Physician Owned Distributor (POD) UCI Ethics Symposium Feb 28, 2014

Scott Lederhaus, M.D.

President Association of Medical Ethics (AME) 2014

Lederhaus, S: Physician-Owned Distributors: The Wave of the Future or End of the Model? Ethics in Biology, Engineering & Medicine—An International Journal 2(4): 233-247 (2011)

CONFLICTS OF INTEREST

- 1 % ownership in the Casa Colina Outpatient Surgery Center, Pomona, CA
- Less than 1% limited ownership in the San Antonio Gamma Knife Center, Upland, CA (made no money in 7 years)
- No consulting arrangements
- No no royalty payments
- No membership in a physician owned distributor, POD
- No money paid back to me in any fashion for use of any implantable devices of any kind.
- No money paid to me by AME for anything.

Physician Owned Distributors (PODs)

Legal or "Inherently Suspect?"

OR

Legal or Unethical & Immoral

OR

Money Corrupts, More Money Corrupts More.

What is a POD?

A POD is a business entity whereby a physician investor purchases shares in the entity which serves as a purchaser and distributor for the implants a surgeon utilizes in his patients. Money is paid back to the POD owner for use of the implants in his/her patients.

POD Supporters Claim:

"Legal" Models

Savings to the Hospital on the implants

Volume purchases for the Hospital

Increased income for the surgeons

Limited or no use of company reps

No conflict of interest

Arguments Against PODs

- Costs may increase due to financial incentives by the physicians to use the POD implants.
- Unfair competition for the hospital and non-POD users.
- Conflicts of interest.
- Questionable quality of implants.
- Question of where the implants are made?
- Pressure on the hospitals to use the implants.
- Are PODs ethical? Are they legal?
- Predatory Pricing.

Potential Laws against the POD

Anti-Kickback (Medicare and Medicaid Patient Protection Act of 1987, CRIMINAL)

Stark Laws (Prohibition of Self Referral for DHS, CIVIL)

False Claims Act (unnecessary services, fraud, Whistleblower)

Civil Monetary Penalty

The California Anti-kickback Statute

California's Physician Outpatient Referral Act (PORA)

Anti-Kickback Statute

Induce Referrals from anyone

Criminal/Civil

The Medicare and Medicaid Patient Protection Act of 1987 (the "Antikickback Statute"), whoever *knowingly* and *willfully (intent must be proven)* offers, pays or solicits any remuneration directly or indirectly, overtly or covertly in return for *referring* an individual for which payment may be made in whole or in part under Medicare or a State health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

Anti-Kickback

- To be found guilty of violating the criminal statute a transaction must be "intended" in the action. The parties do not have to intend to break the law. They just have to intend to engage in a transaction prohibited by the law. In the context of the Anti-Kickback Statute, this means the parties have to intend to give, receive, solicit or arrange for some item of value in exchange for referrals in a manner prohibited by the statute. Example: a hospital doing business with a POD to ensure patient referrals by the physician with paying, soliciting, receiving anything to induce referrals.

- If one purpose is to **induce referrals**, then the Antikickback Statute is violated. Id. at 71.

Safe Harbor Protection From Kickback laws

- The OIG/DHS 1/23/89 Fraud/Abuse Alert. Physicians could invest and receive payment for referrals and avoid anti-kickback laws for their referrals.

Allows for certain arrangements when the entity is:

- Not publicly traded.
- No more than 40% income from physician investors.
- No more than 40% physician owned.
- Receive no referrals from investing physicians.
- Passive investors treated no different than physician investors.
- Passive investors are not required to make referrals.
- Physician owners do not have to divest their interest when they retire.
- Payments are not directly related to the volume of referrals.

Physician Self Referral Act (The Stark Law)

- CMS (Centers for Medicare and Medicaid Services).gov website:
- Section 1877 of the Social Security Act (the Act) (42 U.S.C. 1395nn), also known as the physician self-referral law and commonly referred to as the "Stark Law":
- Prohibits a physician from making referrals for certain Designated Health Services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies.

Physician Self Referral Act (The Stark Law)

- Intends to control unnecessary spending that arise from improper financial relationships with Federal programs. A self referral is a direct relationship.
- Indirect relationship is a Stark exception.
- *Intent* to violate the law does not matter.
- Any physician who has a "financial relationship" defined as a owner of a entity or compensation arrangement with the entity. Cannot make a claim to Medicare for a prohibited referral.
- Prohibits Medicare payments for any DHS services referred by a physician with a prohibited financial relationship.
- Penalties: fines and exclusion from Medicare/Medicaid

Designated Health Services (DHS) Stark Law provisions

PROHIBITS A PHYSICIAN FROM SUBMITTING CLAIMES FOR DHS TO A ENTITY FOR WHICH A PHYSICIAN HAS A FINANCIAL RELATIONSHIP UNLESS THERE IS A EXCEPTION

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

SPINAL IMPLANTS ARE NOT DHS, BUT WHEN IMPLANTED IN A HOSPITAL SETTING THE SERVICE IS A DHS, THUS STARK IS ALWAYS IMPLICATED.

Indirect Compensation
(a Stark Exception)

- In order to avoid the need for Stark exceptions, HLB claim to have set up a legal POD by using the Indirect Compensation exception.
- Indirect compensation is a Stark exception but not relevant to anti-kickback laws.
- Products are sold at fair market value, pricing competes with other companies, price does not vary and must be set out in writing, items sold by the POD and not the physician to the hospital.

False Claims Act

- The FCA is the primary civil enforcement tool for addressing health care fraud.
- The FCA may enforce penalties against any person who *knowingly* submits a false claim for unnecessary services. Fines 3x amount of damages.
- All AKL and Stark violations are actionable under the False Claims Act.
- Whistleblower applies.

Civil Monetary Penalty

- Refers to false claims or offering or paying remuneration to induce the referral of Federal care program business.
- Claims to a Federal health care program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent and violates the anti-kickback statute by knowingly and willfully: (1) offering or paying remuneration to induce the referral of Federal health care program business; or (2) soliciting or receiving remuneration in return for the referral of Federal health care program.
- Penalties: $10k to $50k per violation, but can be up to 3x remuneration

- Feb 2008 Mr. Gregory Demske of the OIG stated: "PODs will be closely scrutinized due to potential for abuse. These groups can be prosecuted under the Federal False Claims Act, Anti-kickback statute, or the Civil Monetary Penalty."

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California Physician Outpatient Referral Act (PORA)

Similar to the Stark Law, but applies broadly to referrals of ALL patients, including those with private health insurance or even cash patients.

Medicare Fraud and Abuse

What Is Fraud & Abuse?

FRAUD happens when Medicare is billed for services or supplies never received.

ABUSE occurs when doctors or suppliers don't follow good medical practices, resulting in unnecessary costs to Medicare, improper payment, or services that aren't medically necessary.

This could prompt a OIG/DOJ/FBI investigation.

www.medicare.gov

Senate Finance Committee
Senator Hatch

- A June 2011 overview of key issues. PODs began in 2003, branched out to orthopedics, spinal implants, cardiac pacemakers and other implants.
- Multiple PODs in at least 20 states.
- 40 PODs in California (2011).
- Requested that PODs be included in the Sunshine Act.
- Requested that the DHS and CMS address loopholes in the POD model as they may relate to the upcoming accountable care organizations along with any conflicts of interest, safety concerns and impact on health care which are all “troubling issues about PODs.”

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The Sunshine Act

Provisions of the Patient Protection and Affordable Care Act.

- Medical Device and Medical Supply manufacturers must report to the HHS the payments or transfers of value made to covered recipients.
- CMS rules: PODs may be considered group purchasing organizations under the Sunshine Act and therefore are subject to the reporting obligations if finalized as proposed. PODs will be included in the reporting.

The "Legal" POD?

- Hopper, Lundy, Bookman (Feb 2011) Nagi, Oppenheimer
- "Not all of these business practices must be followed in every case, nor does observing these business practices alone guarantee that the physician-owned company is lawful. However, adopting these practices, under guidance from experienced legal counsel, will assist the company in navigating the complex laws and regulations that govern the health care field, and achieve its mission of providing medical devices to hospitals at lower costs, with a reasonable return on investment for its investors."

- My Conclusion: HLB will make a POD as legal as possible.

Dr. John Steinmann's POD set-up
Alliance Surgical Distributors
Arrowhead Orthopedics 30 orthopods

http://www.alliancesurg.com/

Attempt to appear to align with Safe Harbors protection and claims a indirect relationship with Stark laws.

Mini-PODs (Direct Implant to payment)

Treat non-utilizer owners no different than utilizer owners, or do they?

The Stance of the OIG in 2011

- Mr. Daniel Levinson, Inspector General of the OIG, provided a statement in September of 2011.
- The OIG will study PODs and give additional guidance.
- Some PODs are more legal than others and thus the OIG will have limited guidance regarding the business structure.
- The OIG will investigate on a as needed basis, but will not give any clear decision as to what constitutes a legal POD or if a POD can be legal.

Mr. Tom Bulleit of Hogan, Lovells in Washington, D.C.

(Attorneys for major implant companies)

Mr. Charles Oppenheim of Hooper, Lundy, Bookman in Los Angeles, CA (Health Care attorney group)

Webinar 9/18/12: Physician Owned Distributors & Device Companies: To Be or Not to Be?

Conclusion: no consensus of what constitutes a legal versus illegal POD model.

Oversight of POD Activity

PEER Review at the hospital level

Hospitals (liable for unethical or Incompetent physicians)

The California State Medical Board

The California State Attorney General (? Take over the Board)

Our Societies (AANS, CNS, AAOS, ABNS)

The OIG/DOJ

Other Issues with PODs

POD Physicians keep their ownership a secret.
Who are the PODs?
Why do they keep it a secret?
Many examples of egregious activity with POD physicians.
Can't get around "Predatory Pricing."
"Inherently suspect."

Office of Inspector General—Special Fraud Alert: Physician-Owned Entities March 26, 2013

Any POD with these issues raise major concerns: 1) corruption of medical judgment, 2) overutilization, 3) increase costs, 4) unfair competition.

Disclosure of involvement in a POD to a patient is not sufficient to assure against fraud and abuse.

The OIG will also be concerned with any physician who: 1) magnifies the number of cases, 2) if there are only a few members of a POD which correlates physician return with physician ownership, 3) alter their practice after being involved in a POD.

The OIG views PODs as "INHERENTLY SUSPECT" under the anti-kickback statute.

Office of Inspector General—Special Fraud Alert: Physician-Owned Entities March 26, 2013
The OIG is "***PARTICULARLY***" concerned when:

- Distributions that are not made in proportion to ownership interest, or paid different prices for their ownership due to expected or actual volumes used by the physicians.
- Physician owners condition their referrals to hospitals through coercion and implying they will force the hospital to use their implants or the business will be taken elsewhere.
- Physicians are required to use the POD implants.
- The POD retains the right to re-purchase the physician owner's interest if the physician is not using the POD devices.
- If the POD is a shell entity without appropriate product evaluations, maintain inventory in it's own facility or employ personnel necessary for the operations. (Trunk of car POD)
- When the hospital requires disclosure of interest but the POD's physician owners fail to inform or conceal through misrepresentations, their ownership in a POD.

Other Legal Risks with PODs

- When physicians become POD owners, they become resellers of implants are are subject to products liability lawsuits. They also become subject to FDA reporting requirements and fall under FDA jurisdiction for enforcement.

- As of Jan 1, 2013 all medical device manufacturers whose products are sold in the US must register with the FDA (overseas outsourcing will no longer be secret).

US Department of Health and Human Services, Office of the Inspector General

Physician-Owned Distributors of Spinal Devices: Overview of Prevalence and Utilization. Daniel Levinson, Inspector General, October 2013

A request by the Senate Finance Committee to investigate PODs for anti-kickback laws, growth of PODs and impact on Federal health care. 589 hospitals involved.

1. 20% of spinal fusions were from a POD in 2011.
2. POD implant costs were not less than non-POD devices.
3. Increased spinal surgeries 3 fold after purchasing from a POD.
4. POD Hospitals performed 28% more surgeries than non-POD hospitals.
5. Most hospitals did not require physicians to disclose POD use to patients.

The stance of Dr. James Bean 2012

- **James R. Bean, MD, FAANS,** is a past-president of the AANS (2008-09). He has served as CSNS chair (1997-1999), Washington Committee chair (2002-2004), AANS Bulletin editor (2003-2005) and AANS Treasurer (2004-2007). He currently is the AANS Professional Conduct Committee chair. The author reported no conflicts for disclosure.
- Are Physician Owned Distributors (PODs) Ethical? AANS Neurosurgeon, volume 21, November 2, 2012
- "The bias toward surgery often can be justified simply by *expanding accepted criteria*, and neglecting individual circumstances, such as age, symptom severity, degree of instability, functional capability, and alternative nonsurgical treatments. The surgeon's financial incentive may be magnified by the additional profit to be gained from the implanted surgical devices supplied by his own POD."
- "The hospital may overlook quality monitoring of the surgeons practice, particularly surgical indications, since quality is generally judged by lack of complications, not surgical necessity or choice of procedure."

Spinal Solutions, LLC, Murrieta CA Work Comp Fraud

- FDA approved implants made by U&I Corporation in South Korea.
- Spinal Solutions used Crowder Machine & Tool Shop in Temecula to copy the implants made by U&I.
- Thousands of implants used as counterfeits made by Crowder Machine & Tool.
- Screws put in at Riverside Community, St. Bernadine, Pacific Hospital of Long Beach, Tri-City Regional Medical Center in Hawaiian Gardens, CA.

"**Whistleblowers Allege Massive Spinal Fusion Scheme**" by Mr. Greg Jones, Western Bureau Chief for work comp August 5, 2013

Pacific Hospital of Long Beach
Mr. Michael Drobot, Mr. Ron Calderon

- Used Spinal Solutions, LLC spinal implants and owned International Implants, LLC in Newport Beach, CA.
- Paid spine surgeons kickbacks of $15k for lumbar and $10k for cervical fusion when using his implants. 33 surgeons involved.
- Paid State Senator Ron Calderon bribes to keep the “spinal pass-through” laws intact.
- Paid Calderon’s son high salary, as a bribe.
- Pacific Hospital was paid $500 million from worker’s comp from 2008 to 2013.
- Patients were transported over 100 miles to have their surgery at Pacific Hospital.
- Tri-City Hospital in Hawaiian Gardens also involved.
- Drobot Indicted on criminal charges on 2/21/14.
- Senator Calderon also indicted on criminal charges 2/21/14.
- Drobot and Calderon will cooperate with “Operation Spinal Cap.”
- Investigation being done by the FBI; IRS; California Department of Insurance; United States Postal Service, OIG.

$25 screw from China "Substantial Equivalent"

COST OF IMPLANTS
POD Implants are less expensive?

One hospital reported implant costs for one spine surgeon $4.6 million ($92,000 per week) in 2011.

My group of 4 surgeons for 2011
$1.3 million.

PREDATORY PRICING

Physicians involved in a POD are able to contract with insurance companies, HMO's, IPA's, etc., at a lower reduced fee for service or capitation arrangement than the non-POD physician.

This creates unfair business practice between POD and non-POD physicians.

Rewards POD physicians over non-POD physicians

May be a violation of the California Unfair Competition Law

Wall Street Journal Articles

Mr. John Carreyrou

Does My Surgeon Profit From My Implants?
7/27/13
Surgeons Eyed Over Deals With Medical-Device Makers
7/26/13
Taking Double Cut, Surgeons Implant Their Own Devices
10/08/11
Senators Request Probe of Surgeons
06/09/11
Hospital Bars Surgeon From Operating Room
04/13/11
Medicare Records Reveal Troubling Trail of Surgeries
03/29/11
Top Spine Surgeons Reap Royalties, Medicare Bounty
12/20/10

HOSPITAL REIMBURSEMENT FOR IMPLANTS

PPO INSURANCE: Each hospital will have their own contract with the insurance company. There may be implant carve outs. Most hospitals hope to just break even on the implant costs with PPO's.

HMO INSURANCE: each hospital will have a individual contract, similar to the PPO, but the reimbursement is less with the HMO's and usually the hospital will lose money on instrumented spine cases.

Medicare: each hospital is paid on a DRG and the hospital will receive whatever Medicare will pay for that DRG independent on how many levels are fused, etc.

High reimbursement for lien cases to hospitals and docs.

How Many Spine Cases can be done?

Most neurosurgeons perform 150 – 250 cases per year, usually about 70% spine.

My Data (averages from 1994 to present):
750 Consults/yr (70% spine consults)
175 Cases (70% spine surgery)
20 Lumbar fusions, (90% one level)
15 Cervical spine fusions
20-25% of consults are surgical.

Over-utilizers are being watched by Medicare
41 over-utilizers in the US: highest number of 3 or more lumbar fusions, 4 in California, 2 in LA area being watched.

AAOS Mission Statement

American Academy of Orthopedic Surgeons: 2011 Mission Statement: When a orthopedic surgeon receives anything of value including royalties, from a manufacturer, the orthopedic surgeon must disclose this fact to the patient. *It is unethical for a orthopedic surgeon to receive compensation (excluding royalties) from a manufacturer for using a particular device or product*. Fair market reimbursement for reasonable administrative costs in conducting or participating in a scientifically sound research clinical trial is acceptable."

AMA Mission Statement 2002

"Physicians may not accept any kind of payment or compensation from a drug company or device manufacturer for prescribing its products. Furthermore, physicians should not be influenced in the prescribing of drugs, devices, or appliances by a direct or indirect financial interest in a firm or other supplier, regardless of whether the firm is a manufacturer, distributor, wholesaler, or re-packager of the products involved."

AANS Code of Ethics

AANS states in their 2008 Code of Ethics: It is unethical for a neurosurgeon to receive compensation of any kind from industry in exchange for using a particular device or medication in clinical practice. A neurosurgeon who has influence in selecting a particular product or service for an entity (organization, institution) shall disclose any relationship with industry to colleagues, the institution and other affected entities. *A "conflict of interest" occurs when a neurosurgeon or an immediate family member has, directly or indirectly, a financial interest or positional interest or other relationship with industry that could be perceived as influencing the neurosurgeon's obligation to act in the best interest of the patient*.

CANS requested a update in 2012 to include PODs

How to know if a doc is involved in a POD and involvement is denied

- Use of a distributor where information is not readily available on the Internet.
- Use of a product that is not known to be a reputable company.
- Cannot find information about the product being used, who makes it or where it is made.
- If the surgeon is resistant to change implants to a different company.
- Suspect if frequent, multilevel fusion procedures are being done, particularly on capitated, unfunded or Medicaid patients.

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Physician’s and their PODs

James Makker---Portland, Omega Solutions
Aria Sabit---Ventura, Apex Medical Technology
Atiq Durrani---Cincinnati, Evolution LLC

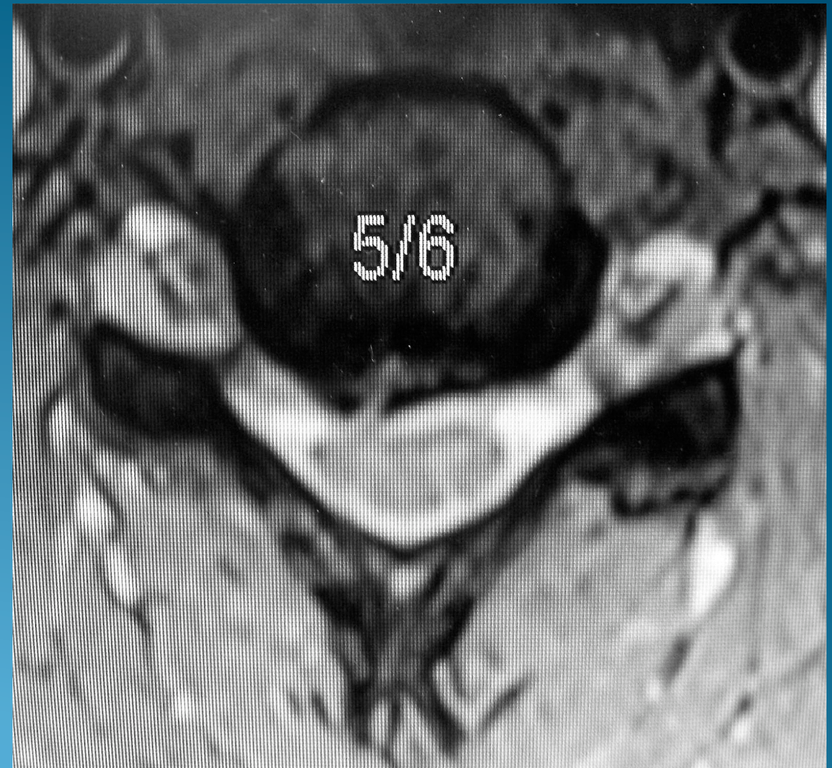
Hospital Liability

In *Elam,* the Court of Appeal held that a hospital may be liable under the doctrine of "*corporate* negligence" for the malpractice of independent physicians and surgeons who were members of hospital staff, and availed themselves of the hospital facilities, but were not agents or employees of the hospital.
(*Elam, supra,* 132 Cal.App.3d at p. 335, 183 Cal.Rptr. 156,)[9] That was because a hospital generally owes a duty to screen the competency of its medical staff and to evaluate the quality of medical treatment rendered on its premises.
(*Id.* at p. 347, 183 Cal.Rptr. 156.) Thus, a hospital could be found liable for injury to a patient caused by the hospital's negligent failure "to insure the competence of its medical staff through careful selection and review," thereby creating an unreasonable risk of harm to the patient. (*Id.* at p. 341, 183 Cal.Rptr. 156.).

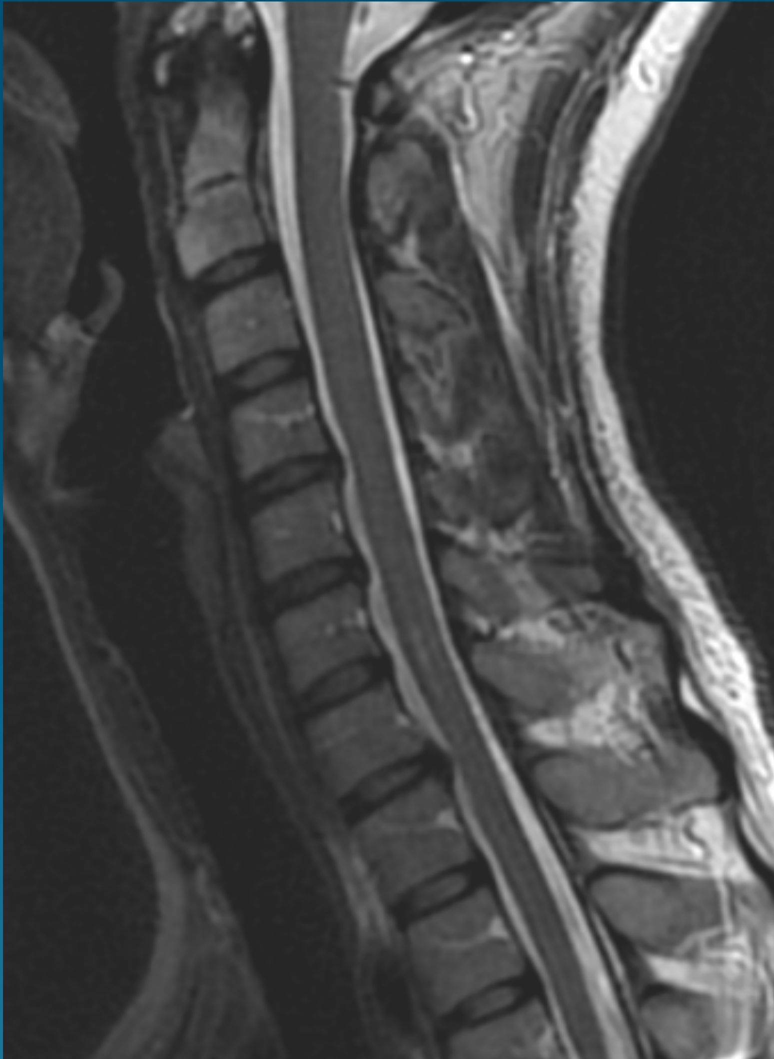
Clinical Examples

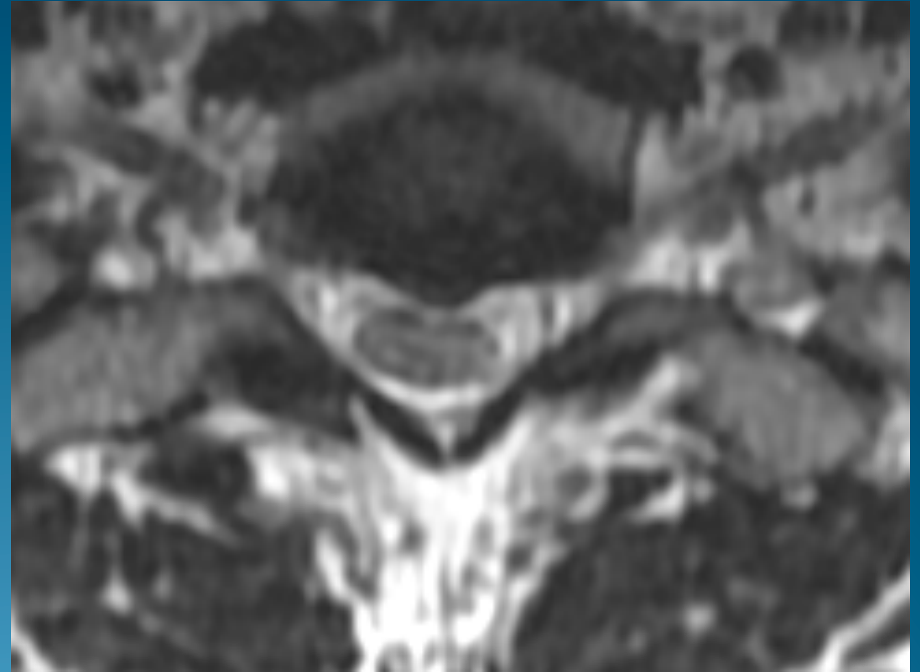
45 yo man with neck pain and right hand numbness. Told he needed a fusion or he could go paralyzed.

Final Diagnosis: carpal tunnel syndrome

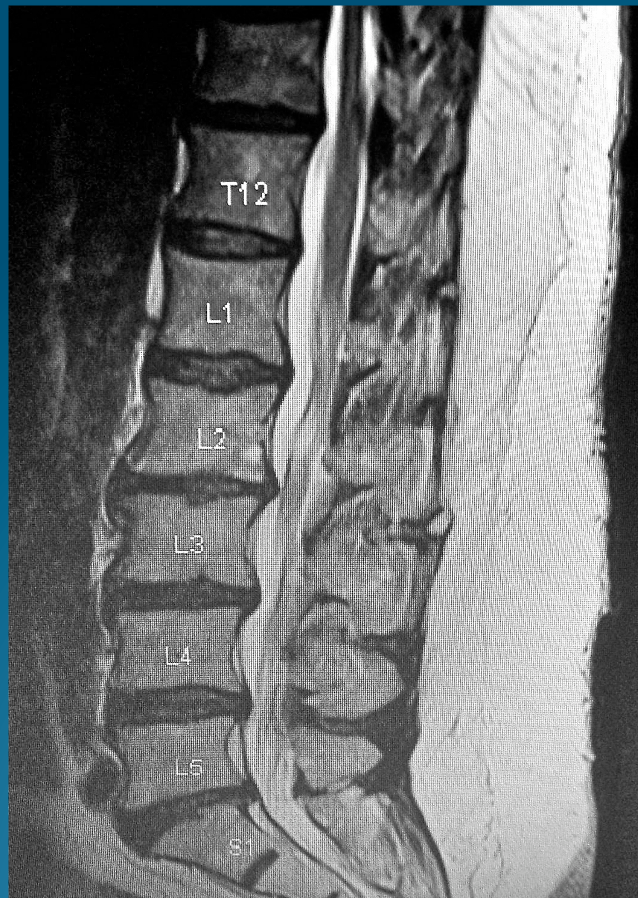


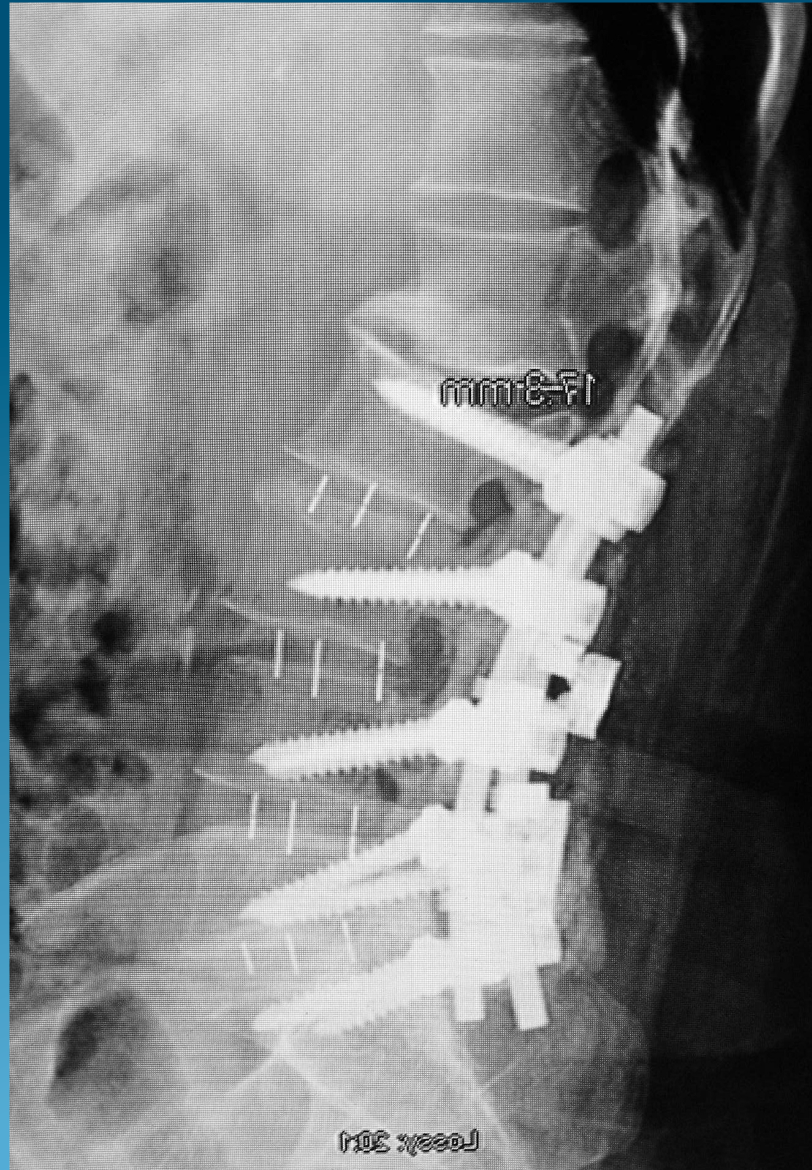
C7/T1 disc bulge. Normal exam, normal EMG. Claimed myelopathy as indication for surgery. 2 level corpectomy claimed. Terminate pregnancy?



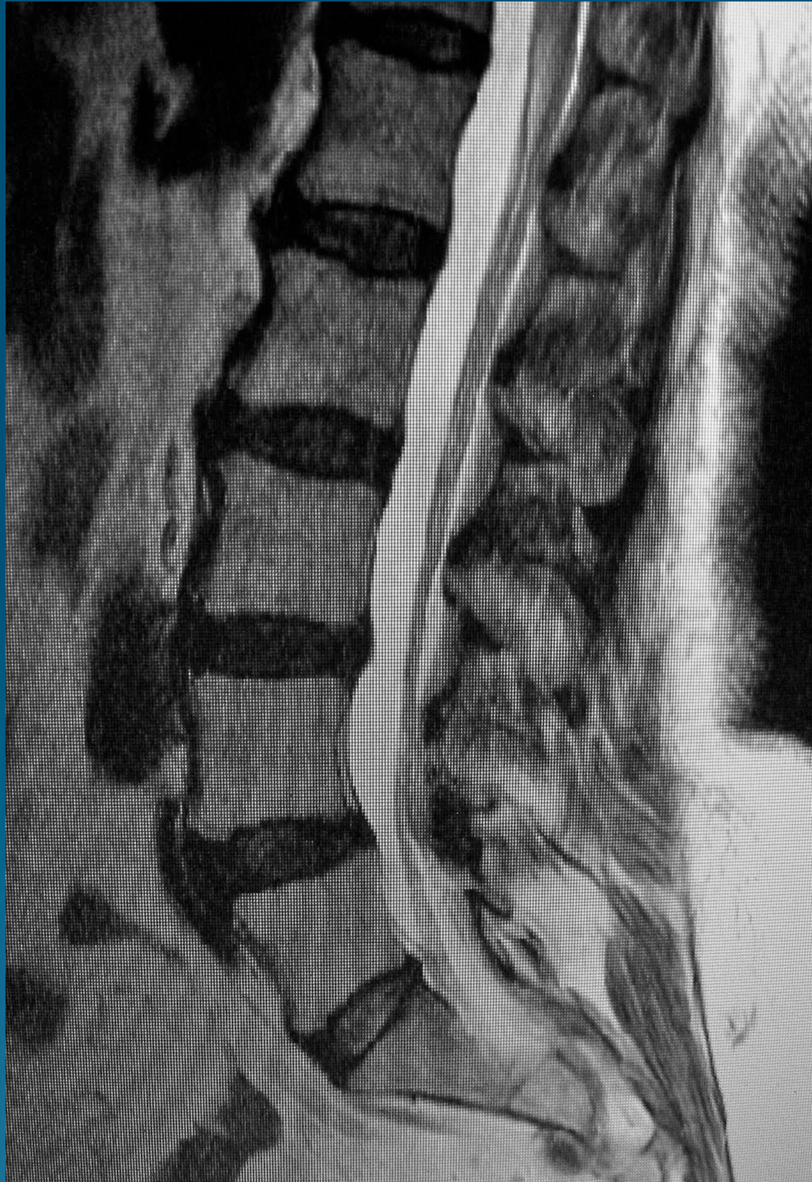


58 yo lady with back pain





One level offset, back pain



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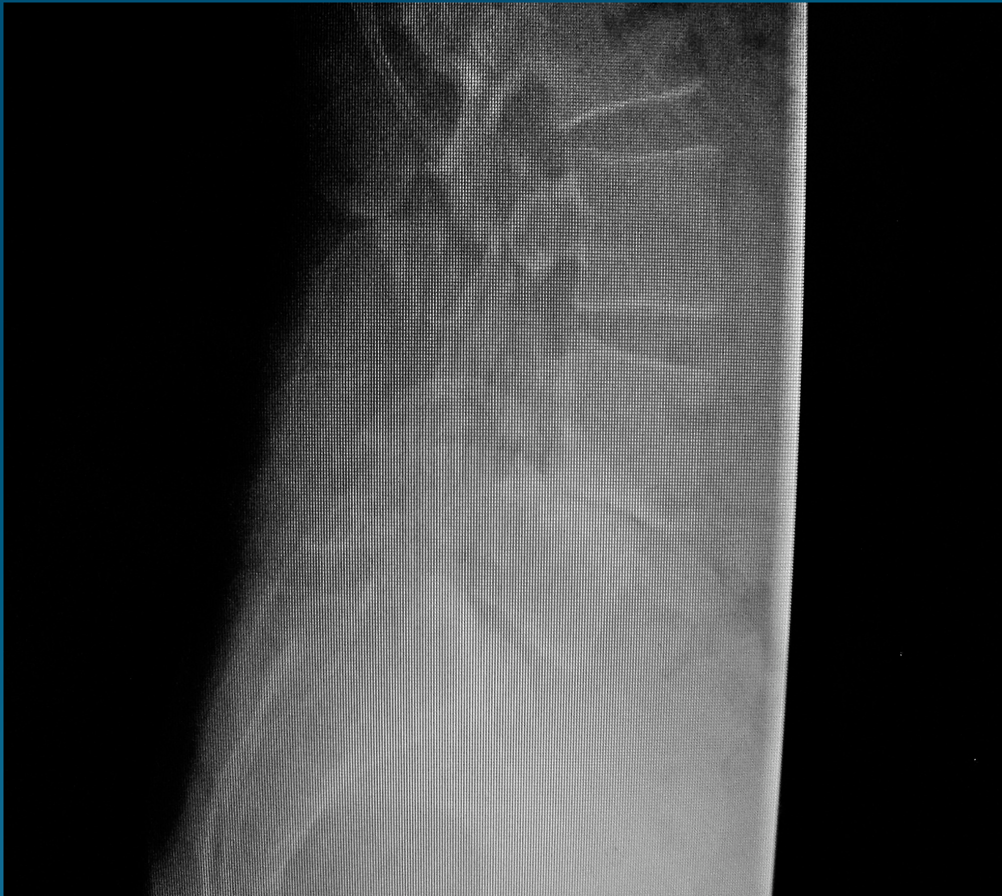
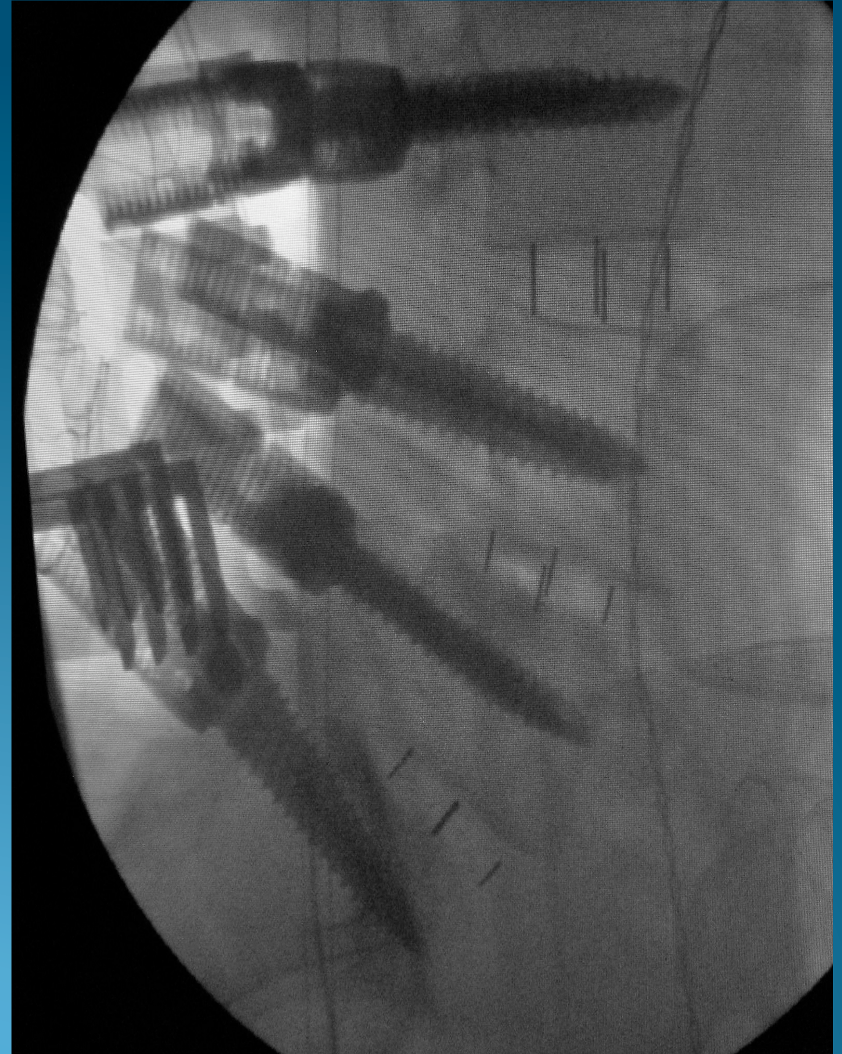
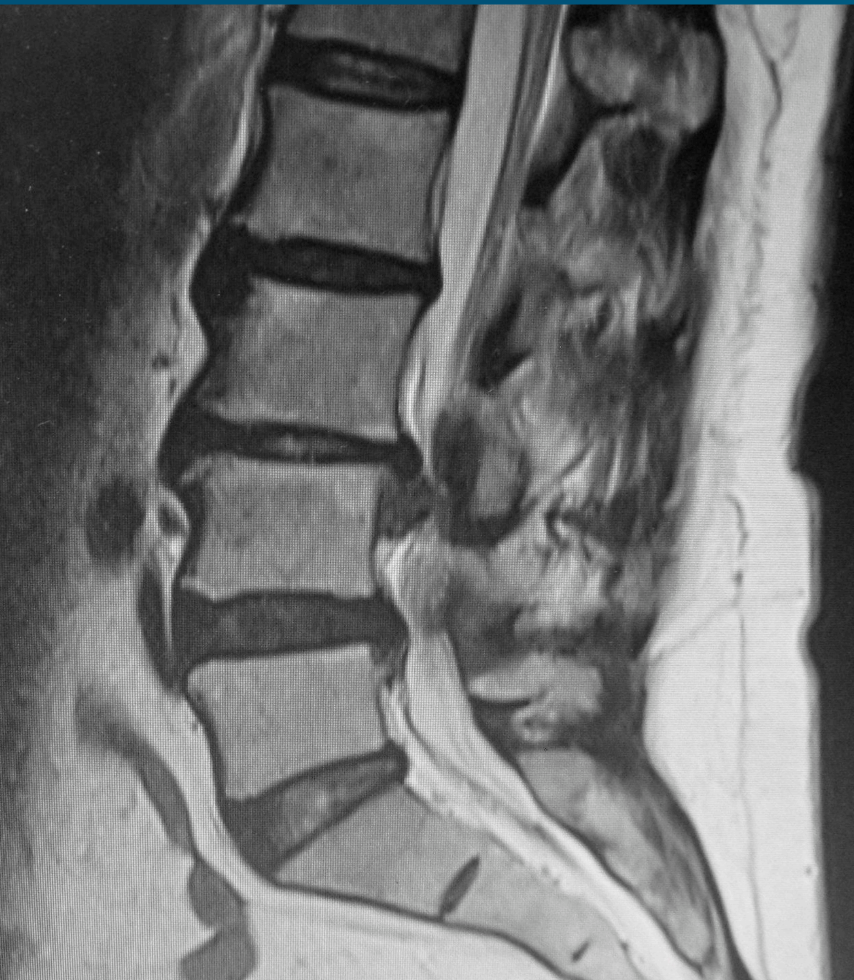
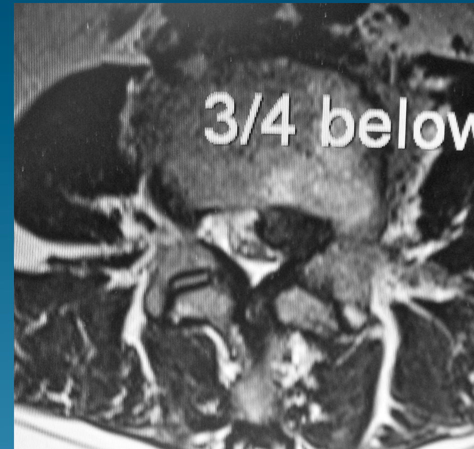
One level instability with stenosis, back pain

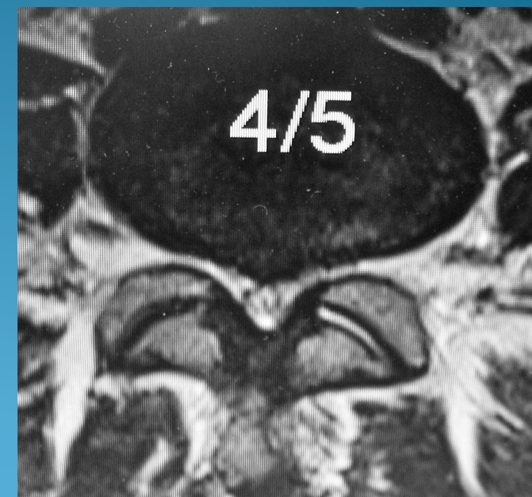




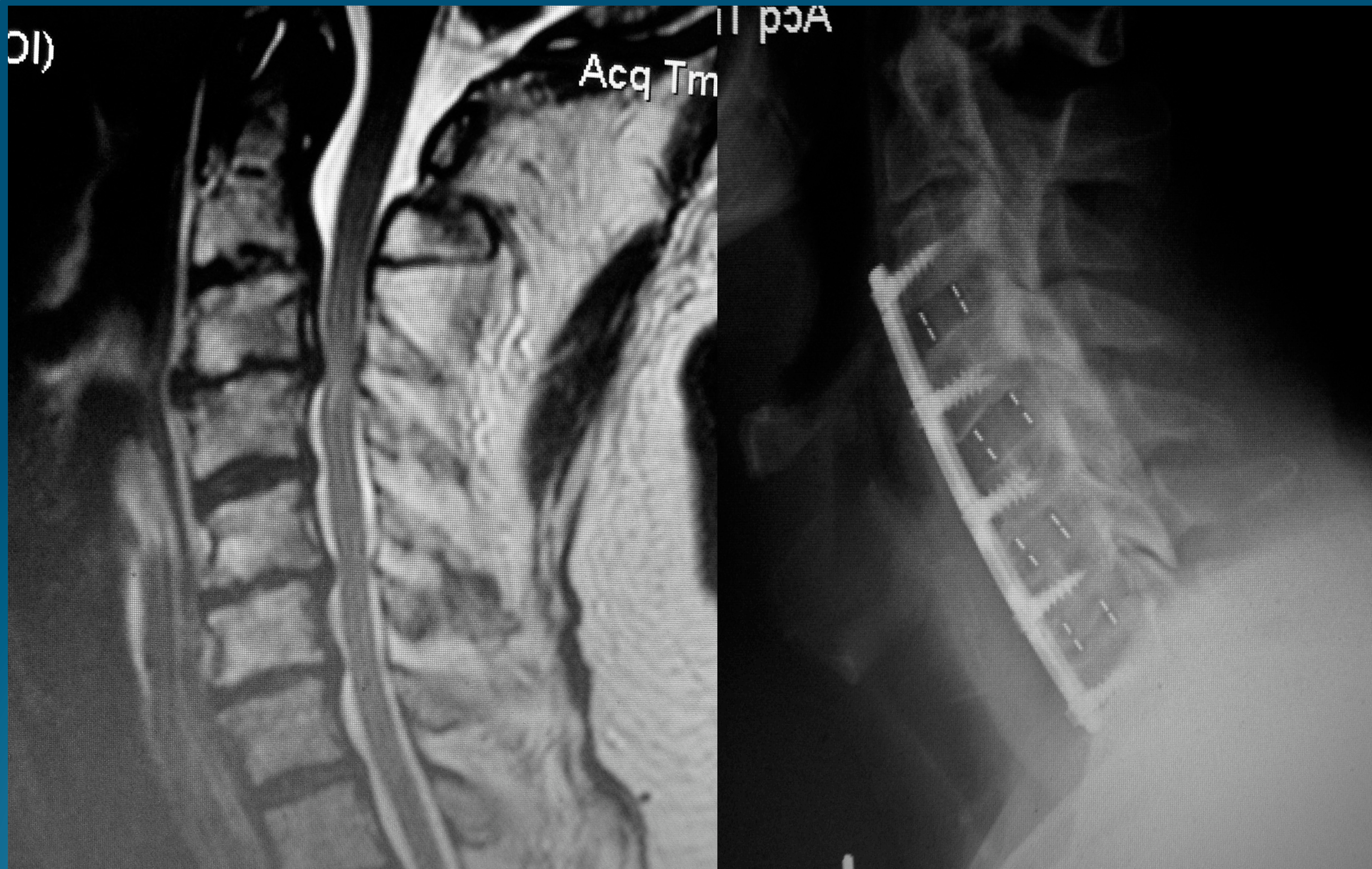
56 yo with left leg pain
What procedure would you do?



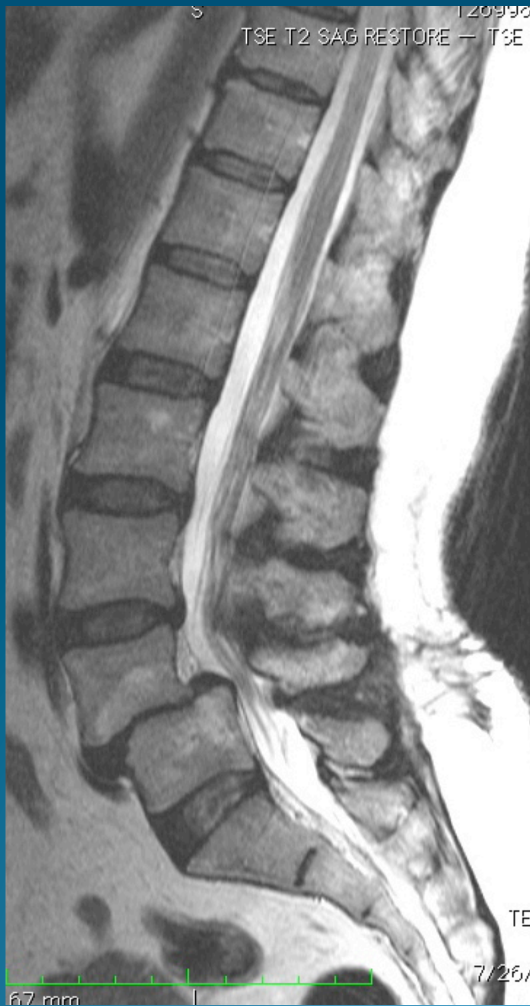


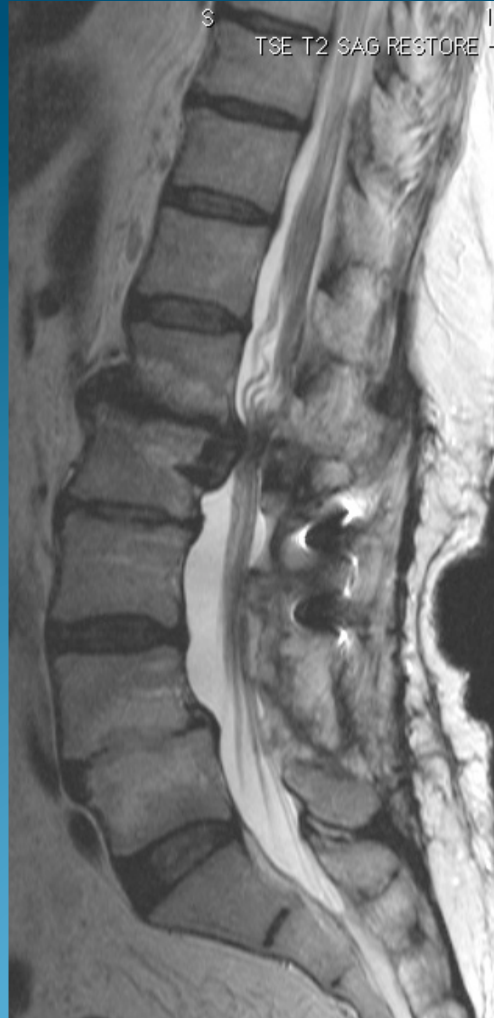


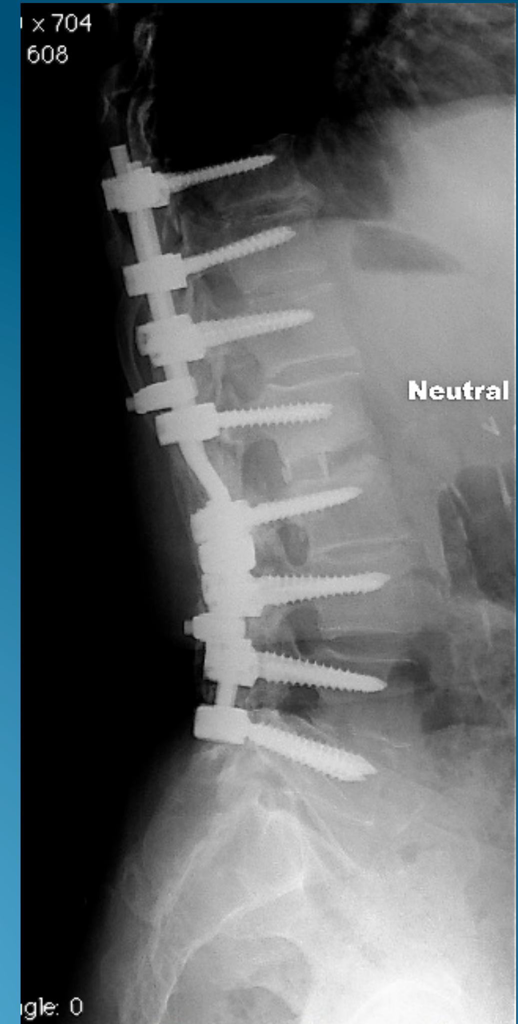
70 yo man with cervical myelopathy



67 year old lady. Back and leg pain, fused L2 to L5. Stress at L1/2 with herniation. Fused T10-L5







What's being done to stop PODs in work comp?

The California legislature recently enacted a bill (AB 378), effective 1 January 2012, that expands the existing state law prohibiting physician self-referral in the context of workers' compensation patients in a way that will now prohibit physicians treating California workers' compensation patients from owning an interest in the company that supplies not only prescription drugs, but also implantable medical devices to their patients.

In Small California Hospitals, the Marketing of Back Surgery (Pacific Hospital of Long Beach, Tri-City Regional Medical Center)

WSJ 2/9/12

What's being done to stop PODs?

HOSPITAL SYSTEMS THAT DO NOT ALLOW PODS
"INHERENTLY SUSPECT" ISSUES:
Catholic Healthcare West, now Dignity Health (40 Hospitals)
Scripps Hospital System in San Diego
Martin Memorial Health System (Florida)
Providence Health & Services (28 Hospitals, Dr. Makker)
Loma Linda University
University of CA, Irvine
The Memorial Care Health System in Orange County, CA
Tenet Health Care.
Ascension Health (70 Hospitals, largest Catholic non-profit)
Intermountain Healthcare (22 hospitals in Utah and Idaho)

Can a POD be legal? Moral or ethical?

1) The POD investors could only own a *fixed, small, percentage* of the company and eliminate multiple small and individual or mini-PODs.
2) Reimbursement from a POD can only based on the *percentage ownership* of a individual POD and not by individual use of product.
3) A POD must have a *large number of physician* owners, perhaps 25 or more with equal percentage ownership..
4) Any implant company could potentially compete for the business at any hospital where there are a preponderance of POD owners.
5) The *physician owners would not purchase the implants* as purchasing a implant would force a physician to use only one particular product which may be inferior quality.
6) The POD *would not accrue implants* but purchase implants from the most cost conscious and quality implants by competition from any of the small or large implant companies.

Can a POD be legal? (cont)

7) POD implants could not be more expensive than major implant company costs.
8) Each hospital who allows PODs must have a *conflict of interest statement* that each physician signs.
9) The POD owner would have to declare in writing to their patients that they have a *financial interest* in the company.
10) If any physician is performing non-indicated, multilevel operations those individuals would be *eliminated from the POD.*
11) There would be *no need for passive investors* as the POD models would not qualify for Safe Harbor protection.
12) Physicians who retire or move out of the area of a particular POD the investor would sell their interests back to the POD.
13) POD owners who care for non-federally funded patients, would follow the same guidelines.

Conclusions

There are enough greedy physicians that we cannot be trusted with today's current POD models and the current physician oversight is inadequate.

Set up appropriately a POD could function well and run in a fair manner that could enhance income to physicians.

The premise of cost savings by PODs has not been shown to be true.

The issue about Predatory Pricing would not be addressed with any POD model.

Short of the OIG defining legal or illegal POD entities there will continue to be confusion about their legality and confusion whether or not physicians and hospitals should enter into a POD ownership agreement.

The costs of implants from the major implant companies and PODs are excessive.

One needs to consider all the potential legal issues before entering into a relationship with a POD.

Thank you

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