

Disclosures

- Depuy Spine Teaching Honorarium
- Globus Spine Teaching Honorarium

Spinal Cord Injury: Traditional Care Timeline

SCI Injury → Pre-Hospital Transport → Emergency Room → Intensive Care → Operating Room → Discharge (rehab/home)



- Epidemiology: 16-17,000 SCI per year
- Triage: EMS chooses wear to take patients
- Usually several hours in ER waiting for admission
- Patients admitted to ICU, then NSU consulted
- NSU takes to OR (24-72 hours after injury)
- Patient discharges: PM&R physicians

Spinal Cord Injury: Traditional Care Model

SCI Injury → Pre-Hospital Transport → Emergency Room → Intensive Care ⇄ Operating Room → Discharge (rehab/home)

Traditional Model	Family/Public	EMS	ER Physicians	Trauma/ICU	Spine Surgeon	PM & R
Todays Talk	Family/Public	EMS	ER Physicians	Trauma/ICU	Spine Surgeon	PM & R
Trauma Triage	Family/Public	EMS	ER Physicians	Trauma/ICU	Spine Surgeon	PM & R
Trauma Triage	Family/Public	EMS	ER Physicians	Trauma/ICU	Spine Surgeon	

Spine Surgeon (below the third row, spanning ER Physicians through Spine Surgeon)

Spine Surgeon (below the fourth row, spanning EMS through Spine Surgeon)

Outline

- Epidemiology and TRACK-SCI
- Early intervention
  - Why? Historic and SFGH Data
- Challenges
  - The need for better diagnosis: Neuroelectrodiagnostics, Imaging
  - Extending Vasopressor support (Spinal perfusion pressure)
  - Convincing surgeons: new prospective data
- The future
  - Data Science
  - Blood Biomarkers
  - Chronic SCI

Outline

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SCI: Epidemiology

- 17,000 people/year in the US
- More common than:
  - GBM (~12,000)
  - operative meningiomas (~15,000)
  - ruptured AVMS (~3,000)
  - spinal cord tumors (2,700)
- high prevalence: 243,000 -347,000
- lifetime cost: \$1.1 – \$4.7 million
- a total societal cost: \$267–\$1,631 billion

Data Registries

- Not possible to create RCT
- Retrospective studies are limited
- Prospective studies are considered the gold standard at this point

TRACK-SCI

- Transforming Research and Clinical Knowledge in SCI (TRACK-SCI)
- Funded in 2013 by the Department of Defense (DoD)
- Prospectively collected comprehensive data repository for all SCI across 3 sites

Authors: Please review all authors' names, academic degrees, affiliations, and contributions, as well as the Disclosure, for spelling and accuracy.

MS# 19-1030, author proof

NEUROSURGICAL FOCUS

Not for reprint

Neurosurg Focus 48 (5):E6, 2020

Transforming Research and Clinical Knowledge in Spinal Cord Injury (TRACK-SCI): an overview of initial enrollment and demographics

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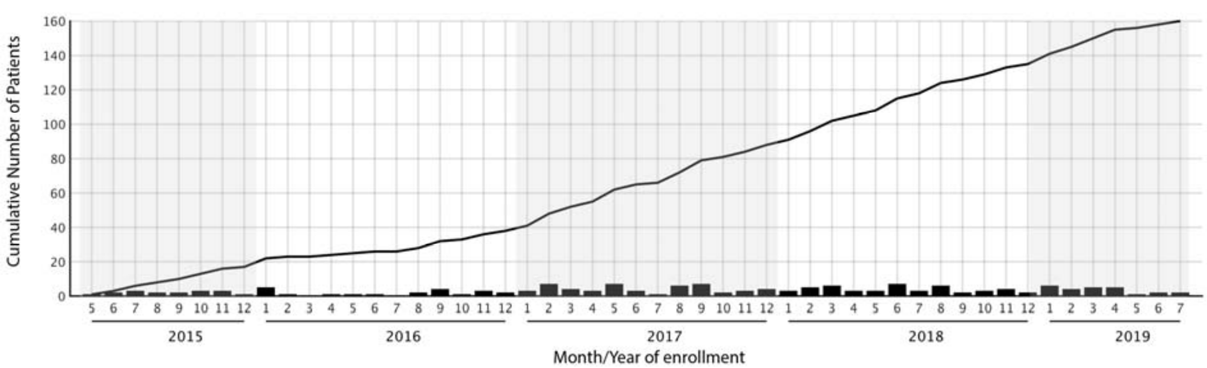
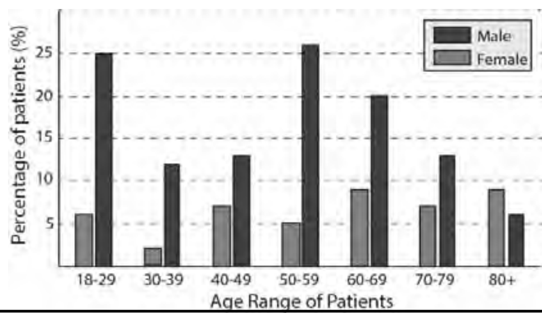
TRACK-SCI

- 3 sites: SFGH, UCSF Fresno, OSU
- Approaching 200 enrollment
- Diversity of patient presentation and injury type



TRACK-SCI

- Large amount of central cord data
- Bimodal age of presentation (M>F)
- 12-month follow up
- Very accurate time to OR



	Number	Percentage (%)
Enrolled	160	
Female	45	28.1
Male	115	71.9
Injury Mechanism		
Assault	24	15.0
Fall	80	50.0
MVC	20	12.5
Other transport	24	15.0
Spinal Level		
Cervical	100	62.5
Thoracic	24	15.0
Lumbar	6	3.8
Fracture Type		
Central Cord	70	43.7
AO-A	21	13.1
AO-B	20	12.5
AO-C	17	10.6
other	32	20.0

Outline

- Epidemiology and TRACK-SCI
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  - Why? Historic and SFGH Data
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  - The need for better diagnosis: Neuroelectrodiagnostics, Imaging
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  - Data Science
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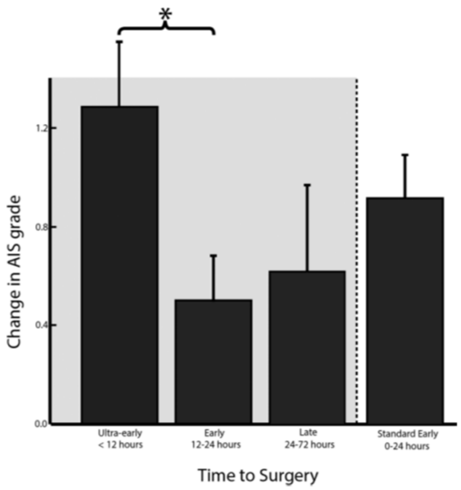
  - Chronic SCI

Early Surgery



- Pilot data: large effect of surgical timing

RESEARCH—HUMAN—CLINICAL STUDIES

Journal Club
CNS

John F. Burke, MD, PhD
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Geoffrey T. Manley, MD, PhD
Phiroz E. Tarapore, MD
Sanjay S. Dhall, MD

Ultra-Early (<12 Hours) Surgery Correlates With Higher Rate of American Spinal Injury Association Impairment Scale Conversion After Cervical Spinal Cord Injury

BACKGROUND: Cervical spinal cord injury (SCI) is a devastating condition with very few treatment options. It remains unclear if early surgery correlated with conversion of American Spinal Injury Association Impairment Scale (AIS) grade A injuries to higher grades.
OBJECTIVE: To determine the optimal time to surgery after cervical SCI through retrospective analysis.
METHODS: We collected data from 48 patients with cervical SCI. Based on the time from Emergency Department (ED) presentation to surgical decompression, we grouped

Early Surgery

Guidelines Paper

AOSPINE

Global Spine Journal
2017, Vol. 7(3S) 195S-202S
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DOI: 10.1177/2192568217706367
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SAGE

A Clinical Practice Guideline for the Management of Patients With Acute Spinal Cord Injury and Central Cord Syndrome: Recommendations on the Timing (≤24 Hours Versus >24 Hours) of Decompressive Surgery

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Grego
Tara J
Sheka
Eric M
Hiroa
Anous
Alexa

Summary of Recommendations

We suggest that early surgery (≤24 hours after injury) be considered as a treatment option in adult patients with traumatic central cord syndrome.
Quality of Evidence: Low
Strength of Recommendation: Weak
We suggest that early surgery be offered as an option for adult acute SCI patients regardless of level.
Quality of Evidence: Low
Strength of Recommendation: Weak

- **Early surgery after cervical SCI may limit secondary injury**
- **2017 consensus guidelines (Fehlings et al) recommend surgery within 24 hours of injury.**

Early Surgery

Favors Early Surgery	Favors Late Surgery
Papadopoulos et al., 2002	Vaccaro et al., 1997
Lenehan et al, 2010	Sapkas et al., 2007
Wilson et al, 2012	Mattiassich et al., 2017
Fehlings et al, 2012	Kim et al, 2018
Jug et al, 2015	Sewel et al, 2018
Dvorak et al, 2015	Aarabi et al, 2020
Grassner et al, 2016	
Bourassa-Moreau et al, 2016	
Burke et al, 2018	
Jug et al, 2019	

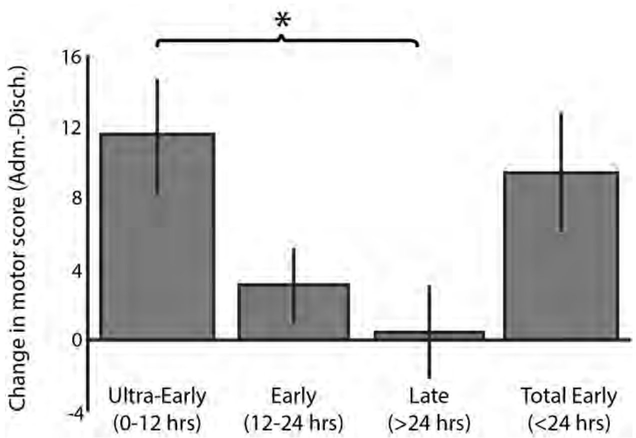
Controversial topic!

Early Surgery

- **TRACK-SCI**
  - Multi-center, prospective data registry
  - Highly granular 20,000 variables per patients
  - Data collection began June 2016
- **Inclusion Criteria**
  - Injury on or before July 2018 (12 months follow up)
  - Injury treated with surgery
  - Cervical lesion
  - Patient survived injury until discharge
  - Patient able to participate in motor exam throughout hospital stay
- **Statistical Analysis**
  - Separate patients by time to OR: Ultra-Early group (< 12 hours), Early group (12-24 hours), and late group (>24 hours)
  - Combined bilateral lower extremity motor exam improvement

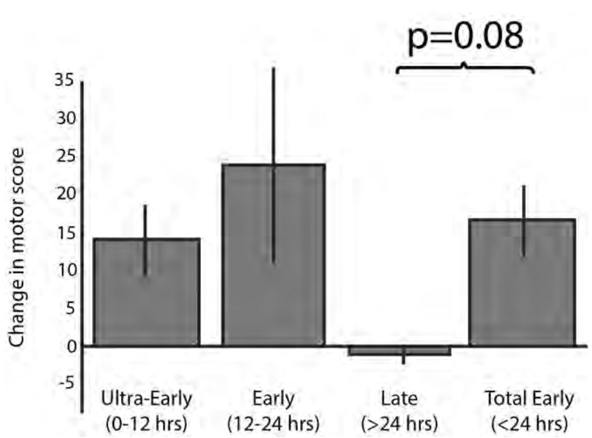
	N	Percentage (%)
Fracture Type		
Central Cord	17	48.6%
AO-A	7	20.0%
AO-B	6	17.1%
AO-C	5	14/3%
MRI characteristic		
BASIC-1	8	22.3%
BASIC-2	8	22.3%
BASIC-3	8	22.3%
BASIC-4	6	17.1%
Unable to Det	5	14.3%
Surgical intervention		
Surgery	35	100.00%
Anterior Only	3	8.6%
Posterior Only	27	77.1%
Ant. and Post.	5	14.3%

RESULTS I



1. Ultra-Early surgery correlates with increased motor outcomes in the immediate recovery period.
   - 37 total patients met inclusion criteria
   - p=0.05 for the effect of timing no motor recovery from admission to discharge
   - post-hoc t-test: p=0.05 comparing ultra-early time window to late time window
   - Early- window (< 24 hours) showed a less statistically robust effect

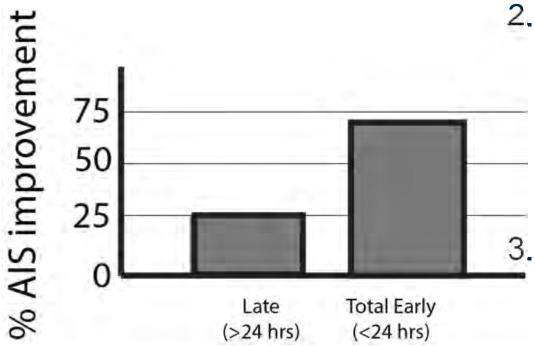
RESULTS II



1. Ultra-Early surgery correlates with increased motor outcomes in the immediate recovery period.

2. At 12 months follow up, there is more variability in ultra-early versus early surgery, but overall early surgery correlated with improved motor recovery
   - Sample size was 17 patients (limited follow up)
   - p=0.08 comparing early (0-24 hours) to late group

RESULTS III



1. Ultra-Early surgery correlates with increased motor outcomes in the immediate recovery period.

2. At 12 months follow up, there is more variability in ultra-early versus early surgery, but overall early surgery correlated with improved motor recovery

3. Increase percentage of patients with improvement in at least one AIS grade.
    1. 25% in late group, 68.75% in early
    2. 4/4 patients with AIS A

Published Data on AIS Conversion

JOURNAL OF NEUROTRAUMA 26:2027–2036 (November 2009)

DOI: 10.1089/neu.2008.0760

Conversion in ASIA Impairment Scale
during the First Year after Traumatic Spinal Cord Injury

Martina R. Spiess[1] Roland M. Müller[1,2] Rüdiger Rupp[3]
Christian Schuld[3] The EM-SCI Study Group, and Hubertus J.A. van Hedel[1]

Published Data on AIS Conversion

- **EMSCI group data:**
  - **72% of AIS A remain AIS at 6 mo**
  - **6.8% are AIS D and 0.5% (n=1) are AIS E at 6 mo**
  - **Nothing about specific surgery, other treatment**

TABLE 1. AIS CONVERSION BETWEEN STAGE 1 AND 6 MONTHS

Initial AIS	AIS A No.	AIS A %	AIS B No.	AIS B %	AIS C No.	AIS C %	AIS D No.	AIS D %	AIS E No.	AIS E %	Total
AIS A	137	71.7	31	16.2	9	4.7	13	6.8	1	0.5	191
AIS B	6	13.3	12	26.7	17	37.8	10	22.2	0	0	45
AIS C	1	2.0	2	4.1	10	20.4	35	71.4	1	2.0	49
AIS D	0	0	0	0	0	0	61	88.4	8	11.6	69
AIS E	0	–	0	–	0	–	0	–	0	–	0
Total	144		45		36		119		10		354

Conclusions

1. **Reduce the variability in existing literature**
   - Early surgery (< 24 hours) is associated with increased motor recovery after SCI.
   - Collectively with other **prospective data**, suggests that surgery < 24 hours should be standard of care

Early Surgery

- Collectively with other **<u>prospective data</u>**, suggests that surgery < 24 hours should be standard of care

Favors Early Surgery	Favors Late Surgery
Papadopoulos et al., 2002	[redacted]
Lenehan et al, 2010	[redacted]
Wilson et al, 2012	[redacted]
Fehlings et al, 2012	[redacted]
Jug et al, 2015	[redacted]
Dvorak et al, 2015	[redacted]
[redacted]	
Bourassa-Moreau et al, 2016	
[redacted]	
Jug et al, 2019	
Current Study	

Conclusions

1. **Reduce the variability in existing literature**
   - Early surgery (< 24 hours) is associated with increased motor recovery after SCI.
   - Collectively with other **<u>prospective data</u>**, suggests that surgery < 24 hours should be standard of care

2. **Identify an optimal window for early surgery**
   - We found that surgery within the ultra-early time window (<12 hours) is associated with improved recovery in the post-op period
   - Further prospective data are needed to determine what effect this immediate recovery has on long term outcomes

Conclusions

1. **Reduce the variability in existing literature**
   - Early surgery (< 24 hours) is associated with increased motor recovery after SCI.
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2. **Identify an optimal window for early surgery**
   - We found that surgery within the ultra-early time window (<12 hours) is associated with improved recovery in the post-op period
   - Further prospective data are needed to determine what effect this immediate recovery has on long term outcomes

3. **What is a "complete" injury in the early time period?**
   - We found that patients in the early group had a high rate of AIS grade conversion
   - 4/4 patients determined to be AIS A improved at least one AIS grade
   - In ultra-early time window, the clinical exam is confounded by spinal shock, and other factors
   - We argue that a poor AIS grade should not influence surgical decision

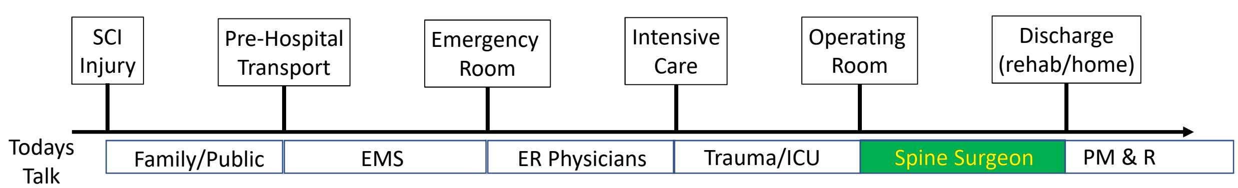
TABLE 1. Comparison of TLICS and SLIC systems

TLICS		SLIC	
Characteristic	Score	Characteristic	Score
Injury morphology		Injury morphology	
No abnormality	0	No abnormality	0
Compression	1	Compression	1
Burst component	2	Burst component	2
Translation/rotation	3	Translation/rotation	3
Distraction	4	Distraction	4
PLC integrity		DLC integrity	
Intact	0	Intact	0
Indeterminate	2	Indeterminate	1
Disrupted	3	Disrupted	2
Neurological status		Neurological status	
Intact	0	Intact	0
Nerve root injury	2	Nerve root injury	1
	2		
SCI	3	SCI	3
Cauda equina injury	3		

Outline

- Epidemiology and TRACK-SCI
- Early intervention
  - Why? Historic and SFGH Data
- Challenges
  - The need for better diagnosis: Neuroelectrodiagnostics, Imaging
  - Extending Vasopressor support (Spinal perfusion pressure)
  - Convincing surgeons: new prospective data
- The future
  - Data Science
  - Blood Biomarkers
  - Chronic SCI

Spinal Cord Injury: Challenges of Early Surgery



1. **Several issues as we move care to the ED**
   - The clinical exam is notoriously unreliable

Spinal Cord Injury: Challenges of Early Surgery

Spinal Cord (2020) 58:247–254
https://doi.org/10.1038/s41393-019-0359-0

ISCoS The International Spinal Cord Society

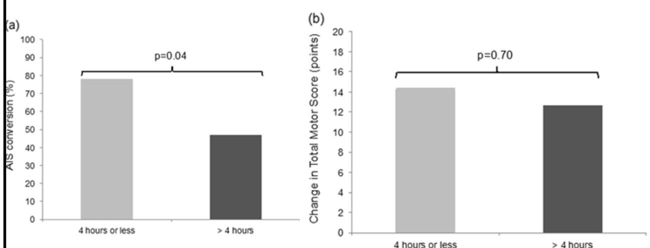
ARTICLE

The influence of neurological examination timing within hours after acute traumatic spinal cord injuries: an observational study

This article has been corrected since Advance Online Publication and a correction is also printed in this issue

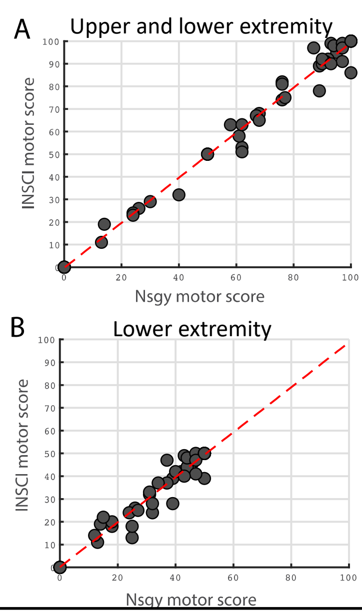
Nathan Evaniew[1] · Babak Sharifi[1] · Zeina Waheed[2] · Nader Fallah[2] · Tamir Ailon[1] · Nicolas Dea[1] · Scott Paquette[1] · Raphaele Charest-Morin[1] · John Street[1,3] · Charles G. Fisher[1] · Marcel F. Dvorak[1,3] · Vanessa K. Noonan[2] · Carly S. Rivers[2] · Brian K. Kwon[1]

Received: 1 August 2019 / Revised: 9 September 2019 / Accepted: 10 September 2019 / Published online: 8 October 2019



- The timing of the exam (not the surgery) had an influence of on AIS conversion
- However, the timing of the exam did not influence motor score improvement

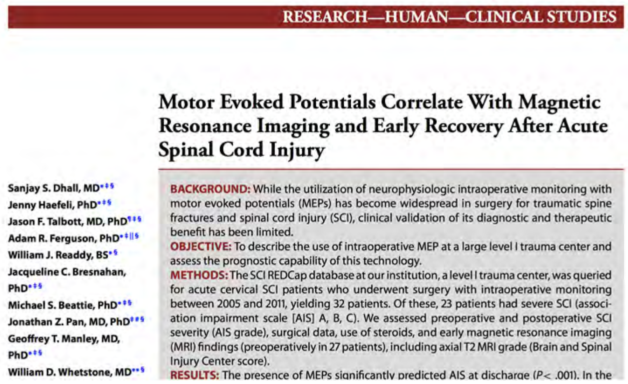
Spinal Cord Injury: Challenges of Early Surgery



- We have to make surgical decisions independent of physical exams
- KEY: standardize timing of neurological exams!
  - ISNCSCI
  - if no ISNCSCI, then NSGY motor score should be done
  - **both have identical information (TRACK-SCI result p<0.01, C>0.98)**
- Example: Follow up data from 2-3 days post injury to 6 months

Spinal Cord Injury: Beyond the Clinical Exam

- Intra-operative neuromonitoring was used to predict outcome after SCI



RESEARCH—HUMAN—CLINICAL STUDIES

Motor Evoked Potentials Correlate With Magnetic Resonance Imaging and Early Recovery After Acute Spinal Cord Injury

Sanjay S. Dhall, MD*‡§
Jenny Haefeli, PhD*‡§
Jason F. Talbott, MD, PhD¶‡§
Adam R. Ferguson, PhD*‡||§
William J. Readdy, BS*§
Jacqueline C. Bresnahan, PhD*‡§
Michael S. Beattie, PhD*‡§
Jonathan Z. Pan, MD, PhD#‡§
Geoffrey T. Manley, MD, PhD*‡§
William D. Whetstone, MD**§

BACKGROUND: While the utilization of neurophysiologic intraoperative monitoring with motor evoked potentials (MEPs) has become widespread in surgery for traumatic spine fractures and spinal cord injury (SCI), clinical validation of its diagnostic and therapeutic benefit has been limited.
OBJECTIVE: To describe the use of intraoperative MEP at a large level I trauma center and assess the prognostic capability of this technology.
METHODS: The SCI REDCap database at our institution, a level I trauma center, was queried for acute cervical SCI patients who underwent surgery with intraoperative monitoring between 2005 and 2011, yielding 32 patients. Of these, 23 patients had severe SCI (association impairment scale [AIS] A, B, C). We assessed preoperative and postoperative SCI severity (AIS grade), surgical data, use of steroids, and early magnetic resonance imaging (MRI) findings (preoperatively in 27 patients), including axial T2 MRI grade (Brain and Spinal Injury Center score).
RESULTS: The presence of MEPs significantly predicted AIS at discharge ($P < .001$). In the

Spinal Cord Injury: Beyond the Clinical Exam

- Intra-operative neuromonitoring was used to predict outcome after SCI
- The presence of MEPs predicted recovery from admission to discharge
- One way to get around the unreliable clinical exam

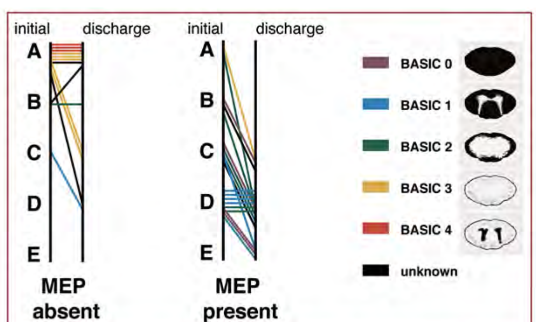
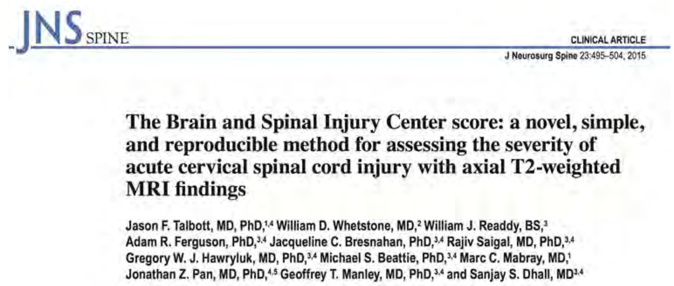


FIGURE. *Change in neurological status by MEP status and axial T2 MRI pattern (BASIC score). Crossover plots for all patients without (left) and with (middle) elicitable MEPs. Each patient on the crossover plots is also color-coded by their axial T2 MRI pattern (legend on far right). A black line indicates that MRI was not performed and axial T2 pattern is therefore unknown.*

Spinal Cord Injury: Beyond the Clinical Exam

- The axial MRI was used to predict recovery from admission to discharge


JNS SPINE

CLINICAL ARTICLE

J Neurosurg Spine 23:495–504, 2015

The Brain and Spinal Injury Center score: a novel, simple, and reproducible method for assessing the severity of acute cervical spinal cord injury with axial T2-weighted MRI findings

Jason F. Talbott, MD, PhD,[1,4] William D. Whetstone, MD,[2] William J. Readdy, BS,[3] Adam R. Ferguson, PhD,[3,4] Jacqueline C. Bresnahan, PhD,[3,4] Rajiv Saigal, MD, PhD,[3,4] Gregory W. J. Hawryluk, MD, PhD,[3,4] Michael S. Beattie, PhD,[3,4] Marc C. Mabray, MD,[1] Jonathan Z. Pan, MD, PhD,[4,5] Geoffrey T. Manley, MD, PhD,[3,4] and Sanjay S. Dhall, MD[3,4]

Spinal Cord Injury: Beyond the Clinical Exam

- The axial MRI was used to predict recovery from admission to discharge

- The BASIC score: developed at SFGH
- Predicts recovery independent of time to OR and IONM

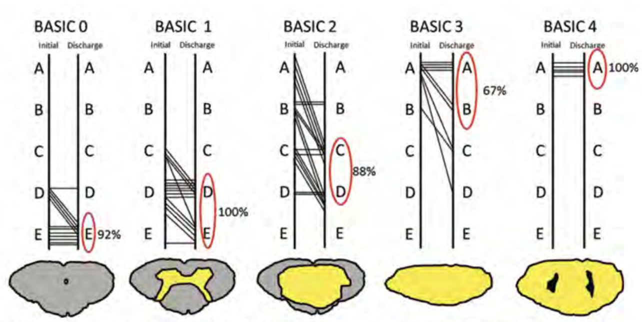


FIG. 5. Admission and discharge AIS grades for all patients in our cohort are plotted within each BASIC score group, with a cartoon schematic of the SCI below each plot. The percentages of patients within each BASIC group with a discharge AIS grade circled in *red* are listed to the right of the discharge AIS grades. Figure is available in color online only.

Jason Talbott, MD

Spinal Cord Injury: Beyond the Clinical Exam

<u>Potential Model</u>

SEVERITY(time) = MRI Findings(time) + E-phys(time) + Clin. Exam(time)

- Big Data: understand these relationships, know when to intervene

Adam Ferguson, PhD

Abel Torres-Espin, PhD

TRACK-SCI
TRANSFORMING RESEARCH AND CLINICAL KNOWLEDGE IN SPINAL CORD INJURY

Spinal Cord Injury: Challenges of Early Surgery

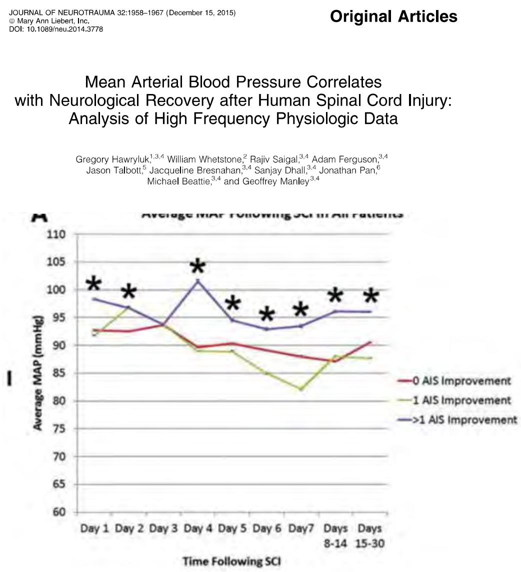
SCI Injury	Pre-Hospital Transport	Emergency Room	Intensive Care	Operating Room	Discharge (rehab/home)	
Family/Public	EMS	ER Physicians	Trauma/ICU	Spine Surgeon	PM & R	

Todays Talk

Spine Surgeon

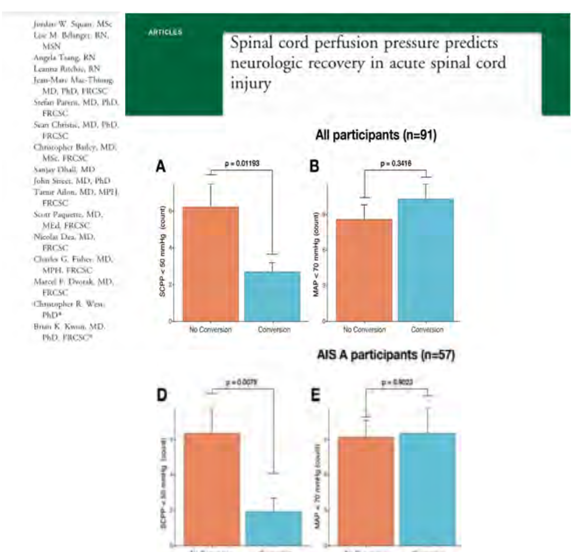
1. **Several issues as we move care to the ED**
   - The clinical exam is notoriously unreliable
   - Extending vasopressor support (Spinal perfusion pressure)

Spinal Cord Injury: Vasopressor Support



- Low MAP is correlated with a decrease in outcome after SCI
- Blood pressure drops: temporary drops is just as bad

Spinal Cord Injury: Vasopressor Support



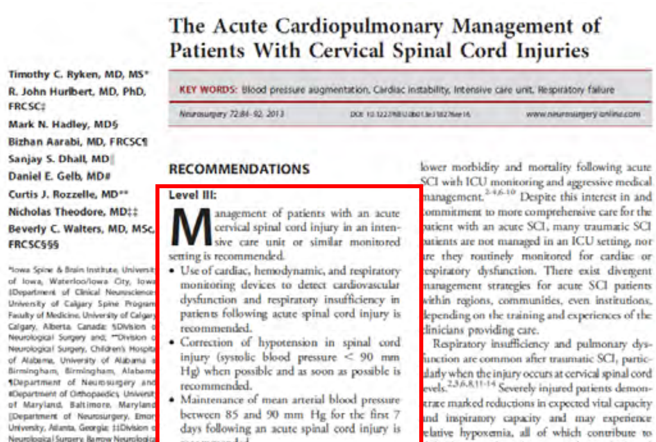
- Low MAP is correlated with a decrease in outcome after SCI
- Blood pressure drops: temporary drops is just as bad
- CAMPER Trial
  - All patients A-C get a lumbar drain
  - Spinal cord perfusion pressure (SCPP) = MAP- ITP
  - Intrathecal pressure (ITP)
  - SCPP >50 mm Hg correlates directly with degree of neuro recovery after SCI
  - MAP does not correlate with recovery

Spinal Cord Injury: Vasopressor Support

Bill Whetstone, MD

- Early vasopressor support in the ED will improve outcome
- Coordination of care between ER physicians and neurosurgery
- Huge ER “buy-in” at SFGH!

Is It Time to Move on from MAP Goals?



The Acute Cardiopulmonary Management of Patients With Cervical Spinal Cord Injuries

Timothy C. Ryken, MD, MS*
R. John Hurlbert, MD, PhD, FRCSC‡
Mark N. Hadley, MD§
Bizhan Aarabi, MD, FRCSC¶
Sanjay S. Dhall, MD||
Daniel E. Gelb, MD#
Curtis J. Rozzelle, MD**
Nicholas Theodore, MD‡‡
Beverly C. Walters, MD, MSc, FRCSC§§§

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KEY WORDS: Blood pressure augmentation, Cardiac instability, Intensive care unit, Respiratory failure

Neurosurgery 72:84-92, 2013 DOI: 10.1227/NEU.0b013e318276ee16 www.neurosurgery-online.com

RECOMMENDATIONS

Level III:

Management of patients with an acute cervical spinal cord injury in an intensive care unit or similar monitored setting is recommended.

- Use of cardiac, hemodynamic, and respiratory monitoring devices to detect cardiovascular dysfunction and respiratory insufficiency in patients following acute spinal cord injury is recommended.
- Correction of hypotension in spinal cord injury (systolic blood pressure < 90 mm Hg) when possible and as soon as possible is recommended.
- Maintenance of mean arterial blood pressure between 85 and 90 mm Hg for the first 7 days following an acute spinal cord injury is recommended.

lower morbidity and mortality following acute SCI with ICU monitoring and aggressive medical management.[2-4,6-10] Despite this interest in and commitment to more comprehensive care for the patient with an acute SCI, many traumatic SCI patients are not managed in an ICU setting, nor are they routinely monitored for cardiac or respiratory dysfunction. There exist divergent management strategies for acute SCI patients within regions, communities, even institutions, depending on the training and experiences of the clinicians providing care.

Respiratory insufficiency and pulmonary dysfunction are common after traumatic SCI, particularly when the injury occurs at cervical spinal cord levels.[2,3,6,8,11-14] Severely injured patients demonstrate marked reductions in expected vital capacity and inspiratory capacity and may experience relative hypoxemia, all of which contribute to global hypoxemia and can exacerbate spinal cord

2013 SCI Guidelines: keep MAP 85-90 mm Hg for 7 days after SCI

ZSFG Spinal Cord Perfusion Protocol

ZSFG Spinal Cord Perfusion Protocol for Severe Traumatic Spinal Cord Injury

Background:

The standard management protocol of blunt traumatic spinal cord injury at ZSFG has included maintaining MAP goals of 85 mm Hg for 5 days after injury as per 2013 published guidelines.

While this has been shown to be beneficial to spinal cord injury patients, it is associated with some morbidity.[4,5] This institution recently participated in a prospective clinical trial (CAMPER) evaluating a different parameter known as spinal cord perfusion pressure (SCPP) in this setting. This involved placing a lumbar intrathecal pressure monitor to measure intraspinal pressure (ISP). Spinal cord perfusion pressure (SCPP) was calculated by subtracting intraspinal pressure (ISP) from mean arterial pressure (MAP).

SCPP = MAP – ISP

A new STANDARD OF CARE !

SCPP was found to correlate directly with neurologic recovery (Figure 1). MAP did **not** correlate with neurologic recovery. Data from this study also showed a direct correlation between relative risk of neurologic recovery and SCPP that plateaued at SCPP of 65 mm Hg. (Figure 2) Finally, multiple studies have documented the morbidity of vasopressor usage in SCI, particularly in elderly patients. For these reasons, the multidisciplinary SCI team at ZSFG have approved an amended SCI management protocol that follows below.

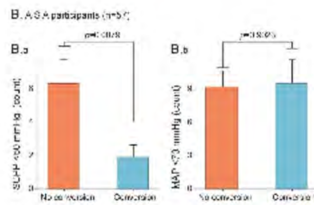

Figure 1. Relationship between SCPP and AIS conversion (recovery) and lack of relationship with MAP[2]

ZSFG Spinal Cord Perfusion Protocol

- No longer utilizing MAP goals in AIS A,B,C SCI
- Every severe SCI patient gets lumbar drain for intraspinal pressure (ISP) monitoring
- Spinal cord perfusion (SCPP) = MAP – ISP

ZSFG Spinal Cord Perfusion Protocol for Severe Traumatic Spinal Cord Injury

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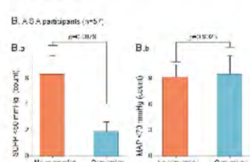
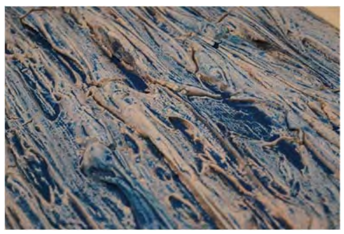


Figure 1. Relationship between SCPP and AIS conversion (recovery) and lack of relationship with MAP[2]

ZSFG Spinal Cord Perfusion Protocol

- First human to receive SCPP protocol outside of trial→ Nov 2017 at ZSFG



ELSEVIER

World Neurosurgery
Available online 14 September 2019
In Press, Corrected Proof

Original Article

Clinical Implementation of Novel Spinal Cord Perfusion Pressure Protocol in Acute Traumatic Spinal Cord Injury at U.S. Level I Trauma Center: TRACK-SCI Study

John K. Yue [1,7], Debra D. Hemmerle [1,7], Ethan A. Winkler [1,7], Leigh H. Thomas [1,7], Xuan Duong Fernandez [1,7], Nikolaos Kyritsis [1,7], Jonathan Z. Pan [2,7], Lisa U. Pascual [3,7], Vineeta Singh [4,7], Philip R. Weinstein [1], Jason F. Talbott [5,7], J. Russell Huie [1,7], Adam R. Ferguson [1,7], William D. Whetstone [6,7], Geoffrey T. Manley [1,7], Michael S. Beattie [1,7], Jacqueline C. Bresnahan [1,7], Praveen V. Mummaneni [1], Sanjay S. Dhall [1,7]

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https://doi.org/10.1016/j.wneu.2019.09.044

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CONCLUSIONS: **In our initial experience of 15 patients with acute SCI, standardized SCPP goal-directed care based on LSAD monitoring for 5 days was feasible. There were no SCPP-related complications. This is the first report of SCPP implementation as clinical standard of care in acute SCI.**

CASPER Trial

- CAMPER 2.0
  - Drain CSF first then drive up MAPs to keep SCPP 60-65 mm Hg

STUDY PROTOCOL

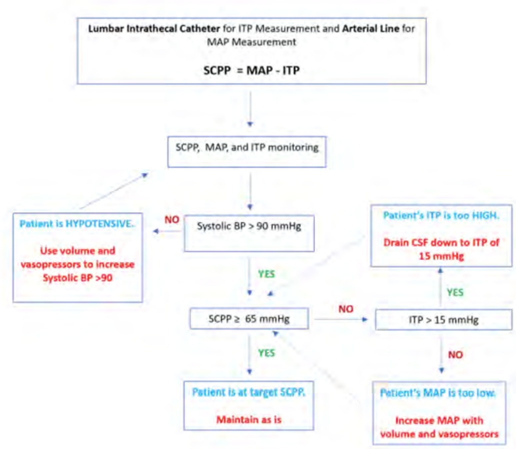
"CASPER" – The Canadian-American Spinal Cord Perfusion Pressure and Biomarker Study"

Sponsors: Rick Hansen Institute
Cervical Spine Research Society

CASPER Trial

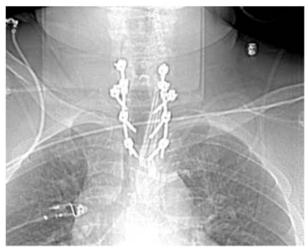
- CAMPER 2.0
  - Drain CSF first then drive up MAPs to keep SCPP 60-65 mm Hg

Figure 16. Algorithm for SCPP Management

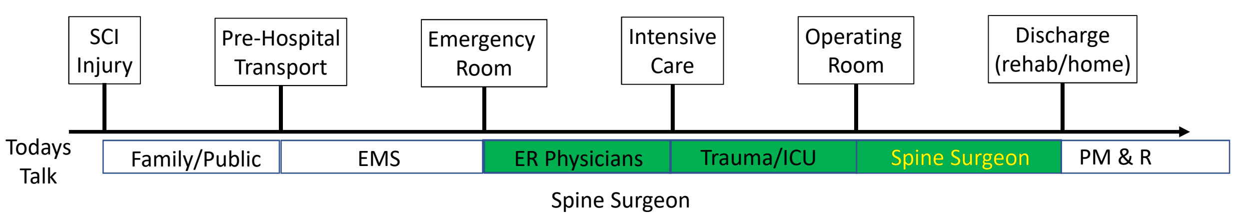


Future Directions: Non-Trauma Spine?

- Is there a role for SCPP and bedside MEPs for high risk degenerative spine cases:
  - Thoracic disk herniation?
  - OPLL?
  - Deformity?

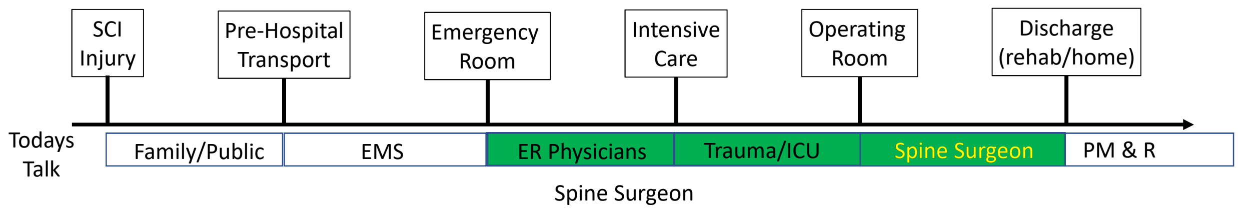


Spinal Cord Injury: Challenges of Early Surgery



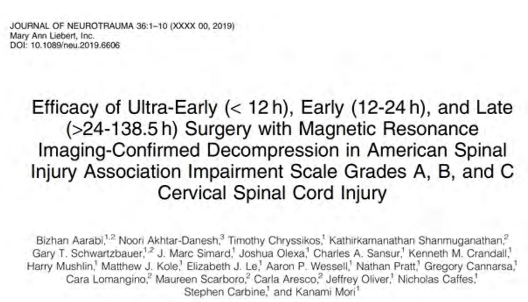
- For early surgery, neurosurgeon changes role
- Quarterback for large team
- We have to get involved early and often!

Spinal Cord Injury: Challenges of Early Surgery



1. **Several issues as we move care to the ED**
   - The clinical exam is notoriously unreliable
   - Extending Vasopressor support (Spinal perfusion pressure)
   - Convincing neurosurgeons!

Spinal Cord Injury: Convincing surgeons



JOURNAL OF NEUROTRAUMA 36:1–10 (XXXX 00, 2019)
Mary Ann Liebert, Inc.
DOI: 10.1089/neu.2019.6606

Efficacy of Ultra-Early (< 12 h), Early (12-24 h), and Late (>24-138.5 h) Surgery with Magnetic Resonance Imaging-Confirmed Decompression in American Spinal Injury Association Impairment Scale Grades A, B, and C Cervical Spinal Cord Injury

Bizhan Aarabi,[1,2] Noori Akhtar-Danesh,[3] Timothy Chryssikos,[1] Kathirkamanathan Shanmuganathan,[2] Gary T. Schwartzbauer,[1,2] J. Marc Simard,[1] Joshua Olexa,[1] Charles A. Sansur,[1] Kenneth M. Crandall,[1] Harry Mushlin,[1] Matthew J. Kole,[1] Elizabeth J. Le,[1] Aaron P. Wessell,[1] Nathan Pratt,[1] Gregory Cannarsa,[1] Cara Lomangino,[2] Maureen Scarboro,[2] Carla Aresco,[2] Jeffrey Oliver,[1] Nicholas Caffes,[1] Stephen Carbine,[1] and Kanami Mori[1]

- Last step is convincing surgeons
- No one wants to operate in the middle of the night

Spiral Cord Injury: Convincing surgeons

rely on pre-operative CT and MRI, with no independent verification of the completeness of spinal cord decompression on post-operative MRI. In our study, when the spinal cord was shown to be decompressed on post-operative MRI, the timing of decompression did not influence AIS grade conversion. Here, we identified intramedullary lesion length as the main predictor of neurological outcome.

- Last step is convincing surgeons
- No one wants to operate in the middle of the night

Spinal Cord Injury: Convincing surgeons

Journal of Neurotrauma

Journal of Neurotrauma: http://mc.manuscriptcentral.com/neurotrauma

LETTER: Efficacy of Ultra-Early (< 12 h), Early (12-24 h), and Late (>24-138.5 h) Surgery with Magnetic Resonance Imaging-Confirmed Decompression in American Spinal Injury Association Impairment Scale Grades A, B, and C Cervical Spinal Cord Injury.

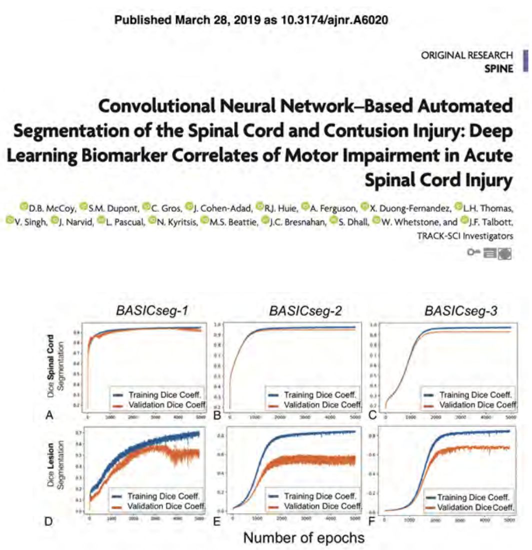
Journal:	*Journal of Neurotrauma*
Manuscript ID	Draft
Manuscript Type:	Letter to the Editor
Date Submitted by the Author:	n/a
Complete List of Authors:	Burke, John; University of California, San Francisco, Neurological Surgery Fehlings, Michael; University Health Network, Division of Genetics and Development, Toronto Western Research Institute, Krembil Neuroscience Program Dhall, Sanjay; University of California San Francisco, Neurological Surgery
Keywords:	spinal cord injury, SURGERY, RECOVERY
Manuscript Keywords (Search Terms):	Letter, Response, Comment

- Last step is convincing surgeons
- No one wants to operate in the middle of the night
- It will take a lot of data to convince spine surgeons that SCI is something that needs their attention with no delay!
- Major errors in paper
  - Early data had more severe injuries
  - Fatal flaw
- No response after two months

Outline

- Epidemiology and TRACK-SCI
- Early intervention
  - Why? Historic and SFGH Data
- Challenges
  - The need for better diagnosis: Neuroelectrodiagnostics, Imaging
  - Extending Vasopressor support (Spinal perfusion pressure)
  - Convincing surgeons: new prospective data
- The future
  - Data Science
  - Blood Biomarkers
  - Chronic SCI

Future of SCI


Published March 28, 2019 as 10.3174/ajnr.A6020

ORIGINAL RESEARCH
SPINE

Convolutional Neural Network–Based Automated Segmentation of the Spinal Cord and Contusion Injury: Deep Learning Biomarker Correlates of Motor Impairment in Acute Spinal Cord Injury

D.B. McCoy, S.M. Dupont, C. Gros, J. Cohen-Adad, R.J. Huie, A. Ferguson, X. Duong-Fernandez, L.H. Thomas, V. Singh, J. Narvid, L. Pascual, N. Kyritsis, M.S. Beattie, J.C. Bresnahan, S. Dhall, W. Whetstone, and J.F. Talbott, TRACK-SCI Investigators

- Data science to use AI to predict who needs early surgery: need open data commons

Future of SCI

JOURNAL OF NEUROTRAUMA 31:19–25 (January 1, 2014)
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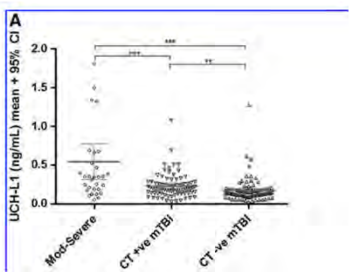
DOI: 10.1089/neu.2013.3040

Original Articles

Acute Biomarkers of Traumatic Brain Injury: Relationship between Plasma Levels of Ubiquitin C-Terminal Hydrolase-L1 and Glial Fibrillary Acidic Protein

Ramon Diaz-Arrastia,[1] Kevin K.W. Wang,[2] Linda Papa,[3] Marco D. Sorani,[4] John K. Yue,[4] Ava M. Puccio,[5] Paul J. McMahon,[5] Tomoo Inoue,[4] Esther L. Yuh,[6] Hester F. Lingsma,[7] Andrew I.R. Maas,[8] Alex B. Valadka,[9] David O. Okonkwo,[5] and Geoffrey T. Manley[4] and the TRACK-TBI Investigators, including Scott S. Casey,[4] Maxwell Cheong,[6] Shelly R. Cooper,[6] Kristen Dams-O'Connor,[10] Wayne A. Gordon,[10] Allison J. Hricik,[5] David K. Menon,[11] Pratik Mukherjee,[6] David M. Schnyer,[12] Tuhin K. Sinha,[13] and Mary J. Vassar[4]



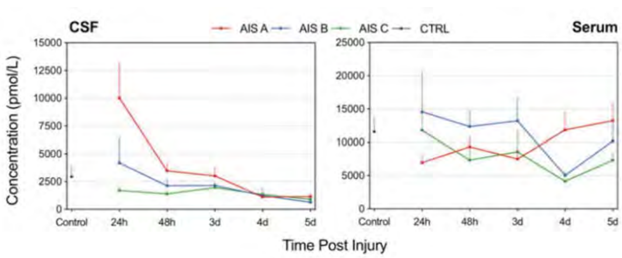
- Data science to use AI to predict who needs early surgery: need open data commons
- Blood biomarkers

Future of SCI

JOURNAL OF NEUROTRAUMA 36:2358–2371 (August 1, 2019)
© Mary Ann Liebert, Inc.
DOI: 10.1089/neu.2018.6256

MicroRNA Biomarkers in Cerebrospinal Fluid and Serum Reflect Injury Severity in Human Acute Traumatic Spinal Cord Injury

Seth Tigchelaar,[1] Rishab Gupta,[1] Casey P. Shannon,[2] Femke Streijger,[1] Sunita Sinha,[3] Stephane Flibotte,[3] Michael A. Rizzuto,[1] John Street,[4] Scott Paquette,[5] Tamir Ailon,[5] Raphaele Charest-Morin,[4] Nicolas Dea,[5] Charles Fisher,[4] Marcel F. Dvorak,[1,4] Sanjay Dhall,[6] Jean-Marc Mac-Thiong,[7] Stefan Parent,[8] Christopher Bailey,[9] Sean Christie,[10] Kendall Van Keuren-Jensen,[11] Corey Nislow,[3] and Brian K. Kwon[1,4]



- Data science to use AI to predict who needs early surgery: need open data commons
- MicroRNA: possible blood and CSF biomarker

Future of SCI

ARTICLE

https://doi.org/10.1038/s41586-018-0649-2

Targeted neurotechnology restores walking in humans with spinal cord injury

Fabien B. Wagner[1,2,15], Jean-Baptiste Mignardot[1,2,15], Camille G. Le Goff-Mignardot[1,2,15], Robin Demesmaeker[1,2], Salif Komi[1,2], Marco Capogrosso[3], Andreas Rowald[1,2], Ismael Seáñez[1,2], Miroslav Caban[4,5], Elvira Pirondini[1,2,6], Molywan Vat[7], Laura A. McCracken[1,2], Roman Heimgartner[1,2], Isabelle Fodor[2], Anne Watrin[4], Perrine Seguin[1,2], Edoardo Paoles[4], Katrien Van Den Keybus[2], Grégoire Eberle[2], Brigitte Schurch[2], Etienne Pralong[7], Fabio Becce[8], John Prior[9], Nicholas Buse[10], Rik Buschman[10], Esra Neufeld[11], Niels Kuster[11,12], Stefano Carda[2], Joachim von Zitzewitz[4], Vincent Delattre[4], Tim Denison[10,13], Hendrik Lambert[4], Karen Minassian[1,2,16], Jocelyne Bloch[2,7,14,16] & Grégoire Courtine[1,2,7,14,16]*

- Data science to use AI to predict who needs early surgery: need open data commons
- Blood biomarkers
- Chronic SCI:
  - 2 major centers
  - converts A to a C
  - epidural stimulation as a therapeutic target

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- Michael Beattie, PhD
- Jaqueline Bresnahan, PhD
- Adam Ferguson, PhD

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- Julia Thompson Gallego, MS, ACNP-BC
- Daniel McGuire, MS, ACNP-BC
- Amy Winkelman, MSN, ACNP-BC
- Twyila Lay, MS, ACNP-BC
- Among others!

BRAIN AND SPINAL INJURY CENTER
San Francisco General Hospital
University of California, San Francisco

UCSF Weill Institute for Neurosciences | Department of Neurological Surgery

References

1. Fehlings, Michael G., et al. "A clinical practice guideline for the management of patients with acute spinal cord injury and central cord syndrome: recommendations on the timing (≤ 24 hours versus> 24 hours) of decompressive surgery." *Global spine journal* 7.3_suppl (2017): 195S-202S.

2. Papadopoulos, Stephen M., et al. "Immediate spinal cord decompression for cervical spinal cord injury: feasibility and outcome." *Journal of Trauma and Acute Care Surgery* 52.2 (2002): 323-332.

3. Lenehan, Brian, et al. "The urgency of surgical decompression in acute central cord injuries with spondylosis and without instability." *Spine* 35.21S (2010): S180-S186.

4. Wilson, J. R., et al. "Early versus late surgery for traumatic spinal cord injury: the results of a prospective Canadian cohort study." *Spinal cord* 50.11 (2012): 840-843.

5. Fehlings, Michael G., et al. "Early versus delayed decompression for traumatic cervical spinal cord injury: results of the Surgical Timing in Acute Spinal Cord Injury Study (STASCIS)." *PloS one* 7.2 (2012).

6. Jug, Marko, et al. "Neurological recovery after traumatic cervical spinal cord injury is superior if surgical decompression and instrumented fusion are performed within 8 hours versus 8 to 24 hours after injury: a single center experience." *Journal of neurotrauma* 32.18 (2015): 1385-1392.

7. Dvorak, Marcel F., et al. "The influence of time from injury to surgery on motor recovery and length of hospital stay in acute traumatic spinal cord injury: an observational Canadian cohort study." *Journal of neurotrauma* 32.9 (2015): 645-654.

8. Grassner, Lukas, et al. "Early decompression (< 8 h) after traumatic cervical spinal cord injury improves functional outcome as assessed by spinal cord independence measure after one year." *Journal of neurotrauma* 33.18 (2016): 1658-1666.

9. Bourassa-Moreau, Etienne, et al. "Do patients with complete spinal cord injury benefit from early surgical decompression? Analysis of neurological improvement in a prospective cohort study." *Journal of neurotrauma* 33.3 (2016): 301-306.

10. Burke, John F., et al. "Ultra-early (< 12 hours) surgery correlates with higher rate of American Spinal Injury Association Impairment Scale conversion after cervical spinal cord injury." *Neurosurgery* 85.2 (2019): 199-203.

11. Jug, Marko, et al. "Window of opportunity for surgical decompression in patients with acute traumatic cervical spinal cord injury." *Journal of Neurosurgery: Spine* 1.aop (2019): 1-9.

12. Vaccaro, Alexander R., et al. "Neurologic outcome of early versus late surgery for cervical spinal cord injury." *Spine* 22.22 (1997): 2609-2613.

13. Sapkas, G. S., and S. A. Papadakis. "Neurological outcome following early versus delayed lower cervical spine surgery." *Journal of Orthopaedic Surgery* 15.2 (2007): 183-186.

14. Mattiassich, Georg, et al. "Functional outcomes in individuals undergoing very early (< 5 h) and early (5–24 h) surgical decompression in traumatic cervical spinal cord injury: analysis of neurological improvement from the Austrian Spinal Cord Injury Study." *Journal of neurotrauma* 34.24 (2017): 3362-3371.

15. Kim, Moinay, et al. "Early (≤ 48 hours) versus late (> 48 hours) surgery in spinal cord injury: Treatment outcomes and risk factors for spinal cord injury." *World neurosurgery* 118 (2018): e513-e525.

16. Sewell, Mathew David, et al. "Results of early and late surgical decompression and stabilization for acute traumatic cervical spinal cord injury in patients with concomitant chest injuries." *World neurosurgery* 118 (2018): e161-e165.

17. Aarabi, Bizhan, et al. "Efficacy of Ultra-Early (< 12 h), Early (12-24 h), and Late (> 24-138.5 h) Surgery with Magnetic Resonance Imaging-Confirmed Decompression in American Spinal Injury Association Impairment Scale Grades A, B, and C Cervical Spinal Cord Injury." *Journal of neurotrauma* (2019).

The Role of Electromyography in the Assessment of Pain

John Engstrom, M.D.
Professor of Neurology
June 2020

Disclosures

Sadly, I have nothing to disclose

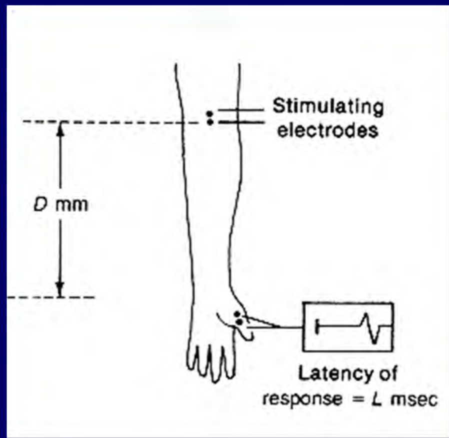
Utility of EMG

EMG studies are a <u>sensitive</u> and <u>semi quantitative</u> extension of the neurologic examination to assess peripheral nervous system function

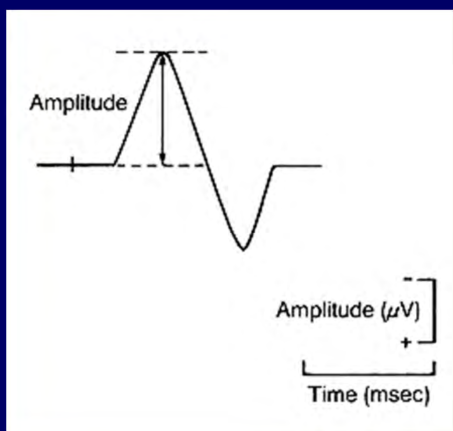
Electromyography

- EMG-usually refers to the combination of needle EMG and nerve conduction studies, but can refer to the needle EMG study only
- Nerve Conduction Studies
  - SNAPs-Sensory nerve action potentials
  - CMAPs-Compound motor action potentials

Nerve Conduction Studies (NCS)



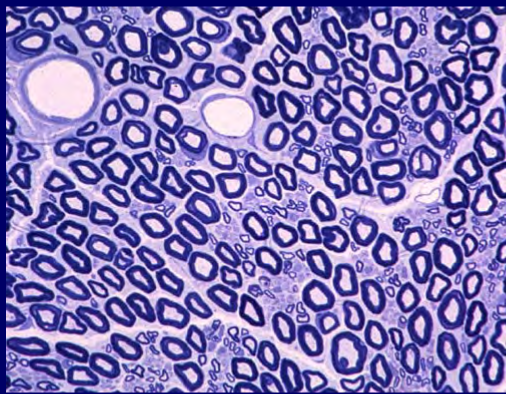
Amplitude is Proportional to the Number of Functioning Axons



Nerve Fiber Function

- Motor-motor nerve fibers-muscle power
- Sensory nerve fibers
  - Large Fiber-light touch, vibration, position
  - Small Fiber-pain, temperature
- Nerve fibers are packed closely together in nerve tissues-all are often damaged together in focal nerve tissue injury

Normal Sural Nerve Biopsy



What EMG Does/Does Not Assess

- EMG is used to assess large fiber function
  - Motor nerve fibers-power
  - Large diameter sensory fibers-light touch, position, vibration
- EMG cannot be used to directly assess small diameter nerve fiber function
  - Pain and temperature
  - Neuropathic burning or electrical sensation
- Pain of non-neurologic origin

EMG in the Assessment of Pain

- The value of EMG in the assessment of pain is the presence of other neurologic findings on the EMG that contribute to an accurate diagnosis
- Neurologic findings with EMG correlates
  - Weakness of specific muscles by exam
  - Focal sensory loss by exam-asymmetric light touch sensory loss in a dermatomal distribution

The Weak Patient: Uses of EMG

True weakness vs. breakaway weakness

Localization-AHC, nerve, NMJ or muscle

Pathology-Axonal vs. demyelination

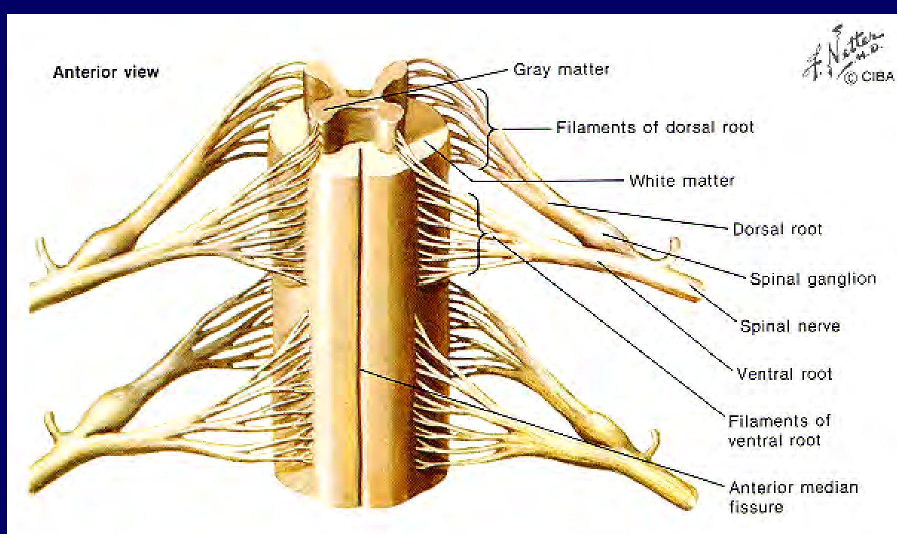
Localize site of nerve damage - entrapment

Quantify severity of nerve tissue injury and prognostic assessment for recovery

Distinguish weakness from PNS, CNS, and combined CNS and PNS weakness

Neurologic Exam Evaluation of Sensory Loss

- Rule of 2 Ps and 2 Cs
- Sensory Loss in a Patch = Peripheral
  – Nerve root distribution
  – Nerve distribution
- Circumferential Limb Numbness = Central
  – Too many nerves or roots to be plausible
  – Exception-circumferential in the distal legs can be polyneuropathy, CNS, or both



EMG Evaluation of Sensory Loss

- Sensory Nerve Action Potentials (SNAPs)
  - Assesses large fiber sensory function both at and distal to the dorsal root ganglia (DRG)
  - Amplitude reflects # functioning sensory axons
  - Nerve-specific, age-adjusted normal values
- Numb patch present on exam and NCS:
  - SNAPs normal- root
  - SNAPs low-nerve

Common Abnormal EMG Scenarios in Assessment of Pain

- If nerve tissue is injured, it is common that motor and sensory (large and small nerve fibers) are damaged together
  - Weakness-abnormal CMAP results
  - Weakness-abnormal needle EMG results
  - Sensory-allow us to tell if a sensory deficit on neurologic exam is due to nerve or nerve root injury

Common Normal EMG Scenarios in Assessment of Pain

- If pain is referred pain from non-neurologic source, then EMG study will be normal
- If only small diameter sensory nerve fibers are injured, then EMG study will be normal
  - Pin sensory loss on exam if small fiber loss
  - Pin sensation preserved if no small sensory nerve fiber loss

EMG if the Neurologic Exam Does Not Provide Clear Findings

- Breakaway weakness due to pain…or with underlying true weakness as well
- Patch of equivocal sensory loss not exactly in distribution of nerve or nerve root?
  - May or may not be clear by light touch sensation on neurologic exam
  - NCS used to quantitatively determine if large fiber sensory nerve tissue injury present distal to the dorsal root ganglion

"Positive" Sensory Symptoms

- Positive sensory symptoms
  - Pain quality burning or electrical "neuropathic"
  - Paresthesias, tingling, pins and needles
  - Indicates electrical firing of abnormal, but alive, sensory neurons
  - "Positive" refers to a new gain of abnl function
- If only positive sensory symptoms are present (no sensory loss), SNAPs normal

Conclusions-I

- EMG is a sensitive, semi-quantitative test of PNS function that is an extension of the neurologic exam
- EMG studies assess function of motor and large diameter sensory fibers that co-locate with pain fibers in nerve roots and nerves
- Sensory loss on exam combined with sensory NCS results can tell if nerve tissue injury is from a nerve root or a nerve

Conclusions-II

- EMG studies do not assess small diameter nerve fiber function (pin sensation) or neuropathic pain symptoms directly
- Diagnostic accuracy improves when anatomy (imaging) and physiology (function measured by neurologic exam or EMG) reach the same diagnostic conclusion

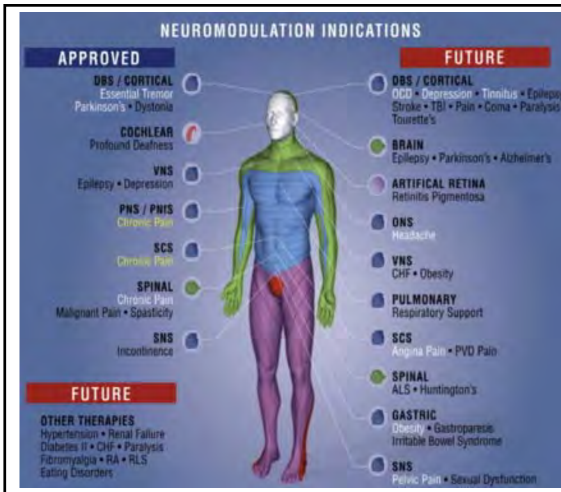
15th annual UCSF Spine Symposium

Spine Pain

Neuromodulation

June 5-6 2020

Line Jacques, MD, MSc., FRCS(C), FACS, DABNS
John Adams Endowed Professorship in Peripheral Nerve and Pain Management
Professor and Vice Chair of Clinical Neurological Surgery
Director of Peripheral Nerve and Pain Surgery
Department of Neurological Surgery, University of California, San Francisco, USA



No Disclosure

Definition

Neuromodulation is an important therapy that modulates/modifies neural responses to a neural stimulus so the body has a different response at the peripheral, spinal, or brain level.
Neuromodulation can be performed by electrical stimulation or by drug delivery.
Mark N. Malinowski, ... Timothy R. Deer, in Neuromodulation (Second Edition), 2018

Background and Epidemiology

Low Back Pain

1.39 per 1,000 person-years in the United States.

Low back pain accounted for 15% of all emergency visits.

Injuries sustained at home (65%) accounted for most patients

Affects up to 80% of the population at some point in life

1% to 2% of the United States adult population is disabled because of LBP.

Spine J. 2012 Jan;12(1):63-70. doi: 10.1016/j.spinee.2011.09.002. Epub 2011 Oct 5.
Low back pain in the United States: incidence and risk factors for presentation in the emergency setting.
Waterman BR[1], Belmont PJ Jr, Schoenfeld AJ.

Failed Back Surgery Syndrome

Definitions

Persistent or recurrent pain in the back/neck or limbs despite surgery or treatment thought likely to relieve pain

Failure rate of 20%

10 in every 100,000 (ranging from 5 to 20 per 100,000 depending upon the frequency of **spinal surgery failure** accepted)

Failed back surgery syndrome – definition, epidemiology and demographics
Simon Thomson BJ Pain March 21, 2013

Failed Back Surgery Syndrome & Spinal Cord Stimulation

Structural causes can be identified post-operatively by CT scan, MRI, myelogram, or X-ray

If no structural cause can be found, persistent pain may be neuropathic - caused by the prolongation of the original condition and/or by the additional physical impact of invasive surgery. Patients may be candidates for neurostimulation therapy

Spinal cord stimulation (SCS) is a commonly used therapy option for chronic pain patients refractory to other treatments, by delivering electricity via implanted electrodes directly to the spinal neural fibers.
The therapy is reversible **and used to** relieve pain **and** reduce **medication intake.**
Unlike surgical interventions for pain, it does not ablate **pain pathways or change anatomy.**

British Pain Society working group consensus guidelines

Patient Selection and Indications for SCS

Criteria for identifying patients suitable for consideration of spinal cord stimulation (SCS)

- Neurogenic pain pathology is the basis of pain complaint
- Clear diagnosis of neuropathic pain is evident, although accompanying nociceptive pain may be present (e.g. FBSS with neuropathic pain in limb(s), CRPS)
- Patient has a suboptimal response to comprehensive conservative therapy (that is, failed trials of physical and functional therapies, polypharmacy including anticonvulsants, antidepressants and other drugs [such as opioids] due to lack of efficacy or serious side effects)
- No significant unmanaged psychological issues present
- Further corrective surgical intervention not indicated
- No serious drug or chemical substance dependence or abuse
- No surgical contraindication to implantation
- Successful trial screening for duration of up to 2 weeks. Too short a trial may mislead success and too long adds potential complications
- Patient understands and is willing to participate in the therapy
- Implantation centre and hospital staff are educated, familiar and willing to participate as a team
- Spinal neural pathway to painful site distally must be preserved to experience pleasant paraesthesia with SCS

CRPS: complex regional pain syndrome; FBSS: failed back surgery syndrome.

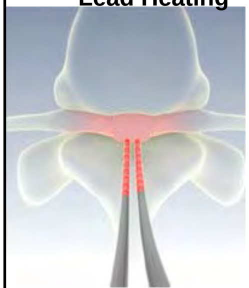
Indications for spinal cord stimulation (SCS). Working Group consensus adapted from the British Pain Society guidelines[1]

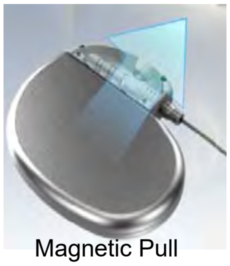
Good indications for SCS (likely to respond)	Intermediate indications for SCS (may respond)	Not indicated for SCS (rarely respond)
• Failed back surgery syndrome • Refractory angina pectoris • Neuropathic pain secondary to peripheral nerve lesion • Radicular pain following cervical spine surgery	• Pain associated with peripheral vascular disease • Intercostal neuralgia, such as post-thoracotomy • Other peripheral neuropathic pain syndromes, such as those following trauma, may respond • Complex regional pain syndrome	• Avulsive brachial plexopathy • Nociceptive axial pain following surgery* • Central pain of non-spinal cord origin • Pain in spinal cord injury • Postherpetic neuralgia • Phantom pain/post amputation

* Except when part of failed back surgery syndrome.

MRI Compatibility/Risk

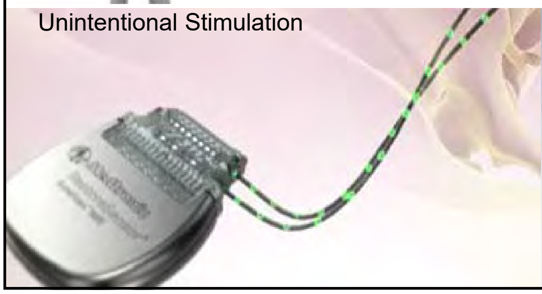
Lead Heating



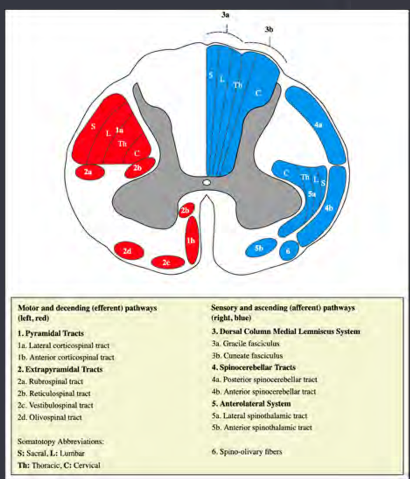


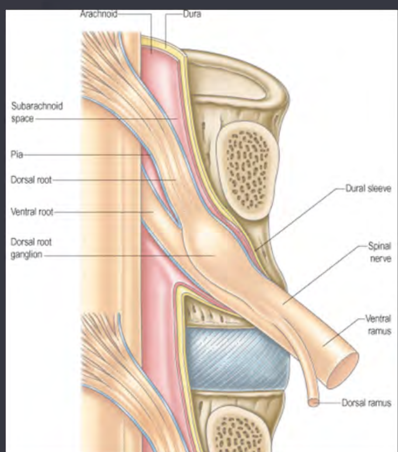
Magnetic Pull

MRI fields, alone or in combination, may interact with and pose concerns for implanted neurostimulation systems.



Anatomy

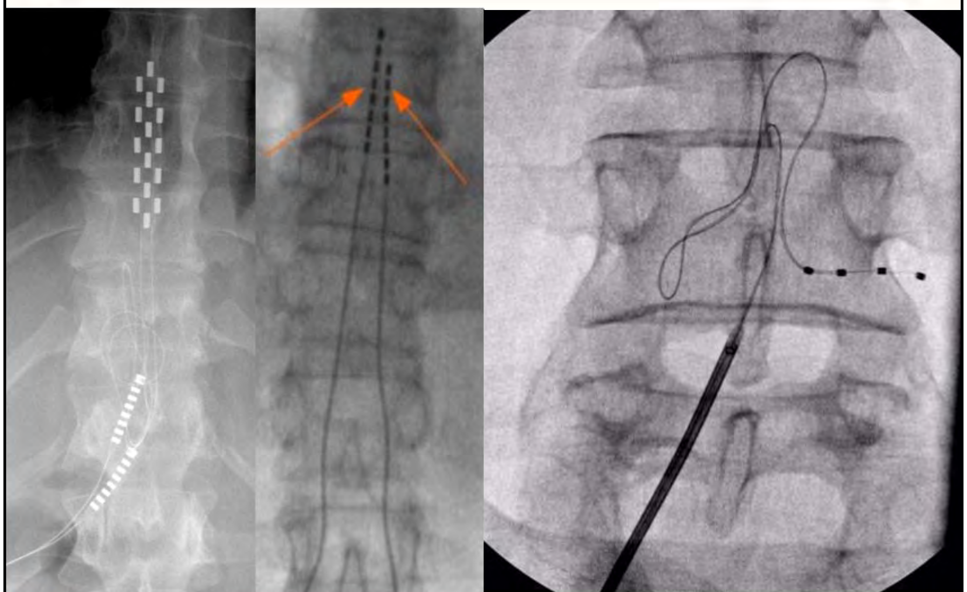




Gray's Anatomy (2005). Standring, E. (Ed.). Elsevier.

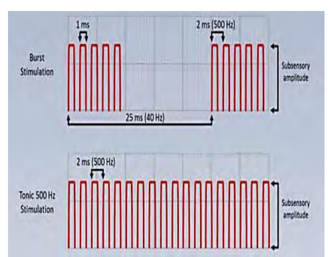
DCS: CNS

DRGS:PNS



DCS: CNS DRGS:PNS

Spinal Cord Stimulation: New technology/New waves



Clinical Trials

BACK PAIN REDUCTION at 6-12 months

Avalon closed-loop

HF10/SenzaRCT(HF10/conv)/SUNBURST(conv/burst)/PROCO 1Khz

(75%/48%/67-45%/-37-45%/-48-54%)

ELSEVIER

World Neurosurgery
Volume 131, November 2019, Pages 264-274.e3

Literature Review

Waves of Pain Relief: A Systematic Review of Clinical Trials in Spinal Cord Stimulation Waveforms for the Treatment of Chronic Neuropathic Low Back and Leg Pain

Jeffery Head [1, 2], Jacob Mazza [1, 2], Victor Sabourin [2], Justin Turpin [1, 2], Christian Hoelscher [2], Chengyuan Wu [2], Ashwini Sharan [2]

These waveforms include traditional paresthesia-based SCS (<100 Hz), paresthesia-free high-frequency SCS (5–10 kHz), burst SCS, and subperception SCS (1–5 kHz). Level 1 evidence critically evaluating the efficacy of these different waveforms is lacking

Future RCT's investigating the optimal choice of stimulation frequency based on pain etiology are warranted

Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results From a Multicenter, Randomized, Controlled Pivotal Trial

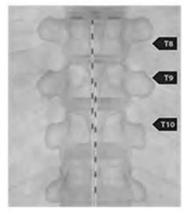
Leonardo Kapural, MD, PhD,[*] Cong Yu, MD,[‡] Matthew W. Doust, MD,[§] Bradford E. Gliner, MS,[¶] Ricardo Vallejo, MD, PhD,[‖] B. Todd Sitzman, MD, MPH,[#] Kasra Amirdelfan, MD,[**] Donna M. Morgan, MD,[‡‡] Thomas L. Yearwood, MD, PhD,[§§] Richard Bundschu, MD,[¶¶] Thomas Yang, MD,[‡] Ramsin Benyamin, MD,[‖] and Abram H. Burgher, MD

Neurosurgery. 2016 Nov; 79(5): 667–677.
Published online 2016 Sep 6. doi: 10.1227/NEU.0000000000001418

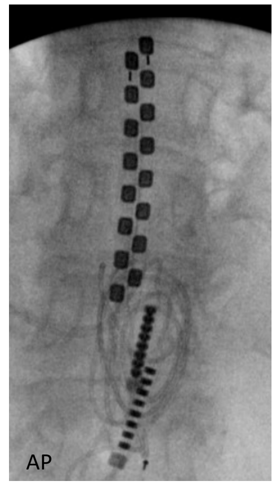
At 24 months, HF10 therapy than traditional SCS (back pain: 76.5% vs 49.3%; leg pain: 72.9% vs 49.3%;

Paresthesia Free Stimulation

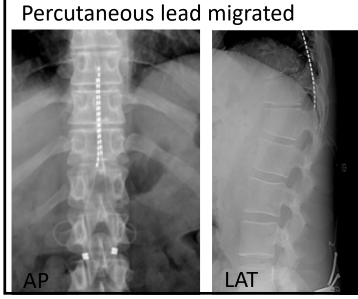
Short duration(30µs)
high-frequency (10 kHz)
low-amplitude (1 to 5 mA) pulses to the spinal epidural space in such a manner as to not produce paresthesia

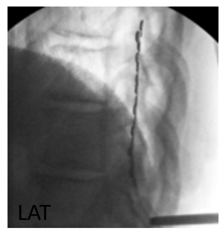


Paddle lead



Percutaneous lead migrated





A Systematic Evaluation of Burst Spinal Cord Stimulation for Chronic Back and Limb Pain.

Neuromodulation. 2016 Jun;19(4):398-405. doi: 10.1111/ner.12440. Epub 2016 May 3.

37-45% trunk reduction(sunburst conv/burst)

A randomised controlled trial has found excellent pain relief and no clinical difference among spinal cord stimulation frequencies from 1kHz–10kHz. Further, the study showed that 1kHz stimulation provides similar pain relief using significantly less energy than higher frequencies.

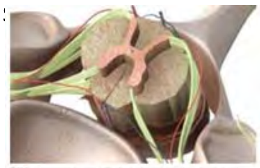
The PROCO (Effects of Pulse Rate On Clinical Outcomes in Kilohertz Frequency Spinal Cord Stimulation) randomized controlled trial is a multicenter, double-blind, crossover study. The results were presented at the International Neuromodulation Society World Congress (INS; 27 May–1 June, Edinburgh, UK).45-54% back pain reduction

Stimulation of the L2–L3 Dorsal Root Ganglia Induces Effective Pain Relief in the Low Back

Frank Huygen, MD, PhD, FIPP*; Liong Liem, MD, PhD, FIPP†; William Cusack, PhD‡; Jeffery Kramer, PhD‡
*Erasmus University, Rotterdam, Maastricht, The Netherlands; †Maastricht University Medical Centre, Maastricht, The Netherlands; ‡Abbott Laboratories, Sunnyvale, California U.S.A.

50% back pain reduction at 12 months

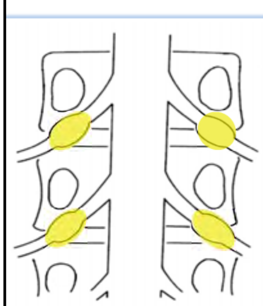
Huygen F, Liem L, Cusack W, Kramer J. **Stimulation of the L2-L3 dorsal root ganglia induces effective pain relief in the low back** [published online May 9, 2017]. *Pain Pract*. doi: 10.1111/papr.12591

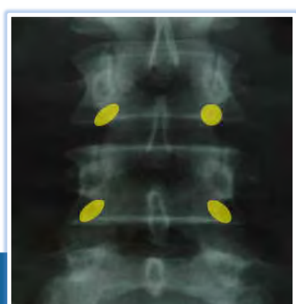


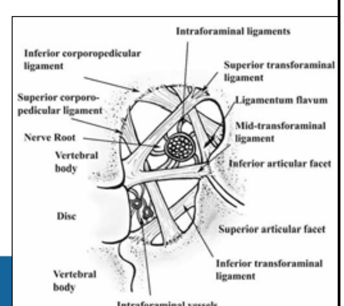
Peripheral nerve field stimulation: Specially designed leads have been approved for this use, especially for treating the neuropathic back pain component of FBSS. Use of this technique, in combination with conventional SCS or alone, has been published with impressive results in case series.[50] However, cost-effectiveness and long-term efficacy are not established. Br J Pain. 2012 Nov; 6(4): 153–161.doi: 10.1177/2049463712470222
PMCID: PMC4590103**Failed back surgery syndrome: a suggested algorithm of care**
Praveen Ganty and Manohar Sharma

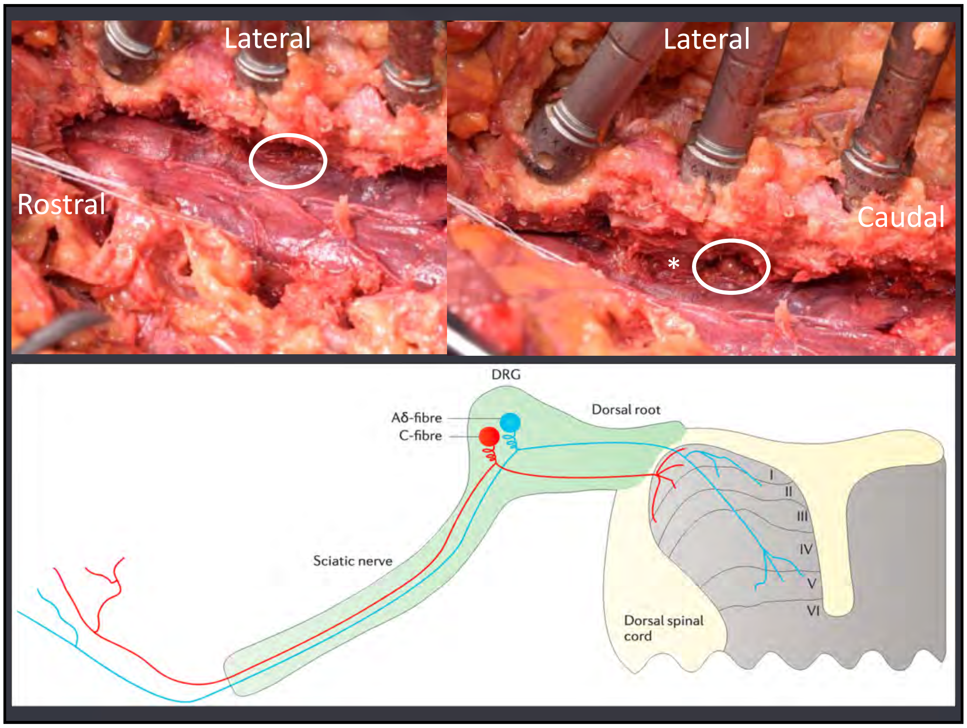
Dorsal Root Ganglion

- Location: Dural sheath, little CSF, bony neural foramen
- Structure: PSN somata (x3) (large-light and dark-small), glia
    - Pseudo-unipolar bifurcating at T-junction
    - Central (divergent vs convergent) vs peripheral projection (receptors)
    - Foraminal Ligaments: Extraforaminal, Transforaminal, Intraforaminal









Clinical studies

A Prospective Study of Dorsal Root Ganglion Stimulation for the Relief of Chronic Pain

Timothy R. Deer, MD*, Eric Grigsby, MD†, Richard L. Weiner, MD‡, Bernard Wilcosky, MD§, Jeffery M. Kramer, PhD¶

Pilot Study (2012): 10 patients, 3-7d fu, ~70% pain relief from various diagnoses (safe, efficacy)

One-Year Outcomes of Spinal Cord Stimulation of the Dorsal Root Ganglion in the Treatment of Chronic Neuropathic Pain

Liong Liem, MD*; Marc Russo, MD†; Frank J.P.M. Huygen, MD, PhD‡; Jean-Pierre Van Buyten, MD§; Iris Smet, MD§; Paul Verrills, MD¶; Michael Cousins, MD, PhD**; Charles Brooker, MD††; Robert Levy, MD, PhD‡‡; Timothy Deer, MD§§; Jeffrey Kramer, PhD¶¶

Prospective Cohort Study (2014): 51 patients, 1y fu, ~56% pain relief from various diagnoses (equivalent to SCS)

Stimulation of Dorsal Root Ganglia for the Management of Complex Regional Pain Syndrome: A Prospective Case Series

Jean-Pierre Van Buyten, MD*; Iris Smet, MD*; Liong Liem, MD†; Marc Russo, MD‡; Frank Huygen, MD, PhD§

**Multidisciplinary Pain Center, Algemeen Ziekenhuis Nikolaas, Sint-Niklaas, Belgium; †Sint Antonius Hospital, Nieuwegein, the Netherlands; ‡Hunter Pain Clinic, Broadmeadow, New South Wales, Australia; §Erasmus University, Rotterdam, the Netherlands*

Prospective Cohort Study (2013): 10 patients, 1y fu,~62% pain relief for LE CRPS, improved function

Dorsal Column Stimulation vs. Dorsal Root Ganglion Stimulation for Complex Regional Pain Syndrome Confined to the Knee: Patients' Preference Following the Trial Period

Catelijne M. van Bussel, MD; Dirk L. Stronks, PhD; Frank J.P.M. Huygen, MD, PhD
Center for Pain Medicine, Erasmus MC–University Medical Center, Rotterdam, the Netherlands

Prospective Randomized Cross-Over Study (2017): 12 patients, 2 weeks (1 wk per modality),~ 10/12 (83.3%) preferred DRG stimulation vs 2 (16.7%) preferred SCS (P = 0.04)

Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial

Timothy R. Deer[a,*], Robert M. Levy[b], Jeffery Kramer[c], Lawrence Poree[d], Kasra Amirdelfan[e], Eric Grigsby[f], Peter Staats[g], Allen W. Burton[h], Abram H. Burgher[i], Jon Obray[j], James Scowcroft[k], Stan Golovac[l], Leonardo Kapural[m], Richard Paicius[n], Christopher Kim[a], Jason Pope[a], Thomas Yearwood[o], Sam Samuel[p], W. Porter McRoberts[q], Hazmer Cassim[r], Mark Netherton[s], Nathan Miller[t], Michael Schaufele[u], Edward Tavel[v], Timothy Davis[w], Kristina Davis[c], Linda Johnson[c], Nagy Mekhail[p]

PRCT: 152 Patients with LE CRPS, DRGS or SCS,

- Primary endpoint:
  - ≥50% pain relief in their primary area of pain at the end of the trial phase, and
  - ≥50% pain relief in their primary area of pain at the 3-month visit post-implant, and
  - Freedom from stimulation-induced neurological deficit through 3 months

Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial

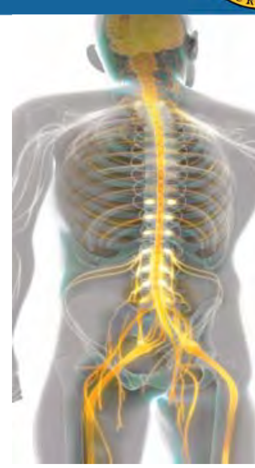
Timothy R. Deer[a,*], Robert M. Levy[b], Jeffery Kramer[c], Lawrence Poree[d], Kasra Amirdelfan[e], Eric Grigsby[f], Peter Staats[g], Allen W. Burton[h], Abram H. Burgher[i], Jon Obray[j], James Scowcroft[k], Stan Golovac[l], Leonardo Kapural[m], Richard Paicius[n], Christopher Kim[a], Jason Pope[a], Thomas Yearwood[o], Sam Samuel[p], W. Porter McRoberts[q], Hazmer Cassim[r], Mark Netherton[s], Nathan Miller[t], Michael Schaufele[u], Edward Tavel[v], Timothy Davis[w], Kristina Davis[c], Linda Johnson[c], Nagy Mekhail[p]

81.2%	DRG patients met the primary endpoint vs 55.7% SCS at 3 months (benefit)
74.2%	DRG patients met primary endpoint vs 53.0% SCS at 12 months (durability)
69.5%	*DRG patients* had ≥80% *pain relief* at 3-months
94.5%	DRG patients had no stimulation *outside primary area of pain* at 12 months

Morgalla MH, Fortunato M, Lepski G, Chander BS. Dorsal root ganglion stimulation (DRGS) for the treatment of chronic neuropathic pain: A single-center study with long-term prospective results in 62 cases. Pain Physician 2018;21:E377–87.

DRGS: Advantages

- LE CRPS
- Less ES AEs
- Less positionally dependent
- Lower amplitude, prolonged battery life
- Less migration
- Difficult targets: foot, perineum, back
- Precise targeting

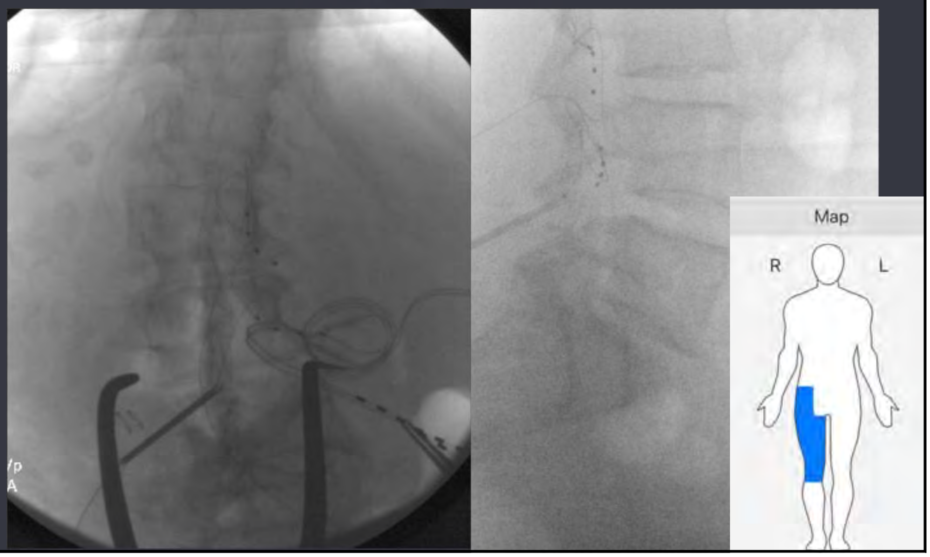


Case

- HPI:
  - 81yo F with prolonged history of R anteromedial thigh pain, N/T
  - Multiple previous modalities trialed:
    - DC SCS several years ago, inserted to treat right leg/quad pain after persistent pain post-MIS laminoforaminotomies
    - Initially good relief used it 24/7, several years later has pain holiday x 1y and didn't use it
    - Pain returned requiring SCS use; helps with pain, though has become less effective and now causes intolerable bilateral foot painful paresthesias
- OE:
  - Strong to bilateral LE 5/5 with symmetrical reflexes
  - Hypoesthesia to anteromedial thigh

Case

Case



Neuromodulation. 2020 Feb;23(2):196-202. doi: 10.1111/ner.12937. Epub 2019 Mar 1.

A Prospective Study of Dorsal Root Ganglion Stimulation for Non-Operated Discogenic Low Back Pain.

Kallewaard JW[1], Edelbroek C[1], Terheggen M[1], Raza A[2], Geurts JW[1].

RESULTS:
Treatment with DRG stimulation reduced LBP ratings (68.3% reduction), from mean 7.20 ± 1.3 at baseline to 2.29 ± 2.1 after 12 months ($p = < 0.001$). Oswestry ratings of disability significantly decreased ($p = < 0.001$) from 42.09 ± 12.9 at baseline to 21.54 ± 16.4 after six months of treatment and to 20.1 ± 16.6 after 12 months. The average quality of life EQ-5D index score at baseline was 0.61 ± 0.12 and 0.84 ± 0.13 after 12 months.

DISCUSSION:
DRG stimulation treatment for discogenic LBP improved the level of pain, function, and quality of life. Further research is necessary into efficacy of DRG stimulation in patients with chronic discogenic LBP and to determine the place of SCS in the treatment algorithm.

Pain Pract. 2019 Feb;19(2):204-210. doi: 10.1111/papr.12734. Epub 2018 Dec 10.

Prospective Cohort Analysis of DRG Stimulation for Failed Back Surgery Syndrome Pain Following Lumbar Discectomy.

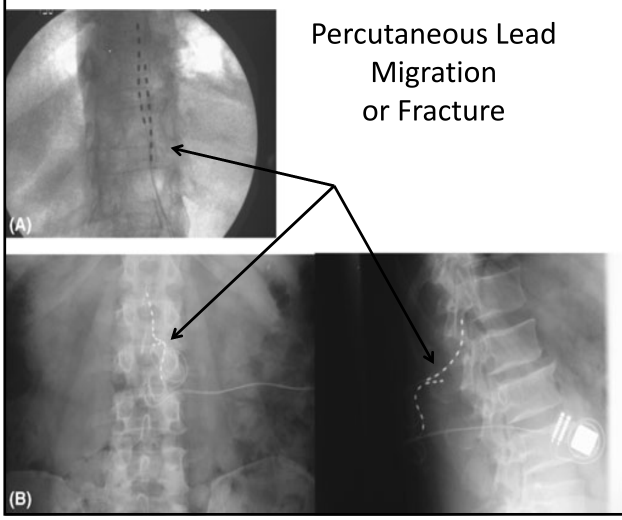
Kallewaard JW[1], Nijhuis H[2], Huygen F[3], Wille F[4,5], Zuidema X[4,5], van de Minkelis J[6], Raza A[7].

RESULTS:
Thirteen patients underwent a trial of DRG stimulation; 11 (84.6%; 95% confidence interval = 57.8% to 95.7%) had good outcomes and underwent permanent device placement. Pain was reduced from a score of 8.64 (±0.92) at baseline to 2.40 (±2.38; n = 9) after 12 months of treatment, a 72.05% average reduction (P < 0.001). Similar improvements were observed across the secondary clinical measures, and safety data were in line with published rates.
DISCUSSION:
These results suggest that DRG stimulation induces pain relief in subjects diagnosed with FBSS. These reductions in pain were also associated with improvements in quality of life and disability. Additional prospective studies are warranted to further investigate this potential application of DRG stimulation, as well as to optimize patient selection, lead placement, and programming strategies

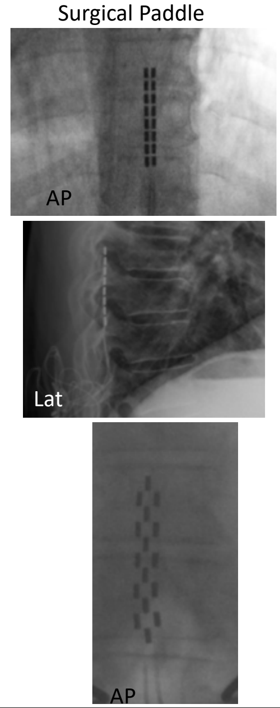
Difficult Anatomy

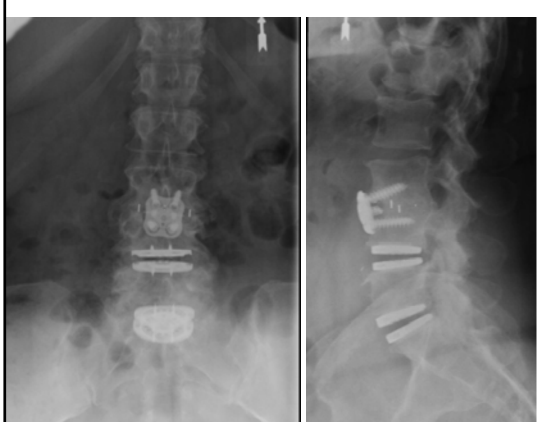
Post Instrumentation
Post instrumentation and failed percutaneous stimulation lead
Post csf leak ,pachymeningitis and infection
Post syrinx/myelomalacia/stenosis/tethered cord/avulsion
Spinal cord injury
Post infection
Recurrent spinal pathology
Simultaneous spinal reconstruction and neuromodulation

Percutaneous Lead
Migration
or Fracture

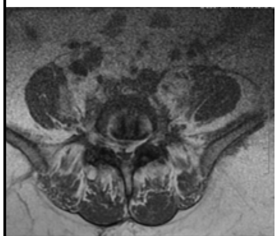


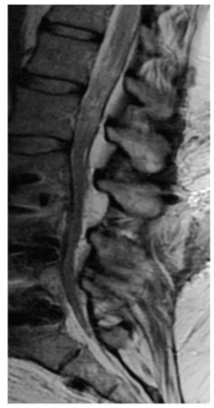
Surgical Paddle





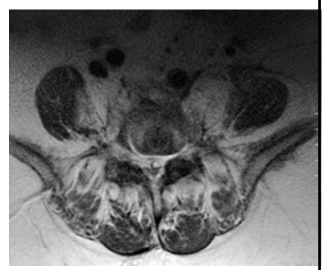
50 year old woman who presents today with chief complaint of lower back pain and for evaluation for intrathecal pain pump.
She underwent an IT trial, however no return of CSF

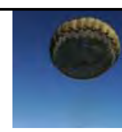


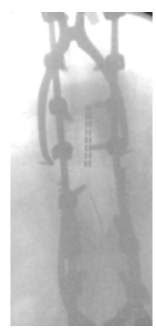


1. No thoracic spinal canal stenosis.
2. Normal thoracic cord signal. Degenerative changes with bilateral facet arthropathy/ligamentum flavum buckling causes indentation of the dorsal thecal sac at T8-9, T9-10, and T10-11.

3. Evidence of prior anterior lumbar fusion with discectomy L3-S1. Prominence of dorsal epidural fat extending from L2 to L5 causing severe effacement of thecal sac, with central crowding and buckling of caudal roots. Multilevel bilateral facet arthropathy.

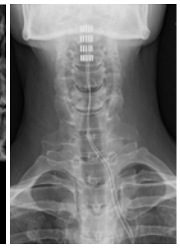




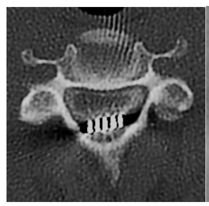
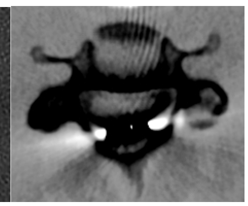


56-year-old right-handed man with status post posterior instrumented spinal fusion and posterior decompression extending from T3 to the sacrum; L2-L3 and L3-L4 fusion 7/2016 Persistent bilateral hip pain, low back pain and legs. He experiences mild numbness and sometimes pins and needles sensation in his feet. He does not experience incontinence. 380pds 5;6 bmi 59.9

Axial Neck Pain and Options

50 year old female physician implanted for axial neck pain
2012 after a positive trial
Progressive spasticity and myelopathy in the last 2 years
Explanted in 2017 and developed weakness in the LLE and remained spastic

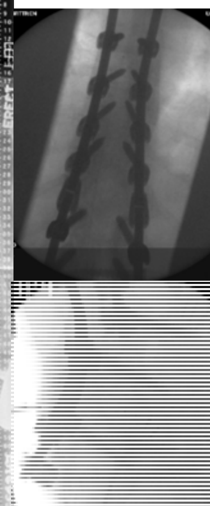




What is the next step ?

Review
The primary indication for SCS
The potential new pathology
The best technology for that patient
    new waves: high-density,
    burst paresthesia free. DRG
    PNS

Intrathecal drug delivery system


Spine re intervention and lead/catheter break: loss of therapy



Therapy-Related Explants After Spinal Cord Stimulation: Results of an International Retrospective Chart Review Study

Van Buyten JP[1], Wille F[2,3], Smet I[1], Wensing C[2,3], Breel J[2,3], Karst E[4], Devos M[1], Pöggel-Krämer K[5], Vesper J[5].
Neuromodulation. 2017 Oct;20(7):642-649. doi: 10.1111/ner.12642. Epub 2017 Aug 18.

Four implanting centers in three countries evaluated 955 implants, with 8720 visits over 2259 years of follow-up.

Median age was 53 years; 558 (58%) were female.

Explant rate was 7.9% per year.

Over half (94 of 180) of explants were for inadequate pain relief, including 32/462 (6.9%) of implants with conventional nonrechargeable SCS, 37/329 (11.2%) with conventional rechargeable and 22/155 (14.2%) with high-frequency (10 kHz) rechargeable SCS.

A higher explant rate was found in univariate regression for conventional rechargeable (HR 1.98, p = 0.005) and high-frequency stimulation (HR 1.79, p = 0.035) than non rechargeable SCS.

Multicenter Retrospective Study of Neurostimulation With Exit of Therapy by Explant

Neuromodulation. 2017 Aug;20(6):543-552. doi: 10.1111/ner.12634. Epub 2017 Jul 17.

Jason E. Pope, MD*;and al

Retrospective chart review of neurostimulation patients who underwent explantation at 18 centers across the United States within the previous five years.

Results: 352 patients were collected and compiled. Failed Back Surgery syndrome was the most common diagnosis (38.9%; n 5 136/350) and over half of the patients reported numerical rating scale (NRS) scores 8 prior to implant (64.3%; n 5 207/322). All patients reported changes in NRS scores across time, with an initial decrease after implant followed by a preexplant increase (F (2, 961) 5 121.7, p < 0.001).

The most common reason for device explant was lack or loss of efficacy (43.9%; 152/346) followed by complications (20.2%; 70/346).

Eighteen percent (18%; 62/343) of patients were explanted by a different physician than the implanting one. Rechargeable devices were explanted at a median of 15 months, whereas primary cell device explants occurred at a median of 36 months (CI 01.434, 2.373; median endpoint time ratio 5 2.40).

Association of Opioid Usage with Spinal Cord Stimulation Outcomes

Ashwini D Sharan, MD and al *Pain Medicine*, Volume 19, Issue 4, 1 April 2018, Pages 699–707,https://doi.org/10.1093/pm/pnx262

5,476 patients (56 ± 14 years; 60% female) were included.

SCS system removal occurred in 390 patients (7.1%) in the year after implant.

Number of drug classes (odds ratio [OR] = 1.11, *P* = 0.007) and MED level (5–90 vs < 5 mg/d: OR = 1.32, *P* = 0.043; ≥90 vs < 5 mg/d: OR = 1.57, *P* = 0.005) were independently predictive of system explant. Over the year before implant, MED increased in 54%

Patients who continued with SCS and increased in 53% (stayed the same in 20%, decreased in 27%) of explant patients (*P* = 0.772). Over the year after implant

Significantly more patients with continued SCS had an MED decrease (47%) or stayed the same (23%) than before (*P* < 0.001).

Chronic pain patients receive escalating opioid dosage prior to SCS implant, and high-dose opioid usage is associated with an increased risk of explant. Neuromodulation can stabilize or decrease opioid usage. Earlier consideration of SCS before escalated opioid usage has the potential to improve outcomes in complex chronic pain

Pocket Pain and Neuromodulation: Negligible or Neglected?

Dietvorst S[1], Decramer T[1,2], Lemmens R[3], Morlion B[4], Nuttin B[1,2], Theys T[1,2].

Neuromodulation 2017 Aug;20(6):600-605. doi: 10.1111/ner.12637. Epub 2017 Jul 12.

The reported incidence of implant site pain is variable, ranging between 0.4 and 35%. Implant site pain has never been systematically studied and no treatment guidelines are available.

Subjective rating of intensity by sending questionnaires (n = 554) to our cohort of neuromodulation patients with IPGs.

Pain patients suffered significantly ($p < 0.05$) more often from IPG site pain than other patients undergoing neuromodulation therapies.

Up to 64% of patients undergoing spinal cord stimulation reported IPG site discomfort or pain.

Severe pocket pain was found in up to 8% of patients.

No association was found between other variables (age, BMI, duration of follow-up, gender, smoking, number of pocket surgeries) and implant site pain. Pocket pain represents an important problem after invasive neuromodulation and is more prevalent in pain patients. We believe further technological improvements with miniaturized IPGs will impact the incidence of pocket pain and could even obviate the need for an IPG pocket.

Sustained Long-Term Outcomes With Closed-Loop Spinal Cord Stimulation: 12-Month Results of the Prospective, Multicenter, Open-Label Avalon Study

Marc Russo, MBBS, DA, Charles Brooker, MD, DSc, Michael J Cousins, MD, DSc, Nathan Taylor, MBBS, Tillman Boesel, MBBS, Richard Sullivan, MBChB, Lewis Holford, MBChB, Erin Hanson, MPH, Gerrit Eduard Gmel, PhD ✉, Nastaran Hesam Shariati, PhD ... Show more

Neurosurgery, nyaa003, https://doi.org/10.1093/neuros/nyaa003
Published: 05 February 2020 **Article history** ▾

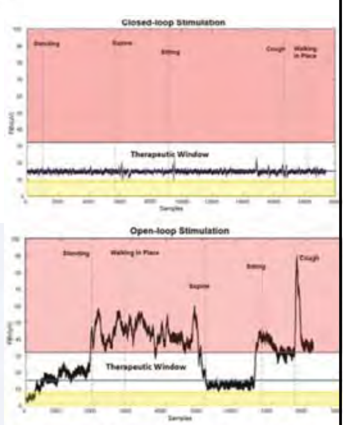


Figure : ECAP Amplitude during Posture Changes in a) Closed-loop and b) Open-loop Stimulation Mode.

RESULTS

At 12 mo, the proportion of patients with ≥50% relief was 76.9% (back), 79.3% (leg), and 81.4% (overall), and the proportion with ≥80% pain relief was 56.4% (back), 58.6% (leg), and 53.5% (overall). Patients spent a median of 84.9% of their time with stimulation in their therapeutic window, and 68.8% (22/32) eliminated or reduced their opioid intake. Statistically significant improvements in secondary outcomes were observed.

CONCLUSION

The majority of patients experienced more than 80% pain relief with stable SC activation, as measured by ECAP amplitude at 12 mo, providing evidence for the long-term effectiveness of the Evoke closed-loop SCS system.

Challenge: bring the best therapy to the right patient
Understand the mechanism of action

Conclusion

Therapeutic Pain Options are rapidly evolving
In case of failure reviewing:
The primary indication for SCS
The potential new pathology
The best technology for that patient: new waves,high-density, burst paresthesia free.
DRG vs PNS vs SCS +PNS
Intrathecal drug delivery system

Hardware failure 10 to 35% ; surgical technique
8 to 15% of explants : selection? Optimize and Personalize
Difficult Anatomy requires multidisciplinary approach
and tailored surgical options
Opioid titration prior to SCS
Evolving technology should be optimized to patients
therapeutic needs

Basic Science of Disc Pain Generators

Jeffrey C. Lotz, PhD

David S. Bradford MD Endowed Chair of Orthopaedic Surgery

University of California at San Francisco

Disclosures

- Founder and Board member, Nocimed LLC
- Founder and Consultant, Relievant MedSystems
- Founder, Bioniks LLC

Low Back Pain is Leading Cause of Disability Globally

3 million Americans with chronic low back pain

A leading indication for opioid prescription

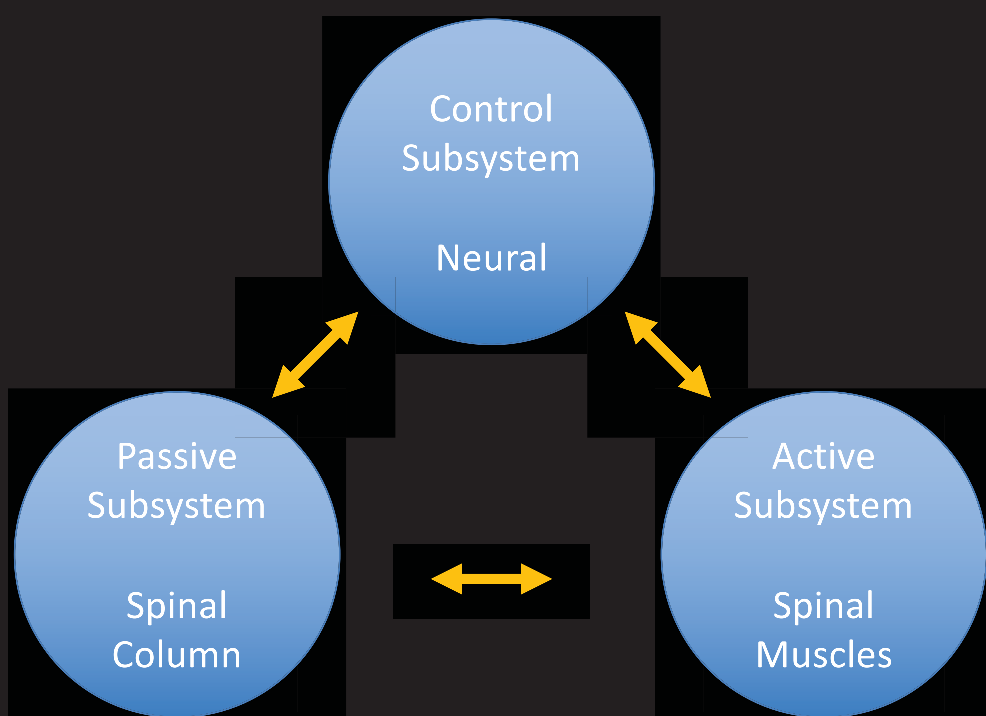
The Target for Back Pain Diagnosis and Therapy is Typically the Intervertebral disc

Degeneration ≠ Pain

(Boden, 1990; Jensen, 1994)

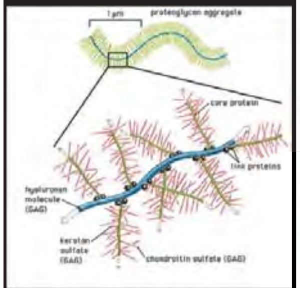
Circular Reliance between Diagnostics and Therapy Efficacy

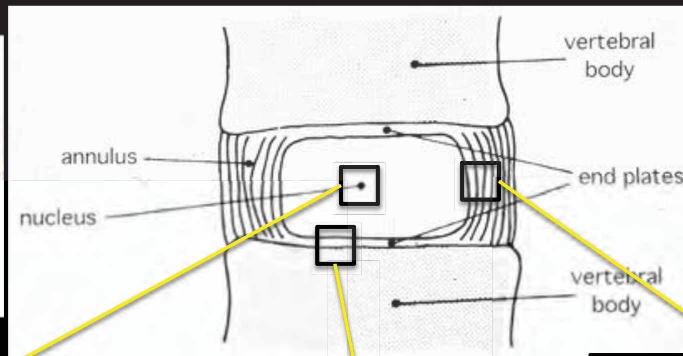
Spinal Stability System Consists of Three Subsystems

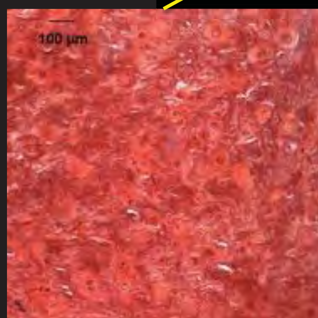


Panjabi, 1992

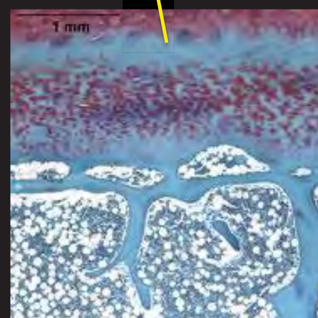
The disc is composed of several tissues with unique roles



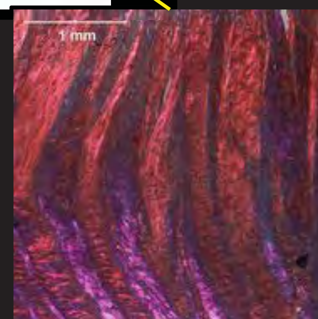




Nucleus - Swelling

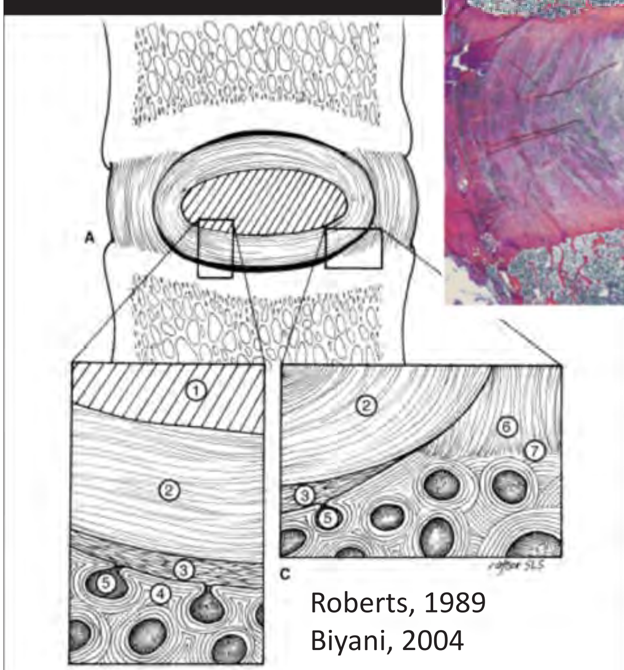


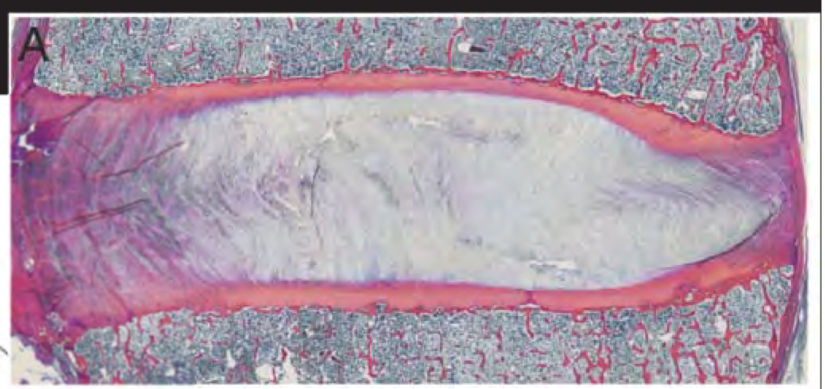
Endplate - Transport, Pressurization



Annulus - Constraint

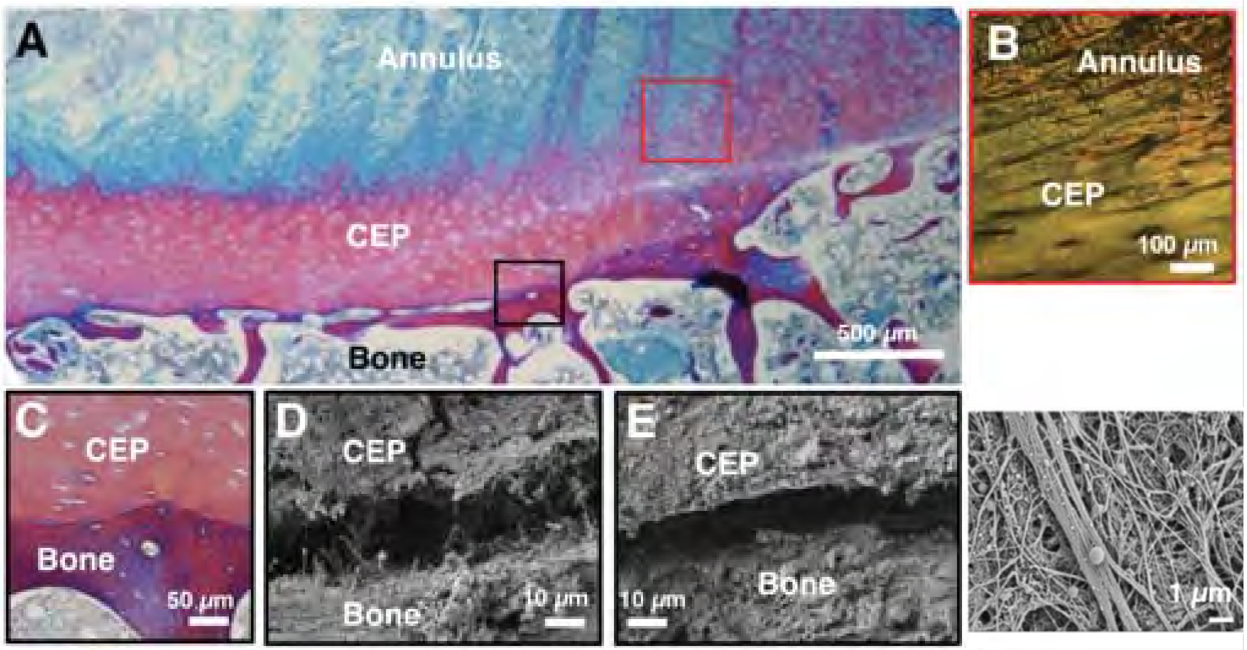
Endplate forms ‘360’ degree containment of nucleus





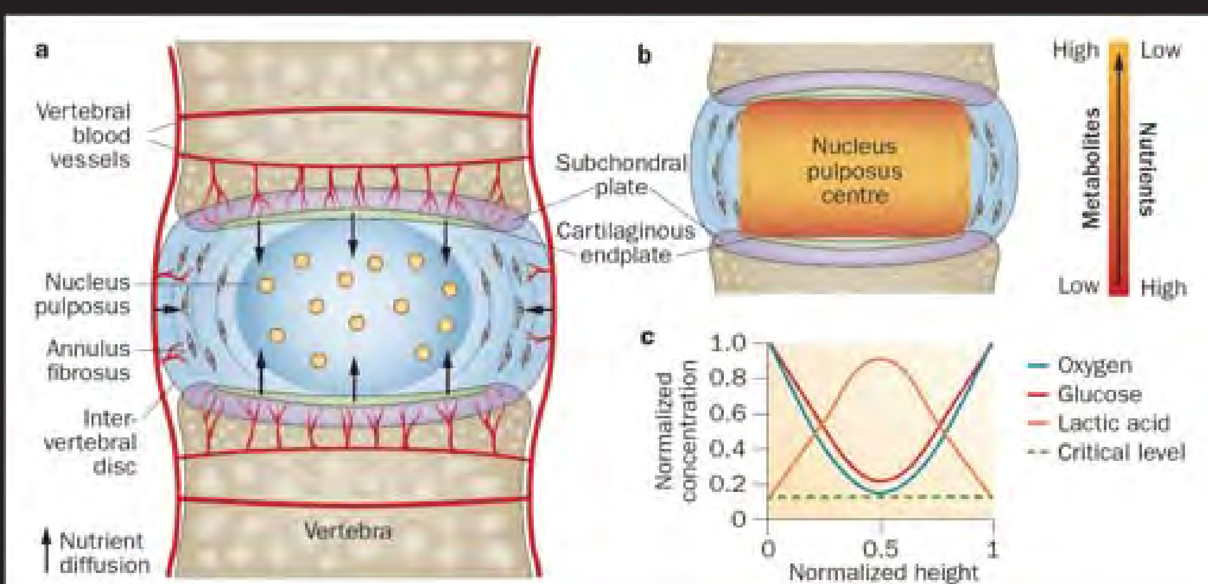
Roberts, 1989
Biyani, 2004

Cartilage Endplate Loosely Adherent



Berg-Johansen, 2017

Disc cells rely on transport from adjacent vertebra

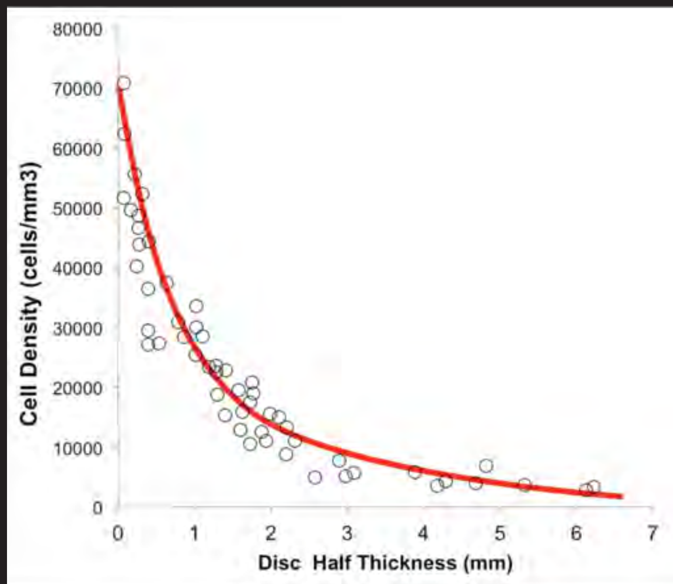


Urban and Winlove, 2007

Diffusion is Critical for Cell Survival

'Square-Cubed Law'

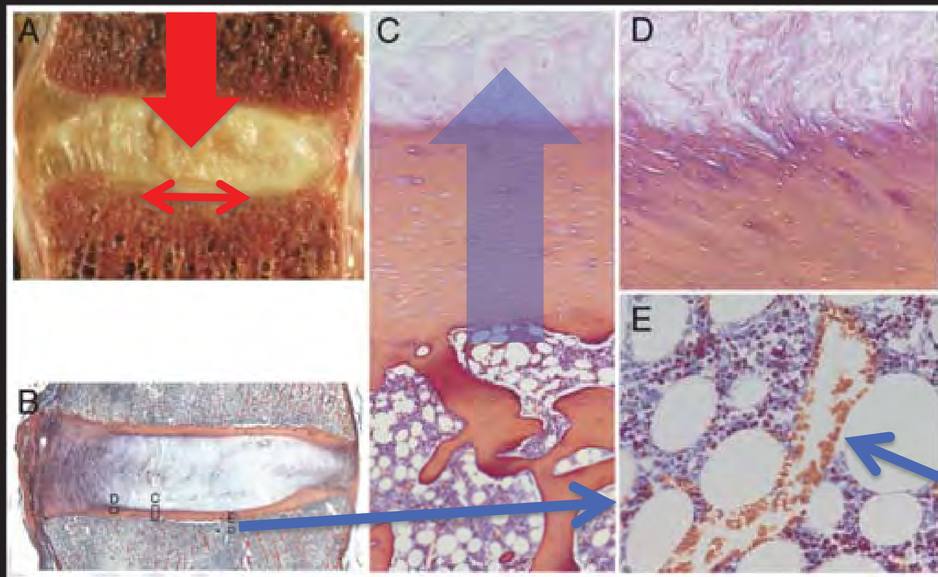
- Cell viability is inversely related to permeability and diffusion distance
- Viable distance is inversely related to cell density



Horner and Urban, 2001

Lumbar Discs Degenerate from the Inside-out

Endplate is a Weak Link



Thick
Non-porous

Thin
Porous

Adams et al. 2000

Urban et al. 1977

Endplate Damage can associate with innervated bone marrow pathologies

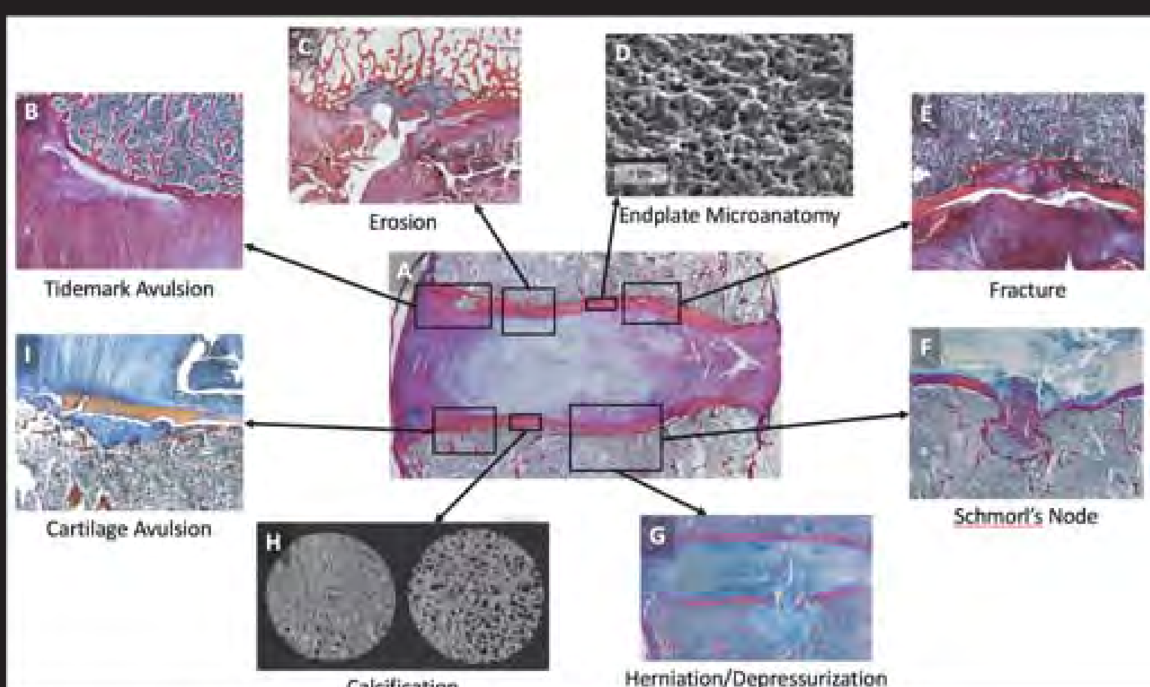
Fields, 2014

Endplate damage regions are more innervated than annular tears

Fields, 2013

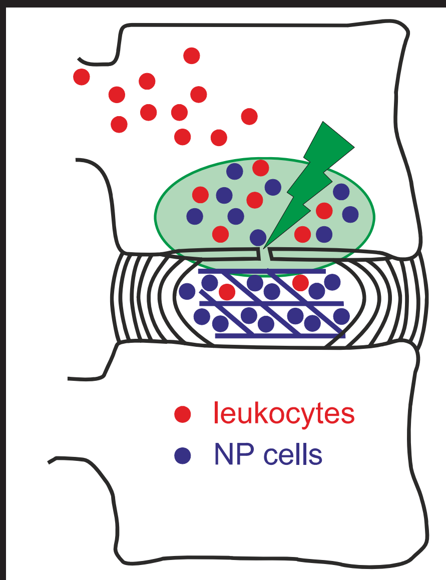
2x nerves at endplate defects than radial tears

Forms of Endplate Damage



Fields and Lotz, 2018

BML may be due to inflammatory factors that diffuse from adjacent discs



Dudli, 2015

Modic and Endplate Changes Associate with Accelerated Disc Degeneration

Presence/change of M1	Presence/change of disc height			
	Constantly normal	Constantly decreased	Further decreased	Total (*n*)
no M1				
M1				
M1				
M1				
Tot				

Table 2 Segments with DD progression (n = 99) were matched by level (p = 1.00), and degree of inital PFG (p = 0.90) at the time of the inital MRI scans to those without progression (n = 99). Logistic regression analysis was performed to test for potential segmental risk factors

Risk factors present at 1. MRI at the same level	No DD prog. (n = 99)	DD prog. (n = 99)	OR	95 % CI	*p* value
MC present	5 (5 %)	12 (12 %)	2.59	0.93–7.26	0.07
MC type 1 present	0 (0 %)	5 (5 %)	*	*	*
Listhesis at the level	3 (3 %)	6 (6 %)	2.06	0.92–9.58	0.27
Apex scoliosis = level	4 (4 %)	11 (11 %)	2.97	0.91–9.58	0.07
EPS ≥ 4	15 (15 %)	29 (29 %)	2.32	1.07–5.01	0.03
EPS = 6	0 (0 %)	6 (6 %)	*	*	*
Age (years mean ± SD)	54.5 ± 17.2	59.9 ± 13.8	1.02	1.00–1.05	0.08
Sex (m/f)	39/60	31/68	1.42	0.64–3.16	0.38
MRI interval (mean ± SD)	4.92 ± 0.83	5.21 ± 0.84	1.51	0.93–2.45	0.10

MC, Modic changes; EPS, endplate score; DD, disc degeneration; PFG, Pfirrmann grades; MRI, magnetic resonance imaging; OR, odds ratio; CI, confidence interval; SD, standard deviation; m, male; f, female

*too small number of events

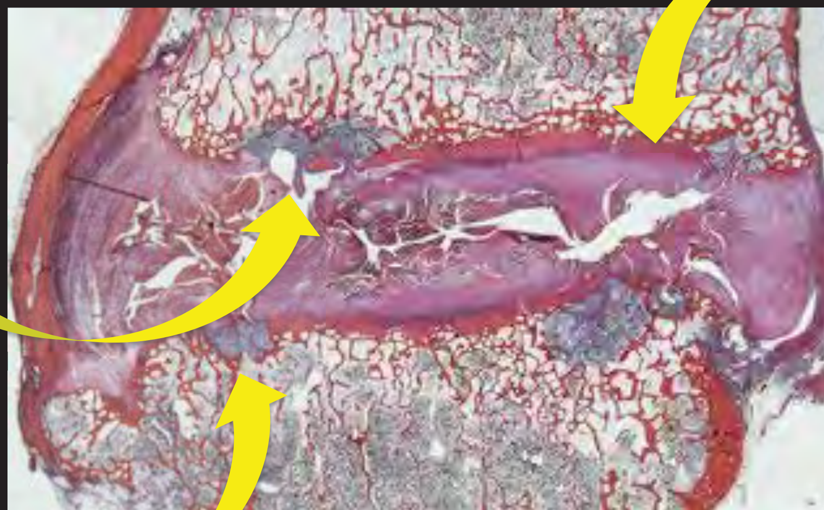
Kerttula, 2012
Farshad-Amacker, 2017

Endplate Insufficiency and Modic Changes

Disc/Vertebra Crosstalk

Inflammation
Instability

Infection

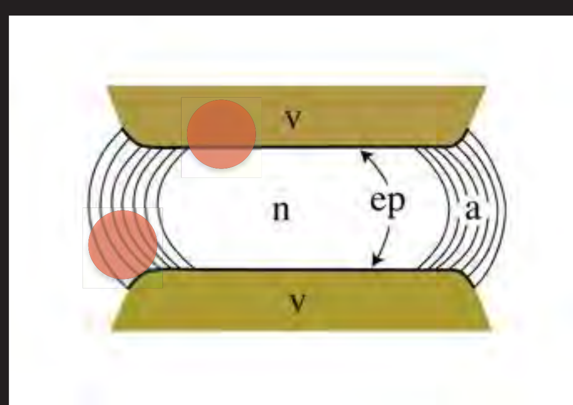


PGE2, NO
IL6, TNF-α

Genetics, Epigenetics

Nguyen et al., 2015

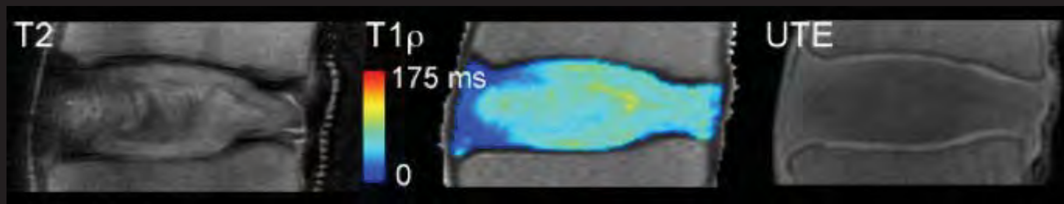
Anchor Imaging to Theoretical Pain Pathways

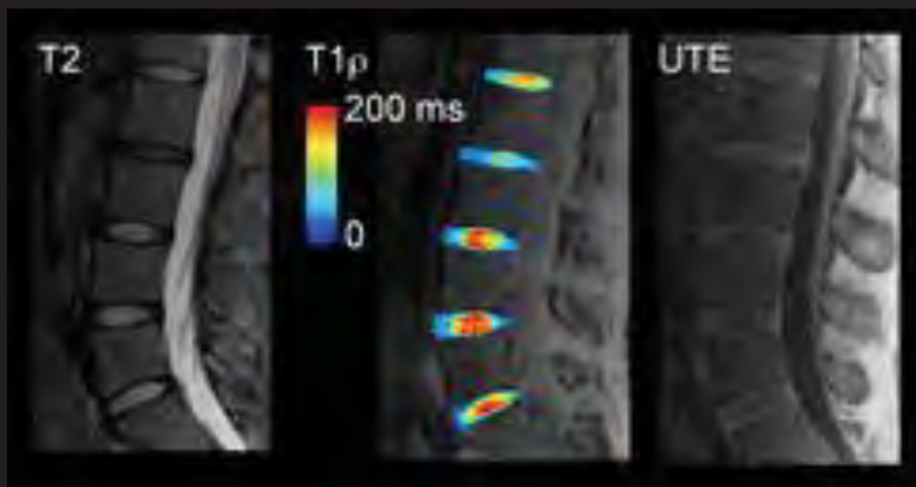


- Damage - ↑ strain
- Pro-inflammatory Chemicals

→ Peripheral Sensitization → Pain

Endplate Properties and UTE MRI

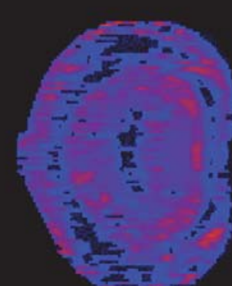




Cartilage Endplate Damage and Modic Associate with CLBP

38 CLBP Patients (VAS ≥ 4, ODI ≥ 30) and 14 Matched Controls

Independent Predictors of CLBP



CEP Damage by UTE OR=14.1, (CI=2.3-85.2)
MC OR=5.4, (CI 1.1-27.5)
Pfirrmann OR=5.2, (CI 1.4-18.9)

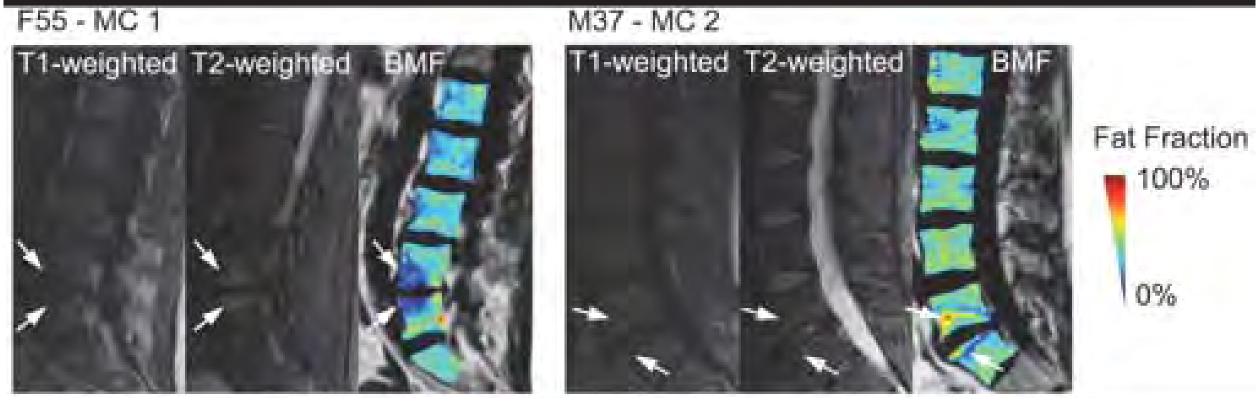
Multiple Linear Regression

CEP Damage after adjusting for MC and Pfirrmann – **OR=26.1**

Dose-Response; OR increases by 1.8 for every additional disc with CEP Damage

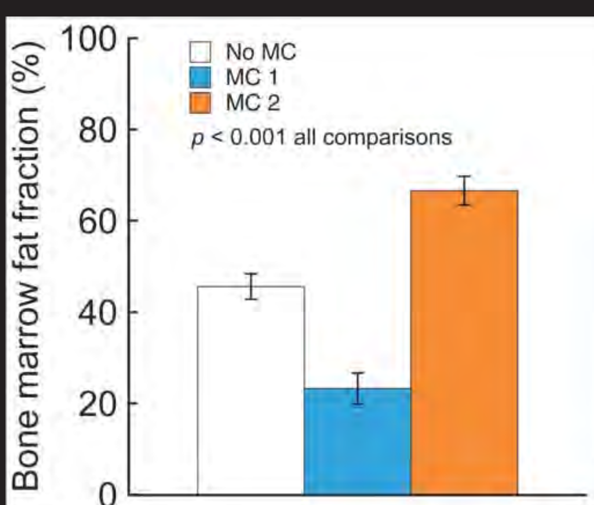
Bailey, Fields, Lotz, 2019

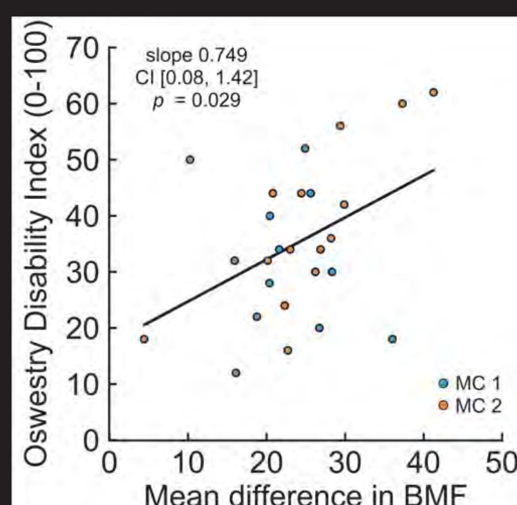
Marrow Properties and IDEAL MRI



Fields, 2020

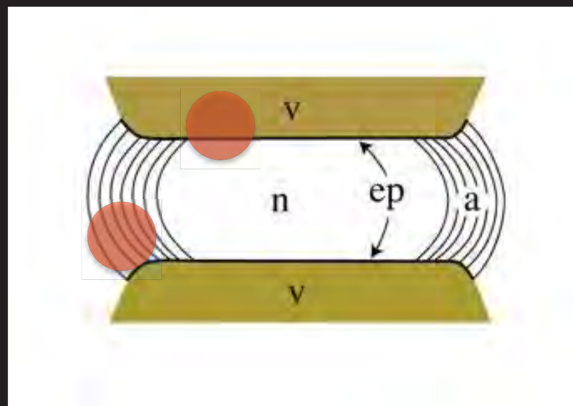
Marrow Properties and IDEAL MRI





Fields, 2020

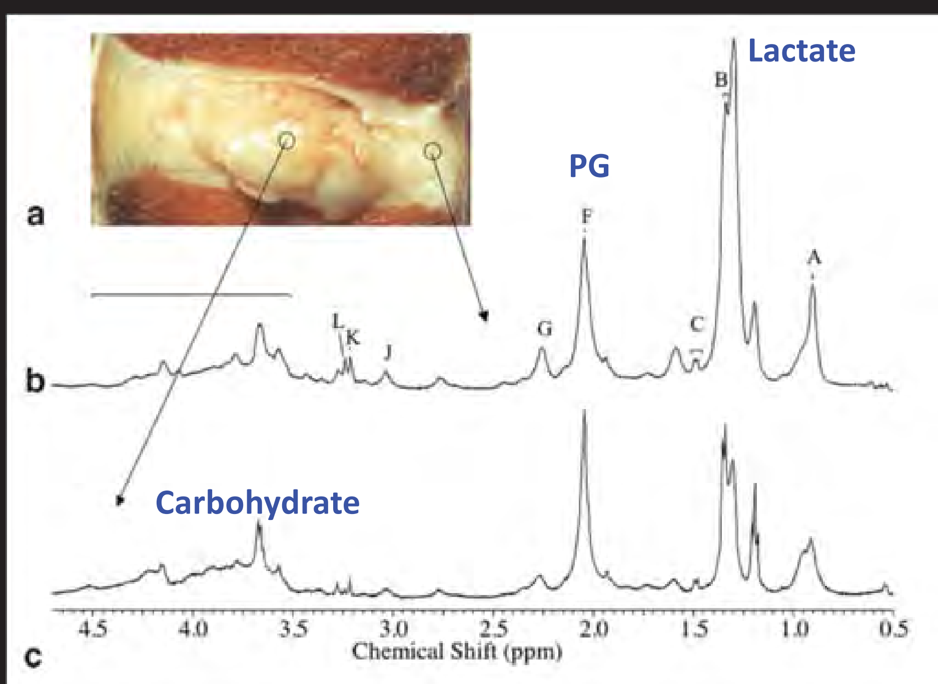
Anchor Imaging to Theoretical Pain Pathways



- Damage - ↑ strain
- Pro-inflammatory Chemicals

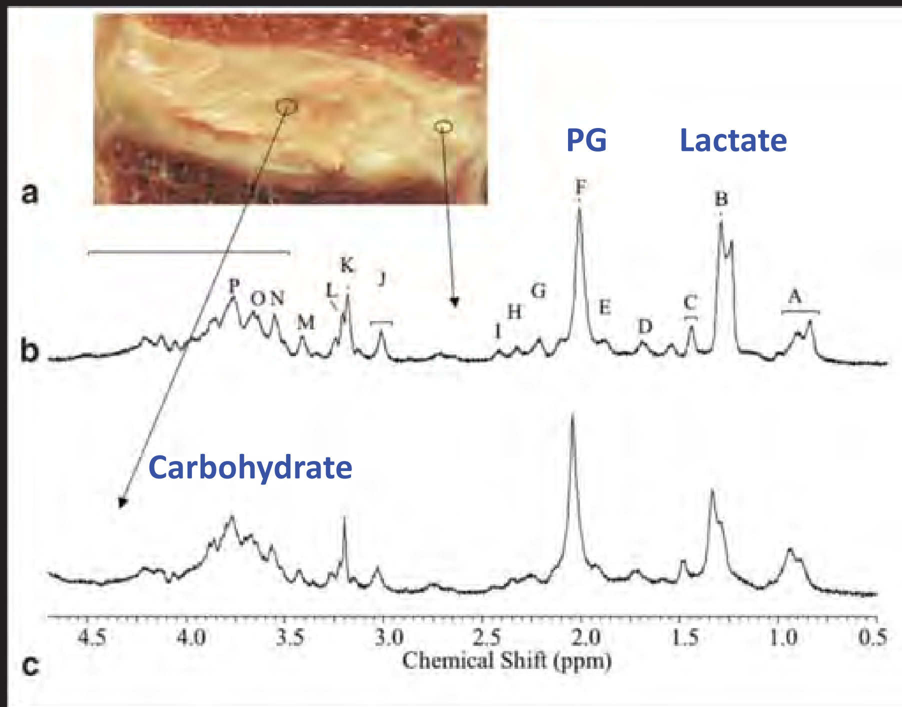
→ Sensitization + Simulation → Pain

MRS Can Characterize Tissue Composition



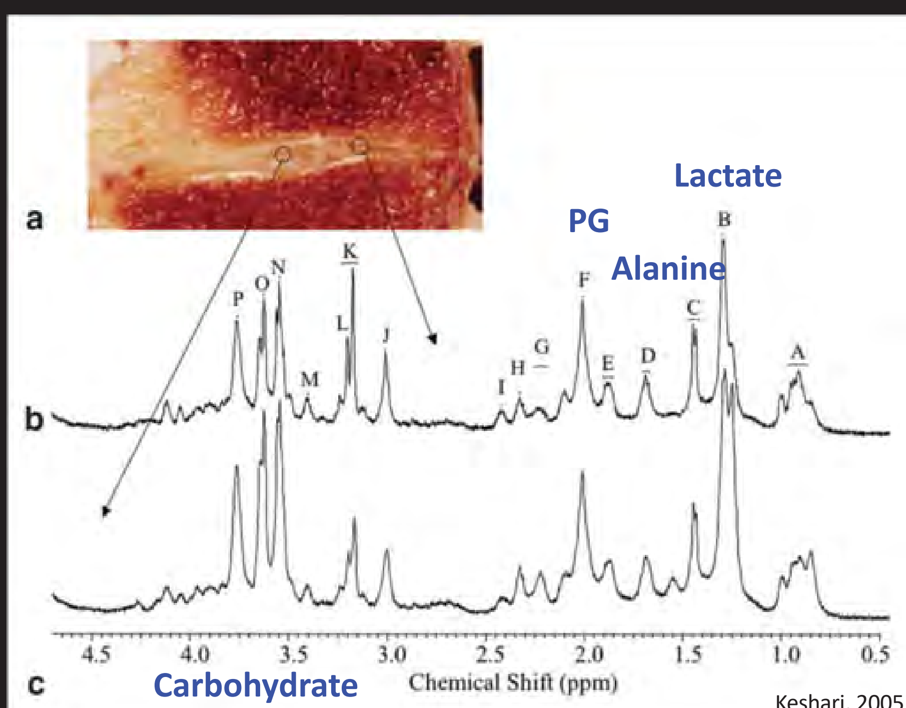
Keshari, 2005

MRS Can Characterize Tissue Composition



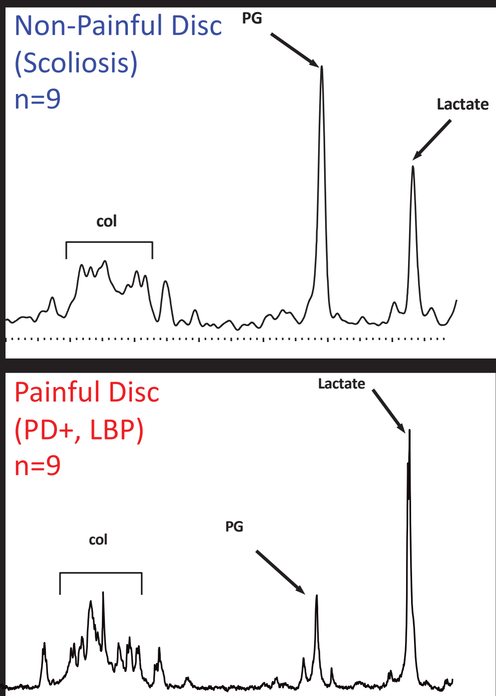
Keshari, 2005

MRS Can Characterize Tissue Composition



Keshari, 2005

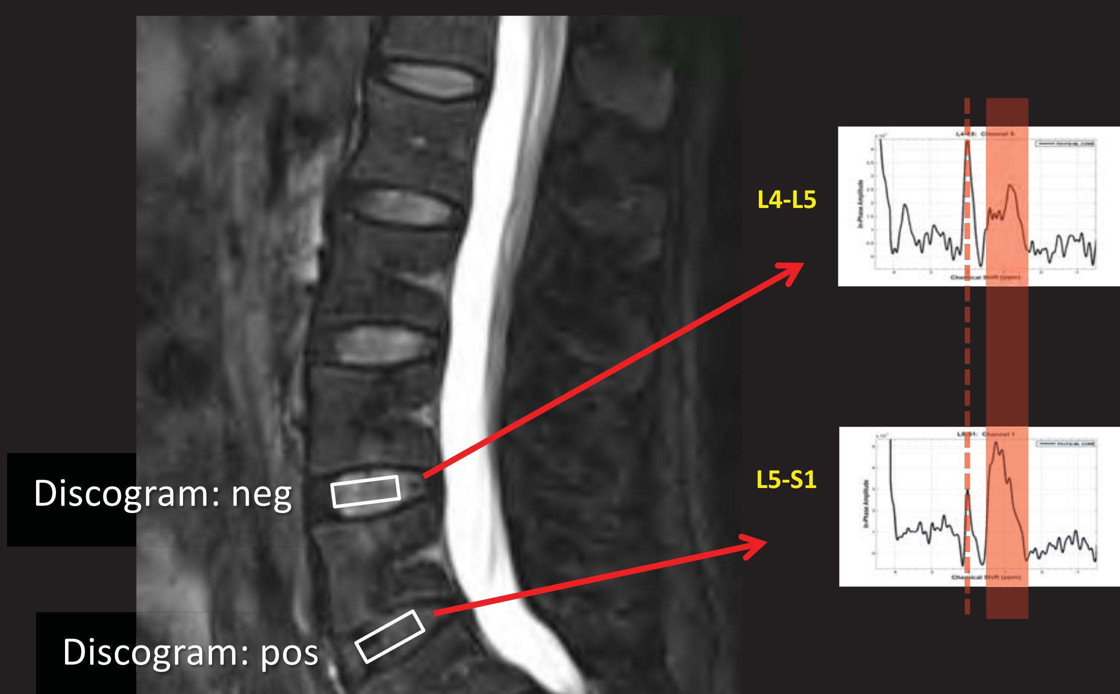
Metabolic Imaging



Elevated Lactate is Associated with:
- Excessive Cellular Demand
- Cell Death and Reduced PG Synthesis
- Nociceptor Activation in Angina

Wang, et al., 2013
Urban and Winlove, 2007
Wu, et al., 2013
Keshari, 2008

Metabolic Imaging - Magnetic Resonance Spectroscopy

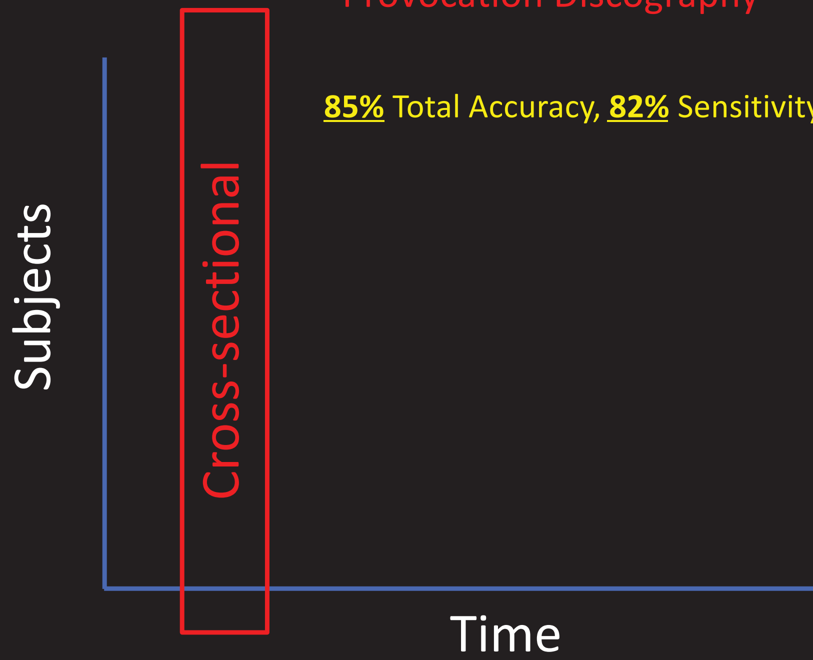


Gornet, 2019

Diagnostic Accuracy – Clinical Validity

206 discs from 139 CLBP Patients

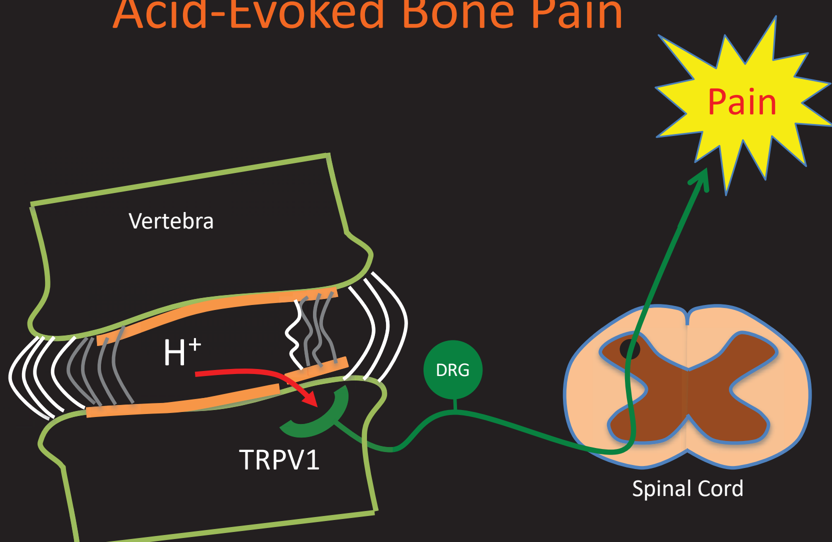
Reference Standard
Provocation Discography



85% Total Accuracy, **82%** Sensitivity, **88%** Specificity

Gornet, 2019

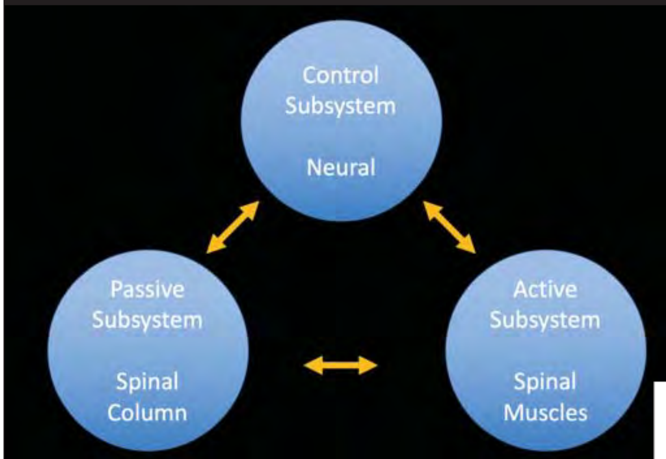
Acid-Evoked Bone Pain

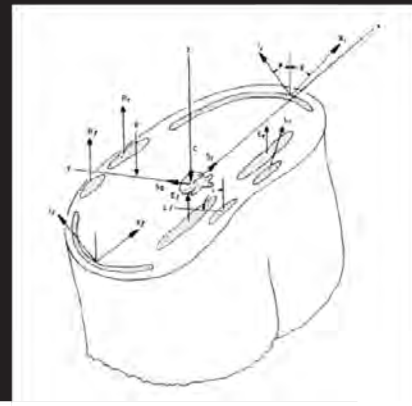


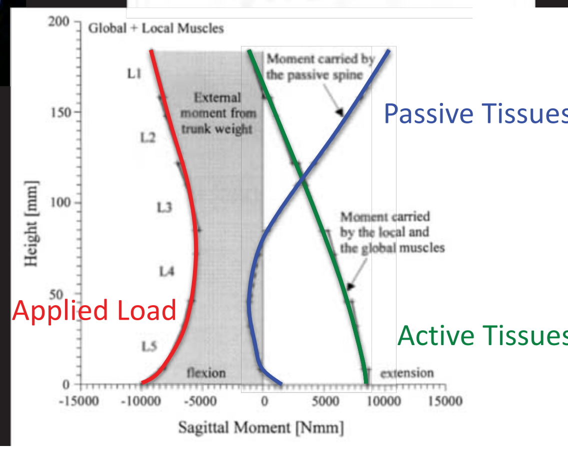
- H^+ is most potent disc nociceptor irritant
- TRPV1 is capsaicin receptor activated by H^+
- H^+ Implicated in Angina, Cancer Bone Pain

Stover, Bowles, 2017
Immke and McCleskey, 2001
Yoneda, 2015

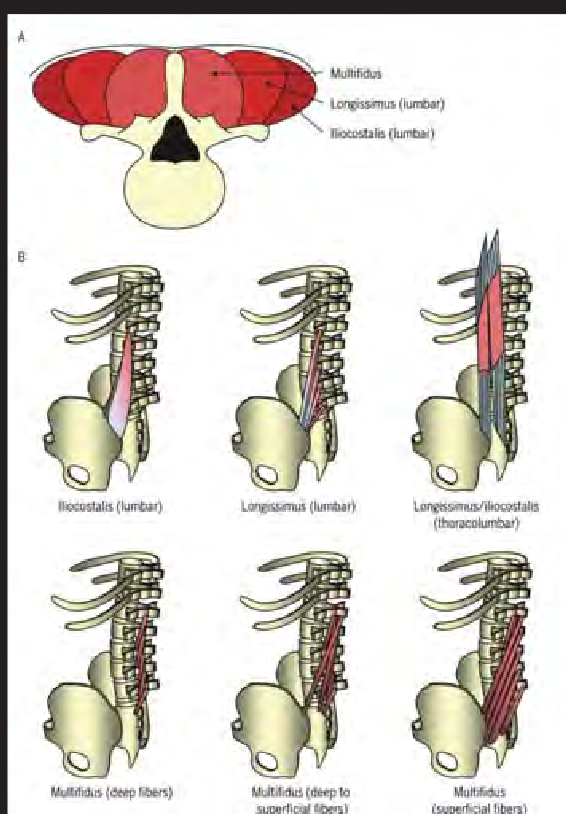
The spinal column is stabilized by passive and active tissues.





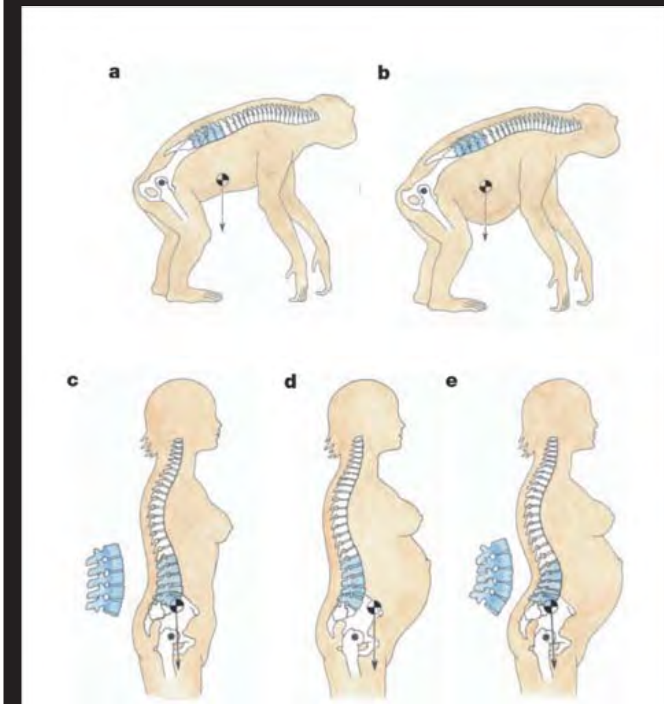


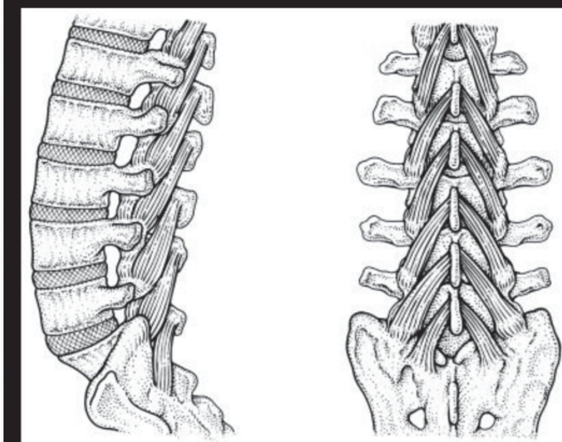
Paraspinal Muscle Anatomy



Hodges, 2019

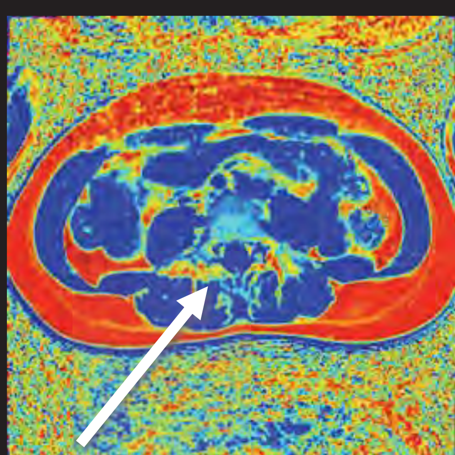
Lordosis, Multifidus and Spinal Balance



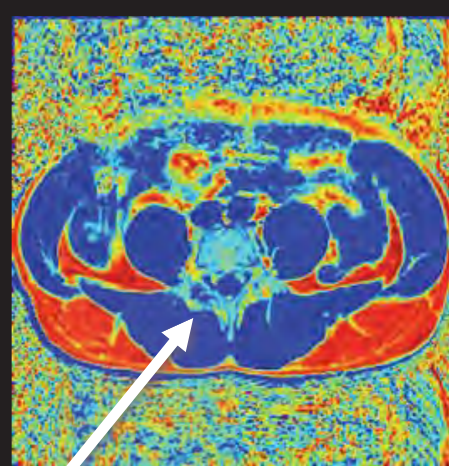


Witcome, 2007

IDEAL MRI quantifies fat fraction and paraspinal muscle quality

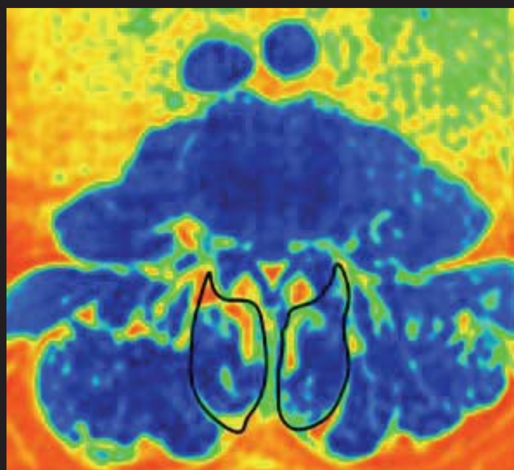


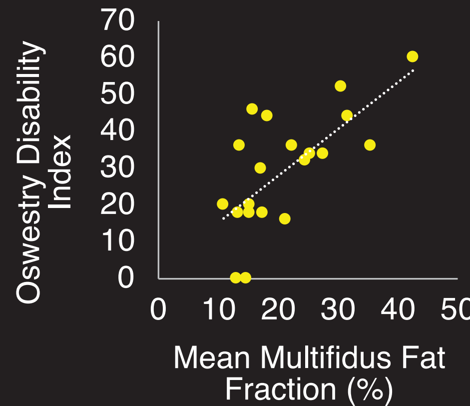
High MF fat fraction



Low MF fat fraction

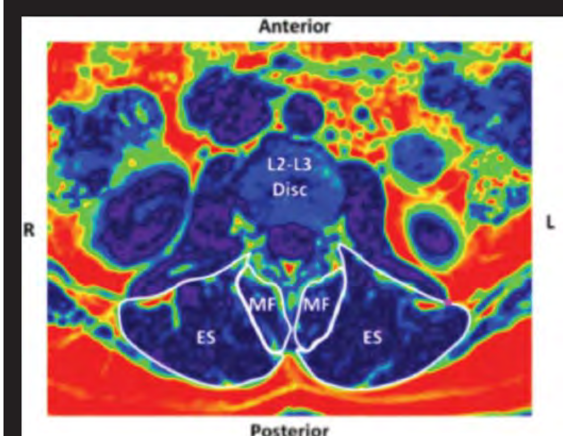
Paraspinal muscle FF associates with disability

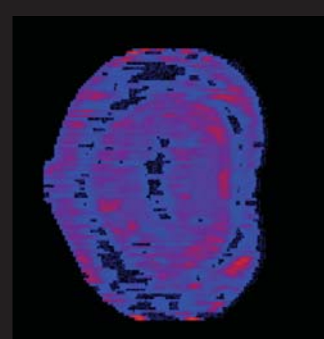




Bailey, 2019

'Good' muscles may protect against 'bad' discs





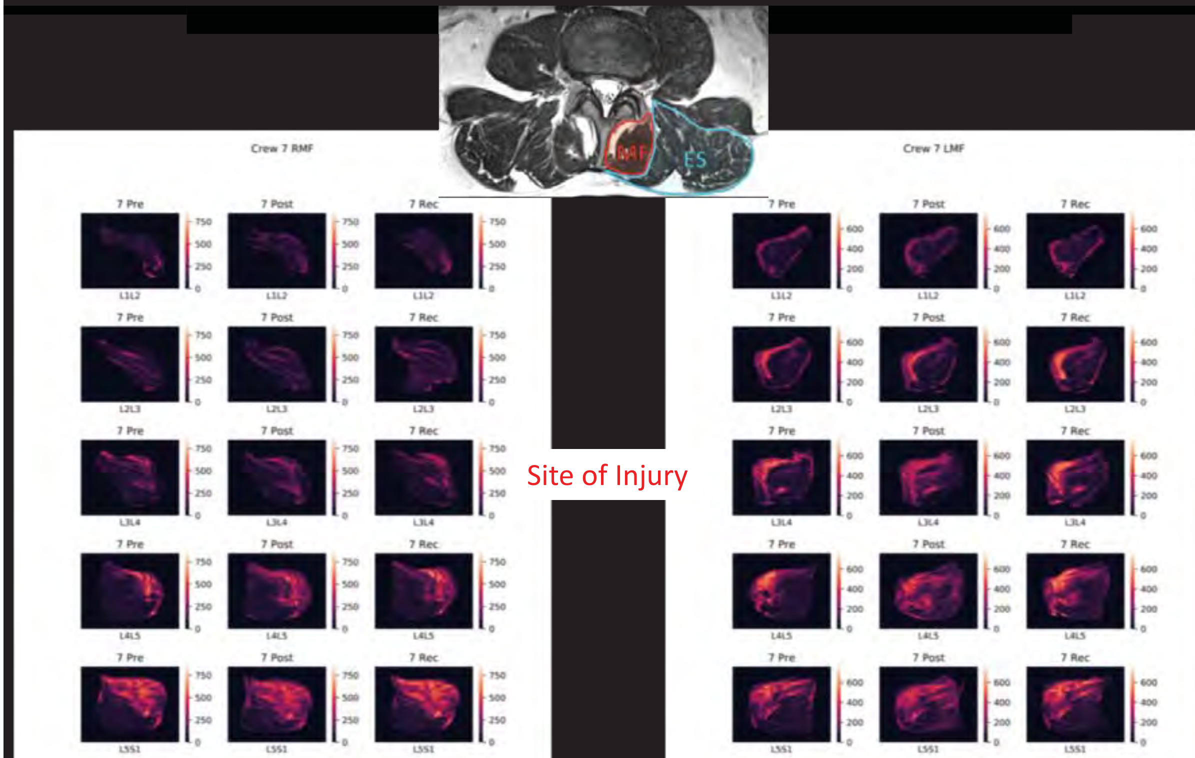
CEP Damage by UTE ~~OR=14.1, (CI=2.3-85.2)~~

MC ~~OR=5.4, (CI 1.1-27.5)~~

Bailey, Fields, 2019

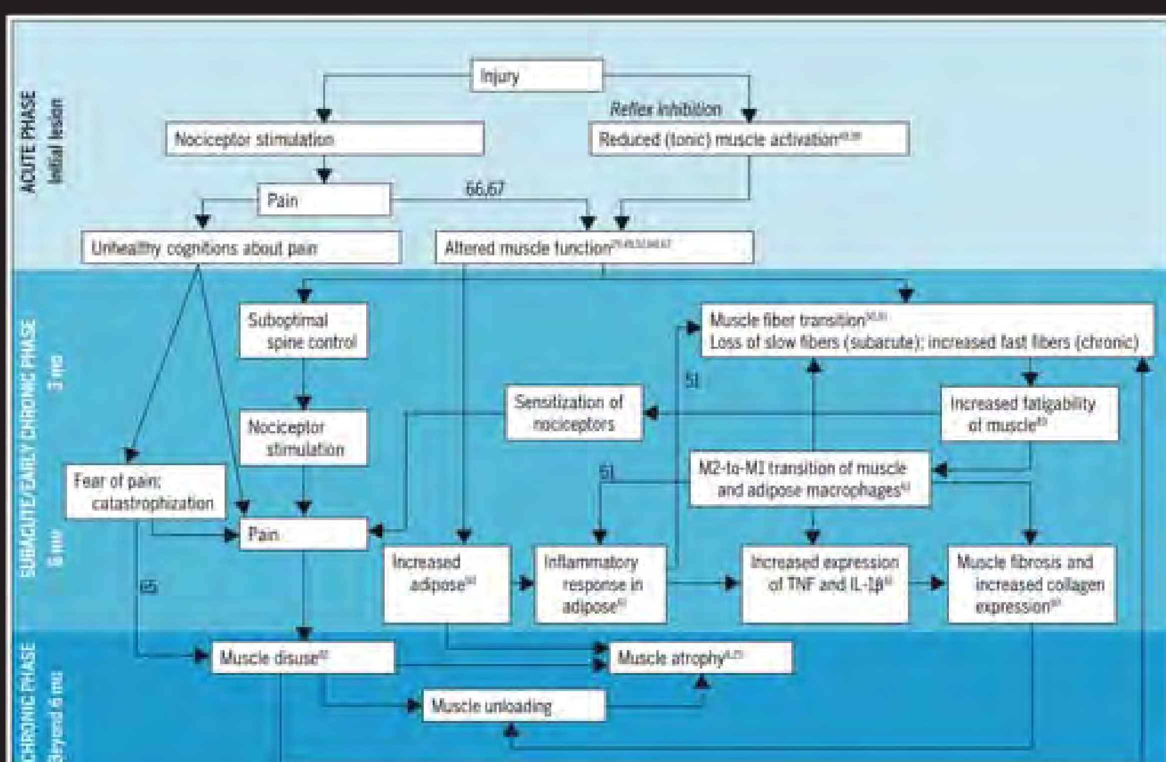
Disc-Muscle Crosstalk

Multifidus Fat Fraction Increased with Disc Injury



Bailey, 2020

Muscle Changes after Disc Injury

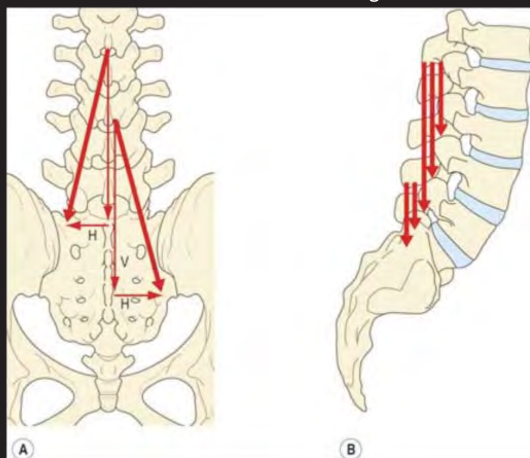


Hodges, 2019

Multifidus provides dynamic stabilization

Mechanical and Biological Cross-talk with Passive Tissues

Acts like a Bowstring



Summary

- Vertebral endplate is a weak link
- Chemical irritation of bone marrow is implicated in cLBP
  - Cross-talk between discs and vertebra
- Advanced imaging protocols can quantify nucleus chemistry, endplate damage, and bone marrow response
- Multifidi are important stabilizers
  - Cross-talk between discs and muscles

Thank You

Aaron Fields
Britta Berg-Johansen
Serge Magnitsky
Ellen Liebenberg
Roland Krug
Stefan Dudli
David Bradford

AR052811, AR063705, AR066262

Pain after Adult Reconstruction Surgery

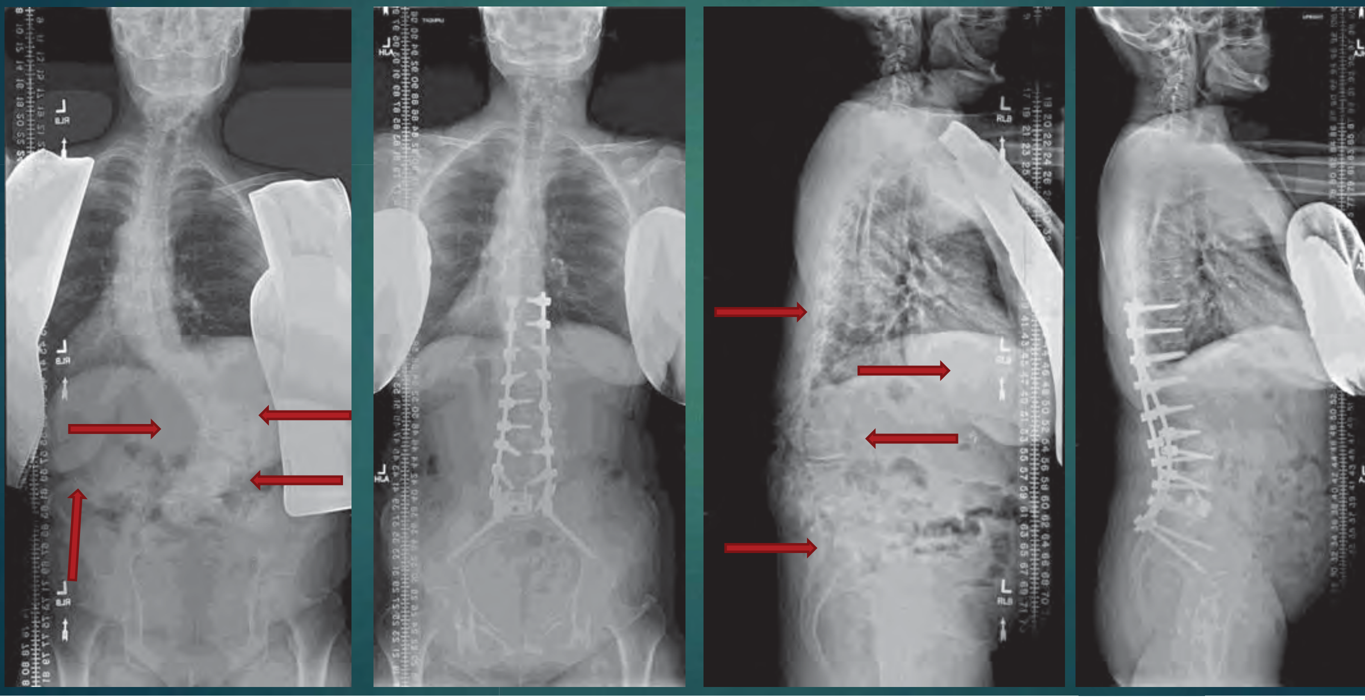
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

JUNE 2020

Disclosures

- Evolution Spine (Consultant / Royalties)

Adult Spinal Deformity



PI 53*

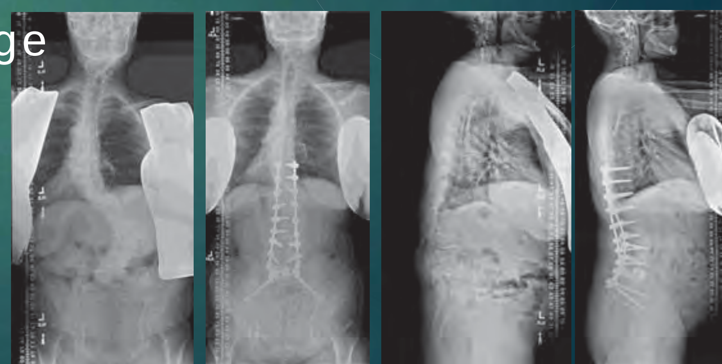
LL 44*

What we do...

- Decompress symptomatic nerve compression
- Stabilize symptomatically degenerated motion segments -> Solid arthrodesis
- Correct deformity to reduce the pain and excess energy expenditure associated with daily activities
- Operate on segments needed to address these goals
  - Avoid doing more than necessary

Why Do We do this

- Adult spinal deformity have enormous disability
- Those who do well have an enormous upside (improvement)
- Proceed when we think that despite the risks an individual patient is a good candidate, wants surgery, exhausted non-op rx
- Selfishly, we enjoy the challenge



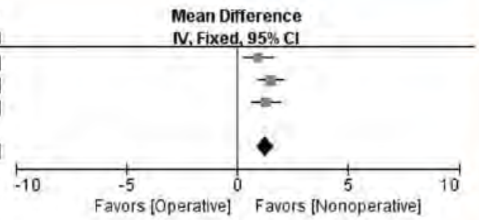
Postop pain is the expectation!!!

Normal Amount of Back Pain after ASD Surgery?

Preoperative

	Operative			Nonoperative				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Bridwell 2009	6.28	2.04	80	5.34	2.15	70	29.3%	0.94 [0.27, 1.61]
Smith 2009	6.3	2.6	147	4.8	2.6	170	40.3%	1.50 [0.93, 2.07]
Smith 2016	6.4	2.3	97	5.1	2.4	97	30.4%	1.30 [0.64, 1.96]
Total (95% CI)			**324**			**337**	**100.0%**	**1.28 [0.91, 1.64]**

Heterogeneity: Chi² = 1.55, df = 2 (P = 0.46); I² = 0%
Test for overall effect: Z = 6.86 (P < 0.00001)



Postoperative

	Operative			Nonoperative				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Bridwell 2009	2.36	2.24	80	5.72	2.39	70	32.1%	-3.36 [-4.10, -2.62]
Smith 2009	2.6	2.6	147	4.8	2.9	170	36.8%	-2.20 [-2.81, -1.59]
Smith 2016	2.7	2.8	97	5.5	2.7	97	31.1%	-2.80 [-3.57, -2.03]
Total (95% CI)			**324**			**337**	**100.0%**	**-2.76 [-3.45, -2.07]**

Heterogeneity: Tau² = 0.24; Chi² = 5.70, df = 2 (P = 0.06); I² = 65%
Test for overall effect: Z = 7.86 (P < 0.00001)

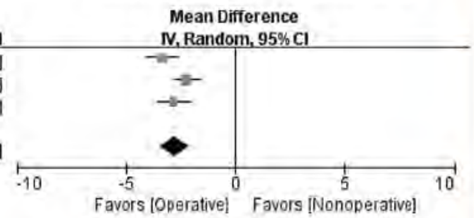


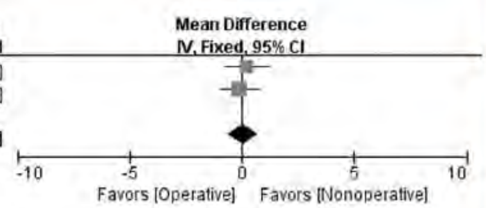
Figure 3. Table and forest plots of numeric rating scale back pain score. IV, interval variable; CI, confidence interval.

Normal Amount of Leg Pain after ASD Surgery?

Preoperative

	Operative			Nonoperative				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Bridwell 2009	3.89	3.12	79	3.68	2.7	62	44.4%	0.21 [-0.75, 1.17]
Smith 2016	3.1	3.2	97	3.2	2.9	97	55.6%	-0.10 [-0.96, 0.76]
Total (95% CI)			**176**			**159**	**100.0%**	**0.04 [-0.60, 0.68]**

Heterogeneity: Chi² = 0.22, df = 1 (P = 0.64); I² = 0%
Test for overall effect: Z = 0.12 (P = 0.91)



Postoperative

	Operative			Nonoperative				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Bridwell 2009	1.72	2.44	79	3.47	3.02	62	47.0%	-1.75 [-2.67, -0.83]
Smith 2016	2.7	2.8	97	5.5	2.7	97	53.0%	-2.80 [-3.57, -2.03]
Total (95% CI)			**176**			**159**	**100.0%**	**-2.31 [-3.33, -1.28]**

Heterogeneity: Tau² = 0.36; Chi² = 2.91, df = 1 (P = 0.09); I² = 66%
Test for overall effect: Z = 4.40 (P < 0.0001)

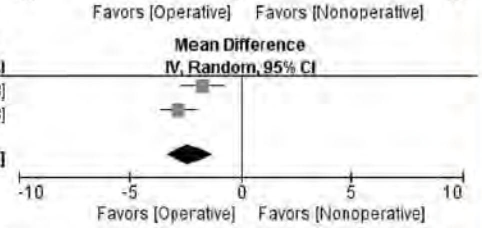
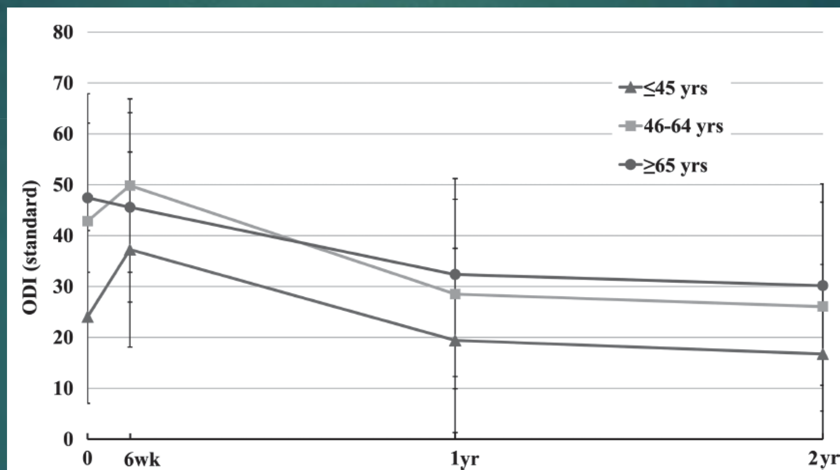


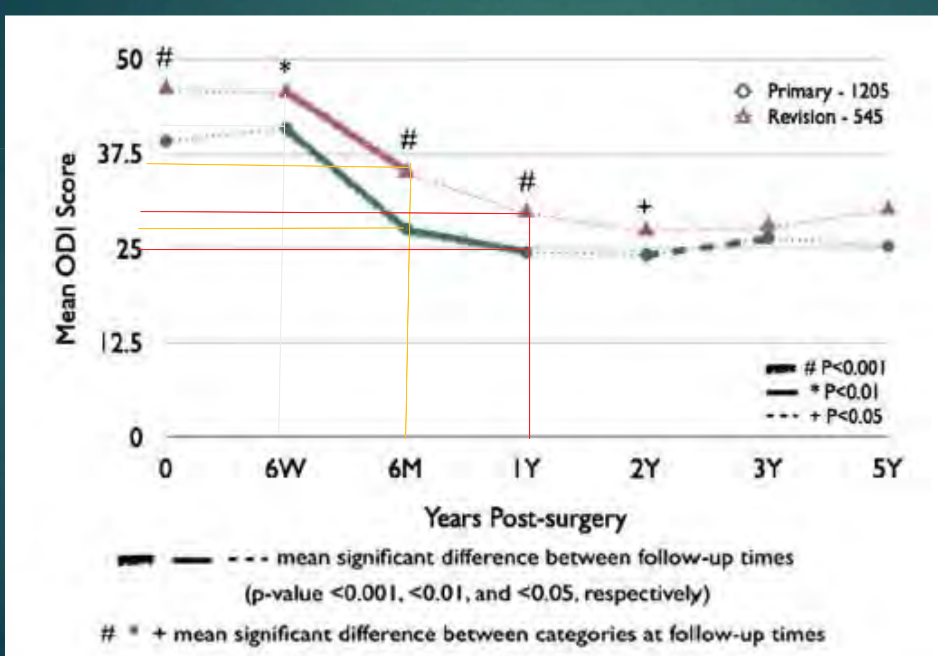
Figure 4. Table and forest plots of numeric rating scale leg pain score. IV, interval variable; CI, confidence interval.

Normal Recovery after ASD Surgery?



Scheer et al, Spine, 2015

Normal Recovery after ASD Surgery?

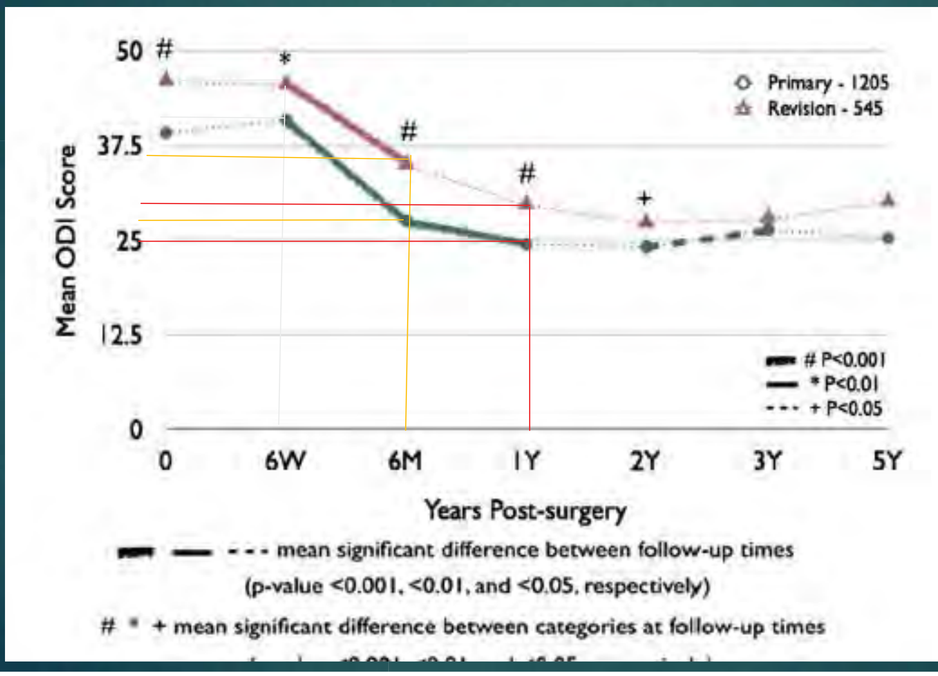


Expected Improvement:

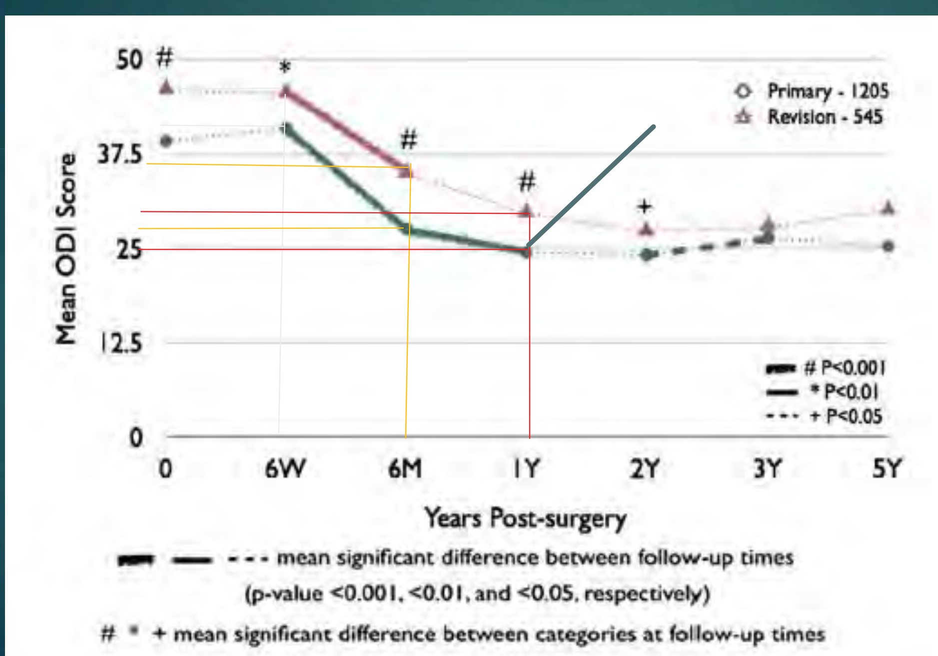
Back Pain:
30% by 3 months
50-75% by 6 months
100% by 1 year

Radicular Leg Pain:
Almost Immediately

When is postoperative pain Abnormal?



When is the Pain Profile Abnormal?



Patient comes in with unexpected pain

Our reaction to the patient's unexpected pain: Internal Monologue

- "I did a great surgery on her, can't believe she is still complaining of pain!"
- "I should have never operated on him."
- "I've gotta get this guy our of my practice…"
- "…SMH"

Our reaction to the patient’s unexpected pain: What we say to patients

- “You really shouldn’t be having pain at this point!”
- “Typically by now you should be doing a lot better!”
- “Your x-rays look great, so I’m not sure what is causing your pain…”
- “There is really nothing else I can do for you ☹”

Our reaction to the patient’s unexpected pain: What we say to patients

- “You really shouldn’t be having pain at this point!”
- “Typically by now you should be doing a lot better!”
- “Your x-rays look great, so I’m not sure what is causing your pain…”
- “There is really nothing else I can do for you ☹”
  - Missed opportunity to help your patient
  - If you are taking on the responsibility to operate on someone, you must take on the responsibility of optimizing there outcome.

Pain after Adult Deformity Surgery

- Postoperative pain is common
- Low level manageable pain is expected (not expectation to be pain free)
- Absence of pain is relatively rare (homerun)
- Significant or worsening pain
  - necessitates our attention
  - Further workup

Early postoperative pain

Pain generator not addressed

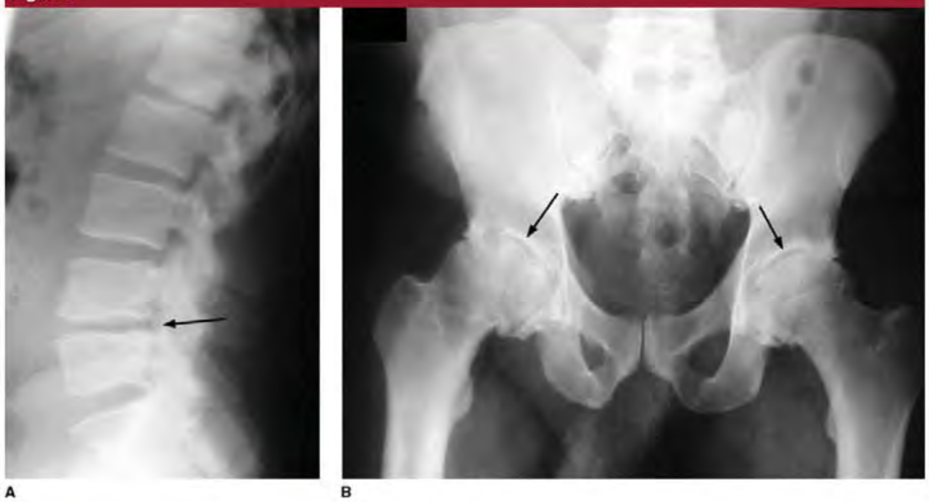
- Residual Stenosis
- Non-spine etiology
  - Wrong diagnosis

New Pain Generator

- Iatrogenic Stenosis / Nerve injury
- Instability
- Implant Related
- Fracture
- Infection
- Trigger Point / Neuroma

Wrong diagnosis

Figure 3



Lateral spine (A) and anteroposterior pelvis (B) radiographs of a 48-year-old man referred for treatment of lumbar spinal stenosis. Further history revealed groin pain more consistent with hip joint arthritis than neurogenic claudication. A, Spondylosis with foraminal stenosis, predominantly at L4-5 (arrow). B, Advanced arthrosis of both hip joints (arrows).

Richard D. Guyer, MD, et al

Late postoperative pain

Recurrent Pain / Radiculopathy

- Pseudoarthrosis
- Non-spine etiology
  - Postop SI joint pain
  - Bursitis

New Pain Generator

- Adjacent Segment
- Proximal Junctional Kyphosis
- Implant fatigue / Failure
- Late Infection
- Non-spinal etiology

Common Location / Onset Patterns

	New Location/Quality	Familiar Location/Quality
Early/Immediate Onset	-Implant Instability -Iatrogenic injury -Fracture -Infection	-Residual Stenosis -Wrong diagnosis
Late Onset	-Adjacent Segment pathology / PJK -Fracture -Infection -Sagittal Imbalance	-Pseudoarthrosis

Steps in dealing with a Patient's Pain after surgery

- Sulk, briefly!
- Detach your own value from the outcome so that you can be objective and effective
  - Believe your patient
- Get specifics to help develop differential dx
  - Location, Quality, provoking, relieving, trajectory
- Determine urgency
- Have an broad differential (Systematic Approach)
  - Ideally broader than your own experience
- Get *information*
  - Imaging and other tests (to support or rule out items on differential dx)
- Confirm the pain generator(s)
- Fix the pain generator
- Get a second opinion (better chance of finding the pebble in the shoe)

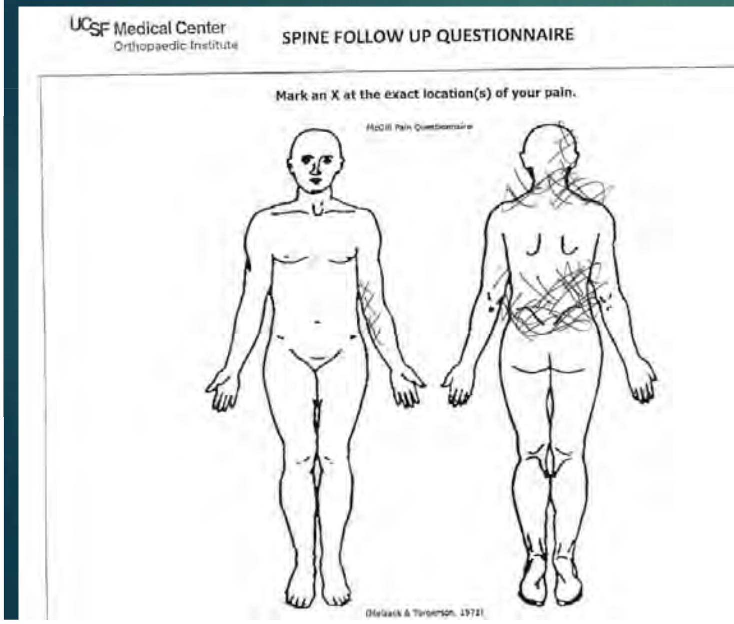
Differential Diagnosis for Residual Back Pain

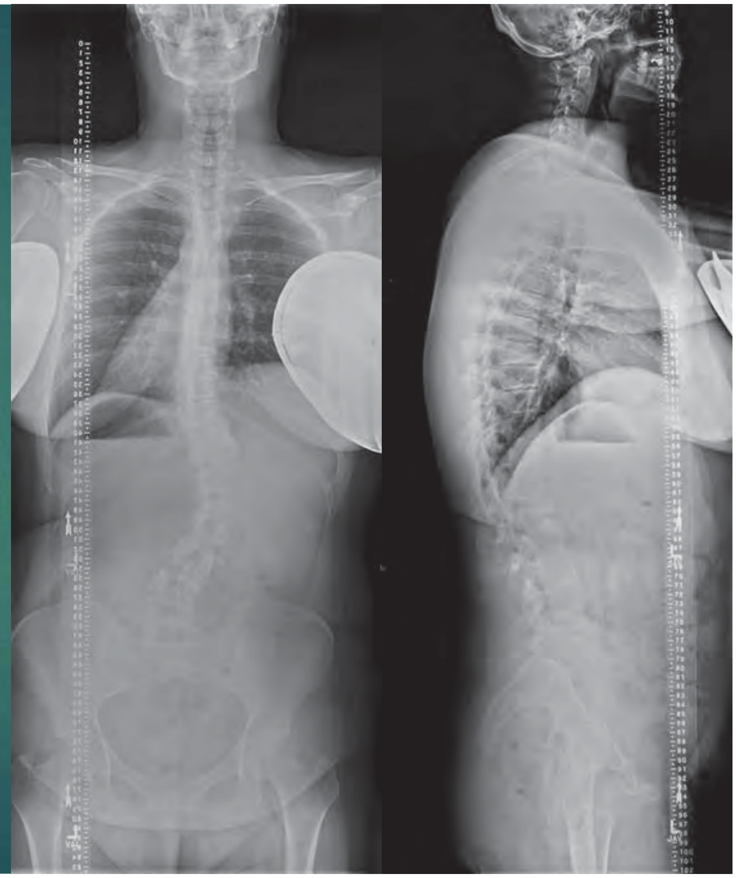
- Surgery Related
  - Postoperative wound related pain (should have plateaued by around 12 months)
  - Infection
  - Pseudoarthrosis
  - Proximal Junctional Kyphosis/Failure
  - Distal Junctional Kyphosis/Failure
  - Instrumentation related
    - Loosening
    - Prominence
    - Breakage
  - Residual Malalignment
  - SI Joint

Work-up of postoperative pain

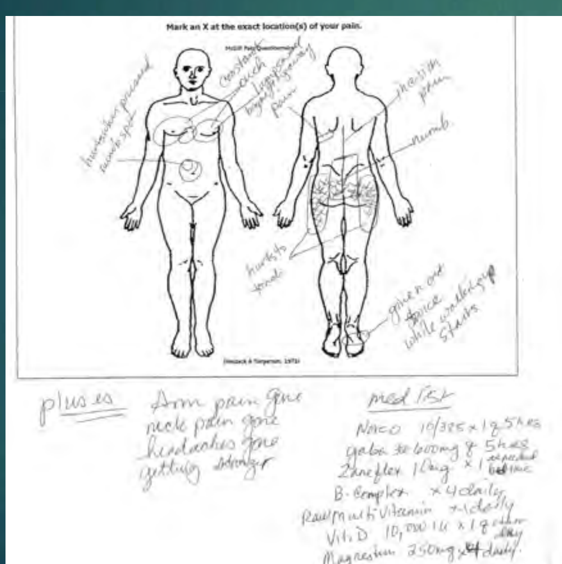
- History
  - Careful pain history taking
    - Onset, location, radiation, quality, exacerbating and alleviating factors
  - Review Prior Records
  - Repeat visits if necessary to look for consistency and evolution of symptoms
- Physical Exam
  - Similar to initial PE
  - Posture, gait, transition from sit to stand, compensatory mechanisms
  - Strength, sensation, reflexes, tension signs, exam of hips / knees
- Diagnostic Studies
  - X-rays, 36 inch AP/lat +/- oblique, Fergusson, flexion extension views
  - CT scan to evaluate for arthrodesis, implant position, and occult fracture
  - MRI to evaluate for neural impingement, adjacent segment Degen, infection, (even if just residual back pain)
  - EMG / NCV to assess nerve function or extent of injury
  - Labs: ESR, CRP Sensitive but not specific for infection
  - Diagnostic Blocks: Confirm location of nerve related symptoms and help predict surgical outcome

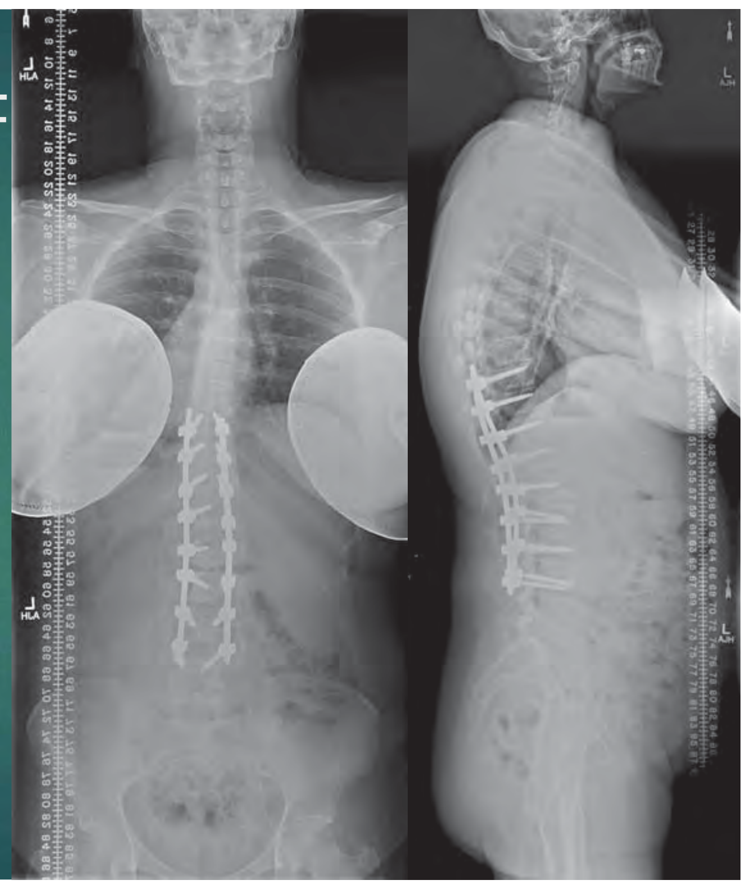
BM 37 yo F s/p T9-L4 PSF
preop   Pain 10/10



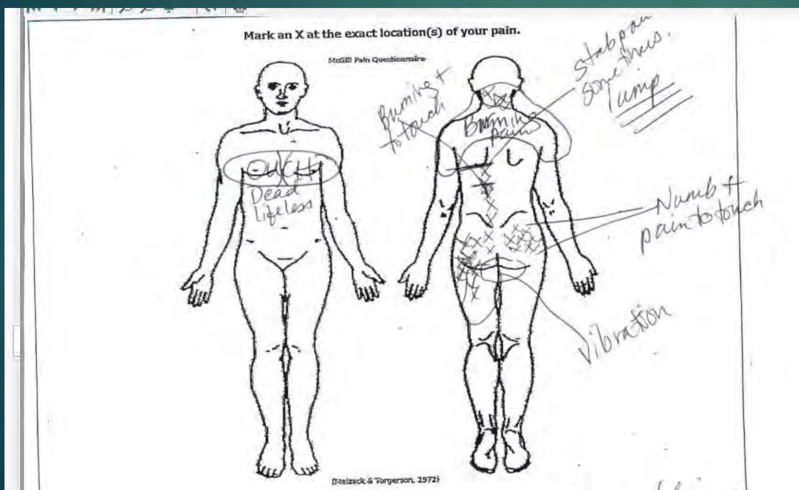


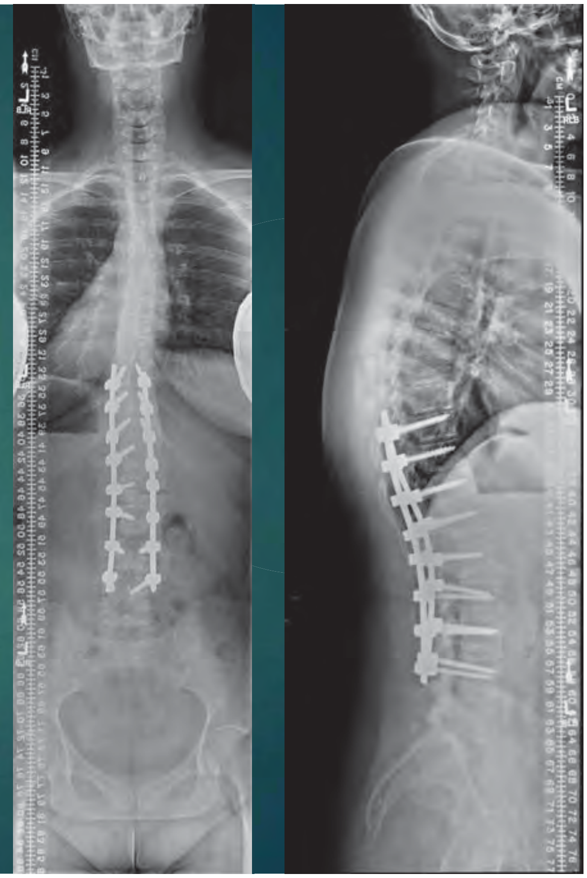
BM 37 yo F s/p T9-L4 PSF
2 wk PO   Pain 8/10



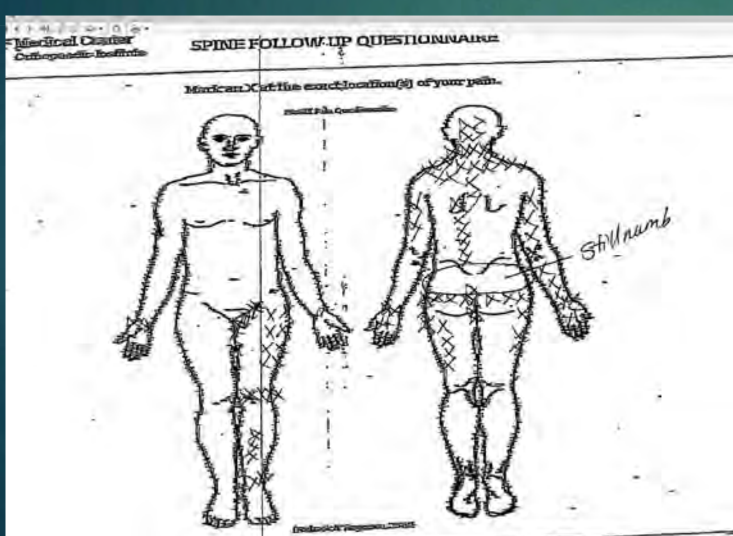


BM 37 F yo s/p T9-L4 PSF
3 mos PO Pain 5/10

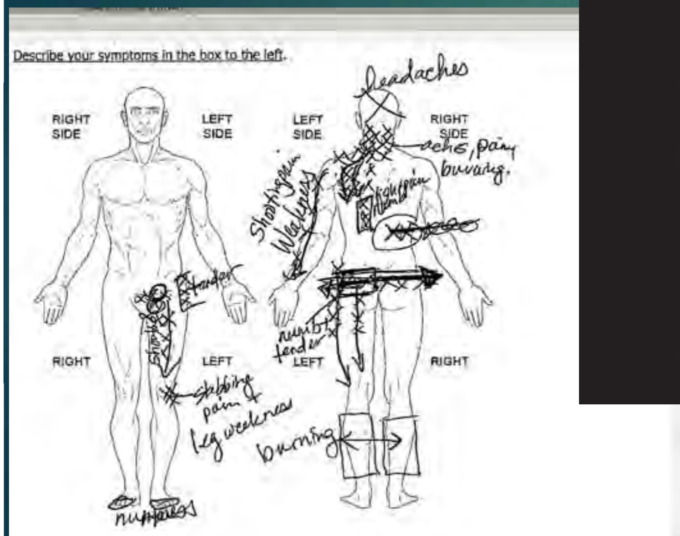


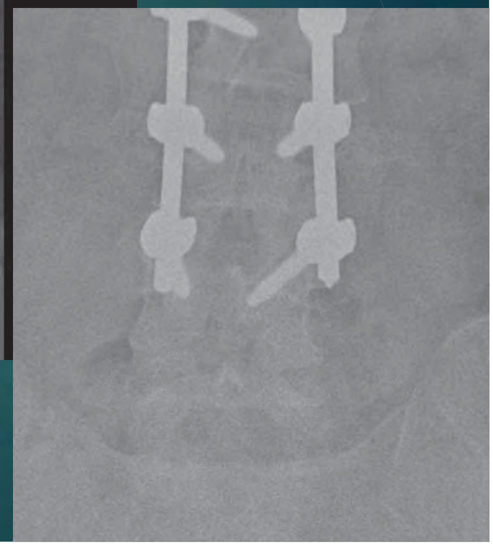


BM 37 yo F s/p T9-L4 PSF
8 mos PO Pain 8/10



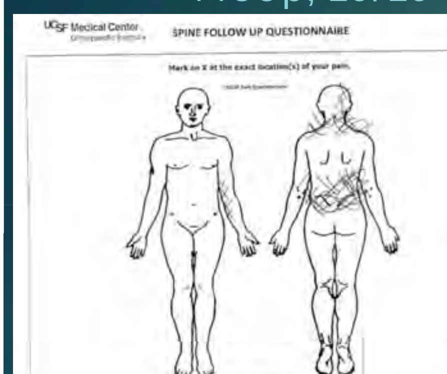
BM 37 yo F s/p T9-L4 PSF
12 mos PO   Pain 8/10



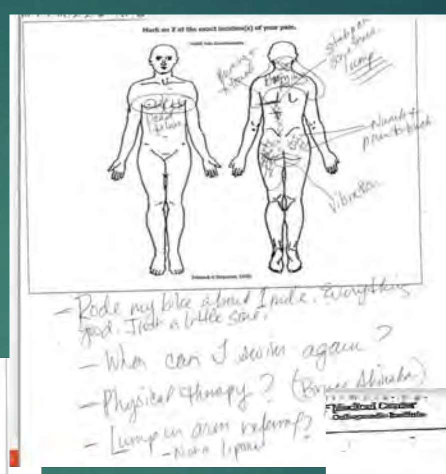


Evolution of Pain

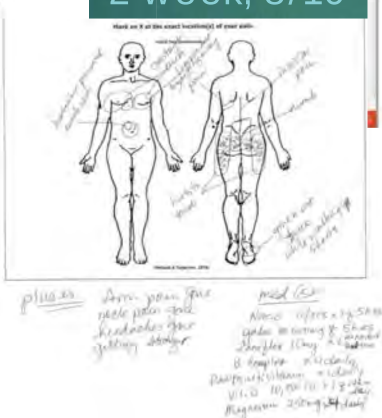
Preop, 10/10



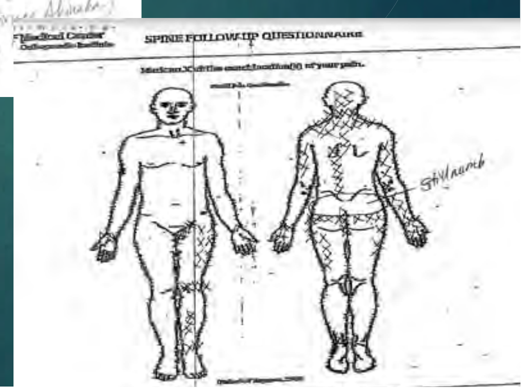
3 mos, 5/10



2 week, 8/10



8 mos, 8/10

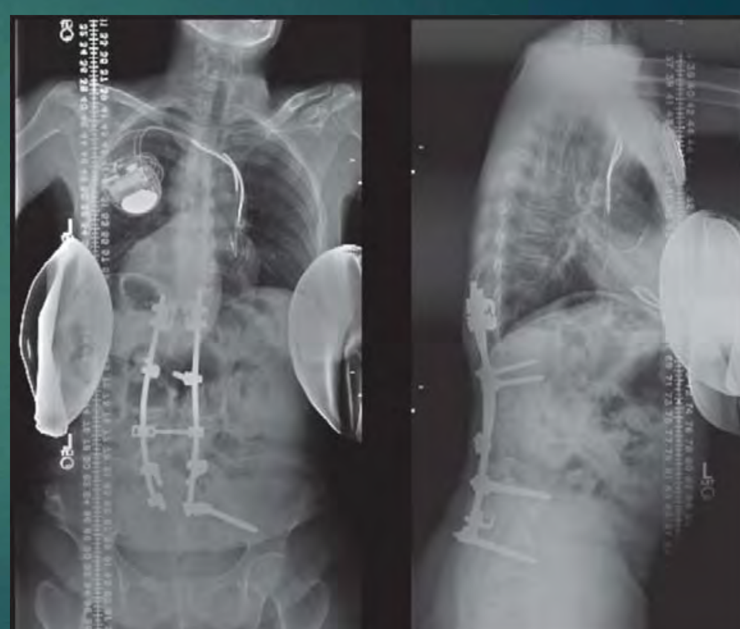


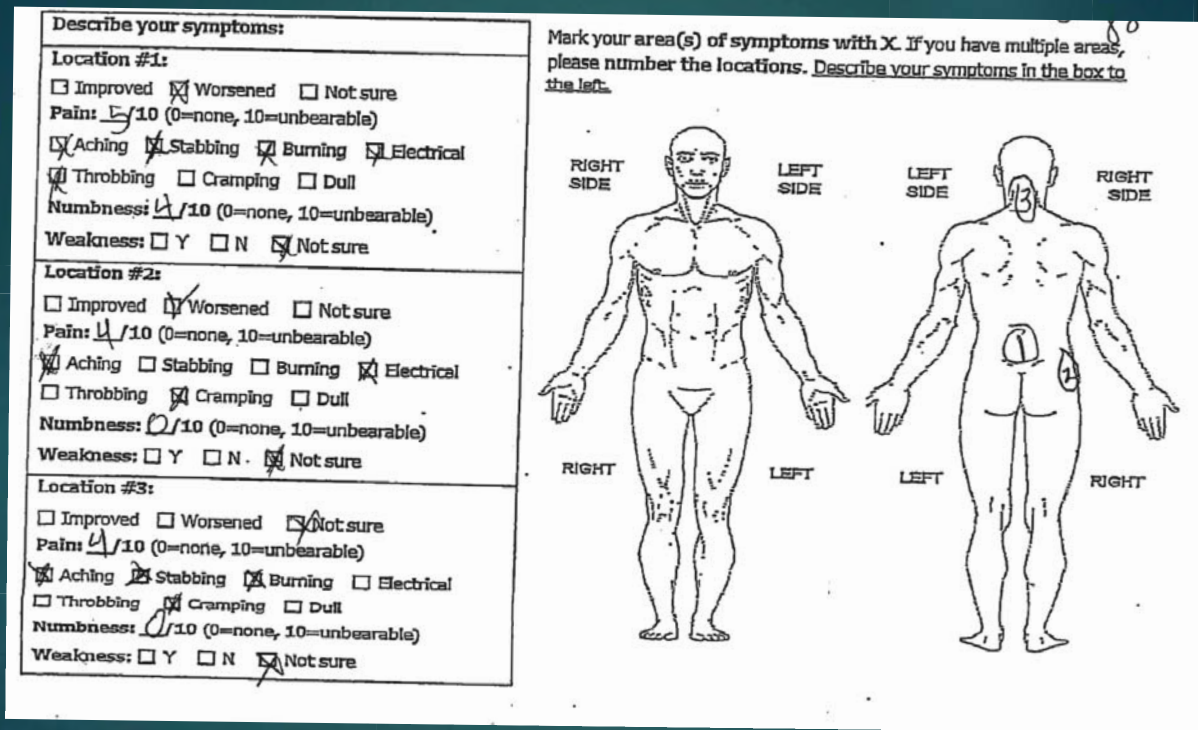
BM 37 yo F s/p T9-L4 PSF
12 mos PO   Pain 8/10

- 37 yo with L3-4 pseudoarthrosis
- Scheduled for lateral interbody fusion and revision PSF

	New Location/Quality	Familiar Location/Quality
Early/Immediate Onset	-Implant Instability -Iatrogenic injury -Fracture -Infection	-Residual Stenosis -Wrong diagnosis
Late Onset	-Adjacent Segment pathology / PJK -Fracture -Infection -Sagittal Imbalance	-Pseudoarthrosis

Type C – Fixed/Stuck deformity





Describe your symptoms:

Location #1:

☐ Improved ☒ Worsened ☐ Not sure

Pain: 5/10 (0=none, 10=unbearable)

☒ Aching ☒ Stabbing ☒ Burning ☒ Electrical

☒ Throbbing ☐ Cramping ☐ Dull

Numbness: 4/10 (0=none, 10=unbearable)

Weakness: ☐ Y ☐ N ☒ Not sure

Location #2:

☐ Improved ☒ Worsened ☐ Not sure

Pain: 4/10 (0=none, 10=unbearable)

☒ Aching ☐ Stabbing ☐ Burning ☒ Electrical

☐ Throbbing ☒ Cramping ☐ Dull

Numbness: 0/10 (0=none, 10=unbearable)

Weakness: ☐ Y ☐ N ☒ Not sure

Location #3:

☐ Improved ☐ Worsened ☒ Not sure

Pain: 4/10 (0=none, 10=unbearable)

☒ Aching ☒ Stabbing ☒ Burning ☐ Electrical

☐ Throbbing ☒ Cramping ☐ Dull

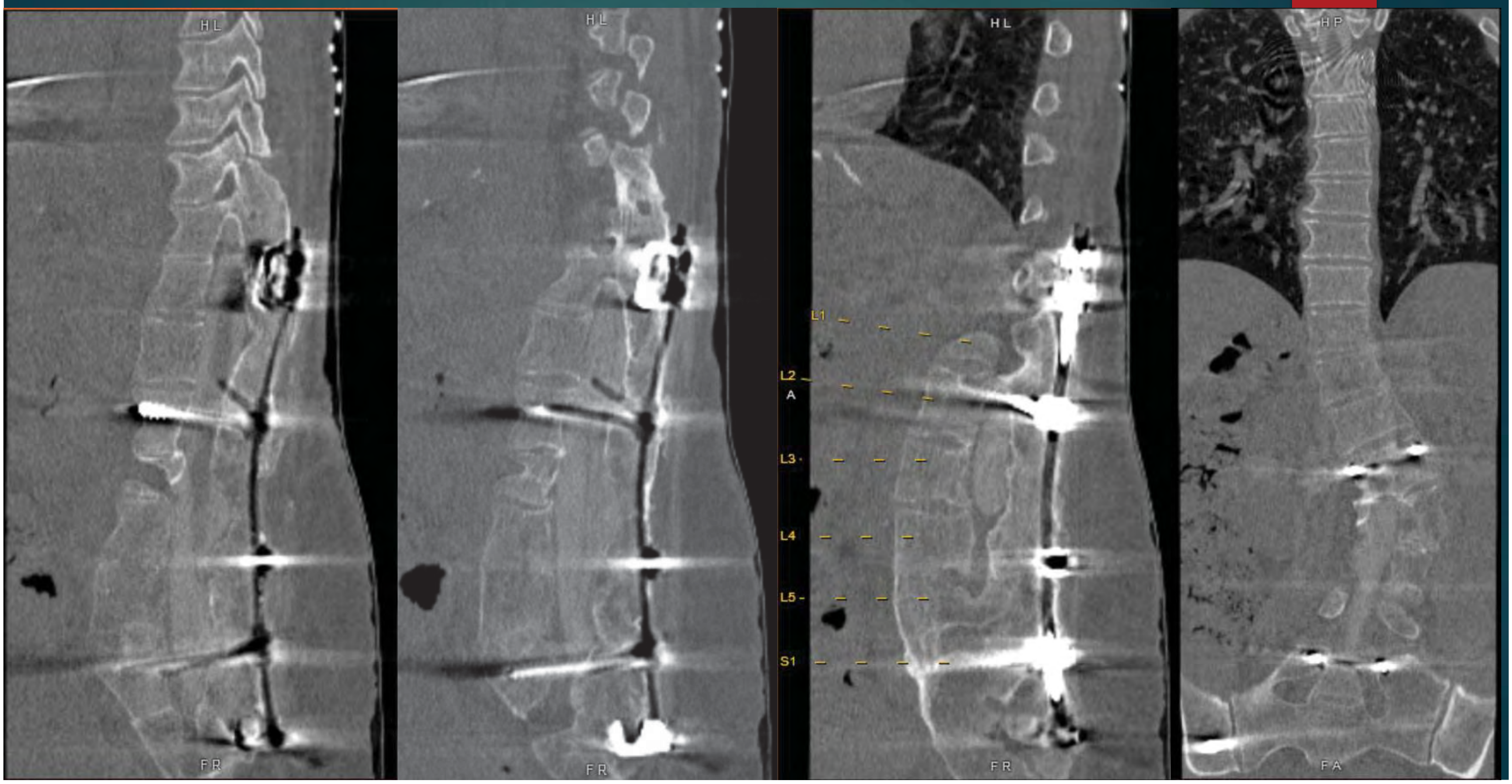
Numbness: 0/10 (0=none, 10=unbearable)

Weakness: ☐ Y ☐ N ☒ Not sure

Mark your area(s) of symptoms with X. If you have multiple areas, please number the locations. Describe your symptoms in the box to the left.

Preop planning for multiply operated patients

- Op notes
- ID instrumentation
- CT myelogram
  - r/o dural issues / arachnoiditis
  - Evaluate implant position, fusion status, and adjacent anatomy
- Removal and reinstrumentation strategies



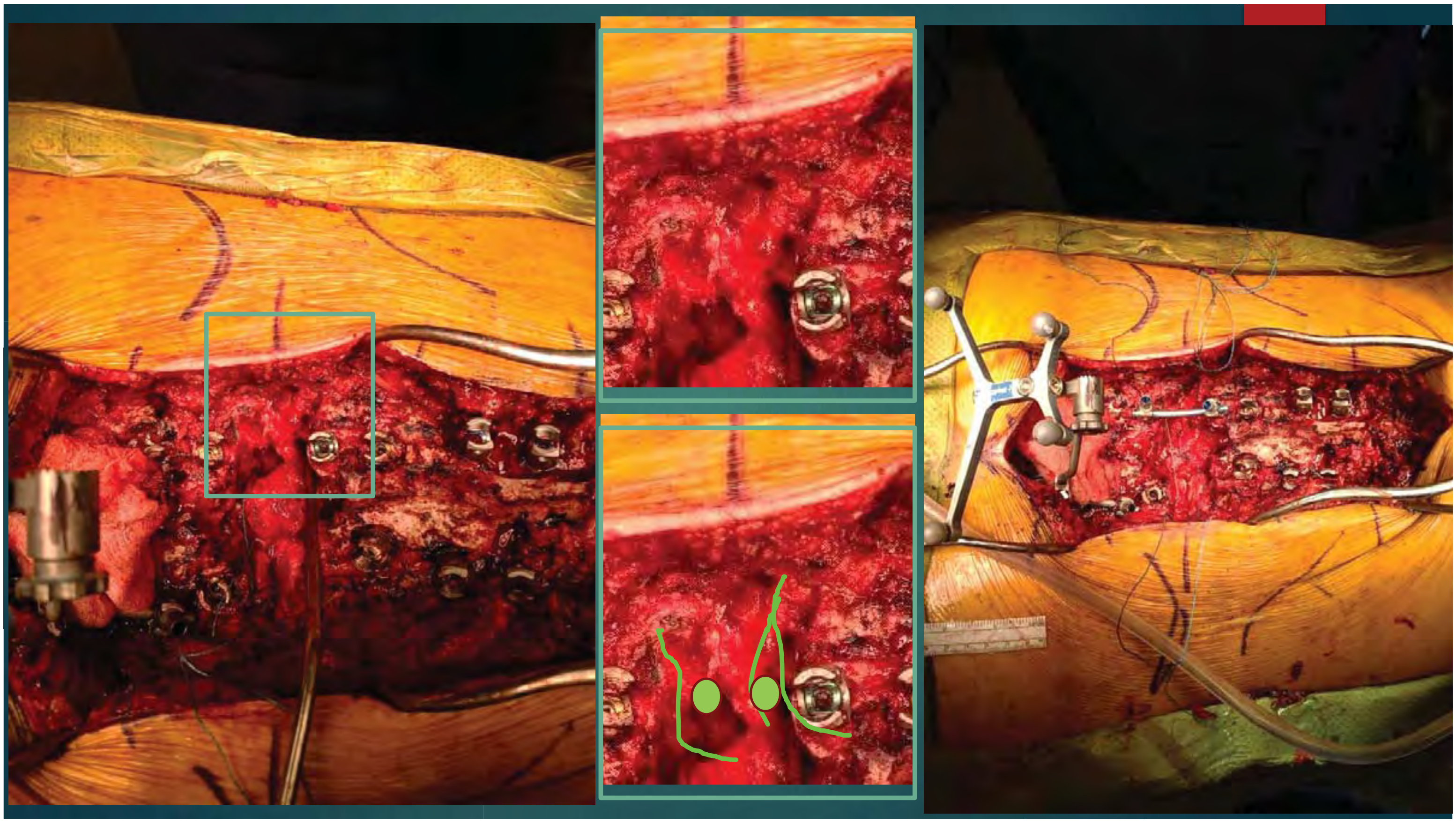
LEVEL	Left Screw dia	length	Decompression /release type	Interbody instrumentation, disc condition	ant col	Right Screw dia	length
T10	5.5		Fused but not instrumented			5.5 jxt	
T11	5.5		Fused but not instrumented			4.5-5.5	
T12	6.5		Bilateral claw construct; left superior hook in canal	Bilateral claw construct		6.5	
L1	6.5					5.5	40
L2	Track good, bicortical, can shorten 5mm or leave bicort					Lateral breach, shorten 5mm	
L3	6.5mm; Small secondary pedicle below		Need distal pedicle resection	28deg		4.5mm pedicle	

LEVEL	Left Screw dia	length	Decompression /release type	Interbody instrumentation, disc condition	Ant col	Right Screw dia	length
L2	Track good, bicortical, can shorten 5mm or leave bicort					Lateral breach, shorten 5mm	
L3a/b	6.5mm; <u>Small secondary pedicle below</u>		Need distal pedicle resection	28deg		4.5mm pedicle	
L4	7.5		PSO	20deg	PSO	Vestigial pedicle	
L5	9.5	50	PCO	25deg, lamina intact		9.5	50
S1	Good track, can increase 5mm			Partially lumbarized		Good track, length good	
S2AI	S2 site covered, should using Iliac screw			Remove hooks, can replace, in good position			
Pelvic	Place iliac screw					Good track, can increase length 10mm	

Surgical Plan

- Lumbarized S1, L3 hemi, Fused to T10, PI=47, LL=14, MM=33
- Equipment: Solera, PSO/VCR set, TLIF cages, Bone scalpel, Aquamantys, Neuromonitoring all modalities, no preflip
- MAP to 75
- Exposes to SP of T10
- Removed Crosslink, lies over L4/5 disc
- Cut rod bil at L4 vs. Cut at L1 to separate claw from lower construct
  - KY jelly and carbide side cutting burr
- Left has S1 screw and upgoing S2 hook
- Right side has S1 screw and Iliac bolt
- Remove claw construct with counter torquing, left superior hook appears in canal, others look to be in fusion mass
- Irrigate 3L

- Place S1 and Iliac screws and revision frame with short rod vs. Spinous process frame at T10
- 2 spins, HD, Large
- Cannulate pedicles and place screws L5, L3, L2, L1, T12, T11 (and do short A to P S2 screws if needed)
- Mark out osteotomy with navigation
- Start L4 PSO with Lami from L2/3 disc, to L5 foramen
- Resect lower Left L3 pedicle
- Complete PSO L4, correct over Titanium cresent cage with goal of 30 deg correction.
- Close PSO with 5.5 CoCr rods and 1 or 2 satellite rods




Desc: X

35 yo with Adult idiopathic scoliosis

- 35 yo
- No relief with non-op management
- Indicated for fusion given debilitating pain
- Back and buttock pain 7-8/10

35 yo with Adult idiopathic scoliosis

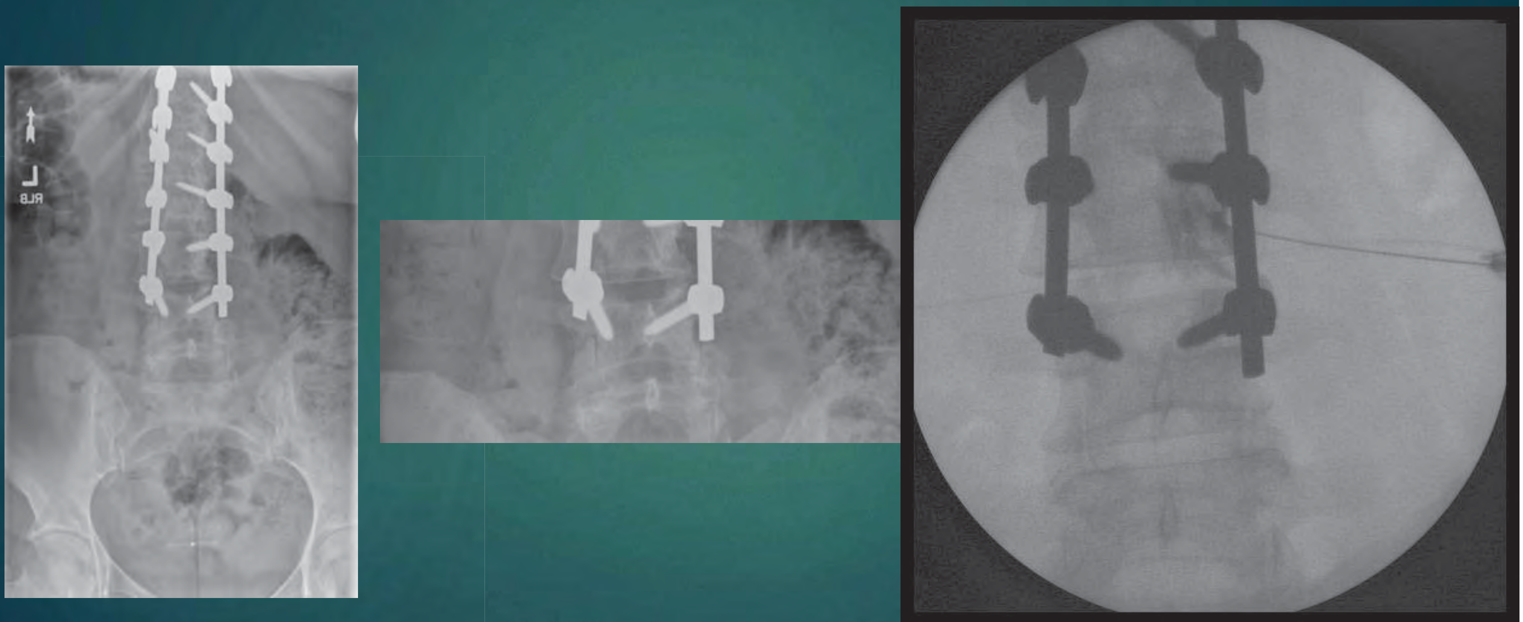
- 35 yo
- Initially did well
- 3 mos diffuse back pain 3/10




35 yo with Adult idiopathic scoliosis

- 35 yo
- Fall at 8 months
- Low back pain increased to 4-5
- Pain in right groin and anterolateral thigh
- MRI of right hip showed acute labral tear
- Hip injection 30% relief of pain


35 yo with Adult idiopathic scoliosis



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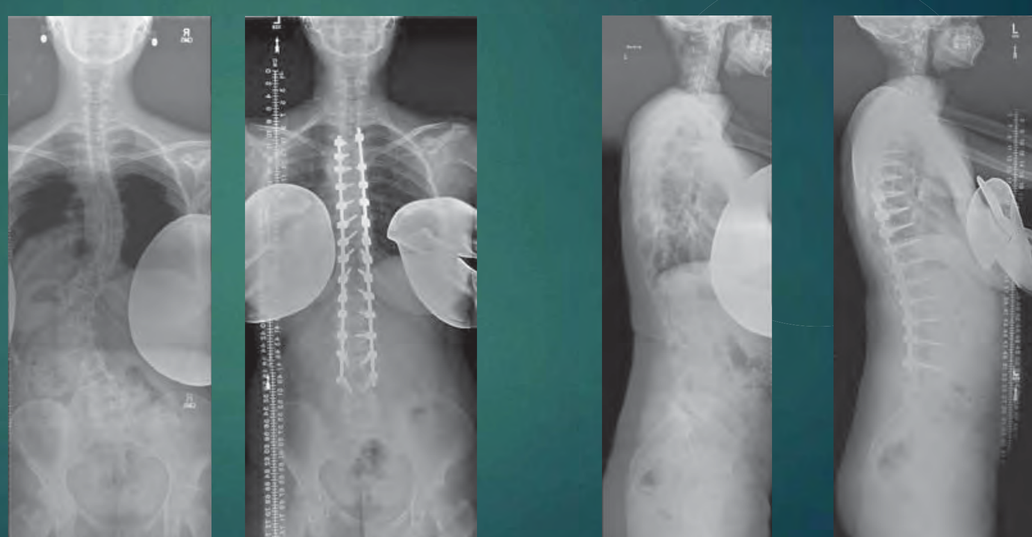

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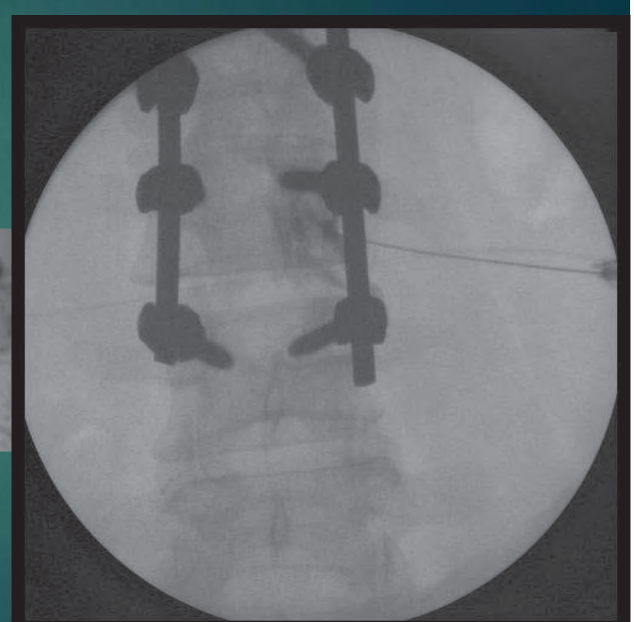
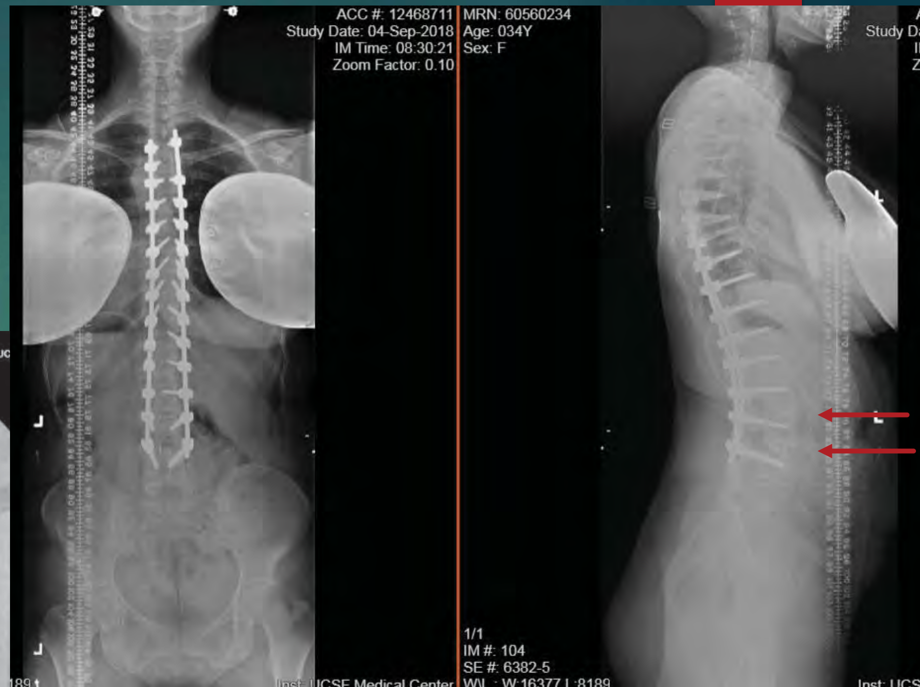
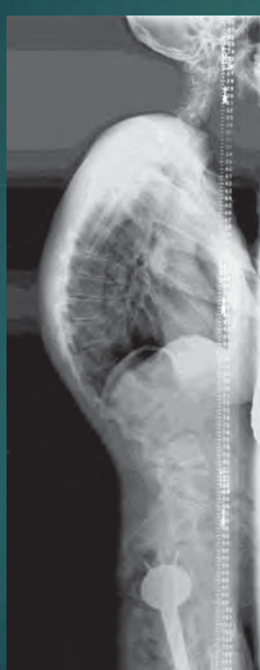
35 yo with Adult idiopathic scoliosis

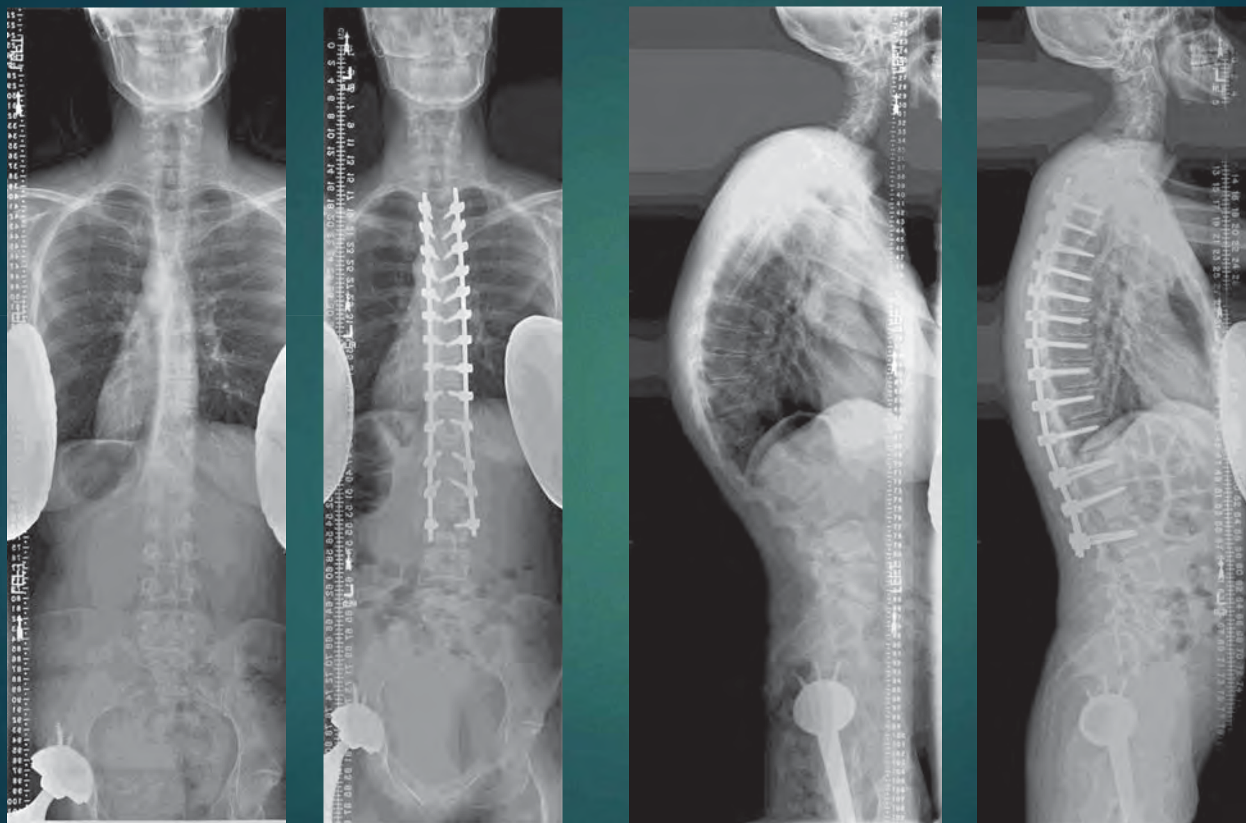




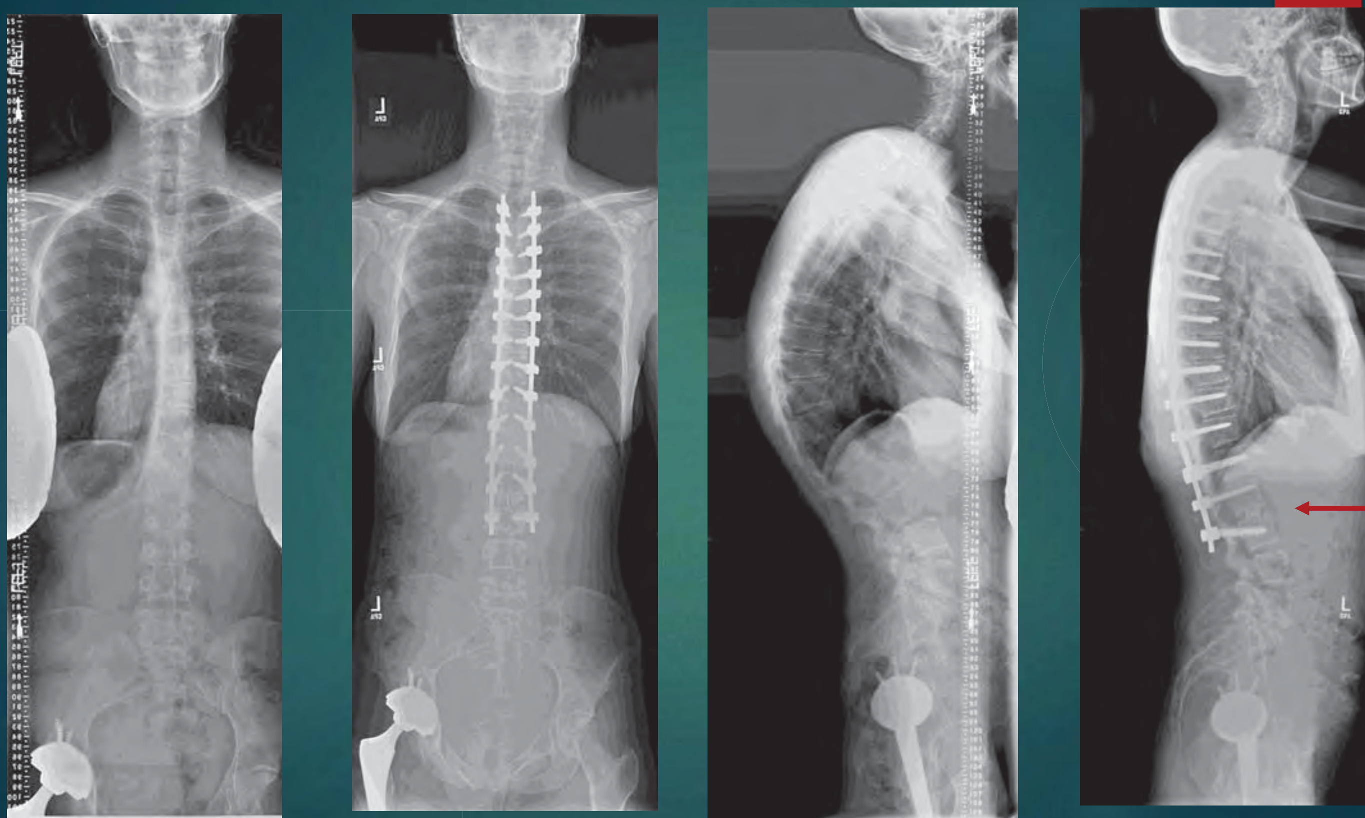
43 yo with Scheuermann Kyphosis



Plan T3-L3 with Staged LLIF



2 mos postop fall, back pain



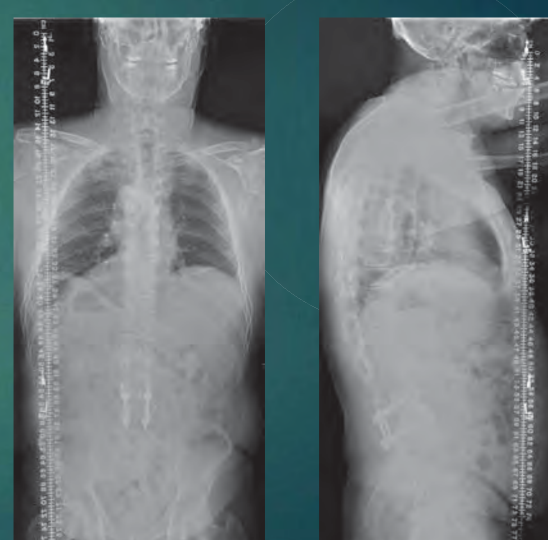
76 yo man with history of L3/4 decompression fusion at OSH

- 9/10 back pain
- Initially did very well after surgery with minimal pain
- At 6 mos started having pain that peak at 1yr

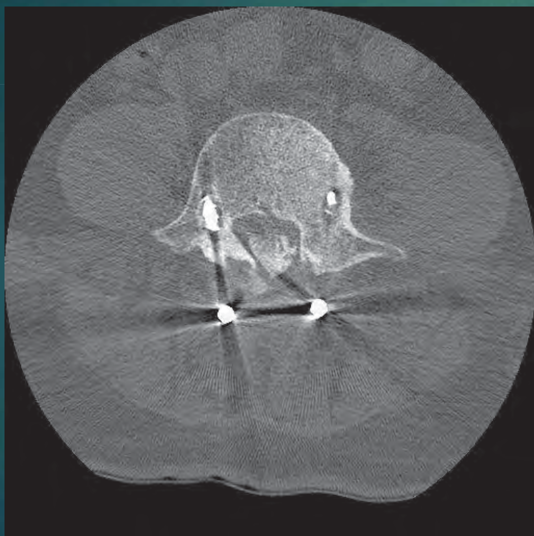
Left Q: 4-, TA: 1, EHL 4-

Right LE full strength

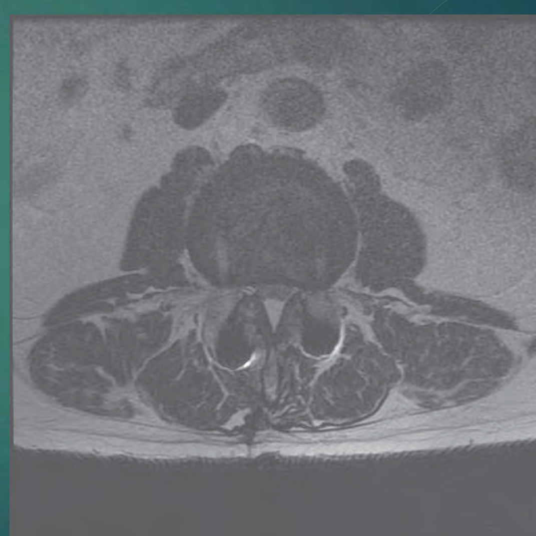
- PI: 55
- LL: 47
- SVA: 1cm



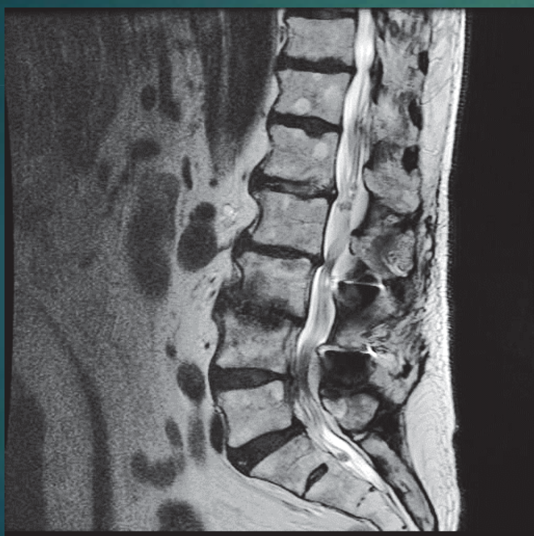
76 yo man with history of L3/4 decompression fusion at OSH

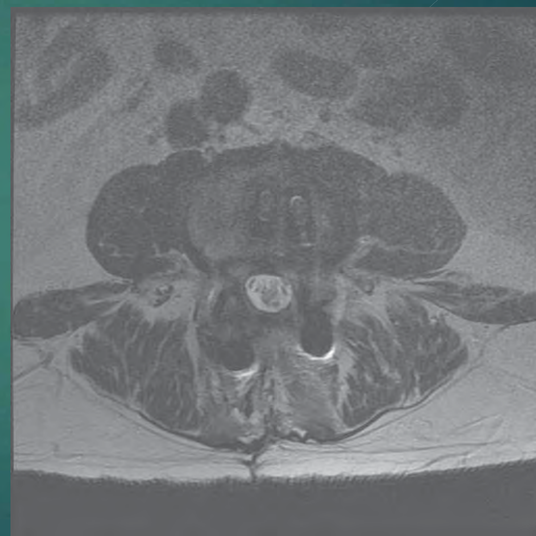


L2/3

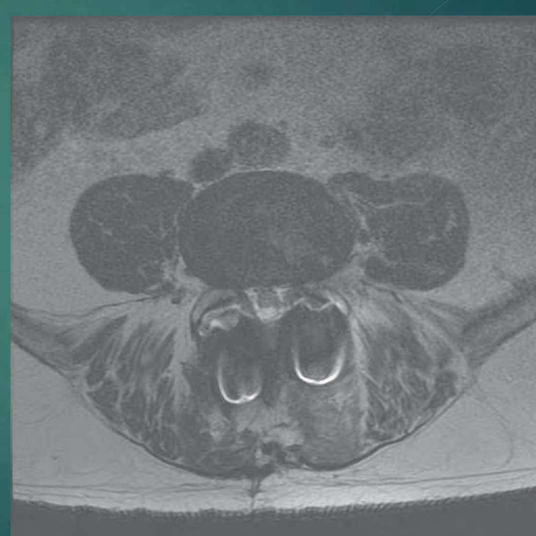


L3/4

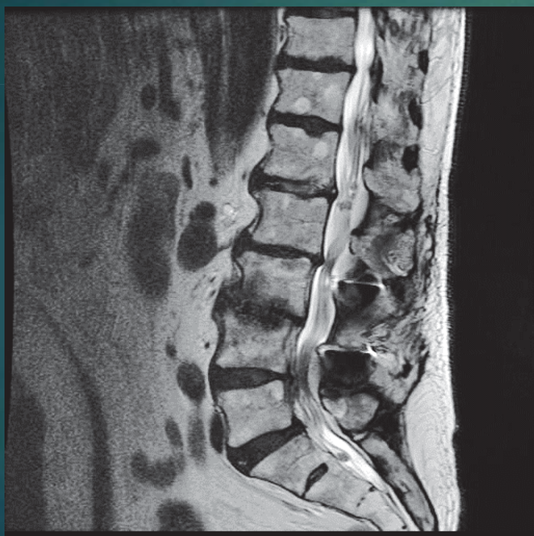




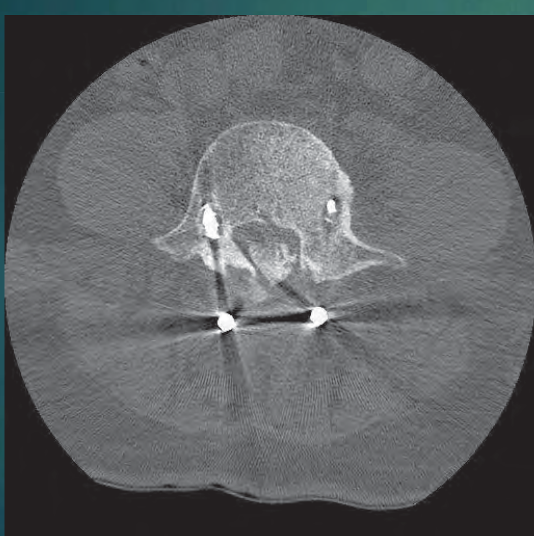
L4/5



Disc extrusion at left L4/5



76 yo man with history of L3/4 decompression fusion at OSH



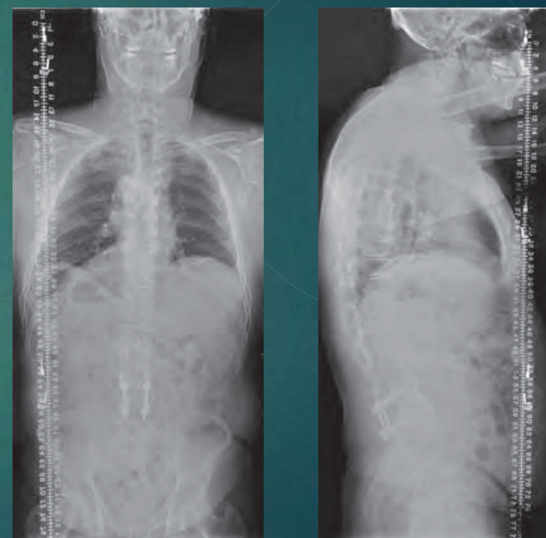
76 yo man with history of L3/4 decompression fusion at OSH

Pain generators

1) pseudoarthrosis L3/4
2) Disc extrusion and stenosis L4/5
3) Adjacent segment degeneration and stenosis L2/3

Negative inflammatory markers

No sagittal imbalance



Common Location / Onset Patterns

	New Location/Quality	Familiar Location/Quality
Early/Immediate Onset	-Implant Instability -Iatrogenic injury -Fracture -Infection	-Residual Stenosis -Wrong diagnosis
Late Onset	-Adjacent Segment pathology / PJK -Fracture -Infection -Sagittal Imbalance	-Pseudoarthrosis

76 yo man with history of L3/4 decompression fusion at OSH

Now 2 weeks s/p LLIF L2/3, L3/4, L4/5, PSF L2-5, decompression L4/5

Doing well

Pain 2/10

Left Q: 4+, TA: 4, EHL 4-

Right LE full strength

76 yo man with history of L3/4 decompression fusion at OSH

Now 3 months s/p LLIF L2/3, L3/4, L4/5, PSF L2-5, decompression L4/5

Not doing well

Pain 9/10 right buttock and posterolateral thigh with walking

4/10 across the low back

- Patient c/o pain right lateral buttock x a few weeks started after physical therapy.
- Pain radiates to lateral right thigh, doesn't radiate past knee.
- Pain worse with walking, and better with using walker and cane.

Left Q: 4+, TA: 4, EHL 4-

Right LE full strength

Postoperative Pars fracture

CT 4 mos postop

With abrupt and persistent change in symptoms advanced imaging indicated

Left pars fracture

Right pars/facet fracture

Common Location / Onset Patterns

	New Location/Quality	Familiar Location/Quality
Early/Immediate Onset	-Implant Instability -Iatrogenic injury -Fracture -Infection	-Residual Stenosis -Wrong diagnosis
Late Onset	-Adjacent Segment pathology / PJK -Fracture -Infection -Sagittal Imbalance	-Pseudoarthrosis

Revision ALIF L5/S1, PSF extended to pelvis

Doing well at 3 months

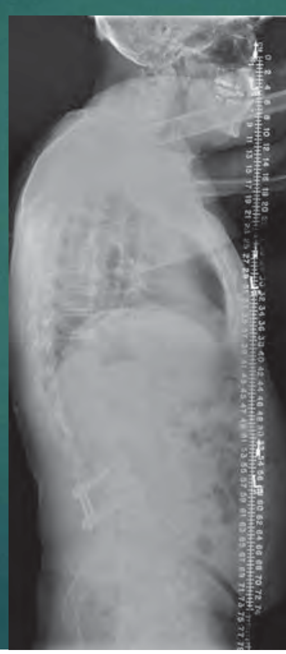
Doing well

Pain 1/10

Left Q: 4+, TA: 4+, EHL 4+

Right LE full strength

Revision ALIF L5/S1, PSF extended to pelvis



Summary

- Pain after Adult Reconstructive surgery is common
- Significant pain requires further investigation
- History and Physical Exam are critical for raising index of suspicion for cause
- Diagnostic Modalities available to confirm or rule out many causes
- Many patients will improve if time taken to diagnose and treat cause of postop pain

Degenerative Spondylolisthesis and QOD

Data Driven Innovation in Clinical Decision Making

Catherine A. Miller, M.D.
Assistant Professor of Neurological Surgery
Department of Neurological Surgery
University of California, San Francisco

SPINE SURGERY QOD

Disclosure

- No disclosures

Study Related
- Regis W. Haid, Jr. NREF Fund
- Medtronic grant to the NREF
- Depuy Synthes grant to the NREF

Agenda

- Introduction
- Fusion versus Non-Fusion
- Comparative Effectiveness
  - Minimally Invasive vs. Open Surgery
- How do special populations fare?
  - Obese Patients
  - Women
- Outcome Prediction

Agenda

- **Introduction**
- Fusion versus Non-Fusion
- Comparative Effectiveness
  - Minimally Invasive vs. Open Surgery
- How do special populations fare?
  - Obese Patients
  - Women
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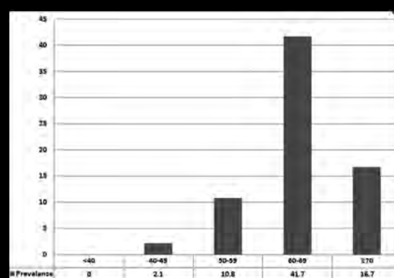
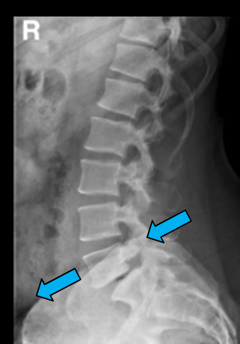
Lumbar degenerative spondylolisthesis

- Degenerative lumbar spondylolisthesis is a major cause of low back pain
  - 11.5% prevalence in the US



Treatments

- Conservative management
  - Opioid and Non-opioid medications
  - Physical therapy, Aquatherapy, TENS unit
  - Injections
- For patients that fail conservative management strategies, surgery is superior to continued non-surgical treatment with regards to pain and function at 2 years



Weinsten et al. NEJM 2007

Agenda

- Introduction
- **Fusion versus Non-Fusion**
- Comparative Effectiveness
  - Minimally Invasive vs. Open Surgery
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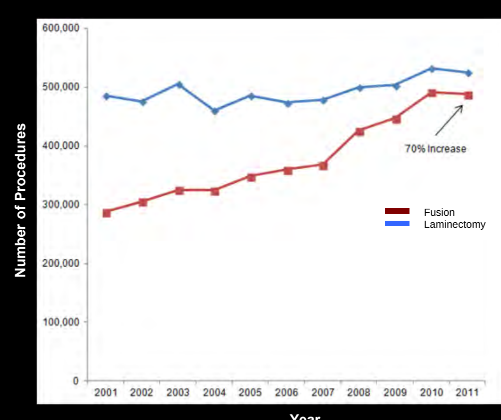
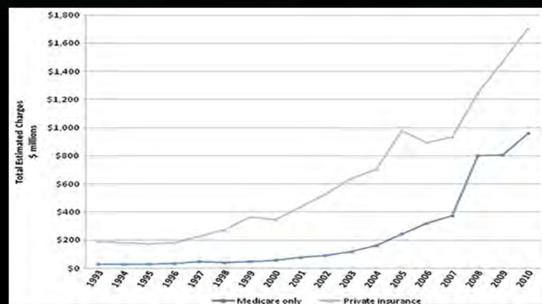
Spinal Fusions

- Rate of spinal fusions in US increased over past several decades
- Significant variation between diagnoses, geographic location, specialty



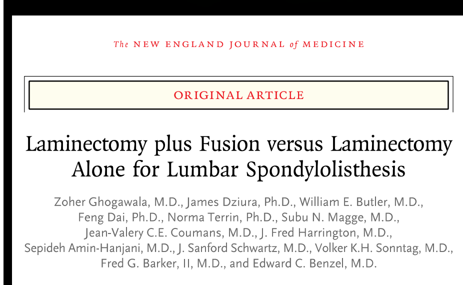
Cost of Fusions



- Spinal fusion accounts for the highest aggregate hospital cost (**$12.8 billion** in 2011) of any surgical procedure performed in US hospitals
- 10 years
  - Medicare: $56 million → $958 million
  - Other patients: $344 million → $1.7 billion

McCarthy et al, Neurosurg Clin N Am 24 (2013)

Differing Conclusions…


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Laminectomy plus Fusion versus Laminectomy Alone for Lumbar Spondylolisthesis

Zoher Ghogawala, M.D., James Dziura, Ph.D., William E. Butler, M.D., Feng Dai, Ph.D., Norma Terrin, Ph.D., Subu N. Magge, M.D., Jean-Valery C.E. Coumans, M.D., J. Fred Harrington, M.D., Sepideh Amin-Hanjani, M.D., J. Sanford Schwartz, M.D., Volker K.H. Sonntag, M.D., Fred G. Barker, II, M.D., and Edward C. Benzel, M.D.


The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 14, 2016 VOL. 374 NO. 15

A Randomized, Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis

Peter Försth, M.D., Ph.D., Gylfi Ólafsson, M.Sc., Thomas Carlsson, M.D., Anders Frost, M.D., Ph.D., Fredrik Borgström, Ph.D., Peter Fritzell, M.D., Ph.D., Patrik Öhagen, Karl Michaëlsson, M.D., Ph.D., and Bengt Sandén, M.D., Ph.D.

Significant improvement in overall health related QOL in fusion cohort

No added benefit of fusion using disability as a primary outcome

Shortcomings

- Swedish Study
  - Heterogeneous study population
    - Stenosis
    - Spodylolisthesis
      - Dynamic and Stable
  - Underpowered to detect difference in disability
  - ODI as outcome (as compared to HRQOL)
    - HRQOL metric may be more in line with modern, patient-centered care
- Randomized control trials
  - Employ stringent inclusion criteria that do not apply to the average patient seen in clinic

"Real-world" Registry Data

- Spine Surgery Quality Outcomes Database
- Spondylolisthesis Study Group
  - Multi-disciplinary
  - Twelve highest-enrolling sites

SPINE SURGERY QOD

Lumbar Spondylolisthesis Study Group

- Prospectively collected registry data
  - July 1, 2014 – June 30, 2016
  - Grade 1 spondylolisthesis
  - Single segment surgery
- Outcomes
  - 30 and 90 day readmission
  - 30 day and 12, 24, 36 month reoperation
  - Patient reported outcomes at 24 months
    - ODI, EQ-5D, NRS Back Pain, NRS Leg Pain
    - NASS Satisfaction
  - Radiographic Fusion
  - Slip Reduction

---

statistical analyses in the Results, Table 6, and Supplemental Tables 1–3.
See the corresponding erratum notice, DOI: 10.3171.2019.1.SPINE17913a.

JNS SPINE

CLINICAL ARTICLE

Laminectomy alone versus fusion for grade 1 lumbar spondylolisthesis in 426 patients from the prospective Quality Outcomes Database

Andrew K. Chan, MD,[1] Erica F. Bisson, MD, MPH,[2] Mohamad Bydon, MD,[3] Steven D. Glassman, MD,[4] Kevin T. Foley, MD,[5] Eric A. Potts, MD,[6] Christopher I. Shaffrey, MD,[7] Mark E. Shaffrey, MD,[7] Domagoj Coric, MD,[8] John J. Knightly, MD,[9] Paul Park, MD,[10] Michael Y. Wang, MD,[11] Kai-Ming Fu, MD, PhD,[12] Jonathan R. Slotkin, MD,[13] Anthony L. Asher, MD,[8] Michael S. Virk, MD, PhD,[12] Panagiotis Kerezoudis, MD, MS,[3] Silky Chotai, MD,[14] Anthony M. DiGiorgio, DO, MHA,[1] Regis W. Haid, MD,[15] and Praveen V. Mummaneni, MD[1]

TABLE 6. Multivariate analysis assessing predictors of 12-month ODI following surgery for grade 1 lumbar spondylolisthesis

Variable	Adjusted β Coefficient (95% CI)	p Value
Addition of fusion to procedure	−4.79 (−9.28 to −0.31)	0.04*

- Interim one-year data analysis
- Fusion associated with significantly lower ODI (primary outcome) at 12 months

- Two year results (not yet published)
- Baseline clinical and surgical characteristics
  - Fusion and decompression: 468 patients
  - Decompression alone: 140 patients

Fusions were younger, more female, higher BMI, more depressed

But less DM

Demographics	Decompression Alone n=140	Decompression and Fusion n=468	p value
Age (yrs), mean ± SD	69.6±11.5	59.9±11.3	<0.001**
Female, n (%)	66 (47.1)	284 (60.7)	0.004**
BMI, mean ± SD	28.7±5.4	30.9±6.6	<0.001*
Smoker, n (%)	15 (10.7)	56 (12.0)	0.69
Comorbidities, n (%)			
Diabetes Mellitus	32 (22.9)	69 (14.7)	0.02**
CAD	22 (15.7)	46 (9.8)	0.05
Anxiety	20 (14.3)	88 (18.8)	0.22
Depression	18 (12.9)	105 (22.4)	0.01**
Osteoporosis	9 (6.4)	29 (6.2)	0.92
ASA Grade			0.16
1 or 2	89 (63.6)	257 (54.9)	
3 or 4	49 (35.0)	188 (40.2)	
ODI, baseline	39.7±18.0	48.8±16.4	<0.001**
NRS Back Pain, baseline	5.5±3.3	7.1±2.5	<0.001**
NRS Leg Pain, baseline	6.3±2.9	6.6±2.8	0.24
EQ-5D, baseline	0.59±0.21	0.52±0.23	0.001**

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EQ-5D, baseline	0.59±0.21	0.52±0.23	0.001**

Fusions had higher disability, worse back pain, and poorer QoL at baseline

Fusions less often had motor deficits at presentation and thus, were more ambulatory

Symptom duration longer for fusions

	Decompression Alone n=140	Decompression and Fusion n=468	p value
Motor Deficit	47 (33.6%)	92 (19.7%)	0.001*
Independently Ambulatory	117 (83.6%)	420 (89.7%)	0.046**
Symptom Duration			0.002**
< 3 months	9 (6.4%)	6 (1.3%)	
> 3 months	128 (91.4%)	443 (94.7%)	
Hispanic or Latino	3 (2.1%)	26 (5.6%)	0.10
4 Years of College Education or More	68 (48.6%)	161 (34.4%)	0.002**
Employment Status			0.003**
Employed or on Leave	48 (34.3%)	227 (48.5%)	

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4 Years of College Education or More	68 (48.6%)	161 (34.4%)	0.002**
Employment Status			0.003**
Employed or on Leave	48 (34.3%)	227 (48.5%)	

Fusions had lower levels of education but were more often employed

More blood loss, longer operative time, and longer hospitalizations for fusions

Perioperative Outcomes	Decompression Alone n=140	Decompression and Fusion n=468	p value
Estimated blood loss (mL)	57.5±86.2	224.5±208.9	<0.001*
Operative time (minutes)	108.7±57.8	193.2±83.1	<0.001*
Length of hospitalization (days)	1.2±1.5	3.2±1.6	<0.001*
Discharge disposition			0.79
Home or Home Health	127 (90.7%)	421 (90.0%)	

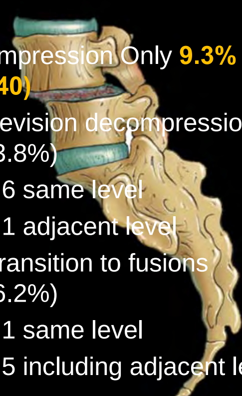
UCSF University of California San Francisco Department of Neurological Surgery

No significant differences in reoperation, readmission, or complication rates

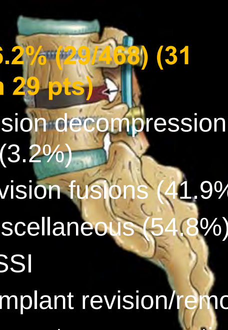
Complications	Decompression Alone n=140	Decompression and Fusion n=468	p value
Related cumulative reoperation, n (%)	**13 (9.3)**	**29 (6.2)**	**0.21**
90-day readmission, n (%)	3 (2.1)	12 (2.6)	0.59
30-day complication, n (%)	6 (4.3)	33 (7.1)	0.24

UCSF University of California San Francisco Department of Neurological Surgery

Reasons for Reoperations



- Decompression Only **9.3% (13/140)**
  - 7 revision decompressions (53.8%)
    - 6 same level
    - 1 adjacent level
  - 6 transition to fusions (46.2%)
    - 1 same level
    - 5 including adjacent levels



- Fusion **6.2% (29/468) (31 reops in 29 pts)**
  - 1 revision decompression for ASD (3.2%)
  - 13 revision fusions (41.9%)
  - 17 miscellaneous (54.8%)
    - 8 SSI
    - 6 implant revision/removal
    - 1 hematoma evacuation
    - 1 revision for suture granuloma
    - 1 spinal cord stimulator

Timing of Reoperations

Timing	Decompression Alone n=140	Decompression and Fusion n=468	p value
< 30 days	0 (0%)	11 (35.5%)	0.02
30 days to 1 year	8 (61.5%)	6 (19.4%)	0.01
1 to 2 years	3 (23.1%)	10 (32.3%)	0.72
2 to 3 years	2 (15.4%)	4 (12.9%)	>0.99
Total	13 (100%)	31 (29 patients) (100%)	

More patients reached ODI MCID when undergoing decompression with fusion at 24 months

ODI MCID Met	Decompression Alone n=140	Decompressio n and Fusion n=468	p value
No	43.4%	27.5%	0.002**
Yes	56.6%	72.5%	

In multivariable adjusted analyses, fusion was associated with superior ODI improvement (primary outcome) at 24 mo

Impact of fusion on outcome	Adjusted β Coefficient (95% CI)	*p* value
ODI change, *24 months*	-7.1 (-10.7 to -3.4)	<0.001**
NRS BP change, *24 months*	-1.2 (-1.8 to -0.6)	<0.001**
NRS LP change, *24 months*	n.s.	n.s.
EQ-5D *change, 24 months*	n.s.	n.s.
	Adjusted[1] Odds Ratio (95% CI)	
ODI MCID, *24 months*	1.8 (1.1 to 2.9)	0.03**
NASS Satisfaction, *24 months*	2.2 (1.4 to 3.5)	<0.001**

Conclusions

- Patients undergoing fusion in addition to decompression had **significantly greater improvements in 24-month ODI** compared to decompression alone
- Patients undergoing fusion had a **significantly higher rate of reaching MCID for ODI change at 24-months** compared to those undergoing decompression alone

BOTTOM LINE

- When spine surgeons select the procedure they think is best for patients, decompression and fusion is effective for patients with grade I lumbar spondylolisthesis at 24 months

Agenda

- Introduction
- Fusion versus Non-Fusion
- **Comparative Effectiveness**
  - Minimally Invasive vs. Open Surgery
- How do special populations fare?
  - Obese Patients
  - Women
- Outcome Prediction

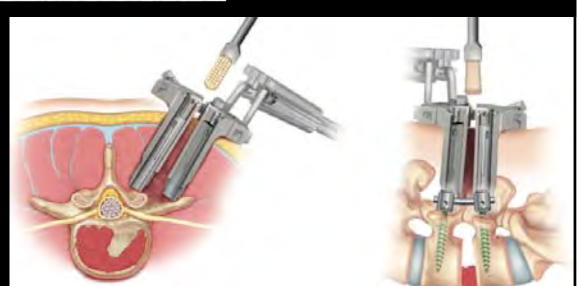
NEUROSURGICAL FOCUS

Neurosurg Focus 43 (2):E11, 2017

Minimally invasive versus open fusion for Grade I degenerative lumbar spondylolisthesis: analysis of the Quality Outcomes Database

Praveen V. Mummaneni, MD,[1] Erica F. Bisson, MD, MPH,[2] Panagiotis Kerezoudis, MD,[3] Steven Glassman, MD,[4] Kevin Foley, MD,[5] Jonathan R. Slotkin, MD,[6] Eric Potts, MD,[7] Mark Shaffrey, MD,[8] Christopher I. Shaffrey, MD,[8] Domagoj Coric, MD,[9] John Knightly, MD,[10] Paul Park, MD,[11] Kai-Ming Fu, MD, PhD,[12] Clinton J. Devin, MD,[13] Silky Chotai, MD,[13] Andrew K. Chan, MD,[1] Michael Virk, MD, PhD,[1] Anthony L. Asher, MD,[9] and Mohamad Bydon, MD[3]

- 345 patients undergoing on- or two-level fusions
  - MIS fusion: 91 patients
  - Open fusion: 254 patients
- Baseline demographics were evenly distributed



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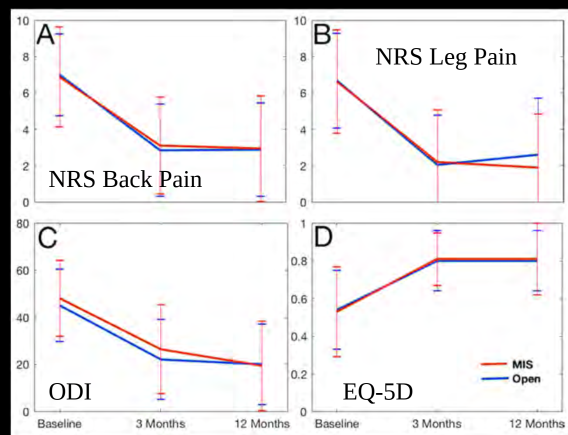
Both single-level fusion groups improved significantly from baseline

1-level fusions



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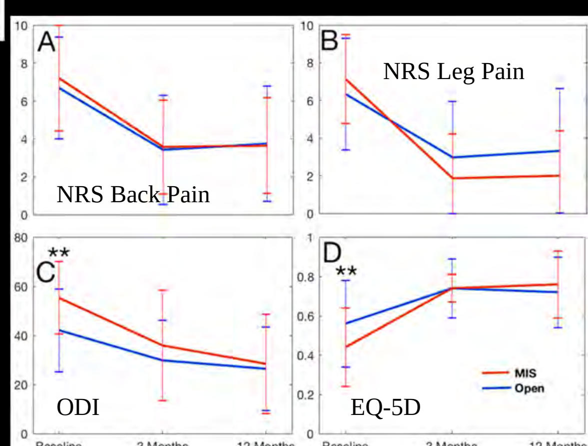
Two-level MIS fusion group improved more for quality of life

2-level fusions



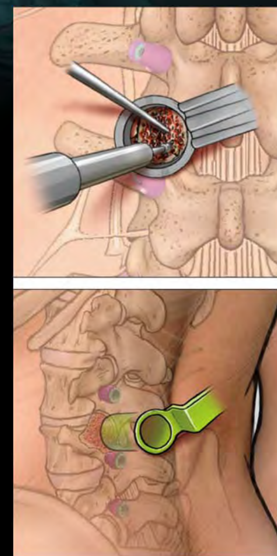
NEUROSURGICAL FOCUS

Neurosurg Focus 46 (5):E13, 2019

A comparison of minimally invasive transforaminal lumbar interbody fusion and decompression alone for degenerative lumbar spondylolisthesis

Andrew K. Chan, MD,[1] Erica F. Bisson, MD, MPH,[2] Mohamad Bydon, MD,[3] Steven D. Glassman, MD,[4] Kevin T. Foley, MD,[5] Eric A. Potts, MD,[6] Christopher I. Shaffrey, MD,[7] Mark E. Shaffrey, MD,[8] Domagoj Coric, MD,[9] John J. Knightly, MD,[10] Paul Park, MD,[11] Michael Y. Wang, MD,[12] Kai-Ming Fu, MD, PhD,[13] Jonathan R. Slotkin, MD,[14] Anthony L. Asher, MD,[9] Michael S. Virk, MD, PhD,[13] Panagiotis Kerezoudis, MD, MS,[3] Mohammed Ali Alvi, MBBS,[3] Jian Guan, MD,[2] Regis W. Haid, MD,[15] and Praveen V. Mummaneni, MD[1]

- No MIS surgeries included in the SLIP trial
- Hypothesis:
  - Do minimally invasive techniques mitigate the advantage of fusion over decompression?



- Hypothesis:
  - Do minimally invasive techniques mitigate the advantage of fusion over decompression?

NO!!

TABLE 3. Reasons for reoperation in the MIS TLIF and MIS decompression cohorts

	No. of Reops (%)	Comment
MIS TLIF (n = 72)	1 (1.4)	ASD requiring extension of fusion w/in 12 mos
MIS Decompression (n = 71)	10 (14.1)	
Revision decompression	6 (8.5)	4 (5.6%) w/in 12 mos; 2 (2.8%) btwn 12 & 24 mos
Fusion	4 (5.6)	2 (2.8%) w/in 12 mos; 2 (2.8%) btwn 24 & 36 mos

ASD = adjacent-segment disease.

- MIS Fusions associated with greater PRO improvement at 24 months
- MIS decompressions had 7-fold higher rate of reoperation (14.1 vs. 1.4%)

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- Differing results from recent RCTs establish a need to identify **groups that may fare best** following surgery for degenerative lumbar spondylolisthesis

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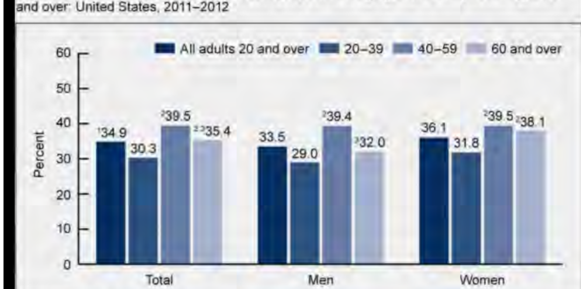
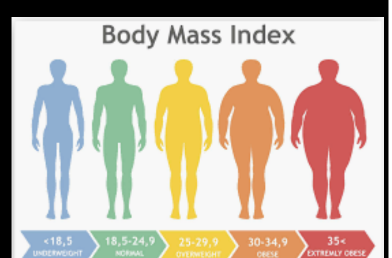
A Big Problem

- According to National Health and Nutrition Examination Survey, approximately **1/3 of adults 20 years and older are obese** in US

Figure 1. Age-adjusted prevalence of obesity, by sex and age group, among adults aged 20 and over: United States, 2011–2012

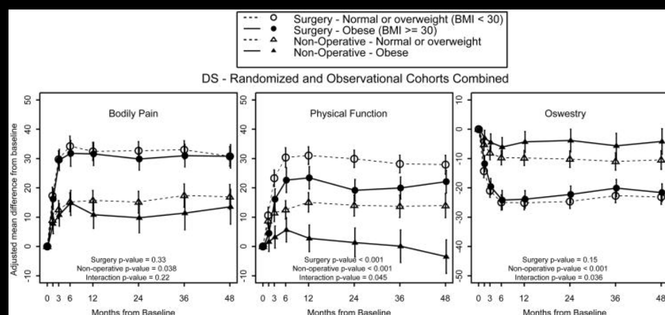


[1]Crude estimate 35.1%.
[2]Significant difference from ages 20–39.
[3]Significant difference from ages 40–59.
NOTE: Estimates are age-adjusted for all adults aged 20 and over by the direct method to the 2000 U.S. census population using the age groups 20–39, 40–59, and 60 and over.
SOURCE: CDC/NCHS, National Health and Nutrition Examination Survey, 2011–2012.



Mixed Results

- Obesity often linked to worse back pain, disability, and quality of life for a variety of spinal pathology, but **sometimes equivalent outcomes**
- Unclear if obesity negatively impacts spondylolisthesis surgery



Rihn et al. Spine (Phila Pa 1976) 2012

RESEARCH—HUMAN—CLINICAL STUDIES

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Obese Patients Benefit, but do not Fare as Well as Nonobese Patients, Following Lumbar Spondylolisthesis Surgery: An Analysis of the Quality Outcomes Database

BACKGROUND: Given recent differing findings following 2 randomized clinical trials on

- **Multivariable Analysis:** Linear Harmful Relationship with BMI <u>per unit BMI Higher</u> for ODI, NRS Leg Pain, and EQ-5D

TABLE 3. Multivariate Analysis Assessing the Effect of BMI on PROs Following Surgery for Grade 1 Lumbar Spondylolisthesis

	Adjusted[1] β Coefficient (95% CI)	P value
NRS back pain	0.03 (−0.01–0.06)	.12
NRS leg pain	0.04 (0.01–0.08)	.01**
ODI	− 0.21 (−0.72–0.30)	.41
EQ-5D	− 0.004 (−0.006–0.001)	<.01**
	Adjusted[1] Odds Ratio (95% CI)	
NASS satisfaction questionnaire score	1.01 (0.99-1.04)	.41

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What predicts the most satisfied patients?

- QOD satisfaction metric
  - NASS Satisfaction Questionnaire

Score	NASS Satisfaction Questionnaire
1 (Highest)	*Surgery met my expectations*
2	*I did not improve as much as I had hoped but I would undergo the same operation for the same results*
3	*Surgery helped but I would not undergo the same operation for the same results*
4 (Lowest)	*I am the same or worse as compared to before surgery*

- Compared the most satisfied to least satisfied patients
  - 53.5% – NASS 1 “most satisfied”
  - 5.5% – NASS 4 “least satisfied”

NEUROSURGICAL FOCUS

Neurosurg Focus 44 (1):E3, 2018

Women fare best following surgery for degenerative lumbar spondylolisthesis: a comparison of the most and least satisfied patients utilizing data from the Quality Outcomes Database

Andrew K. Chan, MD,[1] Erica F. Bisson, MD, MPH,[2] Mohamad Bydon, MD,[3] Steven D. Glassman, MD,[4] Kevin T. Foley, MD,[5] Eric A. Potts, MD,[6] Christopher I. Shaffrey, MD,[7] Mark E. Shaffrey, MD,[7] Domagoj Coric, MD,[8] John J. Knightly, MD,[9] Paul Park, MD,[10] Kai-Ming Fu, MD, PhD,[11] Jonathan R. Slotkin, MD,[12] Anthony L. Asher, MD,[8] Michael S. Virk, MD, PhD,[1] Panagiotis Kerezoudis, MD,[3] Silky Chotai, MD,[13] Anthony M. DiGiorgio, DO, MHA,[1,14] Alvin Y. Chan, BS,[1] Regis W. Haid, MD,[15] and Praveen V. Mummaneni, MD[1]

Predictive model for “most satisfaction” constructed

- **Only being female predictive of most satisfaction**

Variable	Adjusted OR* (95% CI)	p Value
Female	3.33 (1.28–9.26)	0.02†
Private insurance	1.83 (0.70–4.96)	0.22
CAD	0.43 (0.14–1.38)	0.14
BMI	0.94 (0.86–1.01)	0.10
ASA class III or IV	0.99 (0.33–3.01)	0.98
MIS	2.43 (0.77–9.89)	0.16
Readmission w/in 3 mos	0.24 (0.05–1.38)	0.08
Baseline NRS-BP	0.85 (0.64–1.09)	0.22
Baseline ODI	0.98 (0.94–1.02)	0.34
Baseline EQ-5D	1.11 (0.07–17.00)	0.94

Agenda

- Introduction
- Fusion versus Non-Fusion
- Comparative Effectiveness
  - Minimally Invasive vs. Open Surgery
- How do special populations fare?
  - Obese Patients
  - Women
- **Outcome Prediction**

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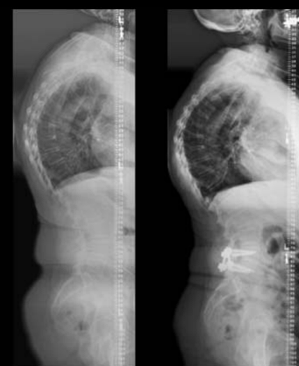
NEUROSURGICAL FOCUS

Neurosurg Focus 46 (5):E12, 2019

Predictive model for long-term patient satisfaction after surgery for grade I degenerative lumbar spondylolisthesis: insights from the Quality Outcomes Database

Praveen V. Mummaneni, MD,[1] Mohamad Bydon, MD,[2] Mohammed Ali Alvi, MBBS,[2] Andrew K. Chan, MD,[1] Steven D. Glassman, MD,[3] Kevin T. Foley, MD,[4] Eric A. Potts, MD,[5] Christopher I. Shaffrey, MD,[6] Mark E. Shaffrey, MD,[6] Domagoj Coric, MD,[7] John J. Knightly, MD,[8] Paul Park, MD,[9] Michael Y. Wang, MD,[10] Kai-Ming Fu, MD, PhD,[11] Jonathan R. Slotkin, MD,[12] Anthony L. Asher, MD,[7] Michael S. Virk, MD, PhD,[11] Panagiotis Kerezoudis, MD, MS,[2] Jian Guan, MD,[13] Regis W. Haid, MD,[14] and Erica F. Bisson, MD, MPH[13]



- Predictor importance analysis for factors associated with patient satisfaction

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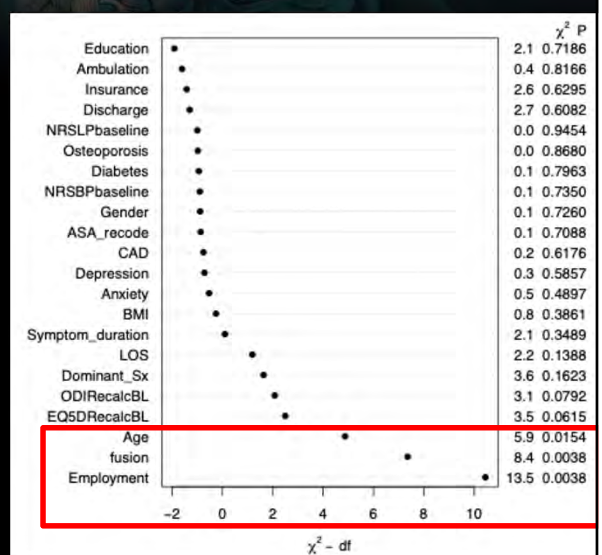
NEUROSURGICAL FOCUS

Predictive model for long-term patient satisfaction after surgery for grade I degenerative lumbar spondylolisthesis: insights from the Quality Outcomes Database

- Predictors of long-term satisfaction with surgery
  - Older age
  - Addition of fusion
  - Active employment



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JNS SPINE

CLINICAL ARTICLE

Predictors of nonroutine discharge among patients undergoing surgery for grade I spondylolisthesis: insights from the Quality Outcomes Database

Praveen V. Mummaneni, MD,[1] Mohamad Bydon, MD,[2] John Knightly, MD,[3] Mohammed Ali Alvi, MBBS,[2] Anshit Goyal, MBBS,[2] Andrew K. Chan, MD,[1] Jian Guan, MD,[4] Michael Biase, BS,[1] Andrea Strauss, BS,[1] Steven Glassman, MD,[5] Kevin T. Foley, MD,[6] Jonathan R. Slotkin, MD,[7] Eric Potts, MD,[8] Mark Shaffrey, MD,[9] Christopher I. Shaffrey, MD,[10] Regis W. Haid Jr., MD,[3] Kai-Ming Fu, MD,[11] Michael Y. Wang, MD,[12] Paul Park, MD,[13] Anthony L. Asher, MD,[14] and Erica F. Bisson, MD, MPH[4]

- Predictors importance analysis for factors associated with discharge to SNF or acute rehab

UCSF

JNS SPINE

CLINICAL ARTICLE

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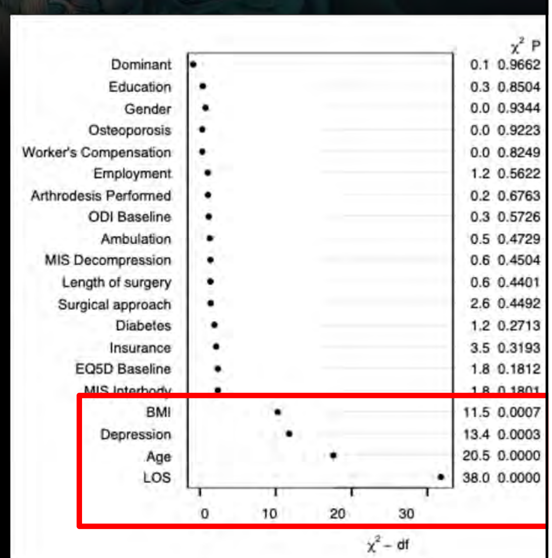
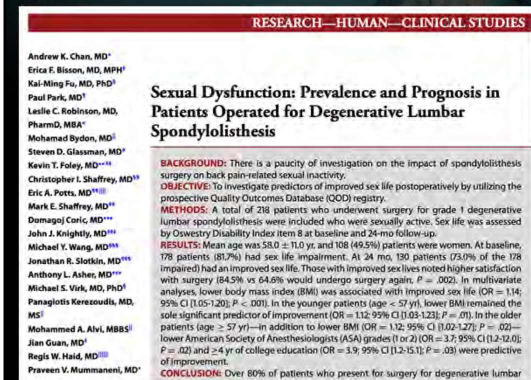
- Predictors of SNF/acute rehab needs:
  - Higher BMI
  - Depression
  - Older age
  - Longer LOS





RESEARCH—HUMAN—CLINICAL STUDIES

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Sexual Dysfunction: Prevalence and Prognosis in Patients Operated for Degenerative Lumbar Spondylolisthesis

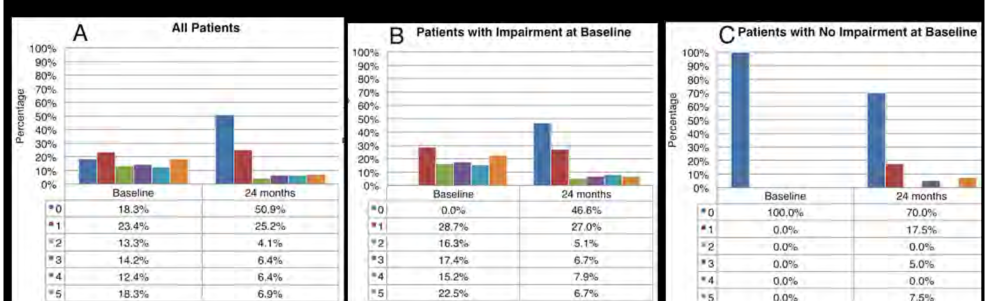
BACKGROUND: There is a paucity of investigation on the impact of spondylolisthesis surgery on back pain-related sexual inactivity.
OBJECTIVE: To investigate predictors of improved sex life postoperatively by utilizing the prospective Quality Outcomes Database (QOD) registry.
METHODS: A total of 218 patients who underwent surgery for grade 1 degenerative lumbar spondylolisthesis were included who were sexually active. Sex life was assessed by Oswestry Disability Index item 8 at baseline and 24-mo follow-up.
RESULTS: Mean age was 58.0 ± 11.0 yr, and 108 (49.5%) patients were women. At baseline, 178 patients (81.7%) had sex life impairment. At 24 mo, 130 patients (73.0% of the 178 impaired) had an improved sex life. Those with improved sex lives noted higher satisfaction with surgery (84.5% vs 64.6% would undergo surgery again, $P = .002$). In multivariate analyses, lower body mass index (BMI) was associated with improved sex life (OR = 1.14; 95% CI [1.05-1.20]; $P < .001$). In the younger patients (age < 57 yr), lower BMI remained the sole significant predictor of improvement (OR = 1.12; 95% CI [1.03-1.23]; $P = .01$). In the older patients (age $\geq$ 57 yr)—in addition to lower BMI (OR = 1.12; 95% CI [1.02-1.27]; $P = .02$)—lower American Society of Anesthesiologists (ASA) grades (1 or 2) (OR = 3.7; 95% CI [1.2-12.0]; $P = .02$) and $\geq$4 yr of college education (OR = 3.9; 95% CI [1.2-15.1]; $P = .03$) were predictive of improvement.
CONCLUSION: Over 80% of patients who present for surgery for degenerative lumbar

- Sex life is an important patient-centered outcome metric not often studied

TABLE 1. Item 8 of the Oswestry Disability Index

This next item will ask whether pain interferes with your sexual activity. With regards to pain, how would you say your sex life is?

Item score	Description
0 (no impairment)	Normal and causes no extra pain
1	Normal, but causes some extra pain
2	Nearly normal, but is very painful
3	Severely restricted by pain
4	Nearly absent because of pain
5 (most impairment)	Not sexually active because of pain



A — All Patients

	Baseline	24 months
0	18.3%	50.9%
1	23.4%	25.2%
2	13.3%	4.1%
3	14.2%	6.4%
4	12.4%	6.4%
5	18.3%	6.9%

B — Patients with Impairment at Baseline

	Baseline	24 months
0	0.0%	46.6%
1	28.7%	27.0%
2	16.3%	5.1%
3	17.4%	6.7%
4	15.2%	7.9%
5	22.5%	6.7%

C — Patients with No Impairment at Baseline

	Baseline	24 months
0	100.0%	70.0%
1	0.0%	17.5%
2	0.0%	0.0%
3	0.0%	5.0%
4	0.0%	0.0%
5	0.0%	7.5%

81.7% had sexual impairment preoperatively, but most improve with surgery

Of those noting impairment, 73% had improvement in function at 24 months

Of those without baseline impairment, 87.5% maintained a normal sex life


RESEARCH—HUMAN—CLINICAL STUDIES

Sexual Dysfunction: Prevalence and Prognosis in Patients Operated for Degenerative Lumbar Spondylolisthesis

Predictive model demonstrated that lower BMI was associated with a higher odds of improvement in sex function postop.

	Adjusted Odds Ratio (95% CI)	p value
Private insurance	1.34 (0.53-3.33)	0.53
Independent ambulation at baseline	2.94 (0.88-10.12)	0.08
BMI	0.88 (0.83-0.95)	<0.001**
4 or more years of college level education	2.27 (0.98-5.65)	0.06
Employed or employed and on leave	1.20 (0.49-2.90)	0.69
ASA grade 1 or 2	1.28 (0.58 – 2.81)	0.53
EQ-5D, baseline	1.00 (0.998- 1.005)	0.40
Use of minimally invasive techniques	2.07 (0.91- 4.93)	0.09

Take Home Points

- Using the prospective QOD registry, we found that **fusion with decompression was superior to decompression alone** for grade 1 degenerative lumbar spondylolisthesis
- The high-quality data contained within the registry - combined with multivariable analytical techniques - can be used to **evaluate comparative effectiveness** in instances when clinical trials are not readily feasible
- The large dataset is **well-suited to predictive modeling** to identify clinical predictors of outcomes
- Large datasets such as the QOD and ASR can be leveraged for **machine learning** purposes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University of Virginia- Mark Shaffrey
SPINE SURGERY QOD


UCSF
Thank You
NEUROLOGICAL SURGERY
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Treatment of Painful Spinal Tumors During the COVID-19 Pandemic

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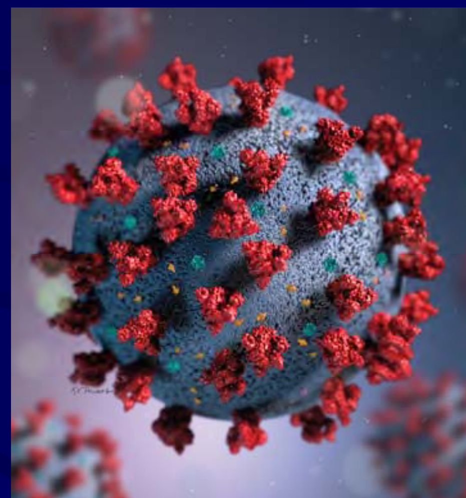

Disclosures

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- Royalties from DePuy Spine, Springer Publishing, and Thieme Publishing.

Central issue: Uncertainty affecting Surgical Care

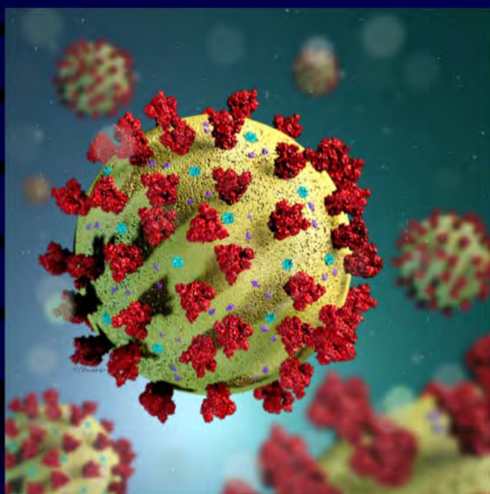
In spine surgery, urgency can be ambiguous.

- Malignant spine tumors
- Cervical stenosis w/ myelopathy
- Herniated disc w/ foot drop

Central issue: Uncertainty affecting Surgical Care

Spine surgeons must balance urgent surgery w/ limited resources during pandemic

- **PPE**
- **Blood bank**
- **Ventilator**
- **ICU space**



NEUROSURGERY

THE REGISTER OF THE NEUROSURGICAL MEME

Burke JF, Chan AK, Mummaneni V, et al. Letter: The Coronavirus Disease 2019 Global Pandemic: A Neurosurgical Treatment Algorithm [published online ahead of print, 2020 Apr 3]. *Neurosurgery*. 2020. doi:10.1093/neuros/nyaa116

Develop objective criteria to classify outbreak

San Francisco

Green:
<1/100000 new cases, or
<6 COVID+ inpatients
No staffing shortages

Yellow:
2-9/100000 new cases, or
7-16 COVID+ inpatients, or
< 20% staffing shortages

Red:
>10/100000 new cases, or
>17 COVID+ inpatients, or
> 21% staffing shortages

Develop objective criteria to classify outbreak

- **Black level: overwhelming pandemic (NYC)**

- **All hands on deck**
  - Cross-specialty MD cross-cover
  - Stopping all surgery except most emergent (“life-or-limb”)
  - Opening as many beds as poss/mobile hospitals

Black:
Significant Assistance needed from outside institutions

Tiers	Action	Definition	Locations	Examples
Tier 1a	Postpone surgery/ procedure	**Low acuity surgery/healthy patient-** outpatient surgery Not life threatening illness	HOPD* ASC** Hospital with low/no COVID-19 census	-Carpal tunnel release -EGD -Colonoscopy -Cataracts
Tier 1b	Postpone surgery/ procedure	**Low acuity surgery/unhealthy patient**	HOPD ASC Hospital with low/no COVID-19 census	-Endoscopies
Tier 2a	Consider postponing surgery/procedure	**Intermediate acuity surgery/healthy patient-** Not life threatening but potential for future morbidity and mortality. Requires in-hospital stay	HOPD ASC Hospital with low/no COVID-19 census	-Low risk cancer -Non urgent spine & Ortho: Including hip, knee replacement and elective spine surgery -Stable ureteral colic -Elective angioplasty
Tier 2b	Postpone surgery/ procedure if possible	**Intermediate acuity surgery/unhealthy patient-**	HOPD ASC Hospital with low/no COVID-19 census	
Tier 3a	Do not postpone	**High acuity surgery/healthy patient**	Hospital	-Most cancers -Neurosurgery -Highly symptomatic patients
Tier 3b	Do not postpone	**High acuity surgery/unhealthy patient**	Hospital	-Transplants -Trauma -Cardiac w/ symptoms -limb threatening vascular surgery

*Hospital Outpatient Department
** Ambulatory Surgery Center
Created by: Sameer Siddiqui MD (used with permission)
Version 3.15.20

ACS COVID triage recommendations

Tier 3 cases are subdivided
- **Emergent cases**:
  - Acute onset paralysis after SCI
- **Urgent level 1**: <24 hours
  - New onset cauda equina
- **Urgent level 2:** <48 hours
  - Spinal pathological fx
- **Urgent level 3:** <1 week
  - progressive deformity + Sx
- **Urgent level 4:**
  - progressive deformity - Sx

	# of COVID-19 cases	Tier 3					Tier 2 / Tier 1
		Emergent cases	Urgent Cases				Elective Cases
			Level 1	Level 2	Level 3	Level 4	
Surge Level	Green: Less than 1/100,000	proceed	proceed	proceed	proceed	proceed	MDSC **
	Yellow: 2-10/100,000	proceed	proceed	proceed	MDSC 75% capacity	MDSC 75% capacity	MDSC**
	Red: >10/100,000	proceed	proceed	proceed	MDSC 50% capacity	MDSC 50% capacity	MDSC**
	Black: Federal/State Assistance needed	proceed	MDSC	MDSC	Cease	Cease	Cease

UCSF Checklist during COVID-19 pandemic

Determine level of urgency of case:

- ☐ Assess for neurosurgical emergency (0-48 hours to OR). Emergent cases include:
  - ☐ cranial trauma/infection.... TBI, depressed skull fractures, space occupying lesions, empyema/abscess
  - ☐ cranial tumor .... pituitary apoplexy, tumor with mass effect
  - ☐ cranial vascular .... intracranial hemorrhage from ruptured aneurysm, AVM, and/or dAVF
  - ☐ cranial CSF diversion .... shunt obstruction, acute hydrocephalus
  - ☐ functional .... hardware infections, sudden DBS battery failures
  - ☐ spine .... spinal instability or spinal cord compression from fracture, tumor, or infection
  - ☐ spine, disc disease .... cauda equina, nerve root compression with progressive motor deficit
  - ☐ In addition, any case meeting the following criteria:
    - ☐ acute and progressive neurological symptoms referable to focal lesion on imaging, AND
    - ☐ determined to be an emergency by board certified neurosurgeon
- ☐ Assess for neurosurgical urgency (2-14 days to OR). Urgent cases include:
  - ☐ any case requiring surgery within a 14 day period that does not meet above criteria
- ☐ Assess for purely elective cases
  - ☐ any case not meeting criteria for urgent or emergent cases (defined above)

Determine availability of operating room:

Universal consensus among periop cmte

Checklist for Perioperative Care During COVID-19 Pandemic

Preoperative checklist

- ☐ Verify sufficient blood products in the blood bank
- ☐ Verify OR personnel available (staff, vendors, etc.)
- ☐ Verify implants, specialized procedural equipment availability (if needed)
- ☐ Verify pathology staff in house (if frozen section needed)
- ☐ Secure postoperative bed before invasive procedure is initiated
- ☐ If patient is PUI/COVID+ then verify
  - ☐ Negative pressure postoperative room secured
  - ☐ Sufficient PPE for staff
  - ☐ Infection control team consult

Postoperative checklist

- ☐ If being admitted to the ICU
  - ☐ Notify ICU team of admission
  - ☐ Confirm bed space +/- ventilator available
- ☐ If being admitted to the ward
  - ☐ Notify nursing manager of admission
  - ☐ Confirm a staffed bed is available

Discharge checklist

- ☐ Discharge needs are established with daily discharge rounds
  - ☐ Verify available home care (shelter in place)
  - ☐ Verify available nursing home or rehabilitation bed
    - ☐ Assess need for COVID-19 testing before discharge

UCSF PPE Scoring

Category	Point Value
1. Surgical Risk	
High: Surgery involving potential aerosolization of SARS-CoV-2	2
Intermediate: General anesthesia	1
Low: Local anesthesia	0
2. COVID+ Status	
Confirmed COVID-19 infection	2
Suspected COVID-19 infection	1
Asymptomatic Patient	0
Point Total	
3-4	**N95/PAPR required** (If not available, case requires consultation with MDPC)
2	**N95/PAPR recommended**
0-1	**Standard surgical PPE** (May use N95/PAPR if available)

CASE #1

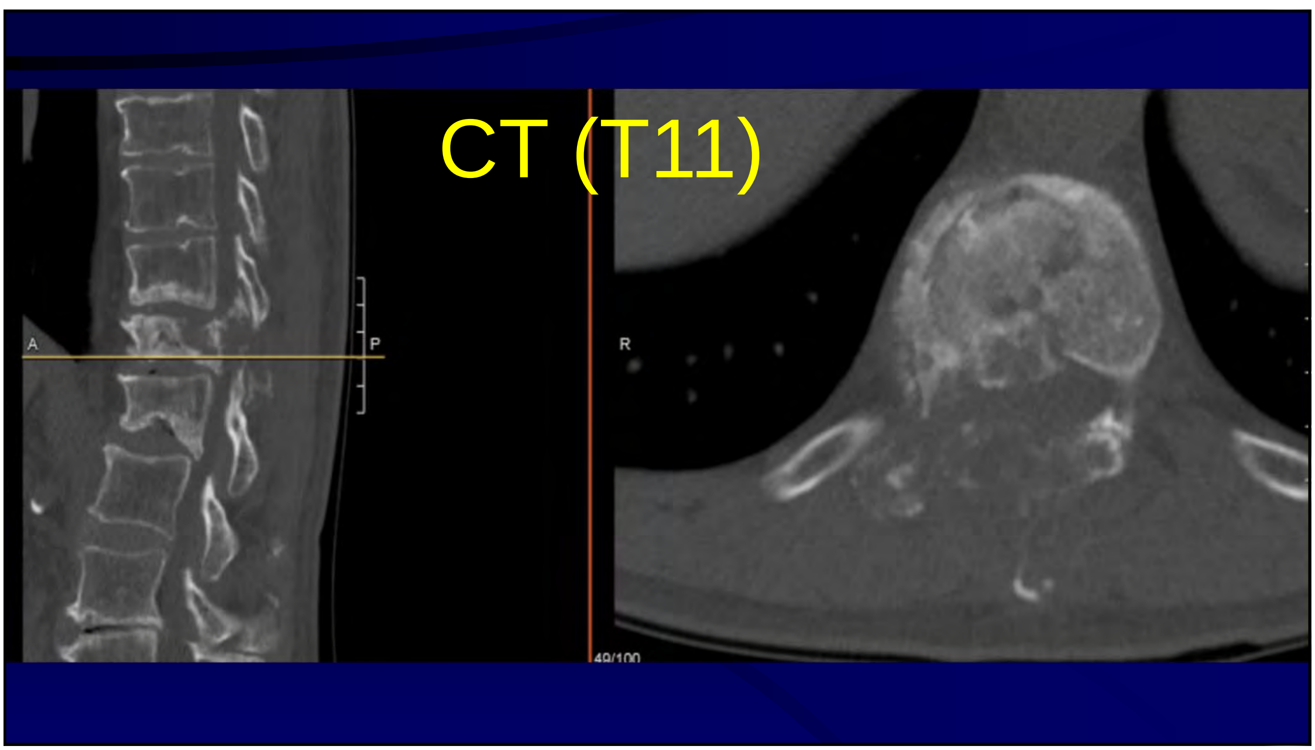
HPI

- 63M prostate cancer
- Thoracic back pain, right leg weakness
  - 1 week
- Unable to walk to bathroom

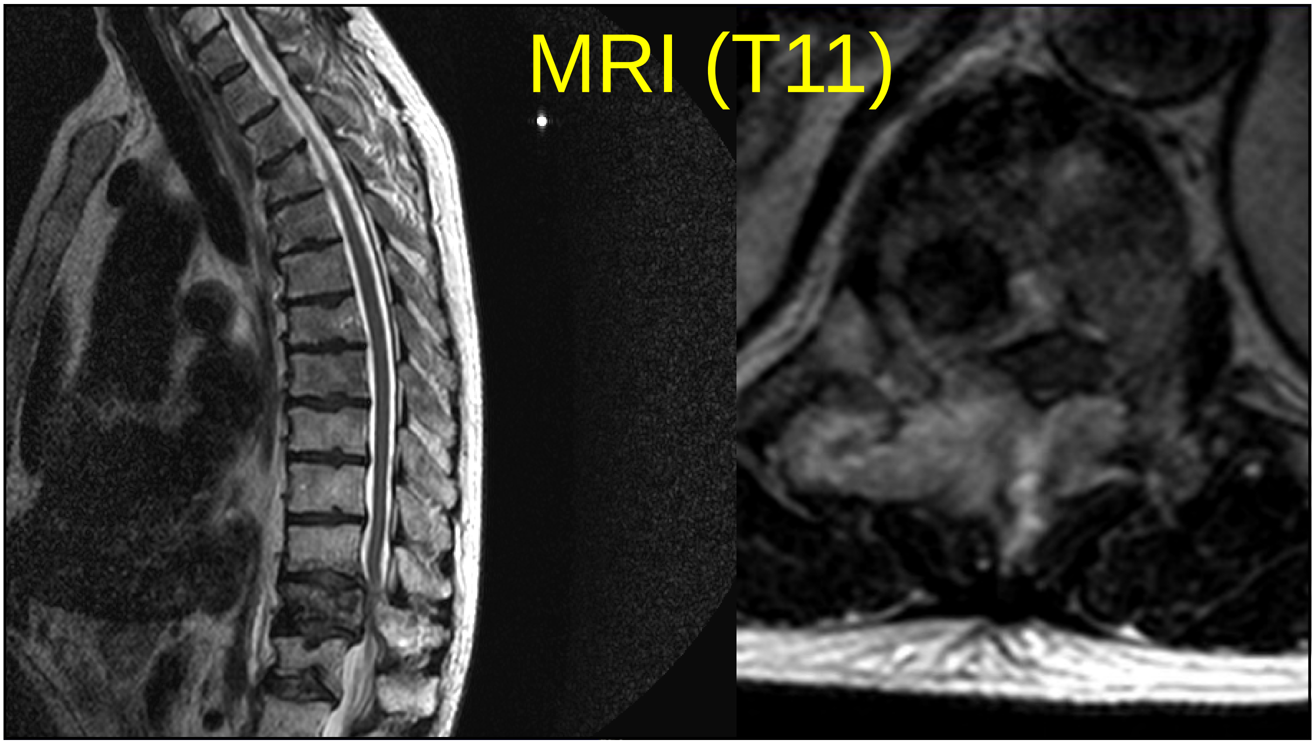
PMH

- s/p radiotherapy to thoracic spine


Telehealth
10
A321


CT (T11)
A
P
R
49/100

MRI (T11)



SINS score

- Junctional = 3
- Pain = 3
- Lytic Lesion = 2
- Kyphosis = 2
- < 50% collapse = 2
- Bilateral posterolateral = 3
- Total = 15

≥13: unstable

Table 8. Summary Table Including All Elements of the SINS

Element of SINS	Score
Location	
Junctional (occiput-C2, C7–T2, T11–L1, L5–S1)	3
Mobile spine (C3–C6, L2–L4)	2
Semi-rigid (T3–T10)	1
Rigid (S2–S5)	0
Pain relief with recumbency and/or pain with movement/loading of the spine	
Yes	3
No (occasional pain but not mechanical)	1
Pain free lesion	0
Bone lesion	
Lytic	2
Mixed (lytic/blastic)	1
Blastic	0
Radiographic spinal alignment	
Subluxation/translation present	4
De novo deformity (kyphosis/scoliosis)	2
Normal alignment	0
Vertebral body collapse	
>50% collapse	3
<50% collapse	2
No collapse with >50% body involved	1
None of the above	0
Posterolateral involvement of the spinal elements (facet, pedicle or CV joint fracture or replacement with tumor)	
Bilateral	3
Unilateral	1
None of the above	0

Fisher et al., Spine, 2010

Level 2 (less than 48 hours)

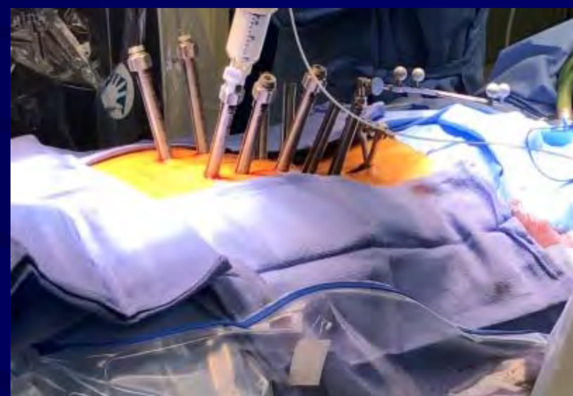
This Case

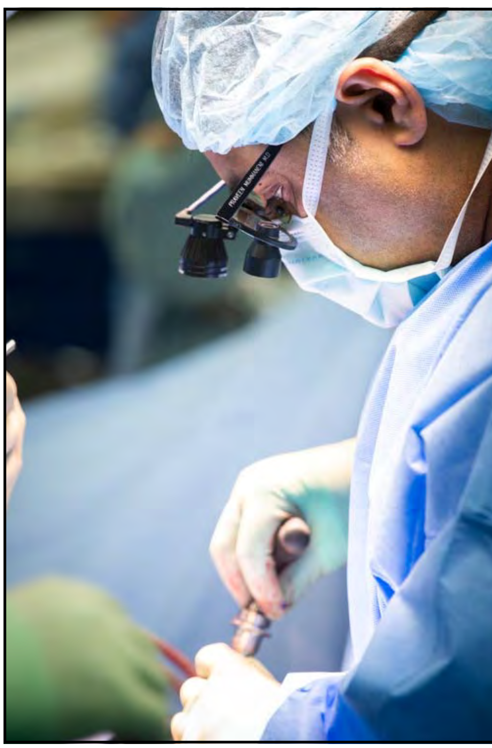
Surge Level	Tier 3					Tier 2 / Tier 1
	Emergent cases	Urgent Cases				Elective Cases
		Level 1	Level 2	Level 3	Level 4	
Green: Less than 1/100,000	proceed	proceed	proceed	proceed	proceed	MDSC **
Yellow: 2-10/100,000	proceed	proceed	proceed	MDSC 75% capacity	MDSC 75% capacity	MDSC**
Red: >10/100,000	proceed	proceed	proceed	MDSC 50% capacity	MDSC 50% capacity	MDSC**
Black: Federal/State Assistance needed	proceed	MDSC	MDSC	Cease	Cease	Cease

Treatment Options?

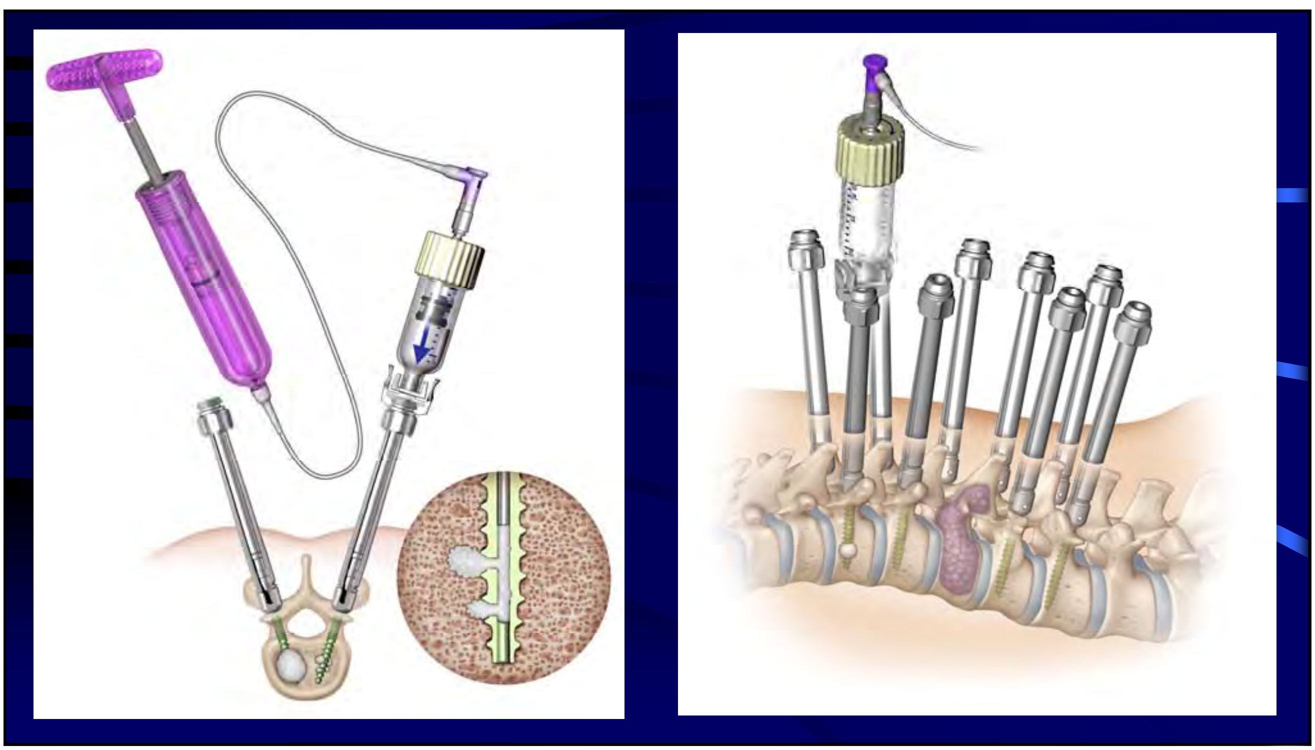
Operative plan:
- T9-L1 perc screws
- MIS T11 lami and transpedicular tumor removal

MIS:
- Minimize blood loss
  - Patient anemic
- Decrease wound issues and infection
  - Prior radiation






Ziehm Vision R FD




Desc: XR SC
L
Standing

Outcome

- No complications
- Complete recovery in leg strength
- Discharged to home
- Follow-up visit (wound check) via telehealth

CASE #2

Case

- 65F with several months of decreased RLE sensation, urinary and fecal incontinence with occasional BLE pain

PMH

- HTN, DM, osteoarthritis, depression, neuropathy

PSH

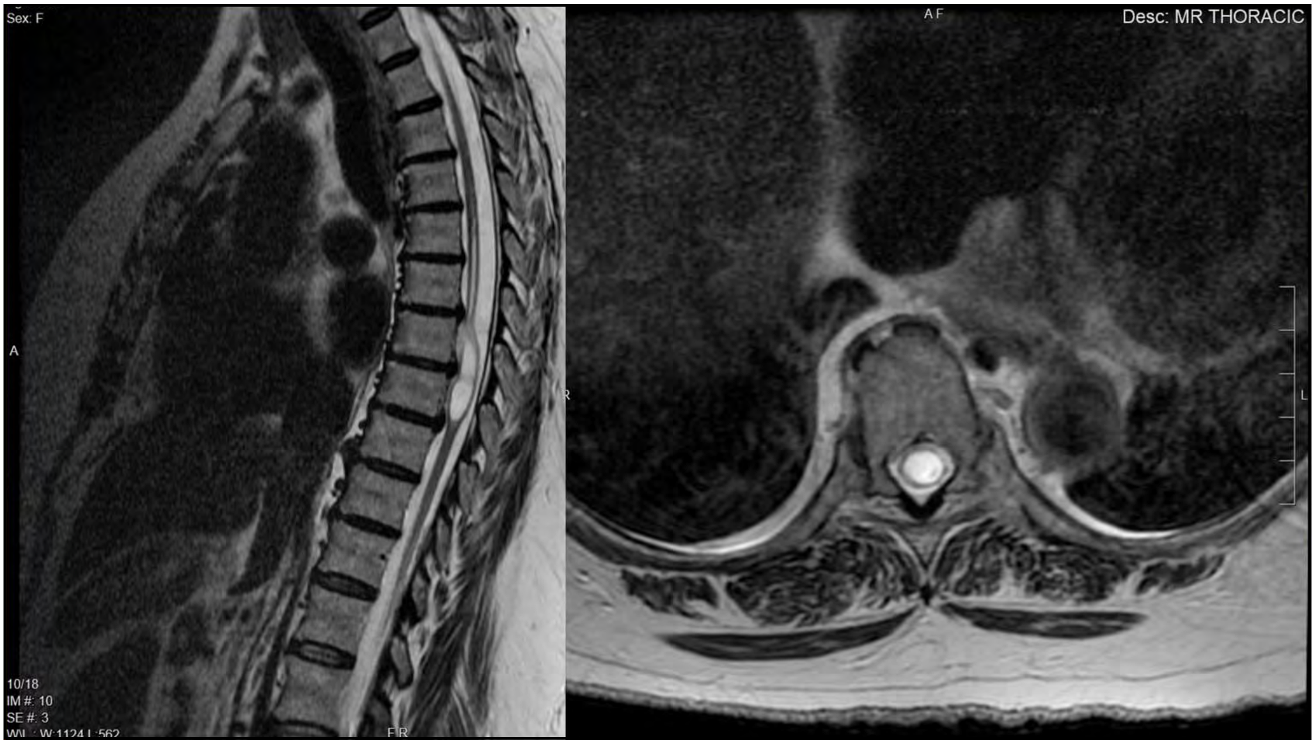
- Left knee replacement

Exam

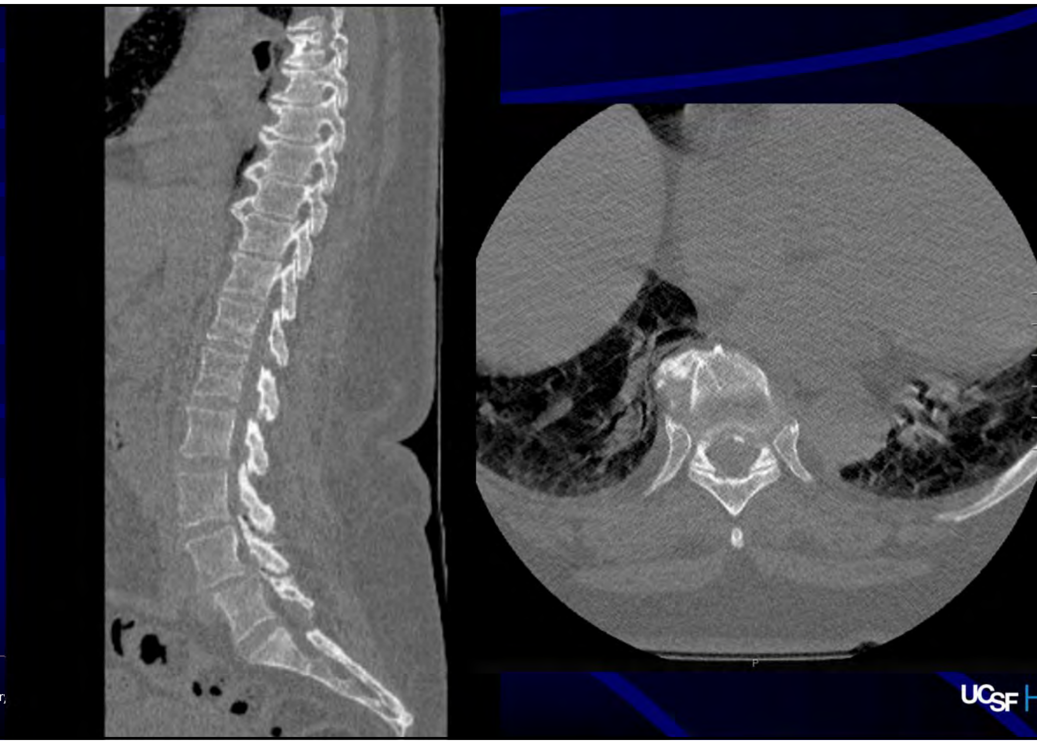
- BUE full strength
- BLE 3/5 ip, 4-5 q, h, ta, ehl, g
- Normal bulk and tone
- BLE dec sensation to light touch
- Rectal sensation and tone decreased

Labs

- Hb 10, plt 286, INR 1.1


Sex: F
Desc: MR THORACIC
A
10/18
IM #: 10
SE #: 3


A
3
Intramedullary Spinal Cord Tumor
UCSF Health



UCSF Health

Next steps?

UCSF Health

Next steps?

- Decadron?
- Surgery?
  - Biopsy?
  - Debulk?
  - Gross Total Resection?
- Radiation alone?
- Chemotherapy?

Operation

- T7-8 laminectomy for intradural, intramedullary spine tumor
- In-situ arthrodesis T6-9

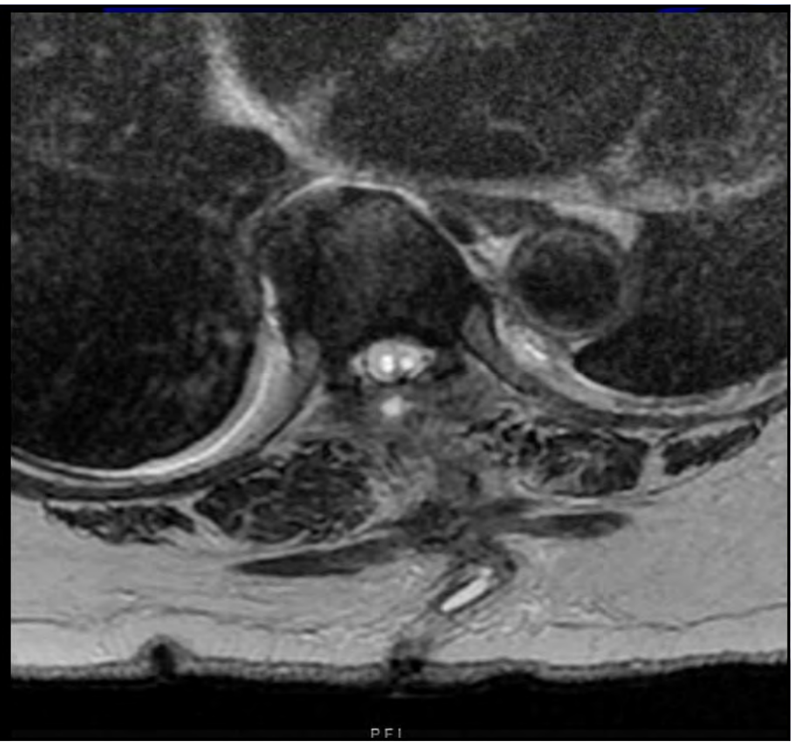
Pathology

- Piloid astrocytic proliferation

-IDH1 R132H: Negative for mutant protein
-ATRX: Retained nuclear expression (negative result)
-p53: Rare positive cells (negative result)
-p16: Rare patchy positive cells (negative result)
-Neurofilament protein: Highlights entrapped axons and nerve bundles
-BRAF V600E: Negative for mutant protein
-H3 K27M: Negative for mutant protein
-H3 K27Me3: Retained nuclear expression (negative result)
-SOX10: Focal positivity
-Ki-67: Labeling index is estimated at less than 1%, with rare staining cells
-EMA: Essentially negative
-GFAP: High background staining; no fibrillary processes highlighted.
-Olig2: Highlights rare, weakly positive oligodendrocytes
-CD34: Highlights endothelial cells

Overall, the morphologic and immunohistochemical features are nonspecific and does not show a definite evidence of a neoplasm. Features are most suggestive of piloid gliosis, which may be seen adjacent to a neoplasm. Correlation with postoperative imaging is suggested to ensure adequate sampling of any suspected lesions. Re-biopsy can be considered if clinically warranted.

UCSF Health



Postoperative Course

- Discharged without event to acute rehab
- Improvement in strength
  - From barely ambulatory to able to walk with walker and stand
- Tumor board
  - Given "Presumed low grade nature of the disease, the recommendation is for surveillance imaging 3-4 months and re-op if clinically indicated with decline or potentially radiation"

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5 months postoperatively

- Worsening back pain and left leg numbness, tingling and return of bowel incontinence
- Next steps?

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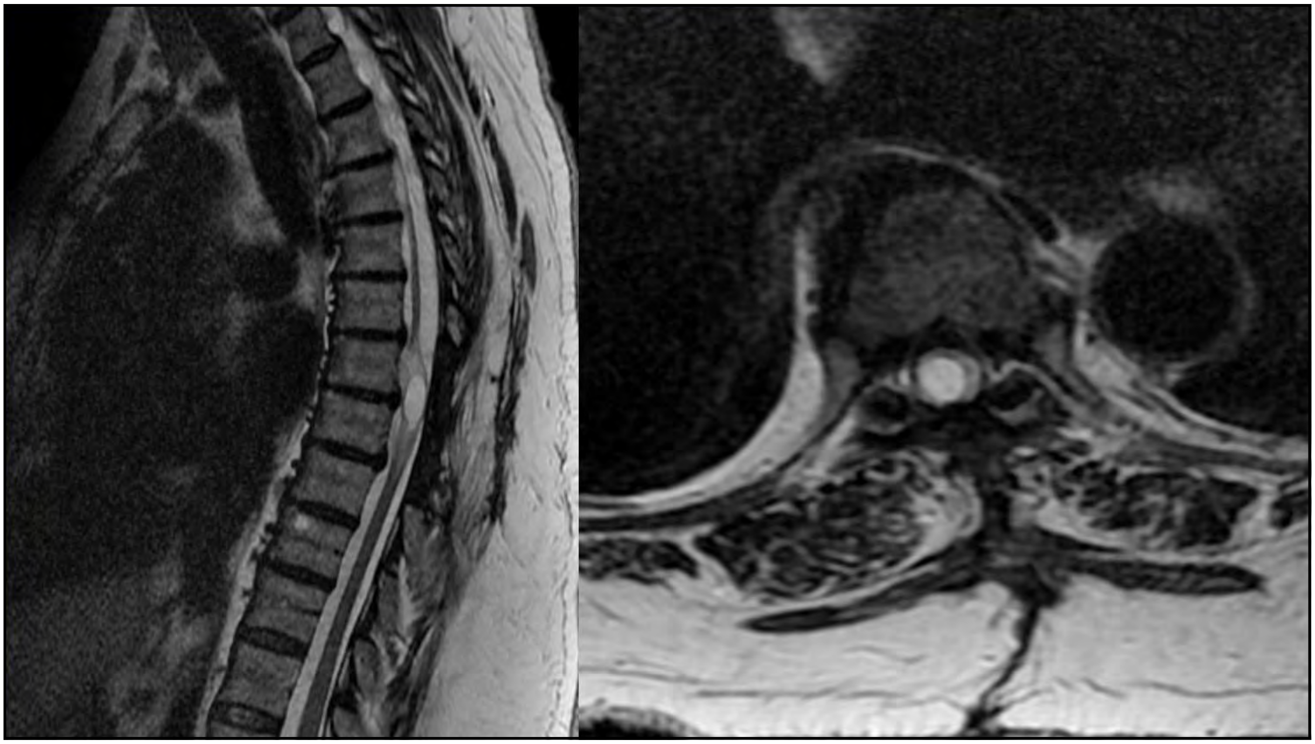
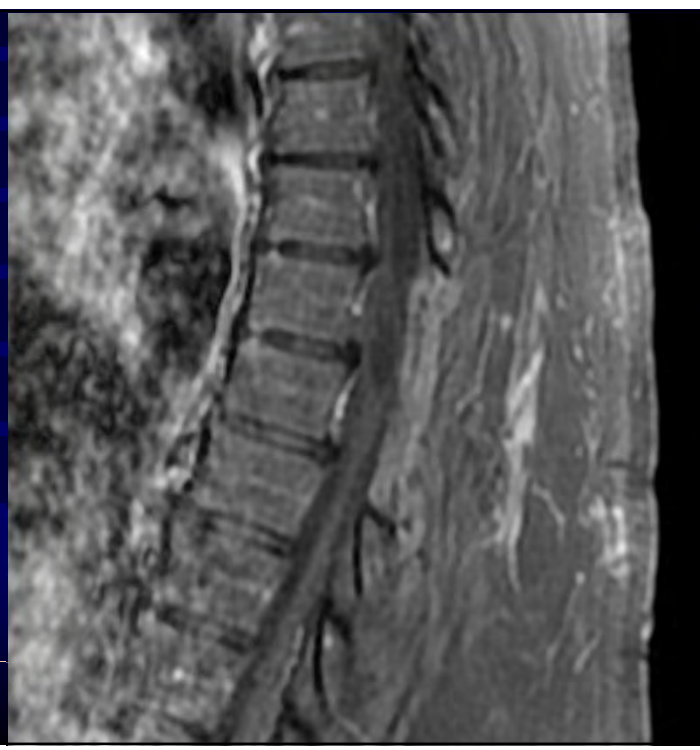
Physical Exam

- RLE 4 ip, 4+ q, h, ta, 4 ehl, 4+5 g
- LLE 4- ip, 4 q, 4- h, 4 ta/ehl/g
- LLE > RLE numbness
- Allodynia LLE > RLE
- 4 beats of clonus in BLE

Next steps?

- Decadron?
- Surgery?
  - Biopsy?
  - Debulk?
  - Gross Total Resection?
- Radiation alone?
- Chemotherapy?





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Next steps?

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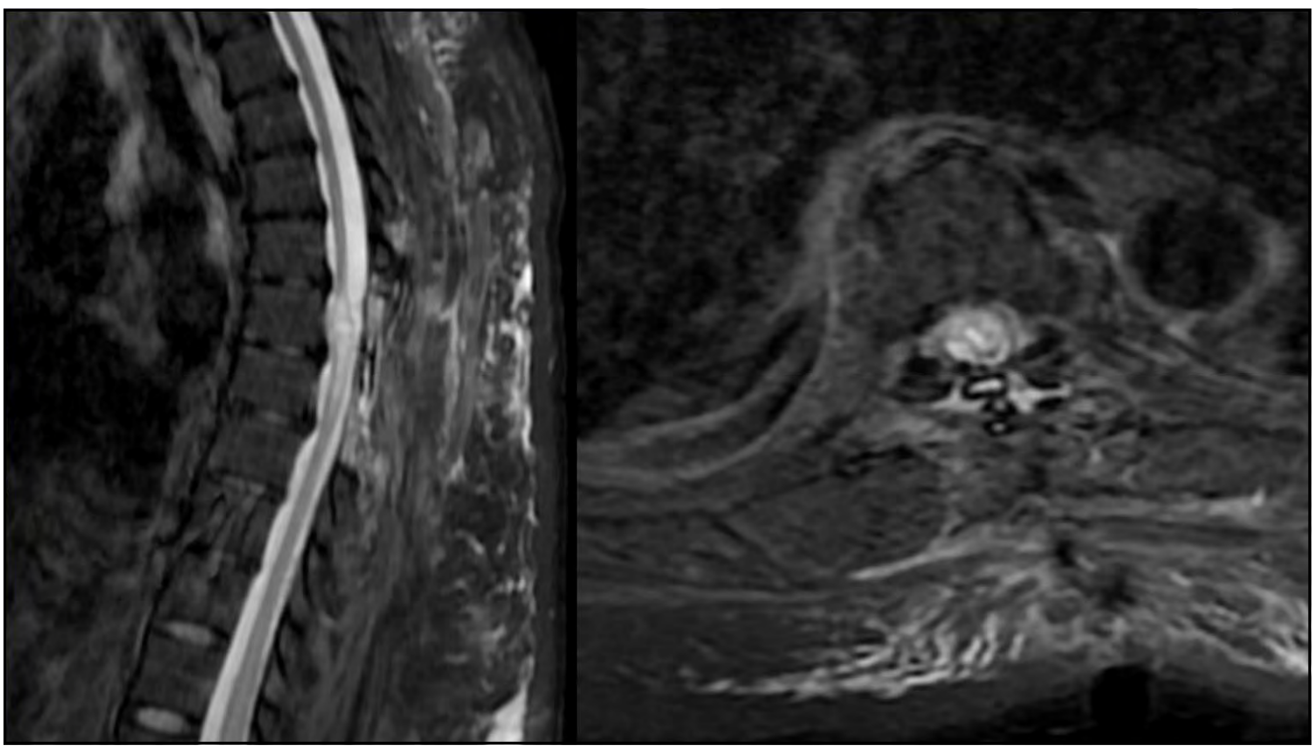
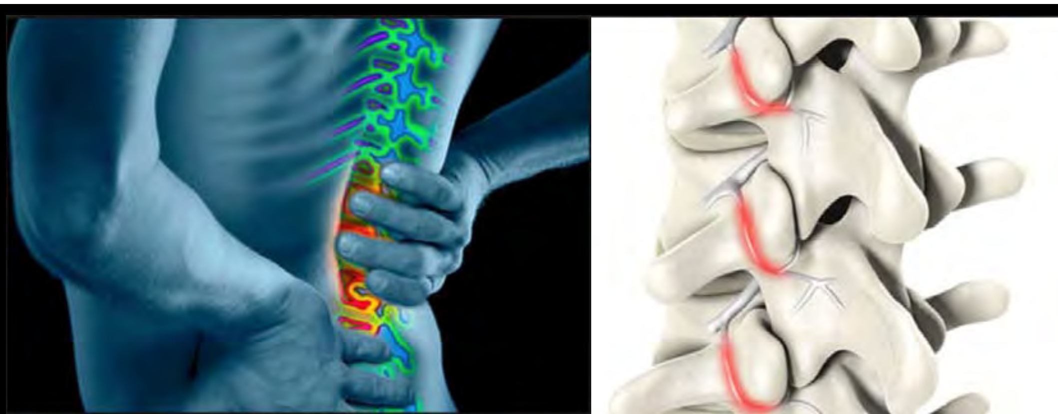
Operation

- Revision laminectomies for cyst drainage and tumor debulking



Thank you



Imaging of Spinal Pain Generators

Vinil Shah, MD
Assistant Professor of Radiology
University of California, San Francisco

Disclosure of Commercial Interest

I have nothing to disclose

Message

❖ ***Pathophysiology of low back and radicular pain is rooted in the biochemistry of inflammation***

❖ ***Inflammation is basis of low back pain syndromes***

Topics to Cover

✓ Imaging pathophysiology of lumbar discogenic & radicular pain

✓ Uncommon imaging presentations of disc herniations

✓ Physiologic imaging of facet pain

✓ Inflammation in the post-surgical spine

Role of Imaging in Low Back/Radicular Pain

- Exclude underlying systemic disease

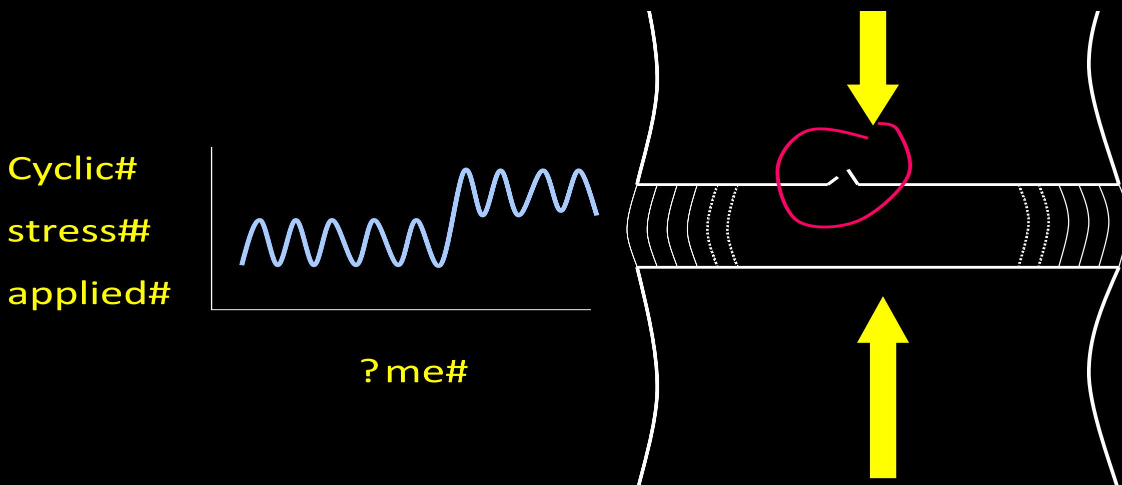
- In patients who have failed conservative management:
  - Identify specific pain generators
  - Guide treatment planning

How to detect inflammation on MRI?

✓Fat-saturated T2 / STIR

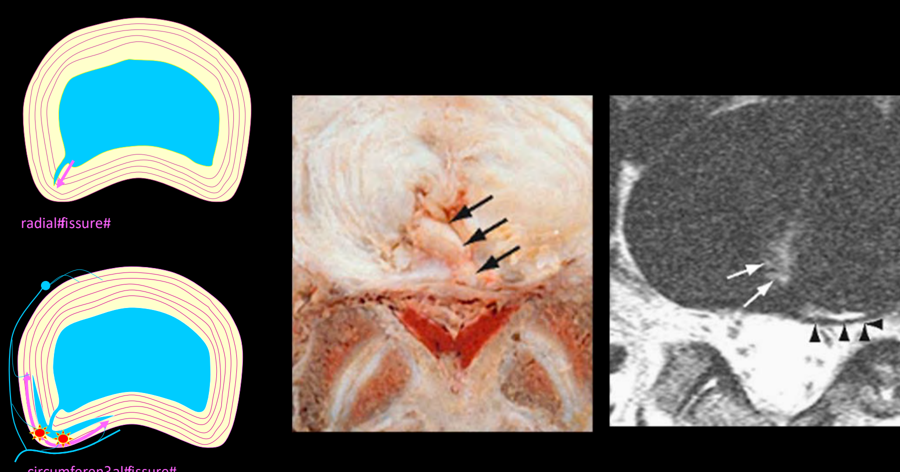
✓Gadolinium enhanced scan
  - ✓Useful problem solving role
    - ✓Unexplained radicular pain
    - ✓Postoperative spine
  - ✓Demonstrates extent of granulation tissue & associated chemical radiculitis

Internal Disc Disruption (IDD): Endplate Fatigue Fracture

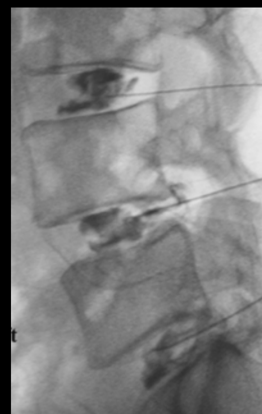


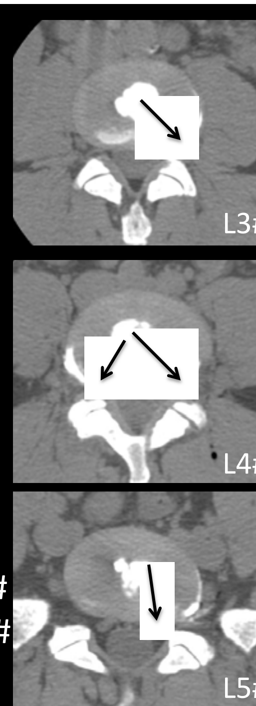
Courtesy: Tim Maus, MD

IDD: Radial Fissures



Internal Disc Disruption
Disc Stimulation





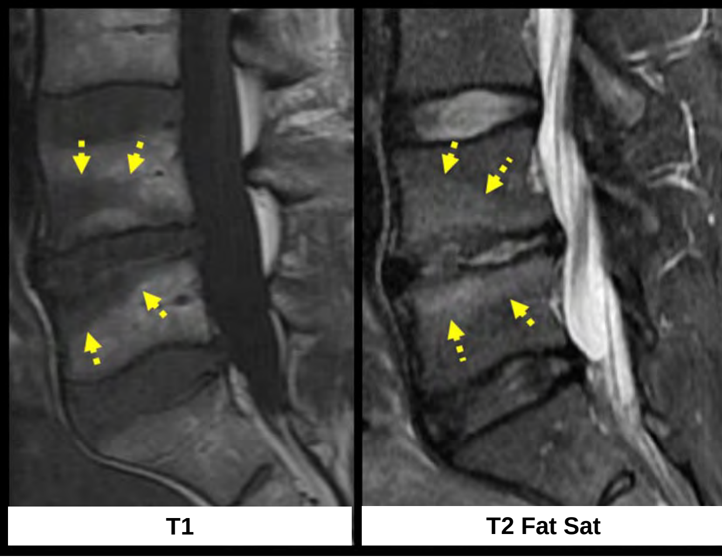
Note#all#Grade#V#discs,#despite#modest#
MRI#findings#

Courtesy: Tim Maus, MD

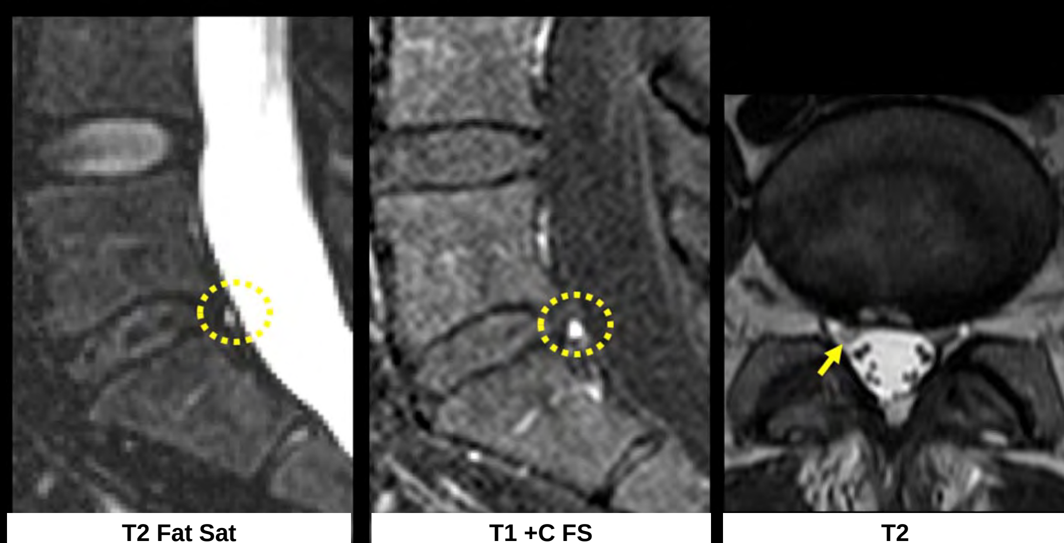
MR Signs of IDD

- ✓Inflammatory end plate changes (Modic I, II)
  - ✓Physiologic response to altered load bearing
- ✓High intensity zones (HIZ)
  - ✓Inflammatory lesion
- ✓Predict painful discs with high specificity, PPV, +LR
- ✓Best visualized on fat sat T2/STIR

MRI Signs of IDD: End plate edema



MRI Signs of IDD: High Intensity Zones



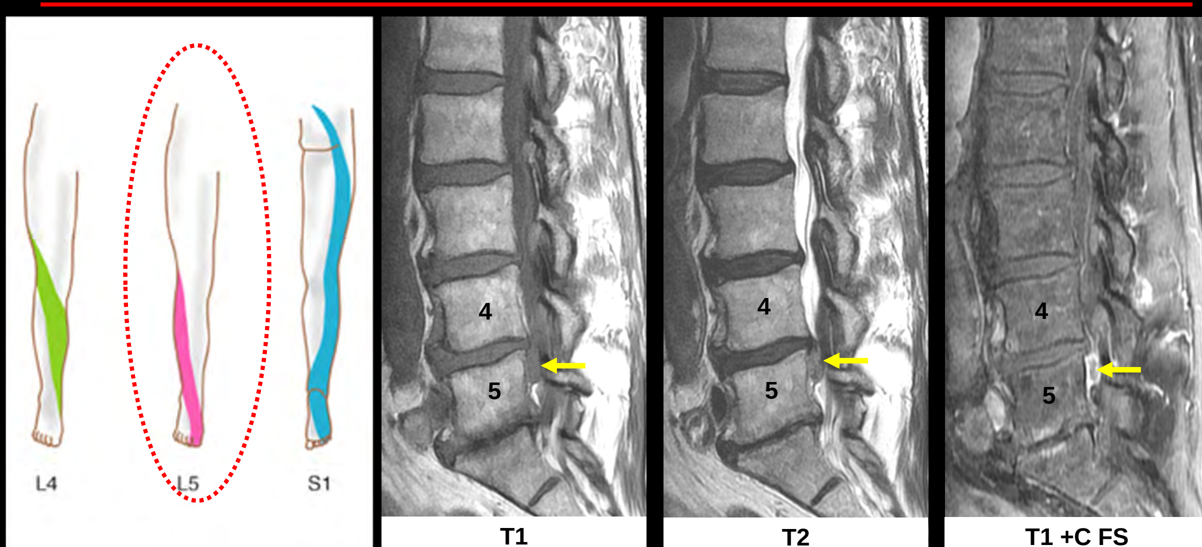
Lumbar Radicular Pain

✓Radial fissure weakens posterior annulus
✓Herniation of nuclear material
✓Shooting, "electric" pain
✓Travels down limb in narrow band

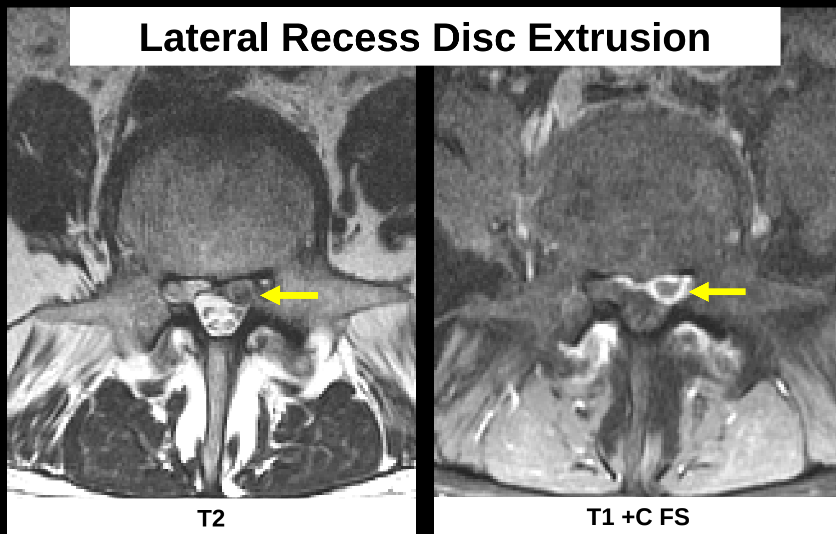
Why do epidural corticosteroids work if disc herniations result in neural compression?

Pain generation requires contact with neural tissue & an inflammatory reaction

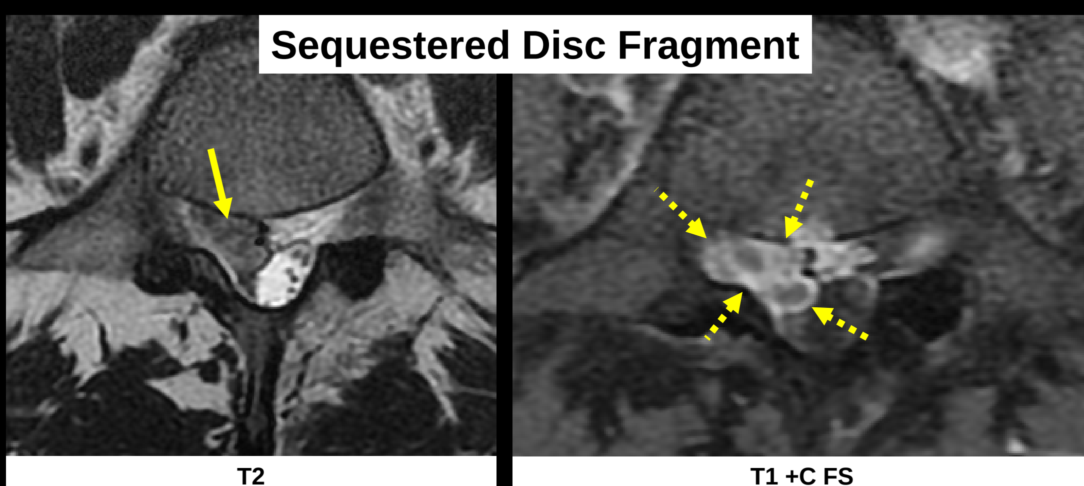
75 y.o. Male, Left Leg Radicular Pain



75 y.o. Male, Left L5 Radicular Pain



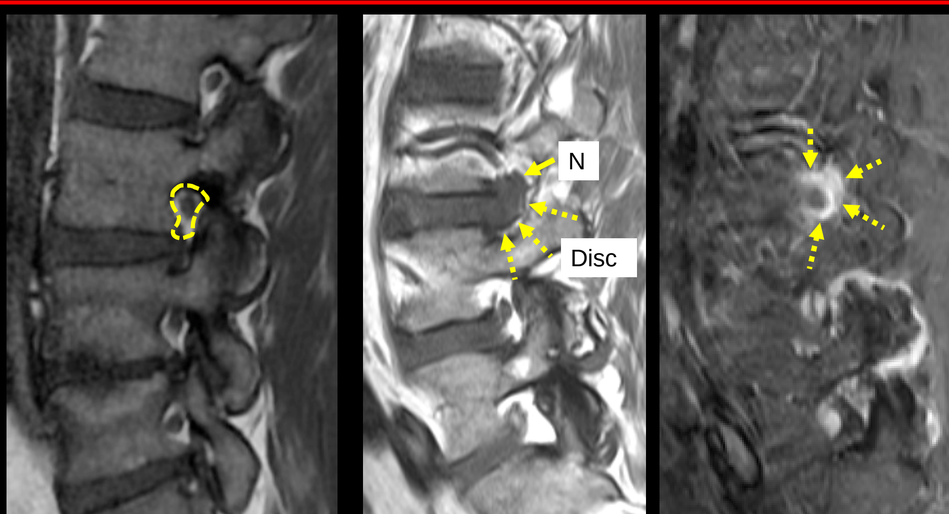
35 y.o. Female, Right Foot Drop



Lumbar Disc Herniation Pearls

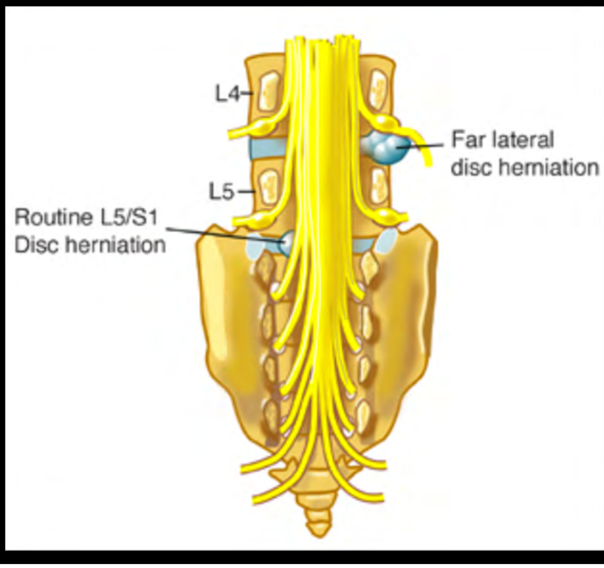
- ✓ 90% occur at L4-L5 or L5-S1
- ✓ Vector of displacement posterolateral
- ✓ Most disc herniations affect traversing rather than exiting nerves

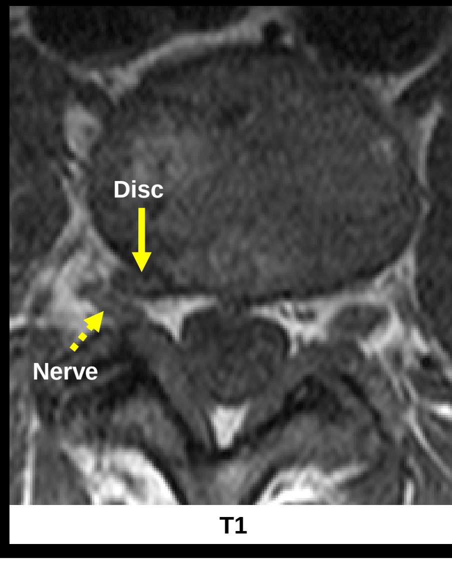
Foraminal / Far-Lateral Disc Herniations



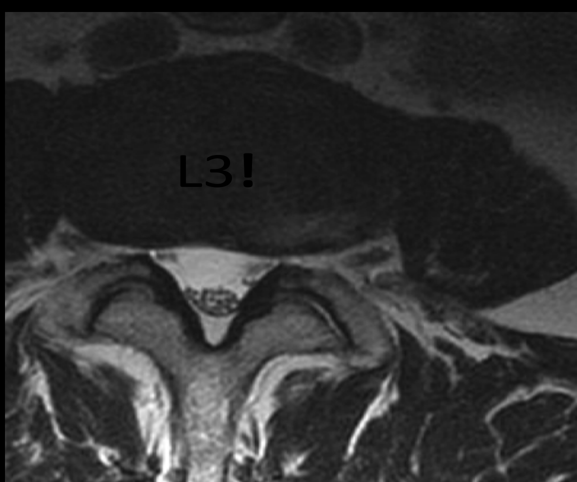
T1 | T1 | T1 +C FS

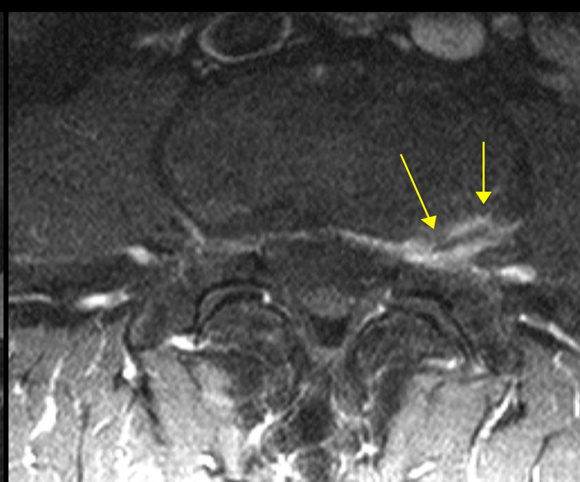
Far Lateral Disc Herniations: Axial T1 is Key

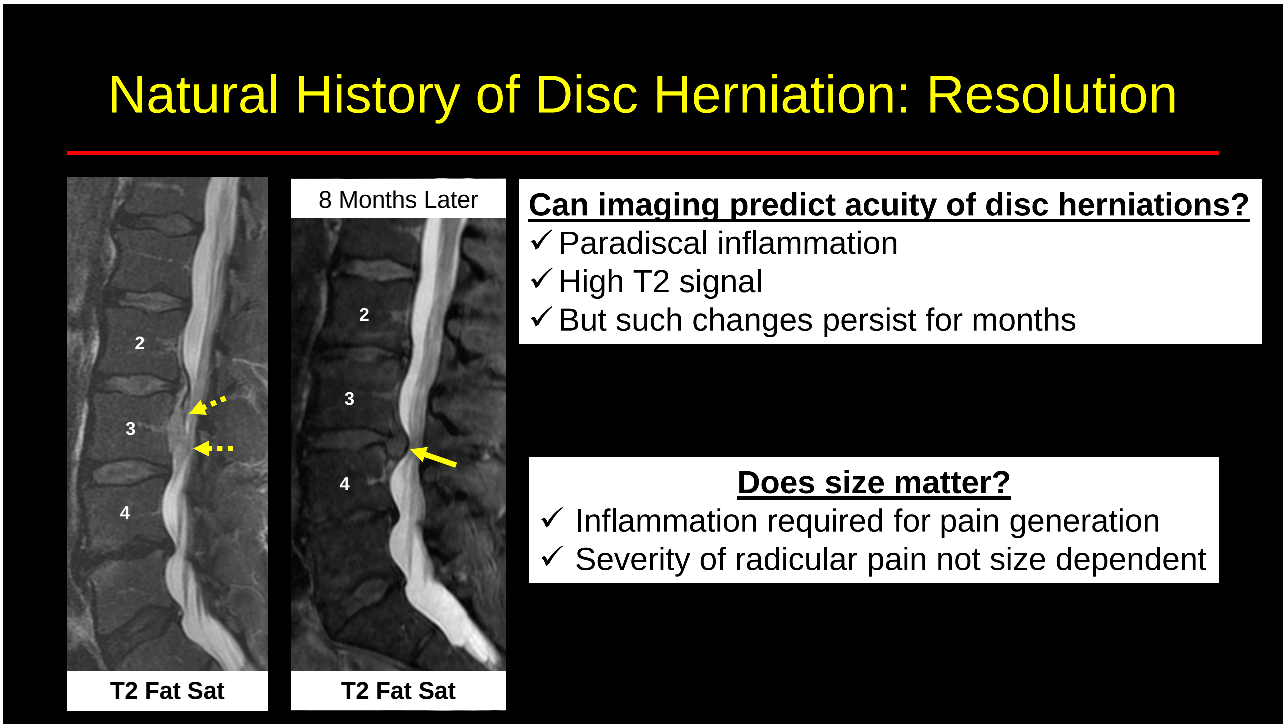


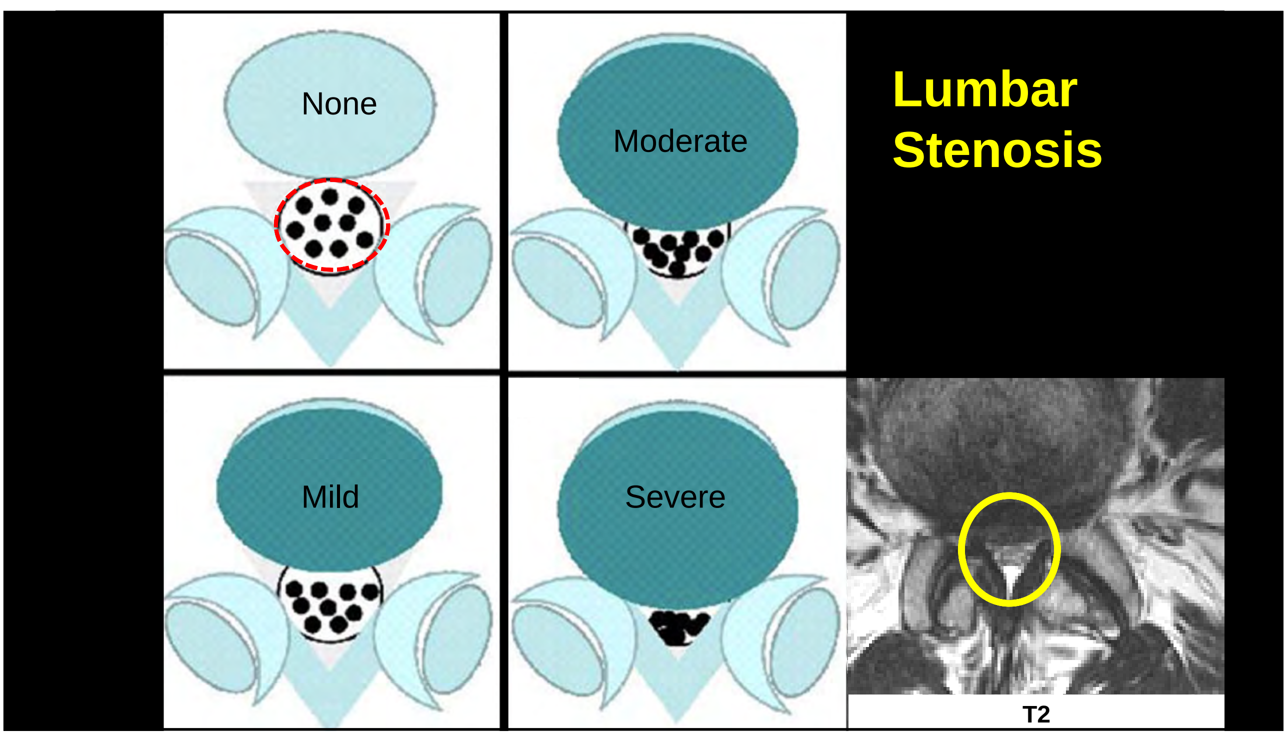


Chemical Radiculitis

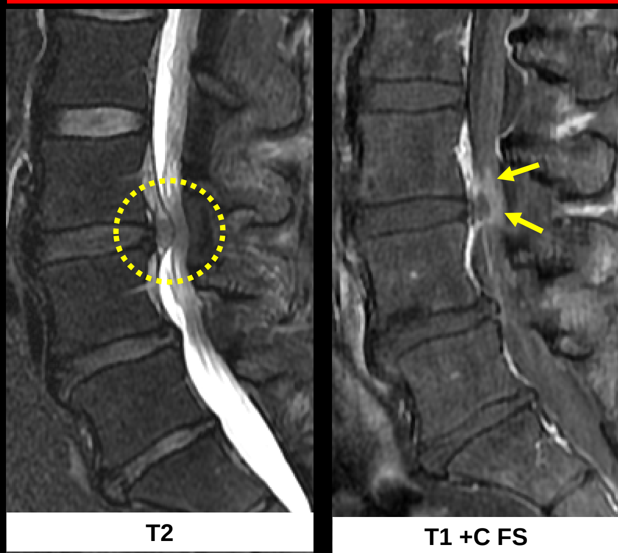





Natural History of Disc Herniation: Resolution
8 Months Later
2
3
4
2
3
4
T2 Fat Sat
T2 Fat Sat
Can imaging predict acuity of disc herniations?
✓ Paradiscal inflammation
✓ High T2 signal
✓ But such changes persist for months
Does size matter?
✓ Inflammation required for pain generation
✓ Severity of radicular pain not size dependent


None
Moderate
Lumbar Stenosis
Mild
Severe
T2

Lumbar Stenosis: Enhancement



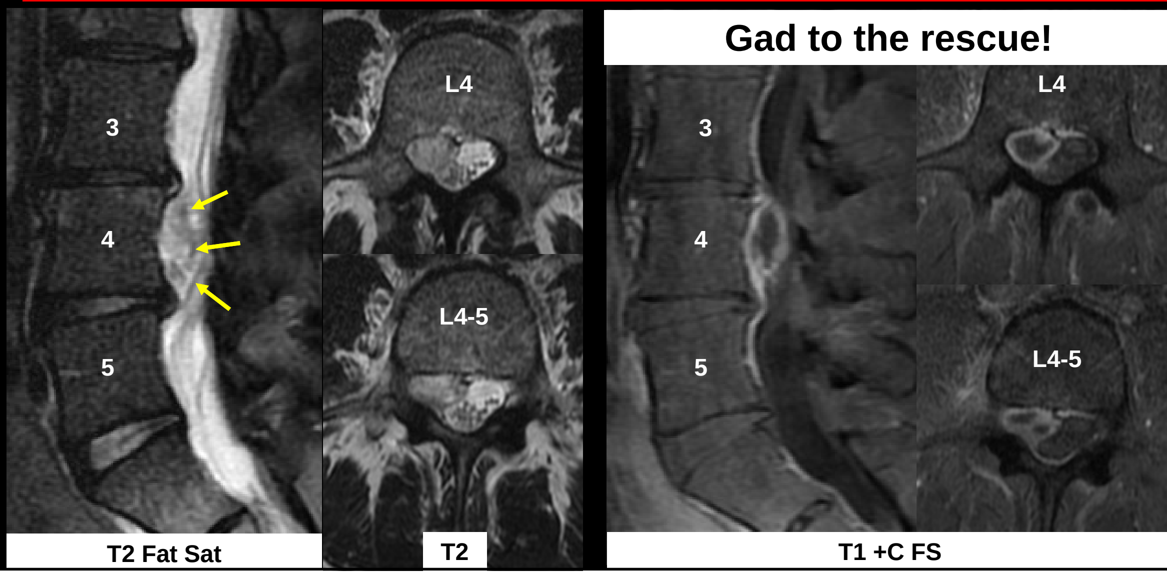
Do not mistake stenosis related intrathecal enhancement for more sinister intradural pathology

Disc Herniations that Mimic Sinister Pathology

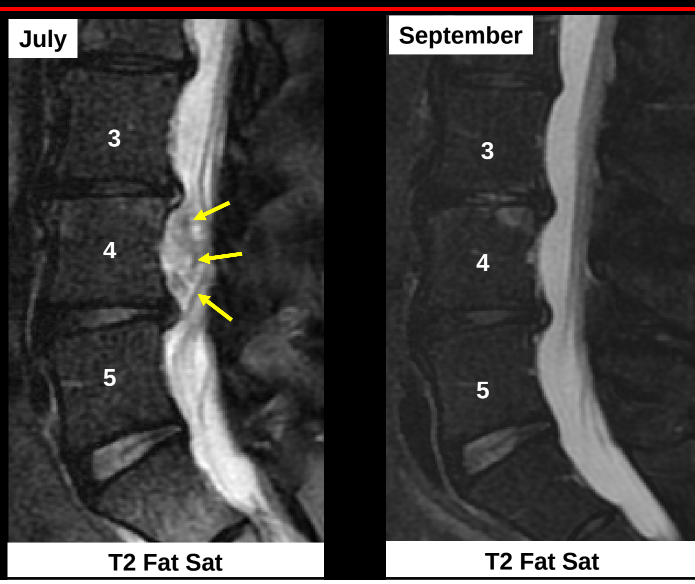
- ✓Sequestered disc herniations
- ✓Dorsal lumbar disc migration
- ✓Acute Schmorl node

Inflammatory changes around disc herniation helpful clue
Postcontrast imaging often the key sequence

52 y.o., 2 week history of right foot drop
Nerve Sheath Tumor?

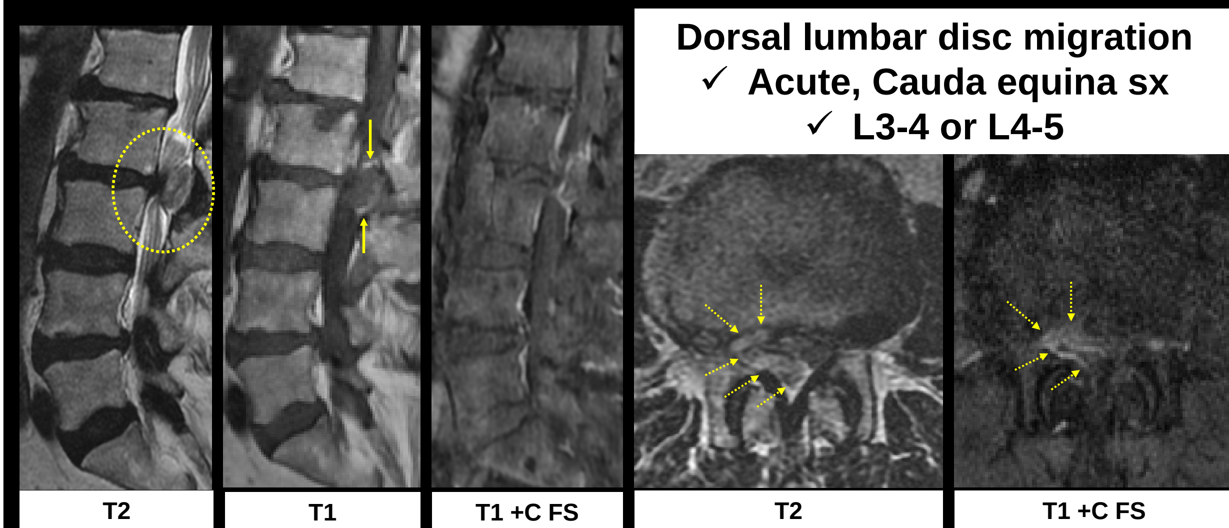


2 months later

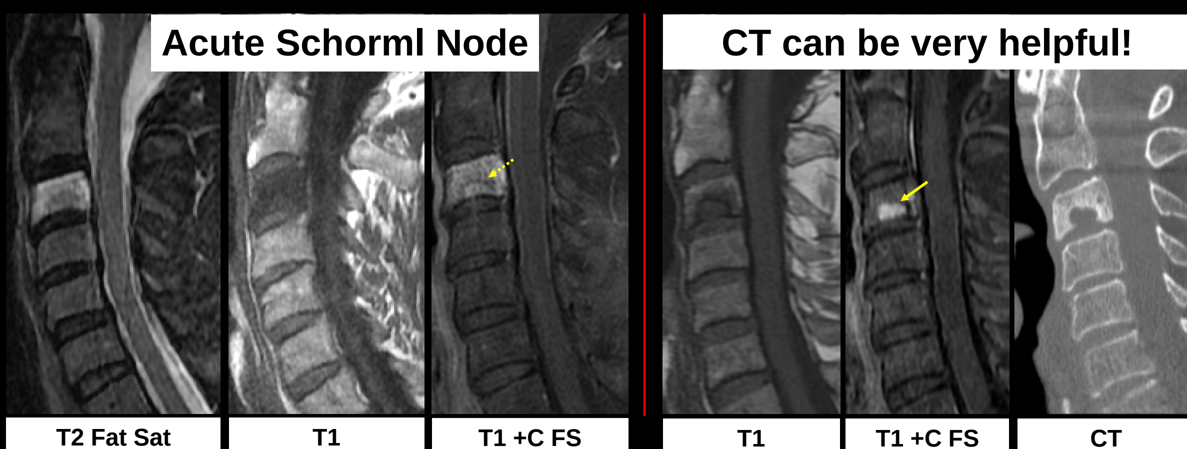


Resolution of Sequestered Disc Herniation

Epidural Abscess/Tumor?



Hx of Lung Cancer. Metastasis?



Posterior Element Pain Generators

- ✓Facet synovitis
- ✓Spondylolysis
- ✓Interspinous bursitis
- ✓Posterior ligamentous complex syndrome

- ✓***Inflammation is common element***

Facetogenic Pain

- ✓Axial back pain

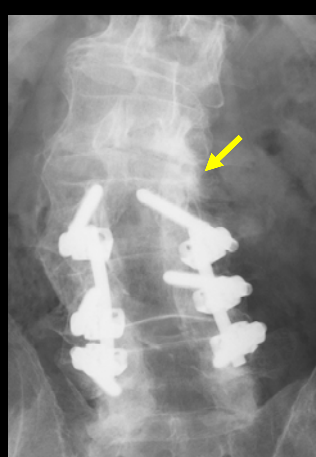
- ✓Nonspecific exam

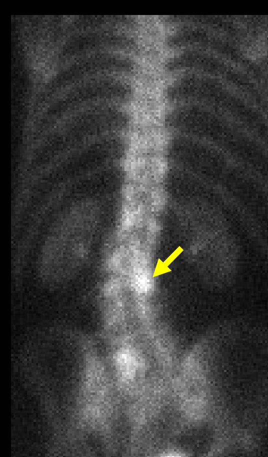
- ✓Structural changes do not correlate with pain

Facet Joint Physiologic Imaging
Where we are headed

MODALITY	MRI	BONE SPECT (+/- CT)	PET (+/- CT or MRI)
BIOMARKER	Edema Gad Enhancement	99mTc-MDP	18F-FDG 18F-NaF
WHAT IS BEING MEASURED?	Facet and peri-facet inflammation Synovitis	Osteoblastic activity Hyperemia	Bone turnover and remodeling Bone Perfusion

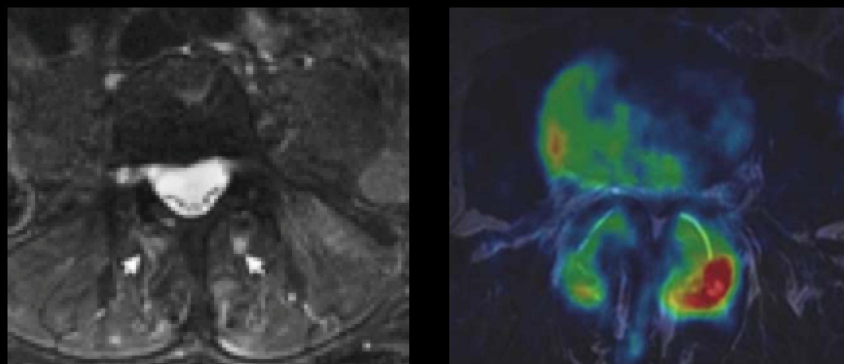
Value of SPECT
Adjacent Segment Disease





- SPECT provides anatomic localization
- No validation against dual medial branch blocks

18F-NaF PET-MR Hybrid Imaging



61M left low back pain; L3-4 level

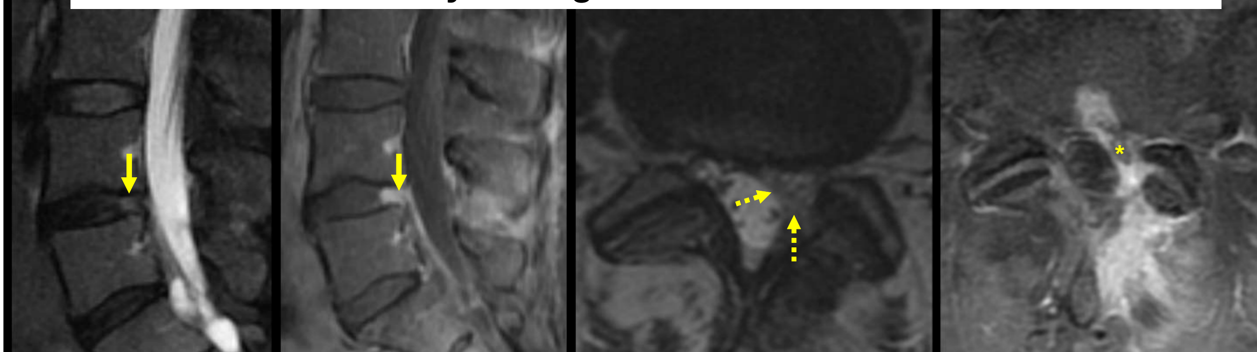
Inflammation in the Post-surgical Spine

✓Expected post-discectomy changes

✓Peridural fibrosis vs recurrent disc

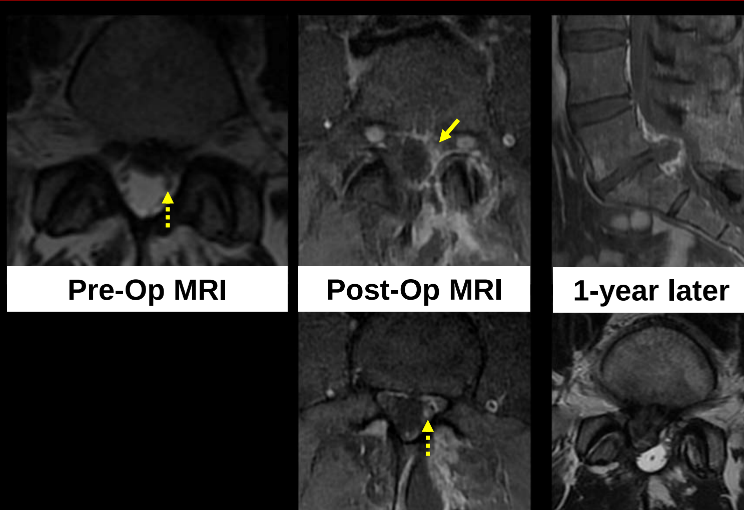
What surgery has this patient had?
Expected changes vs Infection?

Post Discectomy Changes: Start to subside > 6 weeks



- ✓ **Posterior annular high T2 signal +/- enhancement normal upto 3-6 months post-discectomy; may be associated with endplate edema, enhancement**
- ✓ **Peridural fibrosis in all patients at 6 weeks (normal reparative response)**
- ✓ **Postop epidural space edema (expected), may mimic re-herniation**

Peridural Fibrosis vs Recurrent Disc



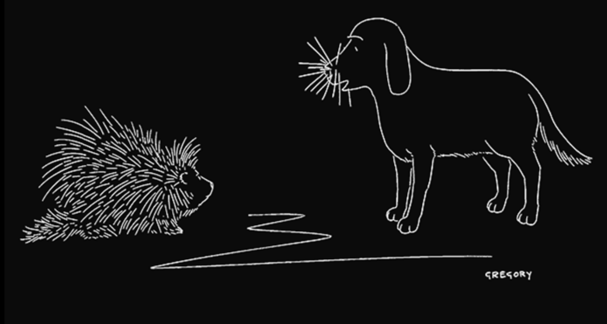
Take Home Points

- ***Pathophysiology of low back and radicular pain is rooted in the biochemistry of inflammation***

- ***Inflammation is basis of low back pain syndromes***

Thank You

Vinil.Shah@ucsf.edu



"On the plus side, you've cured my back pain."

15th Annual UCSF Spine Symposium

June 6th, 2020

When to Say No to Surgery?

Lee A. Tan, M.D.

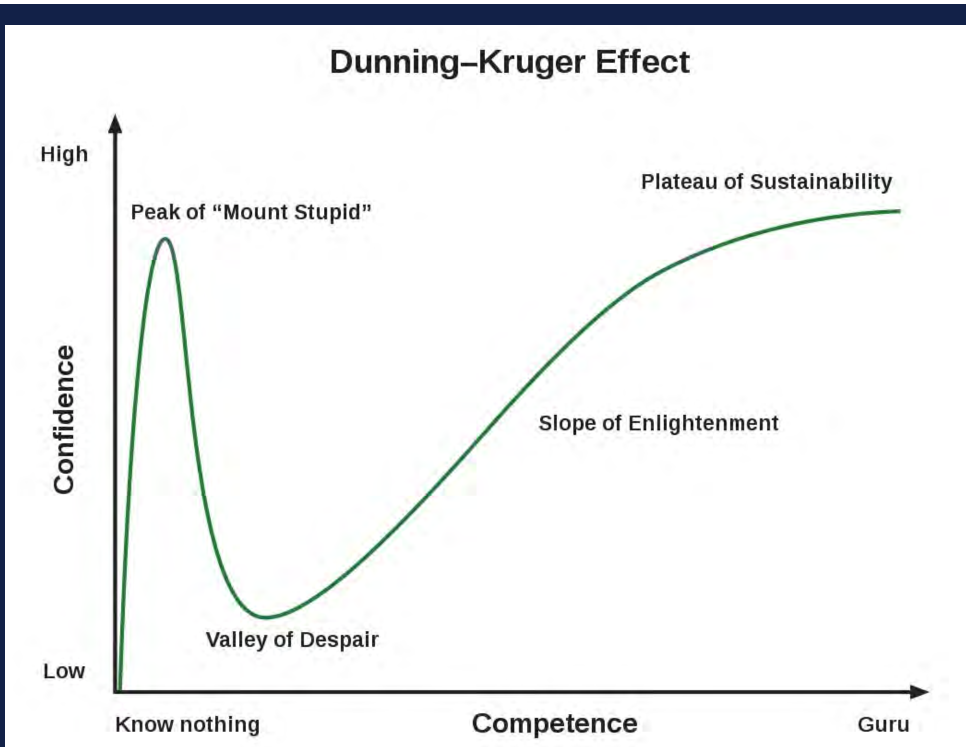
Assistant Professor
Department of Neurosurgery
UCSF Medical Center
San Francisco, CA

Disclosure

- Consultant for Medtronic, Stryker/K2M, Depuy, Integrity Implants

"The first 10 years of my career I fused,
the second 10 years I re-fused,
the third 10 years I refused."

- Rick Fessler



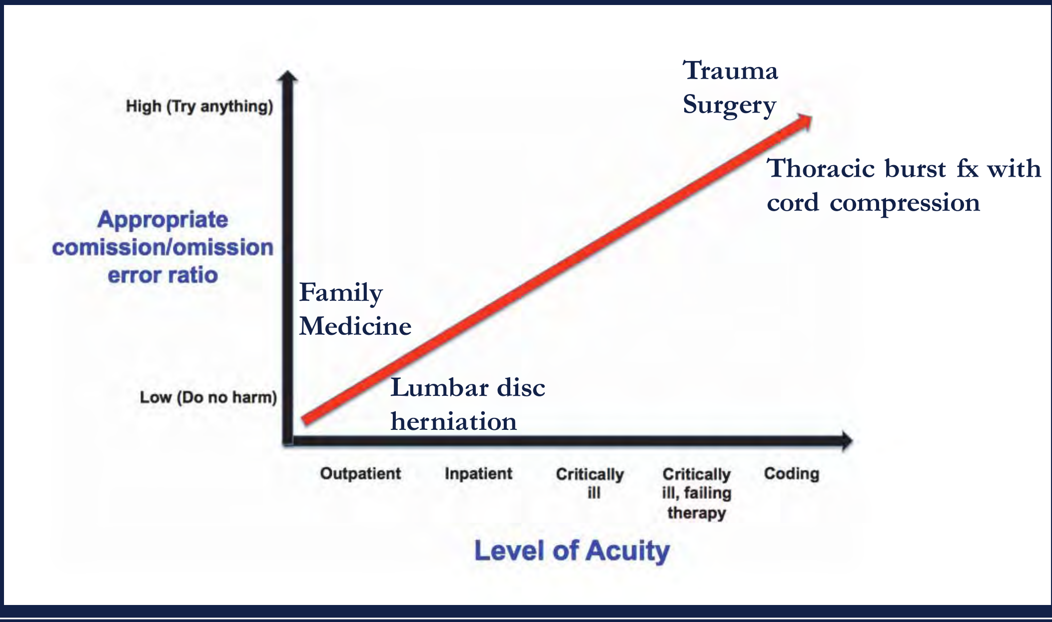
Why saying "no" can be hard for surgeons?

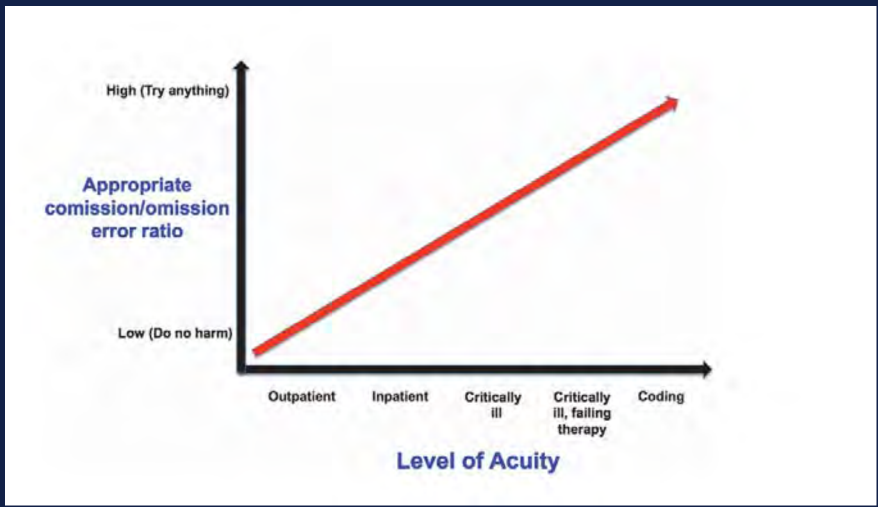
- We want to help patients who are suffering
- We do not want to disappoint our patients
- Patients have tried all other options and have no other choice
- We want to maintain our craft and surgical expertise
- Surgeons are "DOers", we tend to err towards error of commission rather than error of omission

Errors of Omission vs. Commission

- Both can be detrimental for patient care
  - Error of omission = fail to help patients who can benefit from surgery with acceptable risk and low complications
  - Error of commission = performing surgery on poor surgical candidates who have excessively high complications or not enough benefit to justify the risk
- Errors of omission and commission must be balanced
  - We have responsibility both to provide care to patients in need *and* to prevent bad outcomes by avoiding doing surgeries on patients determined to be poor surgical candidates.
- The goal should be to minimize the total amount of errors (ie, to help as many patients as possible, while minimizing complications associated with surgery)

Error of Omission vs Error of Commission





- Some amount of error will always occur
- The aggressiveness of intervention should match the pathology severity

Surgical Outcome

- Patient-related factors
- Surgeon/Procedure-related factors
- Facility/System-related factors

Patient-related factors

- **Modifiable risk factors:**
  - Osteoporosis, smoking, alcohol intake, obesity, diabetes, hypertension, coronary artery disease, atrial fibrillation, cerebrovascular disease, anemia, malnutrition, mental disorders, and medications.

- **Non-modifiable risk factors**
  - Age, gender, genetics, family history, chronic obstructive pulmonary disease, history of stroke or myocardial infarction, congestive heart failure, or chronic kidney disease

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Surgeon/Procedure-related factors

- The surgeon's knowledge, decision-making, technical skills and experience
- The nature and severity of the pathology
- Invasiveness of the planned procedure

System-related factors

- Pre- and postoperative care
- Anesthesia team
- Access or co-surgeons
- Medical management and ICU care
- Rehabilitation
- Follow-up

Surgical Risk Prediction Models

- American Society of Anesthesiology (ASA) Risk Assessment Model
- Revised Cardiac Index Score
- ACS NSQIP
- Spine Sage
- Frailty Score/ modified frailty score
- Machine learning/Neural network/ Artificial intelligence

American Society of Anesthesiology (ASA) Score

- A tool to assess a patient's preoperative general health
- Has a moderate association with cardiac arrest and in-hospital mortality.
- The main purpose of the ASA score is not to predict surgical outcome, but to estimate the amount of a patient's physiological reserve before surgical treatment.

ASA Classification		Examples:
ASA I	A normal healthy patient	Healthy; no smoking, no or very minimal drinking.
ASA II	A patient with mild systemic disease	Smoker; more than minimal drinking; pregnancy; obesity; well controlled diabetes, well controlled hypertension; mild lung disease.
ASA III	A patient with severe systemic disease, not incapacitating	Diabetes, poorly controlled hypertension; distant history of MI, CVA, TIA, cardiac stent; COPD, ESRD; dialysis; active hepatitis; implanted pacemaker; ejection fraction below 40%; congenital metabolic abnormalities.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Recent history of MI, CVA, TIA, cardiac stent; Ongoing cardiac ischemia or severe valve dysfunction; implanted ICD; ejection fraction below 25%.
ASA V	A moribund patient who is not expected to survive without the operation	Ruptured abdominal or thoracic aneurism; intracranial bleed with mass effect; ischemic bowel in the face of significant cardiac pathology..

Revised Cardiac Risk Index model

- Major adverse cardiovascular events are important determinants of postoperative morbidity and mortality
- A Revised Cardiac Risk Index (RCRI) has been suggested to estimate the perioperative risk of a major cardiac event: cardiac death, nonfatal cardiac arrest, or nonfatal myocardial infarction.
- This tool was developed within a cohort study of 2,893 patients and subsequently validated on 1,422 patients older than 50 years undergoing major non-cardiac surgery.

Revised Cardiac Risk Index model

Risk Factors	Points
History of ischemic heart disease	1
High-risk type of surgery	1
History of congestive heart failure	1
History of cerebrovascular disease	1
Preoperative treatment with insulin	1
Preoperative serum creatinine >2.0 mg/dL	1

RISK OF MAJOR CARDIAC EVENT

Points	Class	Risk
0	I	0.4%
1	II	0.9%
2	III	6.6%
3 or more	IV	11%

The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP)

- High-quality standardized data on preoperative risk factors and postoperative complications from participating hospitals within the United States. Information from 393 hospitals and 1,414,006 patients
- A universal surgical risk calculator was developed to predict one of 9 adverse outcomes within 30 days after surgery based on 21 patient-related variables and the planned surgical procedure according to the Current Procedural Terminology code (CPT code).
- A recently updated online version of the calculator based on 3.8 million surgical procedures consists of **20 variables** to predict **15 outcomes**.

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ACS NSQIP – 20 variables

Variable	Categories
CPT code	
Age group	<65/65-74/75-84/>85
Sex	Male/female
Functional status	Independent/partially dependent/ totally dependent
Emergency case	Yes/no
ASA class	I or II/III/IV/V
Steroid use for chronic condition	Yes/no
Ascites within 30 days preoperatively	Yes/no
Systemic sepsis within 48 hours preoperatively	None/SIRS/sepsis/septic shock
Ventilator dependent	Yes/no
Disseminated cancer	Yes/no
Diabetes	No/oral/insulin
Hypertension requiring medication	Yes/no
Congestive heart failure in 30 days preoperatively	Yes/no
Dyspnea	Yes/no
Current smoker within 1 year	Yes/no
History of COPD	Yes/no
Dialysis	Yes/no
Acute renal failure	Yes/no
BMI class	Underweight/normal/overweight/ obesity 1/obesity 2/obesity 3

ACS NSQIP – 15 outcomes

Serious complication (cardiac arrest, myocardial infarction, pneumonia, progressive renal insufficiency, acute renal failure, PE, DVT, return to the operating room, deep incisional SSI, organ space SSI, systemic sepsis, unplanned intubation, UTI, wound disruption)
Any complication (superficial incisional SSI, deep incisional SSI, organ space SSI, wound disruption, pneumonia, unplanned intubation, PE, ventilator > 48 hours, progressive renal insufficiency, acute renal failure, UTI, stroke, cardiac arrest, myocardial infarction, DVT, return to the operating room, systemic sepsis)
Pneumonia
Cardiac Complication (cardiac arrest or MI)
Surgical Site Infection
Urinary Tract Infection
Venous Thromboembolism
Renal Failure (progressive renal insufficiency or acute renal failure)
Colon Ileus (Conditionally displayed based on the selected Procedure)
Colon Anastomotic Leak (Conditionally displayed based on the selected Procedure)
Readmission
Return to OR

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Please enter as much of the following information as you can to receive the best risk estimates.
A rough estimate will still be generated if you cannot provide all of the information below.

Age Group
65-74 years

Sex
Male

Functional Status
Independent

Emergency Case
No

ASA Class
Mild systemic disease

Steroid use for chronic condition
No

Ascites within 30 days prior to surgery
No

Systemic Sepsis within 48 hours prior to surgery
None

Ventilator Dependent
No

Disseminated Cancer
No

Diabetes
No

Hypertension requiring medication
Yes

Congestive Heart Failure in 30 days prior to surgery
No

Dyspnea
No

Current Smoker within 1 Year
No

History of Severe COPD
No

Dialysis
No

Acute Renal Failure
No

BMI Calculation:

Height: 69 **in /** 175 **cm**

Weight: 200 **lb /** 90 **kg**

ACS NSQIP®

Surgical Risk Calculator

AMERICAN COLLEGE OF SURGEONS
Inspiring Quality: Highest Standards, Better Outcomes

Procedure: 22612 - Arthrodesis, posterior or posterolateral technique, single level; lumbar (with or without lateral transverse technique)
Risk Factors: 65-74 years, HTN, Over Weight

Outcomes	Your Risk	Average Risk	Chance of Outcome
Serious Complication	5.6%	7.3%	Below Average
Any Complication	6.2%	8.1%	Below Average
Pneumonia	0.3%	0.6%	Below Average
Cardiac Complication	0.2%	0.3%	Below Average
Surgical Site Infection	1.5%	2.0%	Below Average
Urinary Tract Infection	1.6%	1.4%	Above Average
Venous Thromboembolism	0.9%	1.1%	Below Average
Renal Failure	0.1%	0.3%	Below Average
Readmission	3.9%	5.3%	Below Average
Return to OR	2.4%	3.1%	Below Average
Death	0.1%	0.2%	Below Average
Discharge to Nursing or Rehab Facility	13.9%	13.8%	Average

Predicted Length of Hospital Stay: 3.5 days

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SpineSage

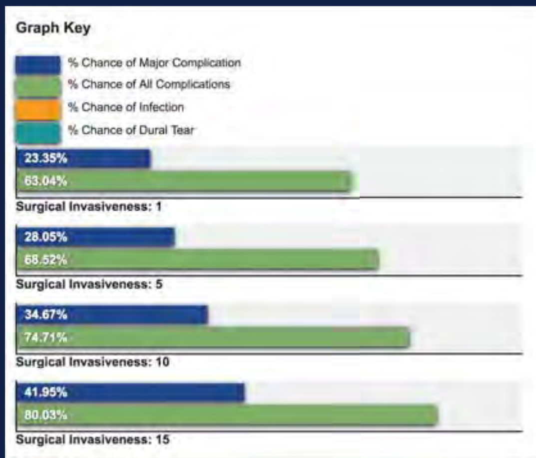
The SpineSage tool is a predictive model based on data from the Spine End Results Registry. The Spine End Results Registry is a prospectively collected data registry for all patients undergoing spine surgery at Harborview Medical Center and University of Washington Medical Center from January 1st 2003, to December 31st, 2004. Extensive co-morbidity and demographic data were defined a priori and collected prospectively for each surgical patient. Complications were defined a priori and were prospectively recorded for at least 2 years following the surgery.

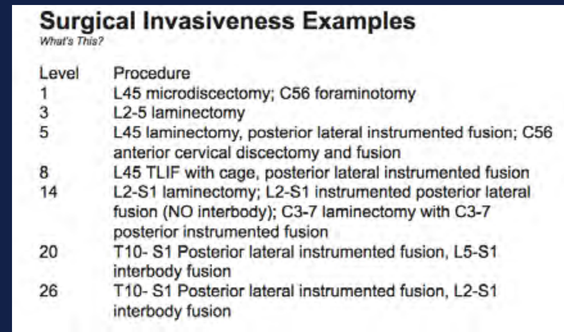
Several multivariate log-binomial analyses were performed to identify and quantif risk factors for these complications after spine surgery and have been published in the peer-refereed literature. Based on these analyses, predictive models for these complications were devised and are the focus of SpineSage.

SpineSage

Patient Age	75
Patient Gender	Male
Does the patient have Cerebrovascular Disease?	Yes
Does the patient have Chronic Obstructive Pulmonary Disease?	No
Does the patient have Asthma?	No
Does the patient have Hypertension?	Yes
Does the patient have Rheumatoid Arthritis?	No
Does the patient have Renal Conditions?	No
Does the patient have pre-existing Neoplasm?	No
Does the patient have a history of Syncope or Seizure?	No

Does the patient have a history of Syncope or Seizure?	No
Does the patient have Anemia?	No
Does the patient have a bleeding disorder?	No
Does the patient have diabetes?	No
Does the patient have congestive heart failure?	Yes
Is this a revision surgery?	No
Has the patient had a previous spinal surgery?	No
Has the patient had previous cardiac complications?	No
What is the patients BMI?	Greater than 30
Primary Diagnosis	Trauma
Level of Surgery	Thoracic
Surgical Approach	Posterior

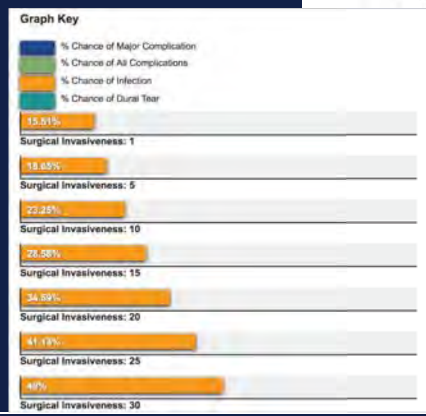




Surgical Invasiveness Examples

What's This?

Level	Procedure
1	L45 microdiscectomy; C56 foraminotomy
3	L2-5 laminectomy
5	L45 laminectomy, posterior lateral instrumented fusion; C56 anterior cervical discectomy and fusion
8	L45 TLIF with cage, posterior lateral instrumented fusion
14	L2-S1 laminectomy; L2-S1 instrumented posterior lateral fusion (NO interbody); C3-7 laminectomy with C3-7 posterior instrumented fusion
20	T10- S1 Posterior lateral instrumented fusion, L5-S1 interbody fusion
26	T10- S1 Posterior lateral instrumented fusion, L2-S1 interbody fusion



Frailty Score

- Frailty score is a relatively new system that has been shown to be a useful predictive tool to assess pre-operative complications rates.
- The score takes into consideration of 40 physician documented and patient reported variables including factors such as presence of HTN, diabetes, depression, cardiac disease, cancer, smoking status, as well as patient reported factors such as difficulty walking, difficulty driving, presence of bowel/bladder incontinence etc.
- Based on these variables, patients can be categorized as non-frail, frail, and severely frail.
- External validation studies have shown that severely frail patients have 4.4x odd ratio for complications compared to non-frail
- “Pre-habilitation” can be used to improve patient’s physiological status pre-op

Modified 5-item Frailty Index (mFI-5)

- Another more concise comorbidity-based risk stratification tool that has been shown to predict complications following adult deformity surgery.

- The mFI-5 score takes consideration of five condition including:
  1) Diabetes,
  2) HTN requiring medication,
  3) CHF within 30 days prior to surgery
  4) COPD or pneumonia
  5) Dependent functional status prior to surgery.

DEFORMITY

The 5-Item Modified Frailty Index Is Predictive of Severe Adverse Events in Patients Undergoing Surgery for Adult Spinal Deformity

Yagi, Mitsuru MD, PhD[*,†,‡]; Michikawa, Takehiro MD, PhD[§]; Hosogane, Naobumi MD, PhD[‡,¶]; Fujita, Nobuyuki MD, PhD[*,‡]; Okada, Eijiro MD, PhD[*,‡]; Suzuki, Satoshi MD, PhD[*,‡]; Tsuji, Osahiko MD, PhD[*,‡]; Nagoshi, Narihito MD, PhD[*,‡]; Asazuma, Takashi MD, PhD[†]; Tsuji, Takashi MD, PhD[‡,||]; Nakamura, Masaya MD, PhD[*,‡]; Matsumoto, Morio MD, PhD[*,‡]; Watanabe, Kota MD, PhD[*,‡]

Author Information

SPINE: September 15, 2019 - Volume 44 - Issue 18 - p E1083-E1091

doi: 10.1097/BRS.0000000000003063

Results.

Of the 281 patients, 63 (22%) had developed SAE at 2 years. The weighted Kappa ratio between the mFI-5 and mFI-11 was 0.87, indicating excellent concordance across ASD surgery. Frailty was associated with increased total complications, perioperative complications, implant-related complications, and SAEs. Adjusted and unadjusted models showed similar c-statistics for mFI-5 and mFI-11 and a strong predictive ability for SAEs in ASD surgery. As the mFI-5 increased from 0 to ≥2, the rate of SAEs increased from 17% to 63% ($P < 0.01$), and the relative risk was 2.2 (95% CI: 1.3–3.7).

Conclusion.

The mFI-5 and the mFI-11 were equally effective predictors of SEA development in ASD surgery. The evaluation of patient frailty using mFI-5 may help surgeons optimize procedures and counsel patients.

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Artificial Intelligence and the Future of Spine Surgery

Rushikesh S. Joshi, Darryl Lau, Christopher P. Ames
Department of Neurological Surgery, University of California, San Francisco, San Francisco, CA, USA

Artificial Intelligence (AI) Can Predict Postoperative Complications Better than Traditional Statistical Testing Following Anterior Cervical Discectomy and Fusion (ACDF)

Varun Arvind, BS[1], Deepak Kaji, BA[1], Jun Kim, MD[2], John M. Caridi, MD[2], Samuel K. Cho, MD[3]

DOI: https://doi.org/10.1016/j.spinee.2017.07.224

Spine (Phila Pa 1976). 2019 Jul 1;44(13):915-926. doi: 10.1097/BRS.0000000000002974.

Artificial Intelligence Based Hierarchical Clustering of Patient Types and Intervention Categories in Adult Spinal Deformity Surgery: Towards a New Classification Scheme that Predicts Quality and Value.

Ames CP[1], Smith JS[2], Pellisé F[3], Kelly M[4], Alanay A[5], Acaroğlu E[6], Pérez-Grueso FJS[7], Kleinstück F[8], Obeid I[9], Vila-Casademunt A[10], Shaffrey CI Jr[10], Burton D[11], Lafage V[12], Schwab F[12], Shaffrey CI Sr[2], Bess S[13], Serra-Burriel M[14]; European Spine Study Group, International Spine Study Group.

When to Say No to Surgery?

- Predicting of surgical risk alone is not enough
- Estimating the potential benefit of surgery is important
- The surgeon's personal experience is also important
- Realistic surgical expectations
- Patient compliance is a factor as well
- Talk to a mentor or colleague when in doubt
- Follow your "gut feeling"

Ann R Coll Surg Engl. 1994 Nov;76(6 Suppl):277-8.

The surgeon's 'gut feeling' as a predictor of post-operative outcome.

Hartley MN[1], Sagar PM.

Abstract

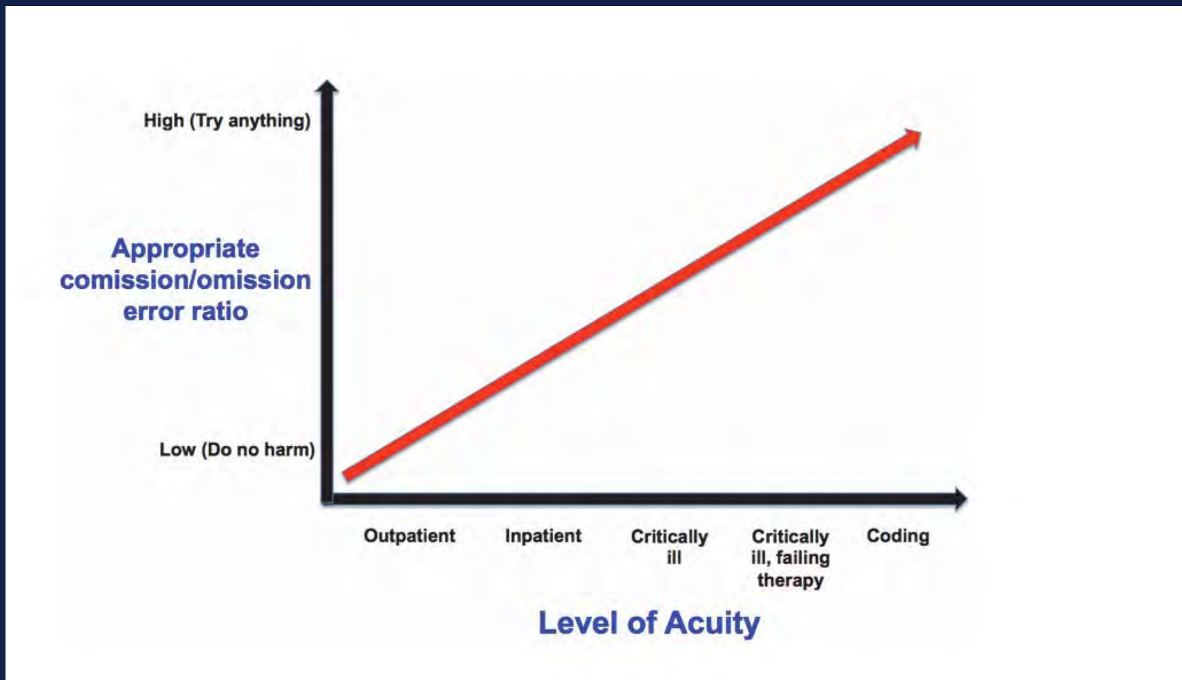
The aim of this study was to identify the accuracy of prediction of the 'gut feeling' of the surgeon immediately upon completion of an operation in the prediction of subsequent outcome. A consecutive series of 120 patients, each of whom underwent gastrointestinal surgery, were studied. The two operating surgeons scored each patient on a scale of 1-3 which related to his expectations of the outcome. This prediction was compared with the prediction generated by the POSSUM scoring system. The surgeon's 'gut feeling' upon completion of a major procedure was a good indicator of the post-operative course of the patient.

Case Example #1

- 36M s/p L2-5 laminectomies at OSH 1 months ago now with worsening BLE weakness and sensory changes from T4 dermatome down. CT myelogram showed severe thoraacic stenosis from T2 to T8, and at T11-12.

- HTN, OSA, Morbid obesity
- BMI = 67.13, Weight = 495lbs, Height = 6ft
- BLE 4/5 except for right EHL/DF 2/5, diminished sensation from chest down, unable to walk for the past two weeks
- + urinary urgency

Outcomes	Your Risk	Average Risk	Chance of Outcome
Serious Complication	24.7%	12.9%	Above Average
Any Complication	26.5%	13.7%	Above Average
Pneumonia	5.4%	1.6%	Above Average
Cardiac Complication	1.9%	0.5%	Above Average
Surgical Site Infection	4.1%	1.9%	Above Average
Urinary Tract Infection	4.1%	2.1%	Above Average
Venous Thromboembolism	3.5%	1.7%	Above Average
Renal Failure	1.6%	0.4%	Above Average
Readmission	14.3%	7.7%	Above Average
Return to OR	7.7%	4.7%	Above Average
Death	6.4%	0.7%	Above Average
Discharge to Nursing or Rehab Facility	73.9%	32.9%	Above Average
Sepsis	3.1%	1.1%	Above Average



High (Try anything)
Appropriate comission/omission error ratio
Low (Do no harm)
Outpatient
Inpatient
Critically ill
Critically ill, failing therapy
Coding
Level of Acuity

Zoom Factor: 1.2
Slice Thickness 0.60000

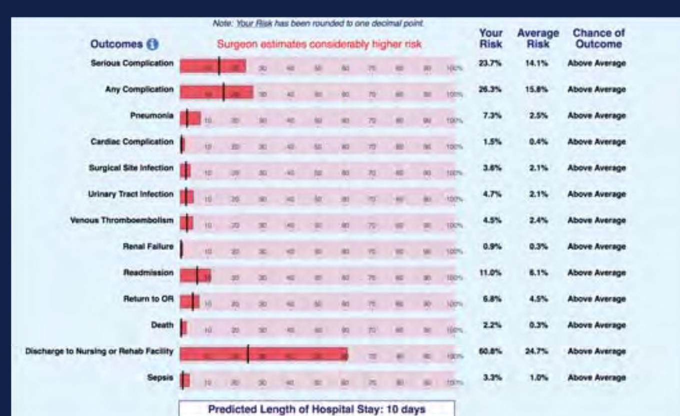
Case Example #2

- 74F with history of schizophrenia, bladder CA, HFpEF, osteoporosis, OSA, HTN, HLD, s/pT9-11 and L1-3 lami/PSF at OSH complicated by recurrent infection with epidural abscess, subsequent T9-11 hardware removal, and Ogilvie's syndrome, now presenting with worsening back pain, with difficulty standing up and ambulating.

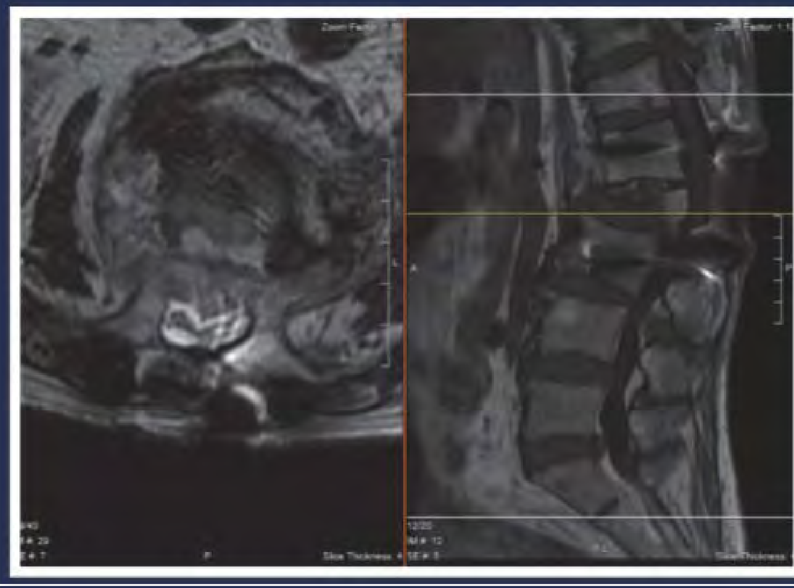
- AAOx3
- MAE at least 4/5

Please enter as much of the following information as you can to receive the best risk estimates.
A rough estimate will still be generated if you cannot provide all of the information below

Age Group: 65-74 years
Sex: Female
Functional Status: Totally Dependent
Emergency Case: No
ASA Class: Severe systemic disease
Steroid use for chronic condition: No
Ascites within 30 days prior to surgery: No
Systemic Sepsis within 48 hours prior to surgery: None
Ventilator Dependent: No
Disseminated Cancer: No
Diabetes: No
Hypertension requiring medication: Yes
Congestive Heart Failure in 30 days prior to surgery: No
Dyspnea: With Moderate exertion
Current Smoker within 1 Year: No
History of Severe COPD: No
Dialysis: No
Acute Renal Failure: No
BMI Calculation:
Height: 61 in / 155 cm
Weight: 150 lb / 68 kg



S/P T9-11 & L1-3 decompression and fusion at OSH



What would you do?

- Good surgeons know HOW to operate,
- Better surgeons know WHEN to operate,
- Best surgeons know when NOT to operate.

High-Risk Patients with Spinal Disorders

Alekos A. Theologis, MD

Assistant Professor
Department of Orthopaedic Surgery
University of California - San Francisco (UCSF)

15th Annual UCSF Spine Symposium
6.6.2020

Disclosures

- **Research**
  - NIH
  - Innovasis
- **Consulting**
  - Depuy Spine
  - Alphatec
  - Intuitive Surgical
- Educational Content Development
  - JBJS Inc.

Spine Surgery Can Help!

Spine (Phila Pa 1976). 2018 Dec 1;43(23):1619-1630. doi: 10.1097/BRS.0000000000002682.

Long-Term Results of Surgery Compared With Nonoperative Treatment for Lumbar Degenerative Spondylolisthesis in the Spine Patient Outcomes Research Trial (SPORT).

Abdu WA[1,2], Sacks OA[1], Tosteson ANA[1,3,4], Zhao W[1,2], Tosteson TD[1,4], Morgan TS[1,4], Pearson A[1,2], Weinstein JN[2,4], Lurie JD[1,3,4].

J Bone Joint Surg Am. 2019 Feb 20;101(4):338-352. doi: 10.2106/JBJS.18.00483.

Operative Versus Nonoperative Treatment for Adult Symptomatic Lumbar Scoliosis.

Kelly MP[1], Lurie JD[2], Yanik EL[1], Shaffrey CI[3], Baldus CR[1], Boachie-Adjei O[4], Buchowski JM[1], Carreon LY[5], Crawford CH 3rd[5], Edwards C 2nd[6], Errico TJ[7], Glassman SD[5], Gupta MC[1], Lenke LG[8], Lewis SJ[9], Kim HJ[10], Koski T[11], Parent S[12], Schwab FJ[10], Smith JS[3], Zebala LP[1], Bridwell KH[1].

- “If done for the right reason and done well!”

- Problem is that a lot of spine surgery is done for the wrong reason….

Derailed By Many Factors

“High Risk Patient”?

“Umbrella term” for patients with factors that have potential to jeopardize outcome

3 Categories

SOCIALLY RISKY

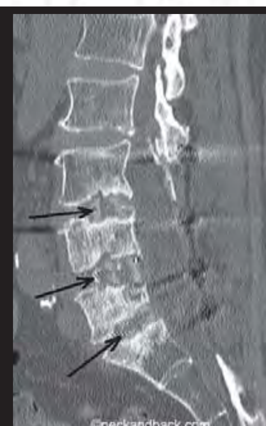
Int J Spine Surg. 2017; 11(4): 29.
Published online 2017 Nov 28. doi: 10.14444/4029

The Effect of Smoking on Spinal Fusion

Daniel Berman, BA,[1] Jonathan H Oren, MD,[2] John Bendo, MD,[3] and Jeffrey Spivak, MD[3]

Conclusions

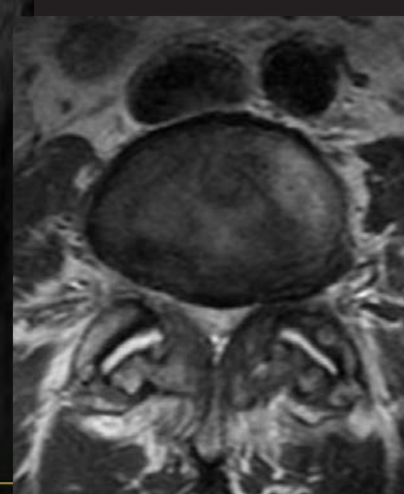
It has been clearly demonstrated from both a biochemical and clinical perspective that smoking increases the rate of perioperative complications for patients undergoing spinal fusion surgery, particularly pseudoarthosis. It has also been shown that there are certain approaches that can reduce the risk of morbidity. The most important recommendation is smoking cessation for four weeks after surgery. In addition, patients may be treated with certain surgical techniques, including the use of BMPs, to reduce the risk of pseudoarthrosis. Lastly, nicotine replacement therapy is an area of continued interest in relation to spinal fusion outcomes and more research needs to be done to determine its efficacy moving forward.



My Approach with Smokers…

- Unless patient has a neurological deficit….
- Smoking cessation!!!
  - x3 months (decompressions/short fusions)
  - x6 months (spinal deformity)
  - Nicotine/cotinine q1 month
- **I assume patients will never quit, so if one must operate, I try to avoid fusions at all costs**

- **52 yo female smoker with back and bilateral buttock pain**
- **Quit smoking x3 months (confirmed by nicotine/cotinine tests)**



L4 laminectomy

Resumed smoking
2 weeks post-op!

Illicit Drugs / Marginally Housed

The number of Norton Leatherman Spine patients with spine infections that required surgery increased twelvefold from 2012 to 2016.

By: Erica Coghill • Posted: November 8, 2018

Preoperative screening for illicit drug use in patients undergoing emergency surgery: A prospective observational study

Jingyi Li, He Ma, Ren Liao, Yanjuan Huang & Guiyong Chen

between the two groups. These findings suggested that the IDUs were associated with increased rates of HIV and syphilis infection; greater consumption of intraoperative opioids, sedatives, and muscle relaxants; increased postoperative complications and a similar mortality rate within 30 days after surgery when compared with non-IDUs.

- 50 year old female
- Back pain, difficulty standing upright, poor cosmoses
- Let's operate!
- Further investigation…

- 47 kg
- Lives in half-way house
- h/o HIV (CD4 954; VL UD)
- h/o IVDU (cocaine, meth)
- Plan
  - Weight gain (~30lbs)
  - qMonth (random drug tests) x1 year

My approach to those who use illicit drugs

- qMonth (random drug tests) x1 year —> if one positive, year restarts
- Screening for HIV and hepatitis (HepB, HepC)
- Social worker consultation to assist with securing housing

J Arthroplasty. 2018 Sep;33(9):3003-3008. doi: 10.1016/j.arth.2018.05.007. Epub 2018 May 9.

Primary Hip and Knee Arthroplasty in a Safety Net Hospital: Substance Abuse and Other Factors Affecting Short-term Complications.

Jergesen HE[1], Thielen ZP[1], Roever JA[1], Vashon TT[1], Wu HH[1], Yi PH[1].

CONCLUSIONS: Specific risk factors were associated with short-term complications in safety net arthroplasty patients. Despite having completed a preoperative sobriety pathway, substance abuse patients had more complications than did others. However, substance abuse alone was not an independent risk factor for adverse surgical outcomes. Other factors, notably HCV and HIV infection that were more common in patients with substance abuse, were most closely associated with adverse outcomes.

MEDICALLY RISKY

- **Wound healing**
  - Rheumatologic disorders (immunosuppressed)
  - Diabetics
  - Cancer (post-radiation, chemotherapy)
- **Bone healing / mechanical complication**
  - Nutritionally deficient
  - Osteoporosis
- **Bleeding**
  - Anemia
  - Thrombocytopenia
- **Other**
  - Elderly
  - Obesity
  - Revision surgeries

Pre-Operative Optimization (Modifiable?)

- **Wound healing**
  - Rheumatologic disorders (immunosuppressed) → Stop immunosuppressants as recommended
  - Diabetics → HgA1 < 7.5
  - Cancer (post-radiation, chemotherapy) → Surgery at least 2 weeks after last spine radiation and chemo; resume both 3 wks post
- **Bone healing / mechanical complication**
  - Nutritionally deficient → Albumin > 3.5; BMI>20
  - Osteoporosis → DEXA forearm/spine/hip —> T-score<-2.0 = Teriparatide x3 months preop/9 months post (all deformities irrespective of age)

Non-Modifiable

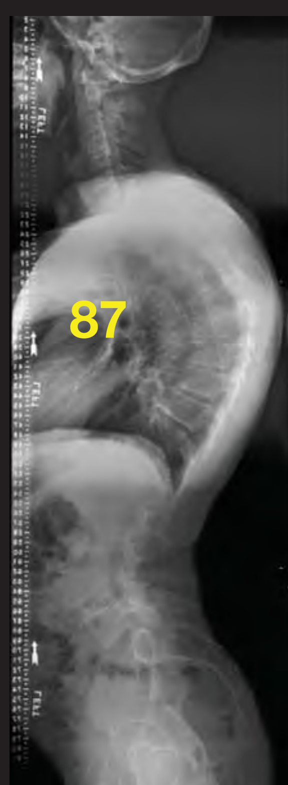
- **Bleeding**
  - Anemia
  - Thrombocytopenia

  →
  1) Pre-op (EPO?)
  2) Intraop (cell-saver, adjust surgical technique —> MIS if possible)
- Other
  - Elderly
  - Obesity
  - Revision surgeries

  →
  1) Dobutamine cardiac stress test
  2) PFTs
  3) Consider preop IVC filter

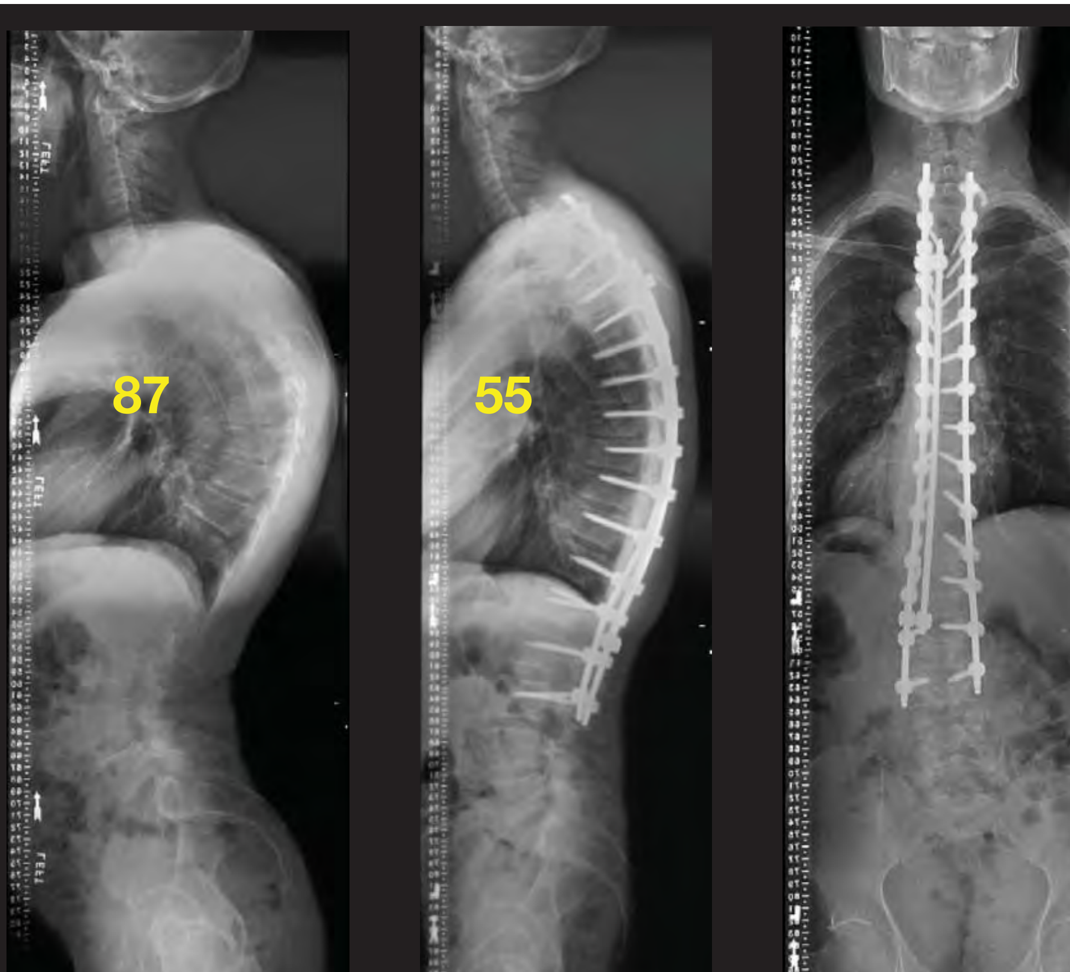
Case Examples

Case #1



- 52 year old male
- Referral from local spine surgeon
- Severe back pain and dislikes posture/cosmesis
- Housed
- Piano player
- Let's operate!
- Addition work-up…
  - DEXA spine/forearm/hip —> T-score hip -2.7

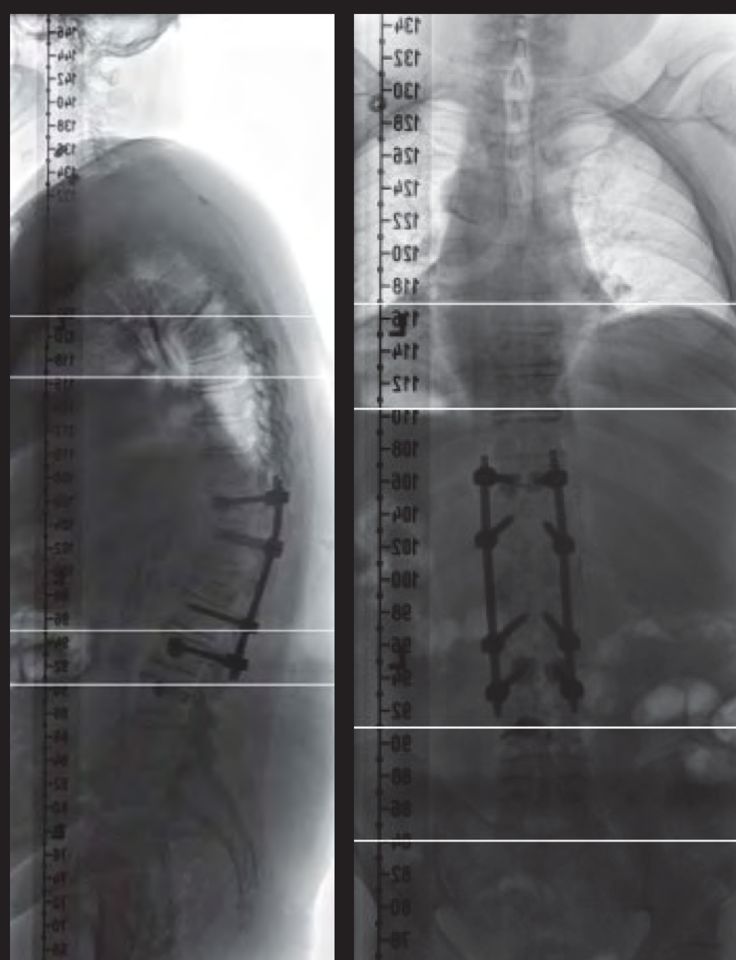
- Teriparatide x3 months pre-op, then 9 months post-op



Case #2

- 74 year old male
- h/o metastatic prostate cancer with new met to L1
- Severe back pain when sitting and standing); unable to walk because of back pain
- No leg pain
- Neurointact
- H/o
    - Radiation to L1 one week prior
    - BMI 34 (250lbs)
    - Chronic thromocytopenia (~50s —> unresponsive to transfusions, IVIg)

- Pre-Op Plan
    - Percutaneous T11-L4 posterior instrumentation w/cement augmentation T11, L4, L5
    - If neuromonitoring changes intro —> laminectomy and possibly VCR
    - Dobutamine cardiac stress test
    - Angiogram/embolization
- Intraop
    - Pre-flip baseline neuromonitoring: normal
    - Post-flip signals: no change
    - EBL 50cc
- Postop
    - Immediate relief of back pain (only tylenol)
    - Discharge home



PSYCHIATRICALLY RISKY

J Neurosurg Spine. 2016 Oct;25(4):477-485. Epub 2016 May 6.

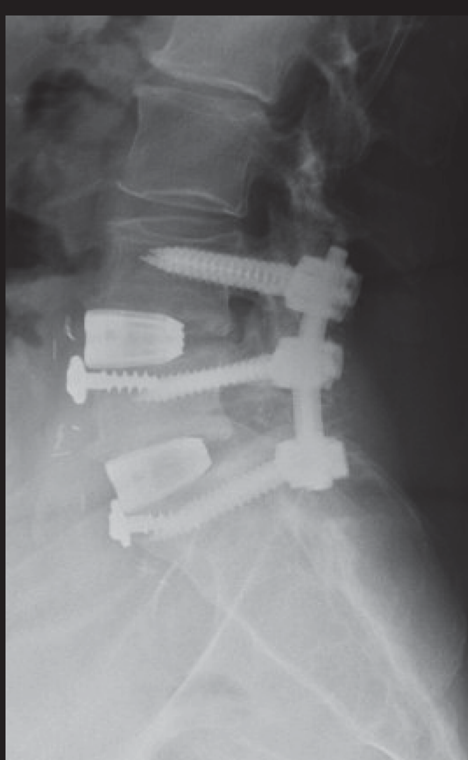
Impact of preoperative depression on 2-year clinical outcomes following adult spinal deformity surgery: the importance of risk stratification based on type of psychological distress.

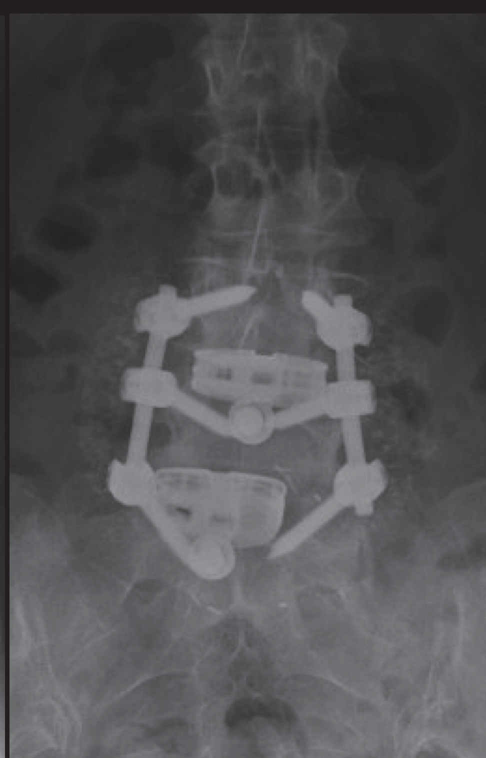
Theologis AA[1], Ailon T[2], Scheer JK[3], Smith JS[2], Shaffrey CI[2], Bess S[4], Gupta M[5], Klineberg EO[5], Kebaish K[6], Schwab F[7], Lafage V[7], Burton D[8], Hart R[9], Ames CP[10]; International Spine Study Group.

CONCLUSIONS A baseline clinical history of depression does not correlate with worse 2-year outcomes after ASD surgery after adjusting for baseline differences in comorbidities, health-related quality of life, and spinal deformity severity. Conversely, DRAM improved risk stratification of patient subgroups predisposed to achieving suboptimal surgical outcomes. The DRAM's MSPQ was more predictive than MCS and SRS mental domain for 2-year outcomes and may be a valuable tool for surgical screening.

Normal	At Risk
Distressed Depressive	Distressed Somatic

60yo female w/back pain and bilateral L5 radicular pain —> 100% improved with two selective L5 nerve root blocks





- ED visit 6 times post-op (last 6 months)
- “urinary and bowel incontinence” and leg weakness —> all normal neurological exams, PVRs 0cc
- MRIs/CT - all normal
- Neurology consult - no localizing symptoms

Conclusions

- High risk patients with spinal disorders
  - Challenging
  - Scrutinize patients’ social, medical, and psychiatric risk profiles
  - Attempt to optimize the optimizable
  - Taylor surgical technique to pathology

- Note: Device shown is TSRH

Finito!

Optimization of Patient Outcomes Along the Continuum of Care

Kushagra Verma, MD, MS
UCSF Fellow 2015 2016
Founder, Verma Spine

Long Beach Memorial and
Miller Children’s Hospital

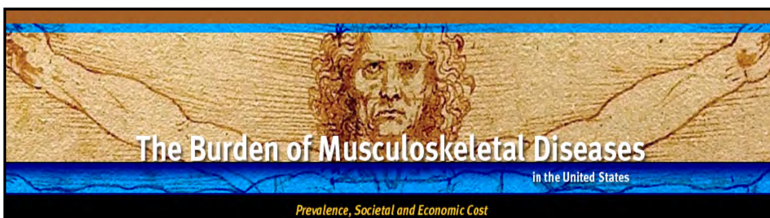
Disclosure

Consulting: Aegis Spine, Depuy Synthes, Medtronic, NuVasive, Innovasis

Special thanks Sigurd Berven for sharing some slides and content

Overview

- Broad Spectrum of Spinal Disorders
  - Multiple Disciplines involved in Spine
  - Variability in Care
- Optimization across the Continuum of Care
  - Non-operative
  - Operative
  - Pre/Postoperative
- Interdisciplinary Collaboration
- Accountability for Outcomes of Care
  - HRQL
  - Research
  - Patient education ➔ Informed Choice

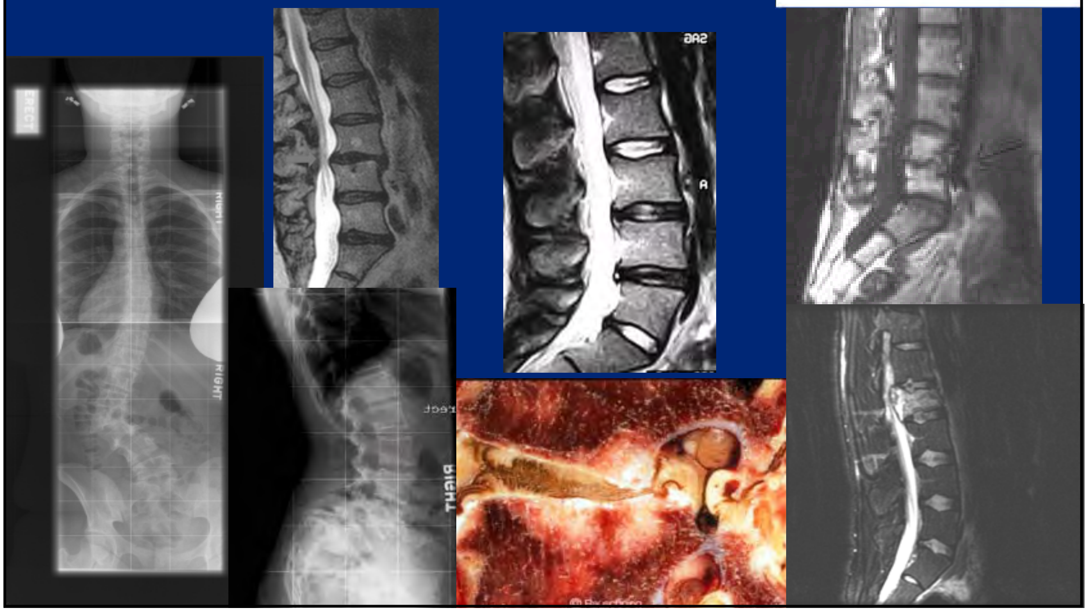


Defining the Burden of Disease

- Prevalence of Disorder
- Health Care Utilization
- Economic Cost
- Impact of Disorder
  - Disability
  - Impact on Health-related Quality of Life

Spectrum Disorders of the Spine

UCSF Health
Redefining possible.



Multidisciplinary Care

UCSF Health
Redefining possible.

MemorialCare
Miller Children's & Women's Hospital Long Beach

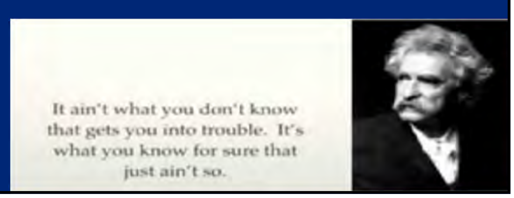
- Orthopaedic Surgery
- Neurosurgery
- Physiatry
- Anesthesia
  - Pain management
- Radiology
- Neurology
- Oncology
- Infectious Disease
- Primary Care
- Emergency Care
- Rheumatology
- Physical Therapy

Variability

- There is significant variability in operative and non-operative care
- An evidence-based approach to care guided by clinical outcomes research and predictive modelling may reduce variability in care

Reducing Variability

- Variability is a proxy for quality of care
  - Reducing variability ➔ improved quality of care
- Clinical Practice Guidelines
- Appropriate Use Criteria
  - Areas of Consensus
  - Areas of Discordance
  - Areas for Further Study



Rand/UCLA AUC Methodology

UCSF Health
Redefining possible.

Making Informed Choices under conditions of Uncertainty

Instructions for Rating Management Procedures and Strategies

	Inappropriate			Reasonable			Appropriate			
Most inappropriate	1	2	3	4	5	6	7	8	9	Most appropriate

An ***inappropriate*** procedure or management strategy is defined as one in which **the value (benefit per unit cost) is LOW**: The expected negative consequences exceeds the expected health benefit such that the procedure should not be performed.	A ***reasonable*** procedure or management strategy is one in which: The balance of risk and benefit are not known, but there is a reasonable chance of positive net benefit, with limited risk.	An ***appropriate*** procedure or management strategy is defined as one in which **the value (benefit per unit cost) is HIGH**: The expected health benefit exceeds the expected negative consequences by a sufficiently wide margin that the procedure is worth doing.

Fitch et al. 2001

Academic Spine Mission

UCSF Health
Redefining possible.

MemorialCare
Miller Children's & Women's Hospital Long Beach

– Comprehensive and effective spine treatment across the continuum of care
– Evidence-based approach
– Education locally and nationally for surgeons
– Apply latest innovation in spine while optimizing value
– Promote collaboration and shared learning
– Research to incrementally improve outcomes

Continuum of Care

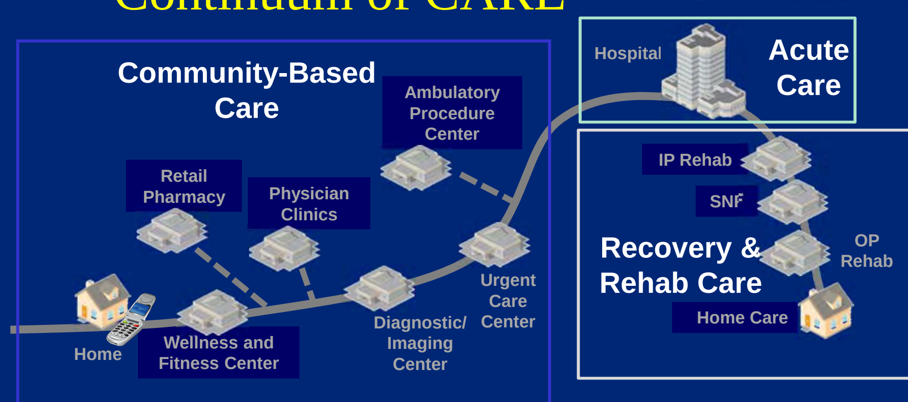
UCSF Health Redefining possible.

MemorialCare. Miller Children's & Women's Hospital Long Beach

- Non-operative Spine
  - Pain Management , PT and Radiology to create an integrated non-operative spine service
- Pre-habilitation
  - Education, nutrition, therapy, comprehensive work-up
- Operative Care
  - Collaboration with anesthesia
  - Dual surgeon approaches, multidisciplinary conferences, Ortho + Neuro
- Rehabilitation
  - Accountability After Discharge

Accountability Across the Continuum of CARE

UCSF Health Redefining possible.



"Expect to take on more financial risk and to be held accountable, clinically and economically, for what happens across the continuum of care—whether we 'own' the continuum or not."

—Michael Sachs, Chairman and CEO, Sg2

CARE = Clinical Alignment and Resource Effectiveness; IP = inpatient; SNF = skilled nursing facility; OP = outpatient.

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MemorialCare.
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Surgical Planning

- By failing to prepare, you are preparing to fail.
- **- Benjamin Franklin**

- Those who plan do better than those who do not plan even thou they rarely stick to their plan.
- **- Winston Churchill**

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Perioperative Surgical Home

Phase	Decision to Operate	Preoperative	Intra operative	Post operative	Post Discharge
Traditional	•Minimal pre-procedure planning	•Variable pre-op assessment, testing and medical treatment	•Provider choice anesthesia •Lack of standardized protocols	•Surgeon managed Post op •Few protocols	•Variable support often leading to ER

PATIENT

Shared Decision Making, Patient Centered Care

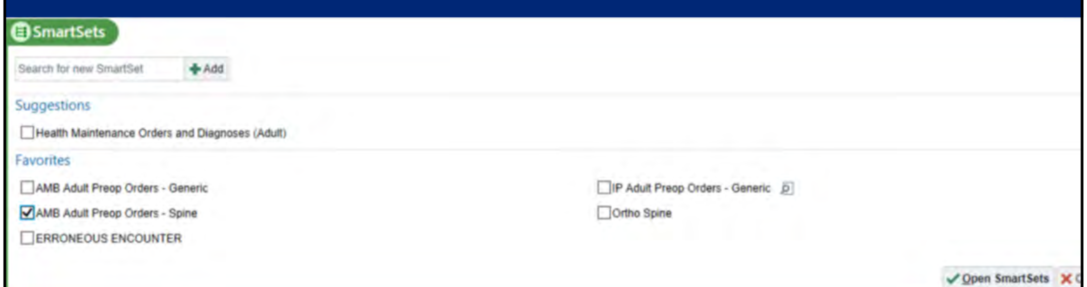
Surgical Home: Seamlessly Integrated, protocolized care at each phase of care

Pre-operative Considerations

Risk Assessment	Medical Optimization	Surgical Planning	Physical Optimization

• Assess risk/benefit
  • Appropriateness of surgery
• Align expectations
• Shared decision making
	• Smoking
	• Nutrition
	• Obesity
	• Diabetes
	• Cardiopulmonary
	• Bone Health
	• Narcotics
		• Multidisciplinary Planning
		  • Preoperative Planning Conference
		• Manage adjacent levels
		• Osteoporosis
		• Guidance system
			• General physical conditioning
			• BMI
			• Physical Therapy
			• Independence
			• Home Support

Standardized Ordersets



Preoperative Ordersets

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▾ Preoperative Optimization Referrals

▾ Preoperative Referrals

- [ ] Ambulatory referral to Social Work - Orthopedic Surgery
- [ ] Ambulatory referral to The Fontana Tobacco Treatment Center
- [ ] Ambulatory Referral to Skeletal Health
- [ ] Ambulatory referral to Anesthesiology
- [ ] Ambulatory referral to Pain Medicine
- [ ] Ambulatory referral to Surgical Wellness Program

- Variability in provider use
- Reliability of referrals

Discharge Position: Home vs All Others (Rehab Facility, Assisted Living, Long-Term Care Facility, Skilled Nursing Facility)

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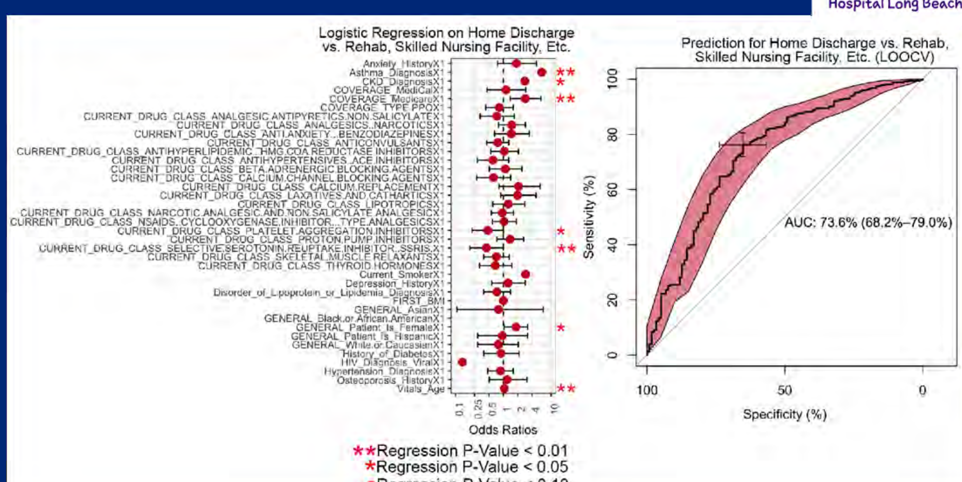

Intra-operative Considerations

Blood Conservation/Fluid Management
- Amicar/TXA
- Cellsaver
- Transfusion Protocol
- Colloid to Crystalloid ratio

Neuromonitoring
- Neuromonitoring protocols
- Algorithm for positive change

Surgical Technique
- Two attendings
- Protocol for staging
- Equipment
- Radiography
- Achieve goals of surgery
  - Intra-op
  - Post-op

Reduce complications
- Pain management
- Antibiotic prophylaxis
- Blood sugar control
- Normothermia

Post-operative Considerations

Pain Management
- Standardized protocol
- Chronic Pain Considerations

Mobilization
- Early Mobilization
- Post-op chairs
- PT protocols

Nutrition
- Early enteric feeding
- 2400kcal/d

Medical Complications
- DVT prophylaxis
- Delirium prevention
- Foley

Discharge Considerations

Home
- Preoperative Preparation
- Home Health Services
- PT/OT

Rehabilitation
- Mobilization protocols
- Communication of Care Plan
- Precautions

SNF
- Mobilization
- PT Protocols

Communication Pathways
- Health Loop
- Nurse Navigator
- Clinic Visits over ER visits
- Measuring outcomes and PROs

Post-operative Accountability

- Measurement of HRQoL/Registries
  - NASS
  - ISSG
  - SRS22, Other HRQL
  - Patient Videos

Conclusions

- Spinal Disorders encompass a broad spectrum of pathologies, and require care from multiple disciplines including non-operative and operative providers
- Optimal Management of Spinal Disorders requires interdisciplinary collaboration, and care plans that span the continuum of care
- Accountability across the continuum of care is an important goal for our spine service, especially in the era of healthcare reform
- Our Spine Surgical Home is directed to integration of the multiple disciplines that care for patients with spinal disorders, and the development of an evidence-based approach to care characterized by consensus rather than variability.

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San Francisco

Injections for Diagnosis of Spinal Pain

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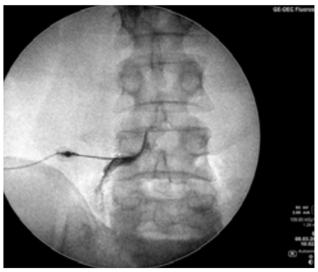
Department of Orthopedic Surgery

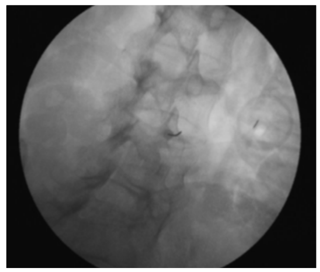
University of California
San Francisco

No relevant disclosures

Diagnostic Injections for the Lumbar Spine



Epidurals



MBBs/IAFs/RFAs

Joint Injections

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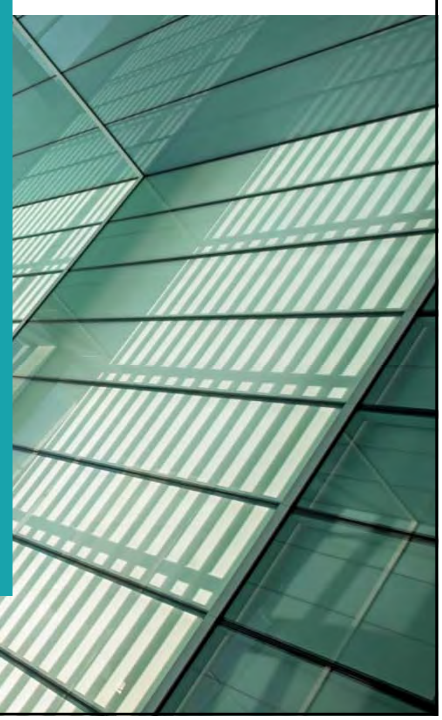
Spinal Procedures for Diagnosis of Facet Mediated Pain

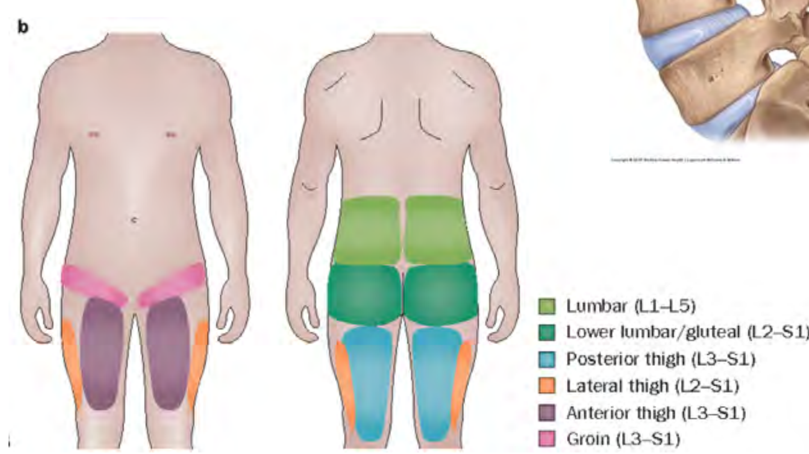
Patricia Zheng, MD
Assistant Professor
Nonoperative Spine and Physiatry
Department of Orthopedic Surgery



Content

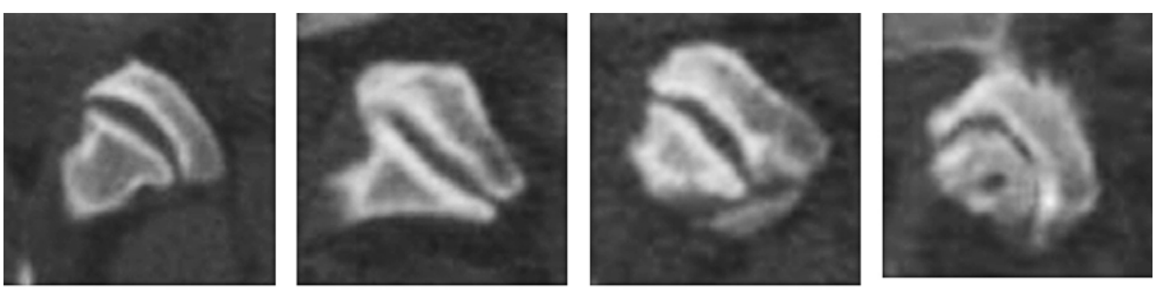
- Difficulties in diagnosing facet mediated pain (slides 6-10)
- Medial branch blocks (slides 11-22)
- Intra-articular facet joint injections (slides 23-33)
- Conclusions

Lumbar Facet Pain



Limited utility of physical exams

Limited utility of standard imaging



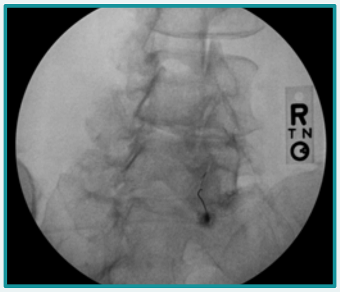
Grade I

Grade II

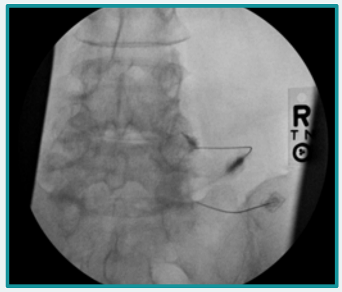
Grade III

Grade IV

Diagnosing facet mediated pain?



IAF



MBB

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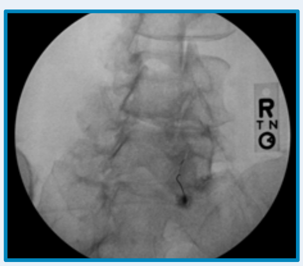
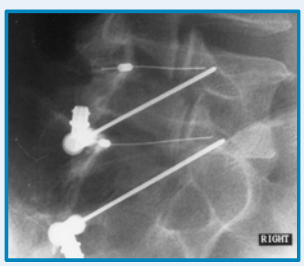
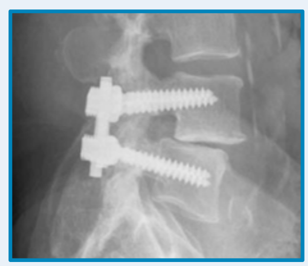
How to prove facet mediated pain?



IAF



RFA



Surgery

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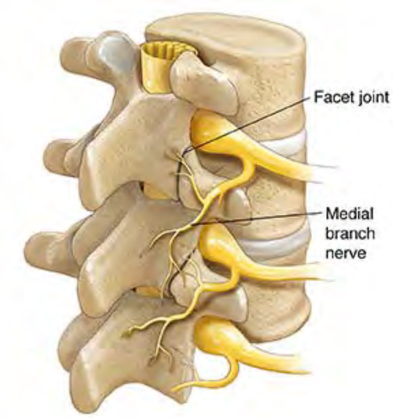
Medial Branch Blocks

Utility of medial branch blocks



Spine (Phila Pa 1976). 1998 Sep 1;23(17):1847-52

The ability of lumbar medial branch blocks to anesthetize the zygapophysial joint. A physiologic challenge.

Kaplan M[1], Dreyfuss P, Halbrook B, Bogduk N

Utility of medial branch blocks

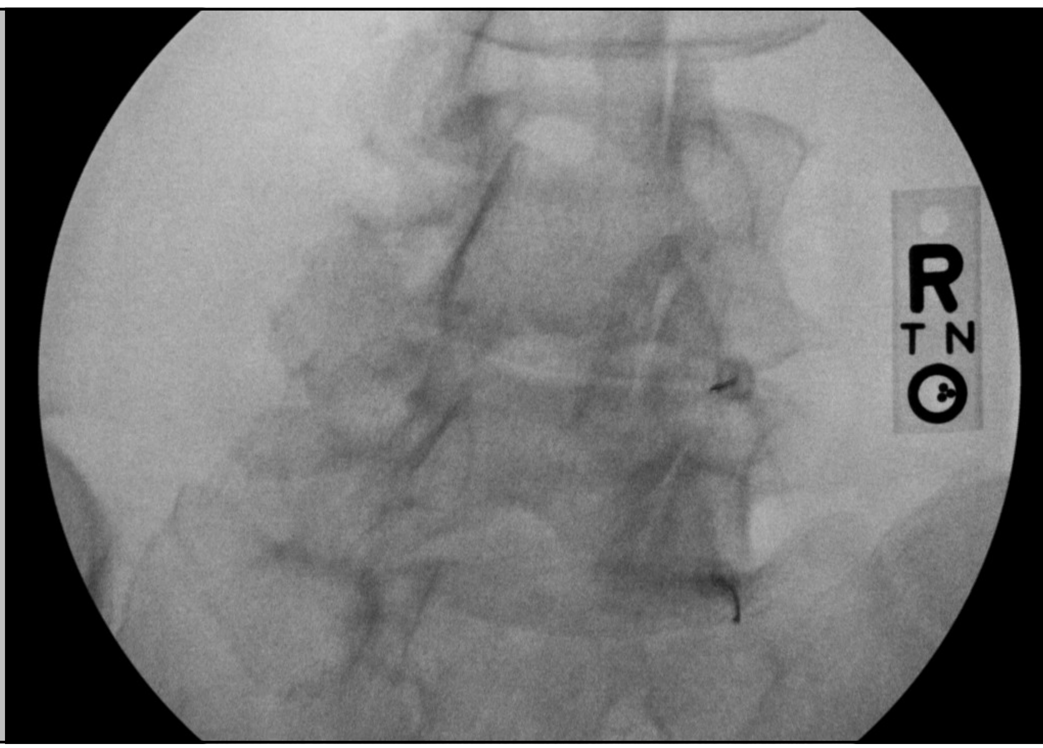
Table 1. The Ability of 2% Lidocaine or Saline Lumbar Medial Branch and L5 Dorsal Ramus Injections to Block Pain From the Lumbar Zygapophysial Joint Following Application of a Known Painful Stimulus in 14 Normal Volunteers (Fisher's Exact Test, $P = 0.003$)

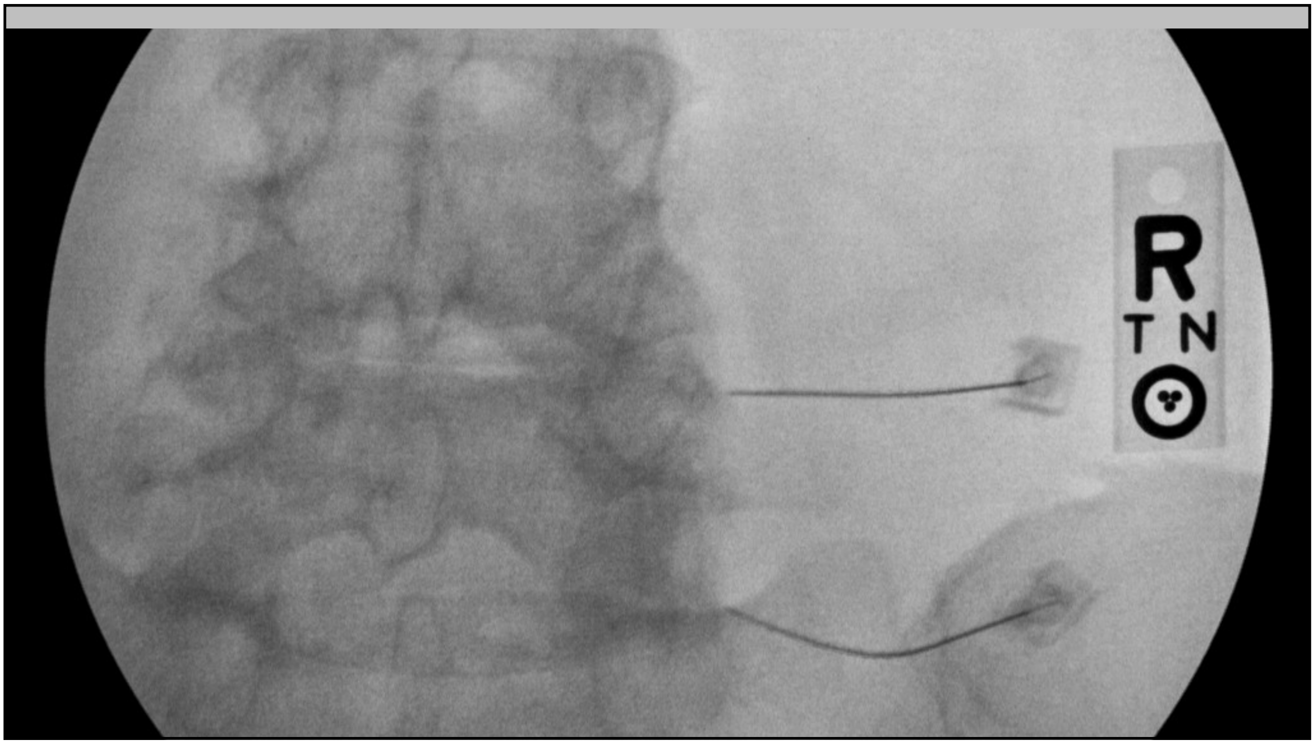
Injection Agent	Pain Evoked	No Pain Evoked
2% lidocaine	1	8
Saline	5	0

Spine (Phila Pa 1976). 1998 Sep 1;23(17):1847-52

The ability of lumbar medial branch blocks to anesthetize the zygapophysial joint. A physiologic challenge.

Kaplan M[1], Dreyfuss P, Halbrook B, Bogduk N





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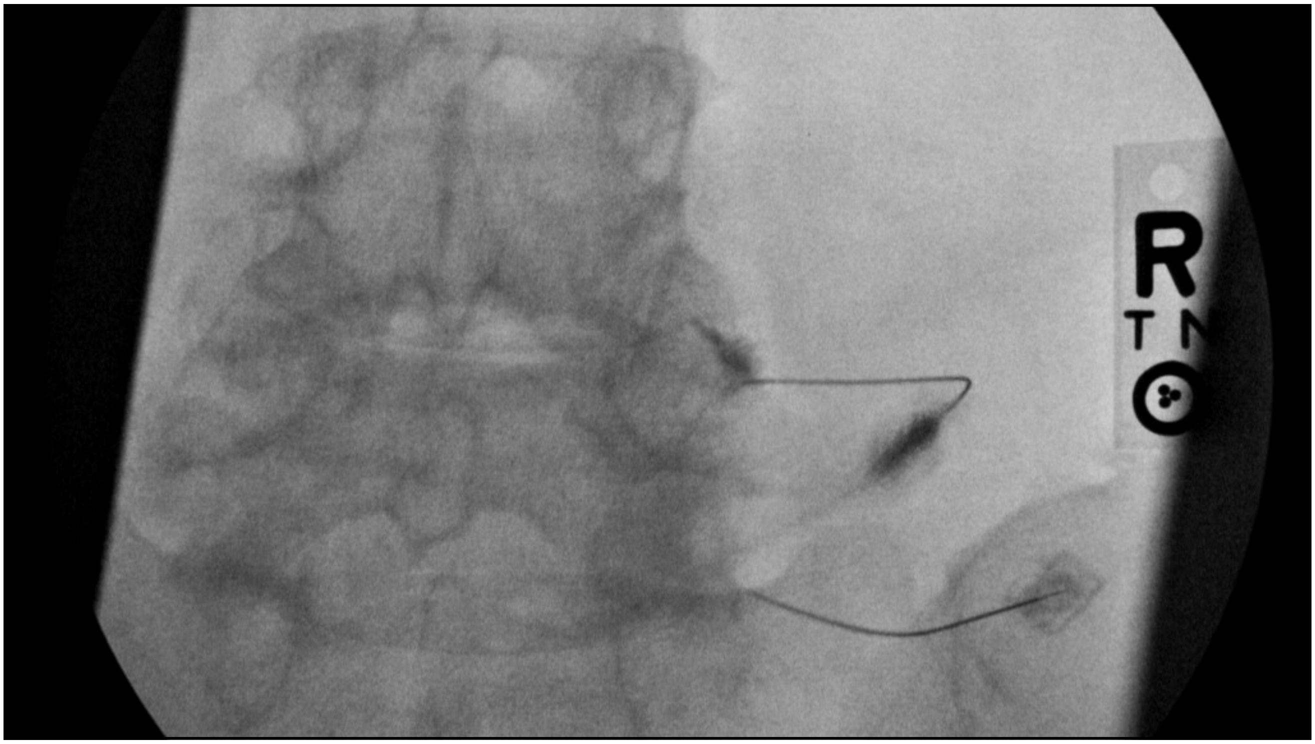
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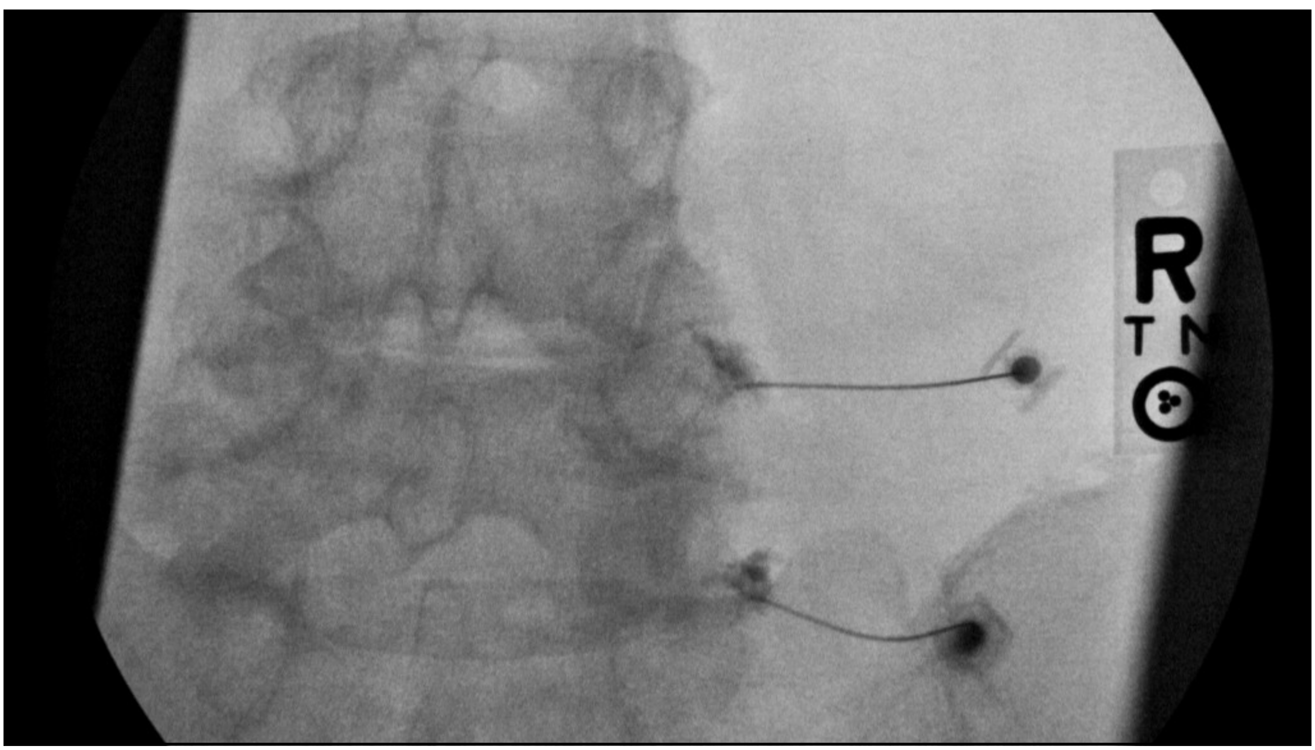
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Therapeutic value of medial branch blocks?

Curr Rev Pain. 2000;4(5):337-44.

The diagnostic validity and therapeutic value of lumbar facet joint nerve blocks with or without adjuvant agents.

Manchikanti L[1], Pampati V, Fellows B, Bakhit CE.

Int J Med Sci. 2010 May 28;7(3):124-35.

Evaluation of lumbar facet joint nerve blocks in managing chronic low back pain: a randomized, double-blind, controlled trial with a 2-year follow-up.

Manchikanti L[1], Singh V, Falco FJ, Cash KA, Pampati V.

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Cohen, 2018: Relief after facet blocks

	IAF (90)	MBB (91)	Saline (47)	p-value
1 month	11 (12%)	10 (11%)	3 (6%)	0.617
3 month	4 (4%)	4 (4%)	1 (2%)	>0.999
6 month	3 (3%)	0 (0%)	0 (0%)	0.400

Effectiveness of Lumbar Facet Joint Blocks and Predictive Value before Radiofrequency Denervation: The Facet Treatment Study (FACTS), a Randomized, Controlled Clinical Trial.

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Risk of intravascular injection

Pain Med. 2016 Jun;17(6):1031-1036. Epub 2016 Jan 6.

Detection of Intravascular Injection During Lumbar Medial Branch Blocks: A Comparison of Aspiration, Live Fluoroscopy, and Digital Subtraction Technology.

Kennedy DJ[1], Mattie R[2], Scott Hamilton A[3], Conrad B[4], Smuck M[2].

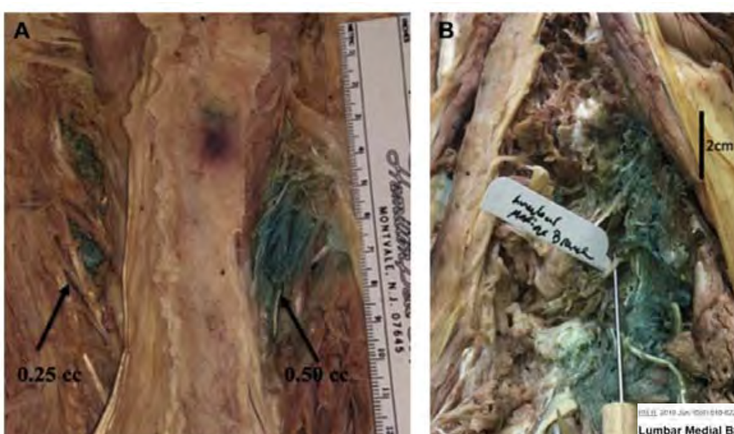
Author information

Anesth Analg. 2008 Apr;106(4):1274-8, table of contents. doi: 10.1213/ane.0b013e318162c358.

Intravascular injection in lumbar medial branch block: a prospective evaluation of 1433 injections.

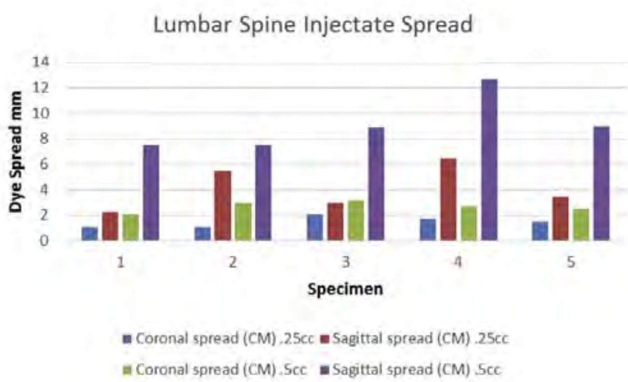
Lee CJ[1], Kim YC, Shin JH, Nahm FS, Lee HM, Choi YS, Lee SC, Ko JS, Kim TH, Sim WS, Kim CS, Cho HS.

Effect of injectate volume



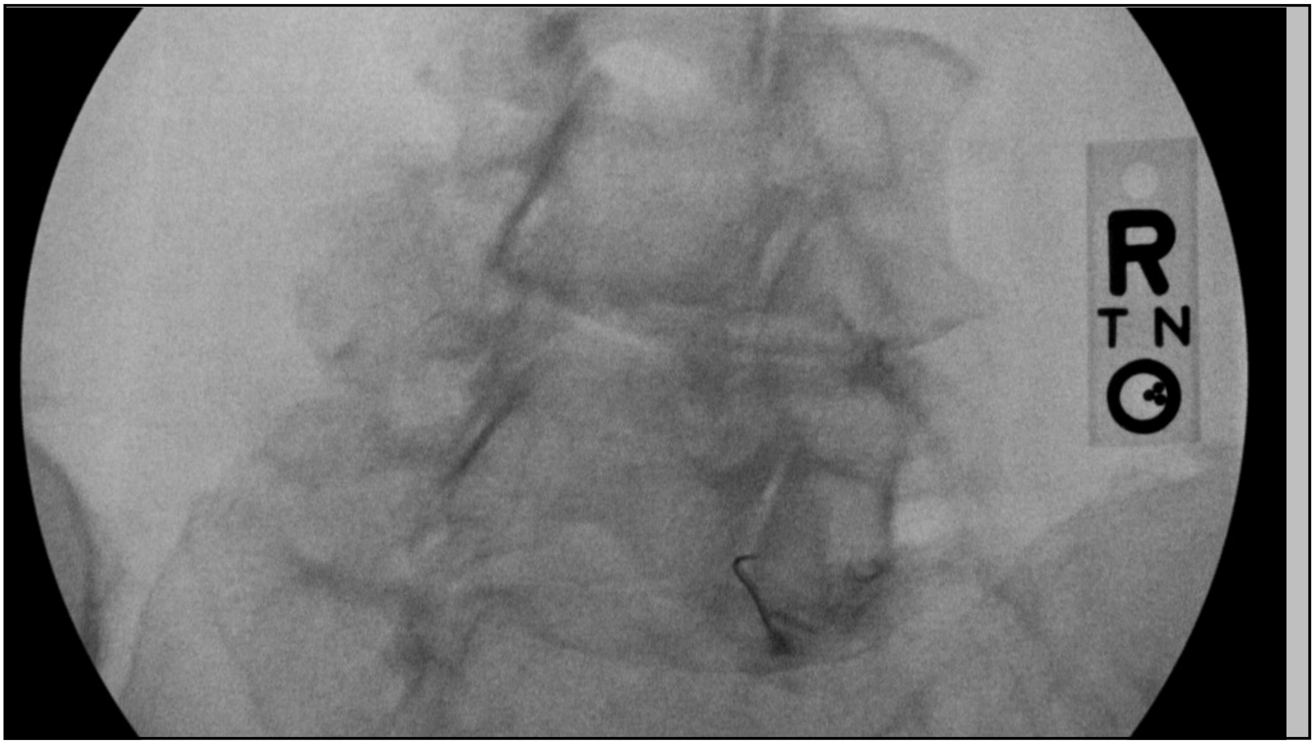
Lumbar Medial Branch Block Volume-Dependent Dispersion Patterns as a Predictor for Ablation Success: A Cadaveric Study.

Effect of injectate volume



Lumbar Medial Branch Block Volume-Dependent Dispersion Patterns as a Predictor for Ablation Success: A Cadaveric Study.

Intra-articular facet injections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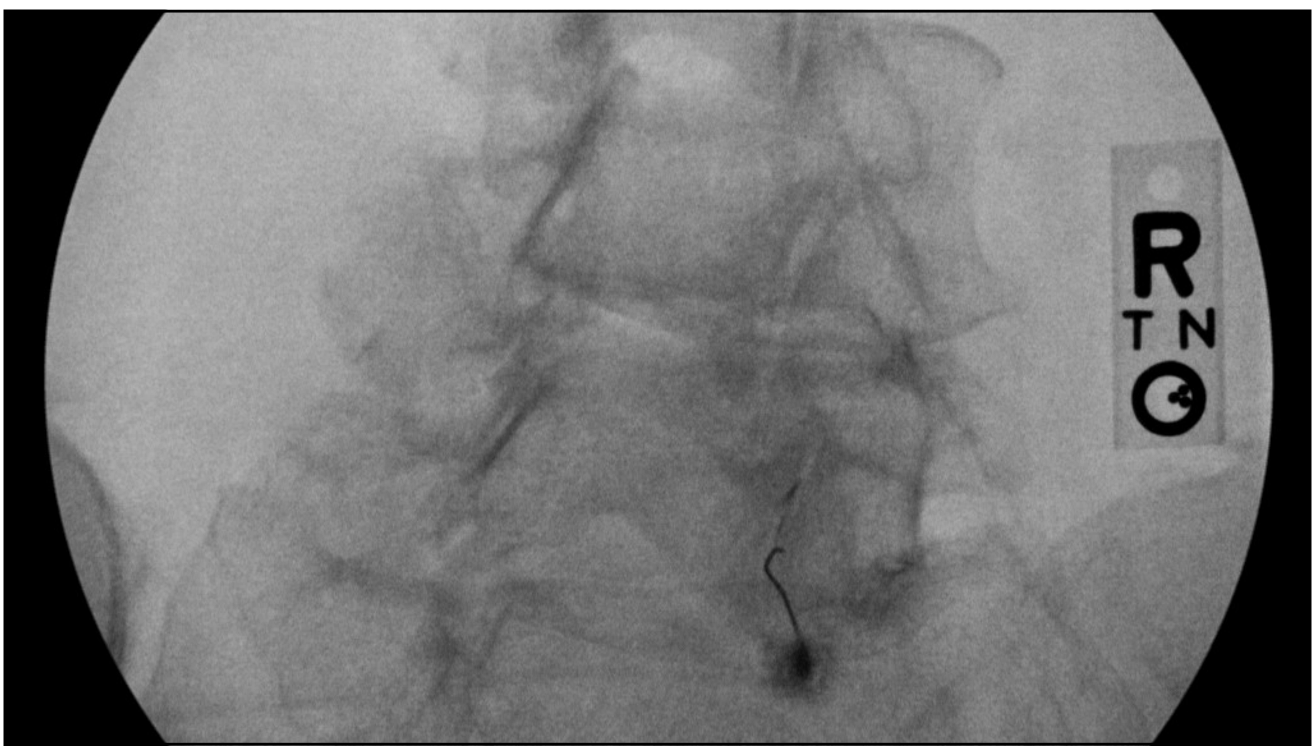
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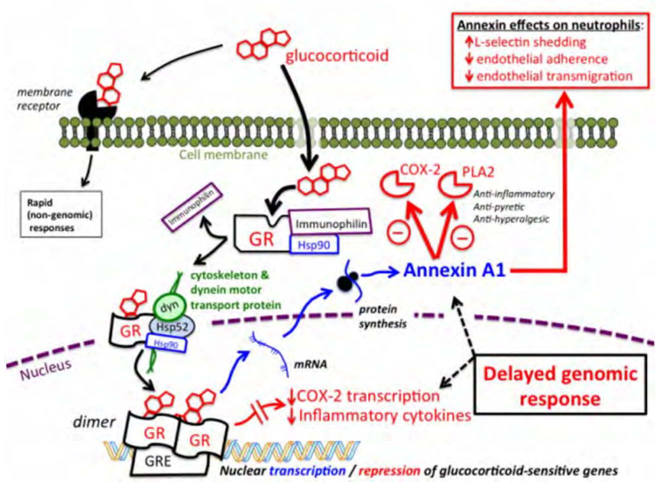
Rationale for corticosteroids



Likely only helpful for subset of patients

Author, Year	# Patients	Conclusion
Barnsley, 1994	41 neck pain	Lidocaine = steroids into cervical joints
Lilius, 1989	109 LBP	Both group improved at 3 months; no difference
Carrette, 1991	97 cLBP	No difference at 1 or 3 months

Likely only helpful for subset of patients

Radiology. 2006 Feb;238(2):693-8.

Low back pain: prediction of short-term outcome of facet joint injection with bone scintigraphy.

Pneumaticos SG[1], Chatzilioannou SN, Hipp JA, Moore WH, Esses SI.

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Diagnostic value of IAFs?

Anesthesiology. 2018 Sep;129(3):517-535. doi: 10.1097/ALN.0000000000002274.

Effectiveness of Lumbar Facet Joint Blocks and Predictive Value before Radiofrequency Denervation: The Facet Treatment Study (FACTS), a Randomized, Controlled Clinical Trial.

Cohen SP[1], Doshi TL, Constantinescu OC, Zhao Z, Kurihara C, Larkin TM, Griffith SR, Jacobs MB, Kroski WJ, Dawson TC, Fowler IM, White RL, Verdun AJ, Jamison DE, Anderson-White M, Shank SE, Pasquina PF.

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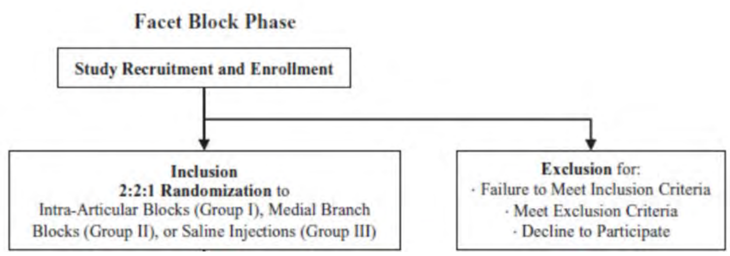
Design: Recruitment/randomization

- Prospective, randomized, controlled
- 2 (IA block): 2(MBB):1(saline)
- Blinding in blocks, injecting investigator was nonblinded, patient, nurse and evaluating physician were blinded



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Technique of blocks

- IAF
  - 22-gauge
  - Arthrogram confirmed
  - 0.25mL of 0.5% bupivacaine + 10mg of Depomethylprednisolone
- MBB
  - 22-gauge
  - Contrast spread confirmed
  - 0.25mL of 0.5% bupivacaine + 10mg of Depomethylprednisolone
- Saline
  - 22-gauge
  - Contrast spread confirmed as MBB
  - 0.5mL saline

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Design: Defining Outcomes

- 6 hour NRS pain diary in 30 minute intervals
- Positive single block constituted ≥50% pain relief for at least 3 hours
- Follow up at 1 month/3 month/6 month or until return of pain
- Also for those who went on to RFA, follow up at 1 month/3 month/6 month or until return of pain

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Results: Relief after blocks (categorical)

	IAF (90)	MBB (91)	Saline (47)	p-value
1 month	11 (12%)	10 (11%)	3 (6%)	0.617
3 month	4 (4%)	4 (4%)	1 (2%)	>0.999
6 month	3 (3%)	0 (0%)	0 (0%)	0.400

34

Results: Relief after RFA based on block (categorical)

	IAF (90)	MBB (91)	Saline (47)	p-value
1 month	30 (67%)	35 (73%)	16 (38%)	0.002
3 month	23 (51%)	27 (56%)	10 (24%)	0.005
6 month	14 (31%)	20 (42%)	7 (17%)	0.036

Conclusion

- Diagnosing facet mediated pain is still an imperfect science
- MBBs and IAFs are both acceptable
  - Balance theoretical advantage of MBBs vs possible therapeutic effects of IAFs

Citations

1. Schwarzer, A. C., Aprill, C. N. & Bogduk, N. The sacroiliac joint in chronic low back pain. *Spine* **20**, 31–37 (1995).

2. Kaplan, M., Dreyfuss, P., Halbrook, B. & Bogduk, N. The ability of lumbar medial branch blocks to anesthetize the zygapophysial joint. A physiologic challenge. *Spine* **23**, 1847–1852 (1998).

3. Cohen, S. P. *et al.* Randomized Placebo-Controlled Study Evaluating Lateral Branch Radiofrequency Denervation for Sacroiliac Joint Pain. *Anesthesiology* **109**, 279–288 (2008).

4. Cohen, S. P. *et al.* Multicenter, Randomized, Comparative Cost-effectiveness Study Comparing 0, 1, and 2 Diagnostic Medial Branch (Facet Joint Nerve) Block Treatment Paradigms before Lumbar Facet Radiofrequency Denervation. *Anesthesiol. J. Am. Soc. Anesthesiol.* **113**, 395–405 (2010).

5. Lee, C. J. *et al.* Intravascular Injection in Lumbar Medial Branch Block: A Prospective Evaluation of 1433 Injections. *Anesth. Analg.* **106**, 1274–1278 (2008).

6. Derby, R., Melnik, I., Lee, J.-E. & Lee, S.-H. Correlation of Lumbar Medial Branch Neurotomy Results with Diagnostic Medial Branch Block Cutoff Values to Optimize Therapeutic Outcome. *Pain Med.* **13**, 1533–1546 (2012).