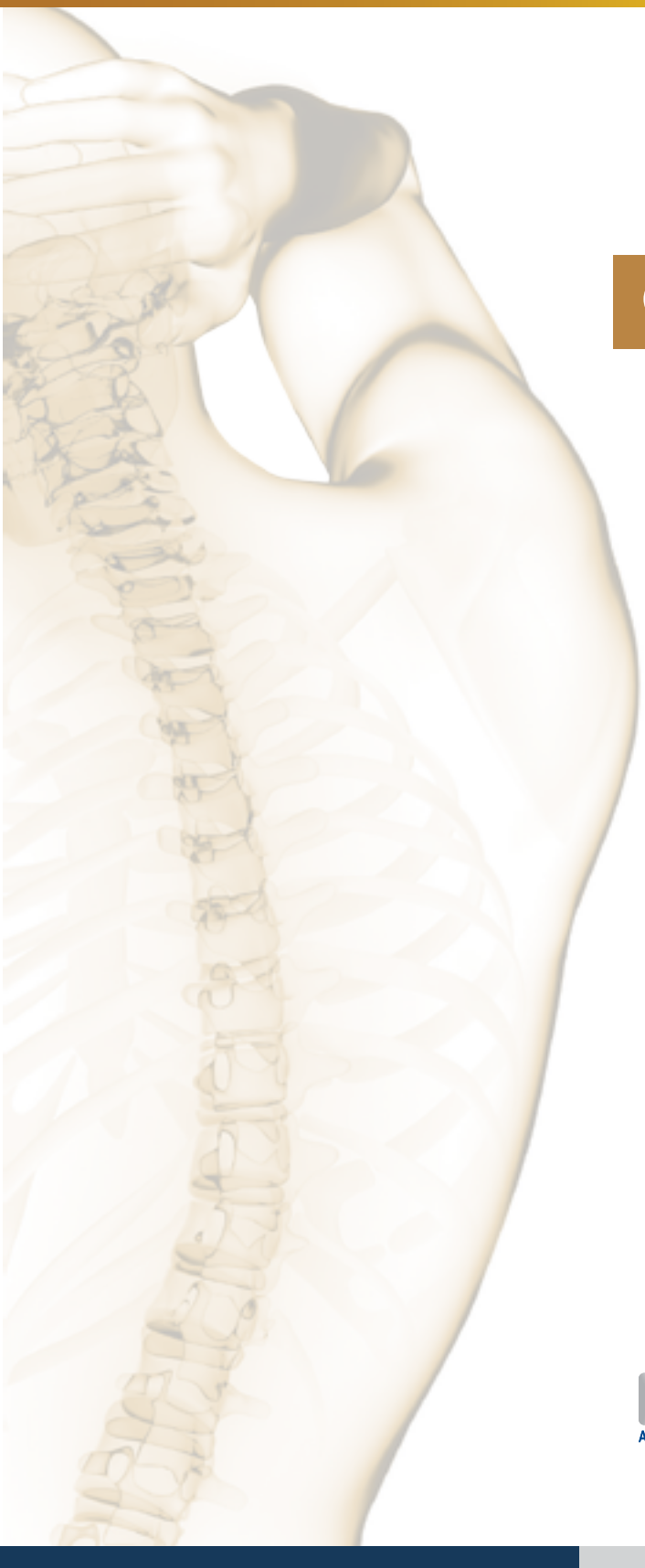
ARABSPINE COURSE DIPLOMA



Module 1

Course Highlight Day-2

Lumbar Spine: Basic & Practice Essential

Lumbar Disc Herniation & Sciatica

Lumbar Canal Stenosis

Spondylolisthesis

Axial Back Pain/ Sacroiliac Join Pain

Facet Joint Pain, Evidence, Outcome & Clinical Pearls

NASSi ADVANCING GLOBAL SPINE CARE

ArabSpine

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CONTENTS

MODULE 1 - DAY 2

ARABSPINE COURSE DIPLOMA
ASCD
الدبلوم العربي لجراحة العمود الفقري

Biomechanics of Lumbar Spine

Architicture of the dorsolumbar spine

- Orientation of facets
- Smaller contribution
- of discs
- Shorter appendages..lesser ms lever arm
- Contains the cord..main function is protection not motion

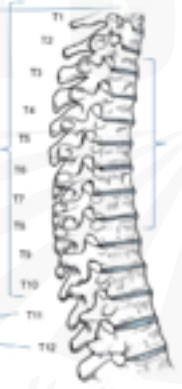
The dorsal spine is 1RY kyphotic region
Rigid
More rigidity by rib cage

Lumbar spine is lordotic
More flexible

T1 is a cervical spine like vertebra even in the presence of uncinate process

The first 10 thoracic vertebrae and their corresponding ribs articulate with the sternum to form the rib cage.

The T11 and T12 vertebrae represent a transition between the thoracic and lumbar spines.



T2 to T8 represent the typical thoracic vertebral anatomy.

Thoracic spine profile

Shoulder obscure upper dorsal kyphosis—so angle can be measured at T4-T12

- Three successive wedged vertebrae more than 5 degrees
  - Kyphosis apex—T7
- Schmorls nodules
  - Regional angle very widely variant 20-50

- Rigid curves

Kyphosis gradually reduces till inflection of the TLS where spine is neutral

Dorsal spine

- Motion +
- Protection ++++
- Wt. bearing ++

- Facet direction limits motion
- Rib cage limits motion
- Minimal sized appendages—less lever arm for ms action—limited motion
- Less disc height – limited motion

- Stronger and thicker canal boundaries
- Rib cage—absorbs energy of trauma
- Shares in visceral protection

Gradually increasing vertebral body size

T1 is a cervical spine like C vertebra even in the presence of uncinate process

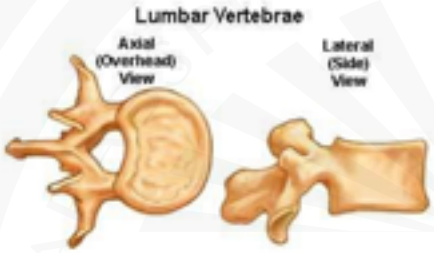
The first 10 thoracic vertebrae and their corresponding ribs articulate with the sternum to form the rib cage.

The T11 and T12 vertebrae represent a transition between the thoracic and lumbar spines.

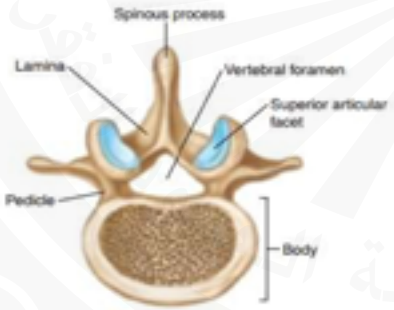
T2 to T8 represent the typical thoracic vertebral anatomy.

LUMBAR REGION

- **Body**
  - Massive
  - Transverse diameter > anterior diameter& height
  - Supports compressive loads

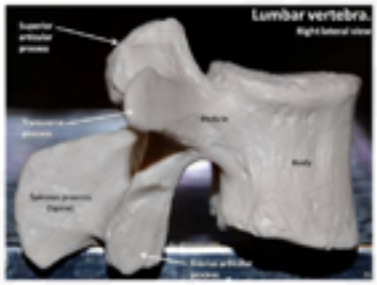


- **Pedicles** : short and thick and project posterolaterally
- **Laminae** : short and broad
- **Transverse Process** : long, slender; extends horizontally



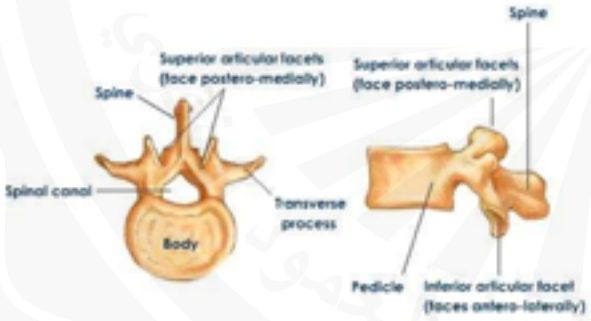
- **Accessory processes** : small, irregular bony prominences, located on posterior surface of transverse process near its attachment to the pedicle

- Attachment sites for multifidus
- **Spinous process** : broad, thick, extends horizontally

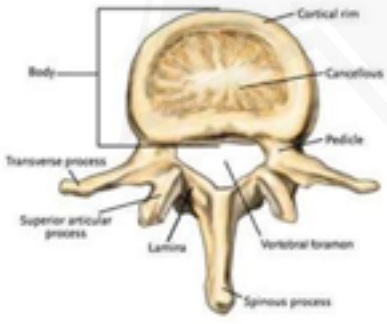


- **Mamillary processes** : located on posterior edgeof each superior zygapophyseal facet
- Attachment sites for multifidus

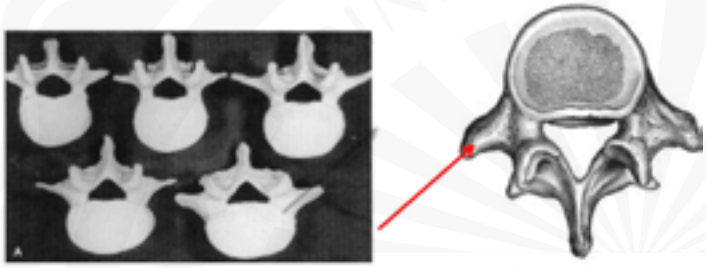
- **Zygapophyseal Articular Processes (facets)**: superior and inferior; vary in shape andorientation



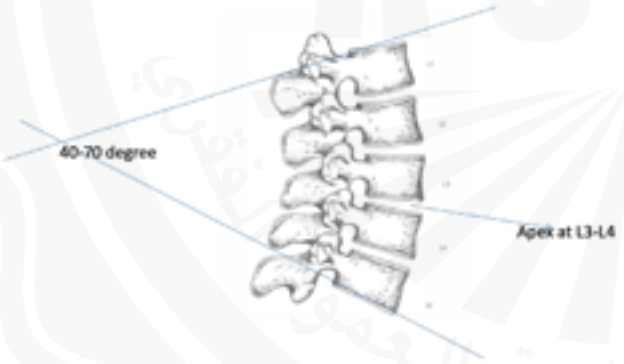
- **Vertebral foramen** : triangular, larger than thoracic vertebral foramen but smaller than cervical vertebral foramen



- **Fifth lumbar vertebra** is a transitional vertebra: wedge-shaped body
- Superior diskal surface area 5% greater
- Inferior diskal surface area smaller
- Spinous process is smaller, transverse processes are large and directed superiorly and posteriorly



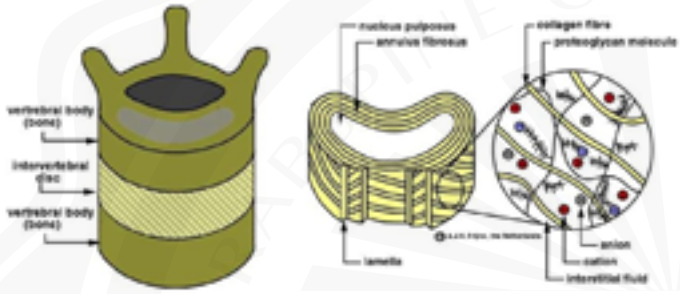
Lumbar profile



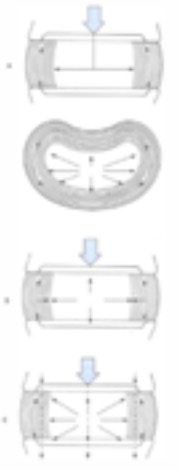
Lumbar spine	• Motion++++ • Protection++++ • Wt. bearing++++	• Facets allows motion • Large appendages---powerful ms action • Large discs---increased flexibility
		• Wide canal • Strong bony trabiculation • Voluminous CSF space
		Largest vertebral bodies

Intervertebral Disks

- Largest
- Collagen fibers of anulus fibrosus are arranged in sheets: **lamellae**
- Concentric rings surrounding nucleus



- Resist tensile forces in nearly alldirections
- Shape of each disk is not purely elliptical but concave posteriorly
- Provides greater cross-sectional area of anulus fibrosus posteriorly and hence increased ability to resist tension that occurs with forward bending



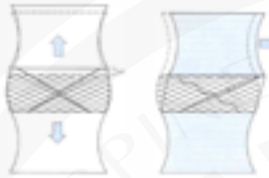
The mechanism of weight transmission in an intervertebral disc.

(A) Compression raises the pressure in the nucleus pulposus. This is exerted **radially** onto the **anulus fibrosus** and the tension in the anulus rises.

(B) The tension in the anulus is exerted on the nucleus preventing it from expanding radially. **Nuclear pressure** is then exerted on the **vertebral end plates.**

(C) Weight is borne, in part. by the anulus fibrosus and by the nucleus pulposus. The radial pressure in the nucleus braces the anulus. and **the pressure on the endplates** transmits **the load** from one vertebra to the next.

Distraction of the interbody joint Separation of the vertebral bodies **increases the height** of the intervertebral disc and all the collagen fibres in the anulus fibrosus are lengthened and tensed, regardless of their orientation.

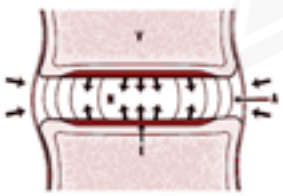


Sliding movements of an interbody joint. Those **fibres of the anulus** that are orientated in the direction of movement have their points of attachment separated, and therefore they are **stretched.**

Fibres in every second lamella of the anulus have their points of attachment approximated,and these fibres are **relaxed.**

Rocking movement of the interbody joint.
Rocking caues compression of the anulus fibrosus in the direction of movement, and stretching of the anulus on the opposite side.

Disc load



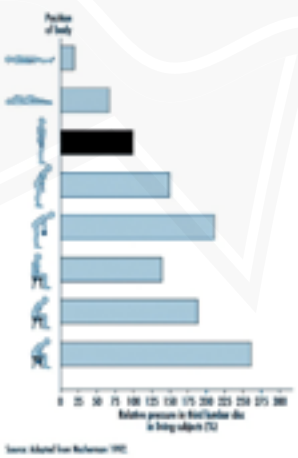
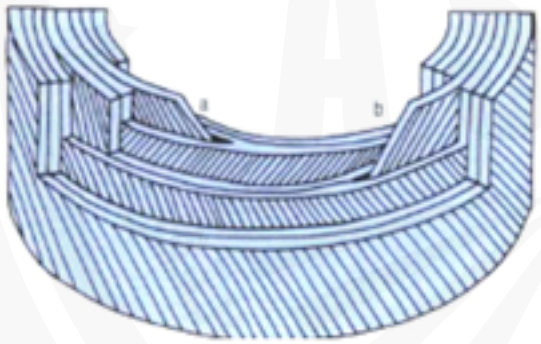
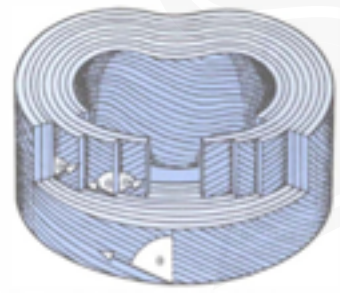


Figure 2.17 Discs that are concave posteriorly have a greater portion of anulus fibrosus located posteriorly. Therefore, concave discs have more anulus available to resist the posterior stretch that occurs in flexion.



The appearance of incomplete lamellae of the anulus fibrosus. At 'a', two subconsecutive lamellae fuse around the terminal end of an incomplete lamella. At 'b', two subconsecutive lamellae become apposed, without fusing, around the end of another incomplde lamella.



The detailed structure of the anulus fibrosus. Collagen fibres are arranged in **10-20 concentric circumferential lamellae**. The orientation of fibres alternates in successive lamellae but their orientation with respect to the: vertical (0) is always the same and measures **about 65°**.

Annulus Fibrosis

Mostly avascular

Lack innervation
- Outermost layers
- Sinovertebral nerve

Thickest anteriorly.

Sharpie's fibers
- Connected to body
- Outer 2/3 connect to the end plate

Disc physiology

- Compressive load decreases hydration
- Decreases its mechanical function.

Water content
- Decreased by 80-90% with age.

Disc volume
- Reduced 20% daily (reversible)
- Loss 15-25 mm of VC height

Acts as a hydrostatic
Uniform distribution of pressure
Nutrition is mainly by diffusion.

Disc Herniation

Cervical C5-6 & C6-7

Lumbar L4-5 & L5-S1 (MOST MOBILE)

Disc herniation
- **Protrusion or bulge - contained**
  - **Annulus intact.**
- **Extrusion - migration through all layers**
  - **Annulus opened**

ARTICULATIONS

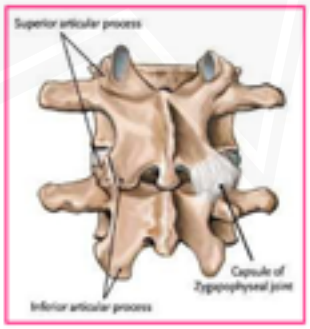
1. Interbody Joints

- Capable of translations and tilts in all directions

2. Zygapophyseal articulation

- True synovial joints
- Fibroadipose meniscoid structures

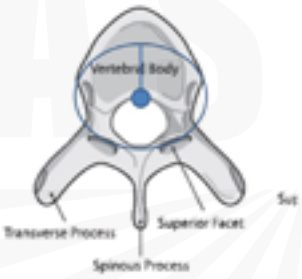
- Facet joint capsule restrains axial rotation
- Resistance to anterior shear.



The orientation of the facet joints, which is different in the cervical, thoracic, and lumbar regions, has a great impact on spinal stability and mobility.

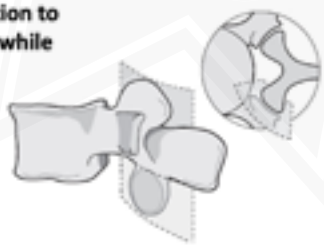
The thoracic facets are oriented in the coronal plane, thus preventing forward motion,

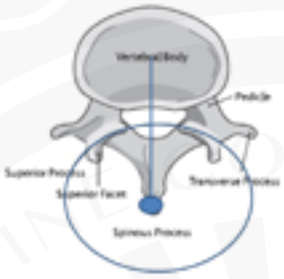
All this permits the group of 12 thoracic vertebrae to turn about **35 degrees** in either direction, or **3 degrees per vertebra**. Were it not constrained by its attachments to the rib cage, the thoracic spine would enjoy even greater freedom of rotation.



All this permits the group of 12 thoracic vertebrae to turn about 35 degrees in either direction, or 3 degrees per vertebra. Were it not constrained by its attachments to the rib cage, the thoracic spine would enjoy even greater freedom of rotation.

lumbar facets are oriented mostly in the sagittal plane, preventing axial rotation and lateral movement of one vertebra in relation to neighboring vertebrae while allowing flexion and extension.





As this axis does not correspond with the centre of the disc, the disc is subjected to considerable shearing force. Disc and vertebral body must slide past one another in opposite directions. The possibility for rotation is dramatically reduced – only 5 degrees in either direction for the entire lumbar spine (5 vertebrae), or 1 degree per vertebra

Figure 3.1 A posterior view of the L3-4 zygapophysical joints. On the left, the capsule of the joint (C) is intact. On tge right, the posterior capsule has been resected to reveal the joint cavity, the articular cartilages (AC) and the line of attachment of the joint capsule (--). The upper joint capsule (C) attaches further from the articular margin than the posterior capsule.

VARIANT ORIENTATION OF THE LUMBAR FACETS

unstable

More stable

The incidence of flat and curved lumbar zyapophysial joints at different segmental levels. (Based on Horwitz & Smith 1940) [16]

	Joint level and percentage incidence of feature				
	L1–2	L2–3	L3–4	L4–5	L5–S1
Flat	44	21	19	51	86
Curved	56	79	81	49	14
Number of specimens	11	42	73	80	80

The varieties of orientation and curvature of the lumbar zygapophysial joints

A. Flat joints orientated close to 90° to the sagittal plane.

B. Flat joints orientated at 60° to the sagittal plane.

C. Flat joints orientated parallel (0°) to the sagittal plane.

D. Slightly curved joints with an average orientation close to 90° to the sagittal plane.

E. C-shaped joints orientated at 45° to the sagittal plane

F. J-shaped joints orientated at 30° to the sagittal plane.

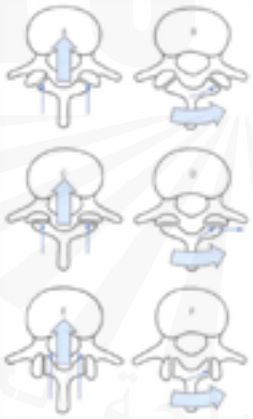
The mechanics of flat lumbar zygapophysial joints.

•Medial is inferior

•**A flat joint at 60 degrees** to the sagittal plane affords **resistance to both forward displacement and rotation** .

•**A flat joint at 90°** to the sagittal plane **strongly resists forward displacement** but during **rotation** the inferior articular facet can **glance off** the superior articular facet.

•**A flat joint parallel to the sagittal plane** offers **no resistance to forward** displacement but strongly **resists rotation**

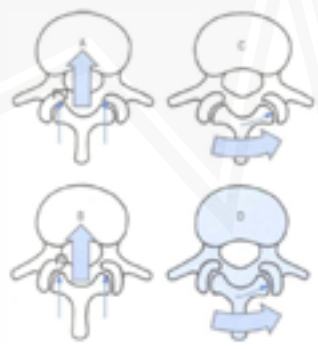


The mechanics of curved lumbar zygapophysial joints.

• C-shaped joints have a wide anteromedial portion which faces backwards (indicated by the bracket), and this portion resists forward displacement.

• J-shaped joints have a narrower anteromedial portion (bracket) that nonetheless resists forward displacement.

•C- and J-shaped joints resist rotation as their entire articular surface impacts.



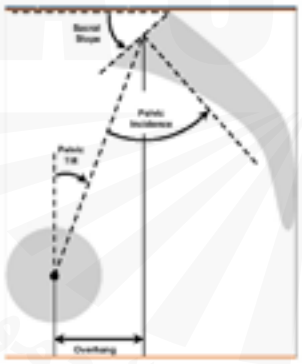
3. *Lumbosacral articulation*

- 5th lumbar vertebra and 1st sacral segment.
- 1st sacral segment is inclined slightly anteriorly and inferiorly, forms an angle with horizontal: **lumbosacral angle**

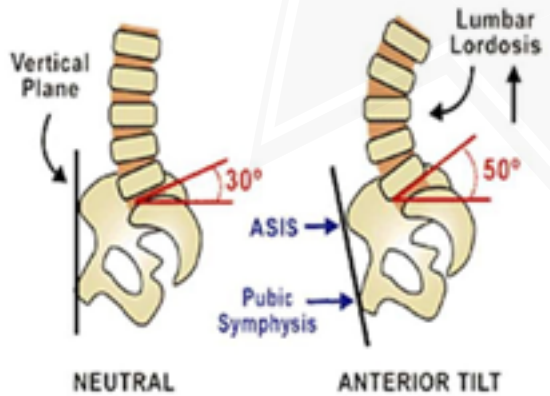
On **whole spine** Xray (C7 – hip)
Sacropelvic parameters:

- Pelvic incidence (PI): (50°-60°)
- Sacral slope (SS)
- Pelvic tilt angle (PT)

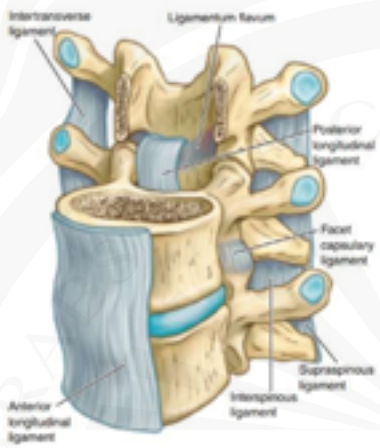
"PI = SS+PT"
" Lumbar lordosis is greatly related to PI"



- Increase in angle : increase in lumbar lordosis
- Increase shearing stress at lumbosacral joint



LIGAMENTS



❖ **Supraspinous ligament**

- Well developed only in upper lumbar region
- Most common termination site - L4
- May terminate at L3

❖ **Intertransverse ligaments** are not true ligaments in lumbar area and are replaced by the iliolumbar ligament at L4

❖ **Interspinous ligament** has least overall stiffness and joint capsules the highest

❖ **Anterior longitudinal ligament** is strong and well developed in this region

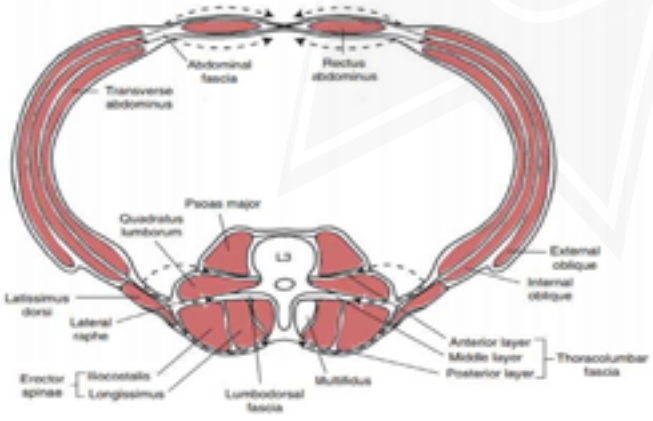
❖ **Posterior Longitudinal Ligament** is only a thin ribbon in lumbar region, whereas ligamentum flavum is thickened here

❖ **Iliolumbar Ligaments**

- Series of bands extend from tips and borders of transverse processes of L4 and L5 to attach bilaterally on iliac crests of pelvis
- 3 bands: ventral / anterior
  dorsal / posterior
  sacral

Ligaments	Function
Anterior longitudinal lig	Limits extension
Posterior longitudinal lig	Limits forward flexion
Ligamentum flavum	Limits forward flexion
Supraspinous ligament	Limits forward flexion
Interspinous ligaments	Limit forward flexion
Intertransverse ligaments	Limit contralateral lateral flexion
Iliolumbar ligament	Resists anterior sliding of L5 & S1

MUSCLES OF THE LUMBAR REGION

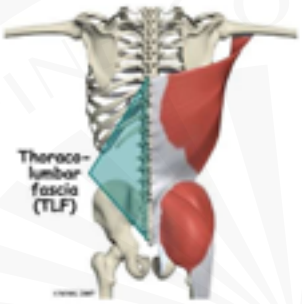


Muscles of lower spine region serve roles of:

- Producing and controlling movement of trunk
- Stabilizing trunk for motion of lower extremities
- Assist in attenuating extensive forces that affect this area

POSTERIOR MUSCLES

3 layers: superficial
intermediate
deep



1. Thoracolumbar fascia

- Most superficial structure

3 layers: posterior, middle, and anterior

- ***Posterior layer*** **:** large, thick arises from spinous processes and supraspinous ligaments of the thoracic, lumbar, and sacral spines.

- Gives rise to latissimus dorsi cranially, travels caudally to sacrum and ilium, and blends with fascia of contralateral gluteus maximus

- Also gives rise to internal and external abdominal oblique, and transversus abdominis

- ***Anterior layer*** : passive part - transmits tension produced by contraction of hip extensors to spinous processes

- ***Posterior layer*** : active part - activated by a contraction of transversus abdominis muscle

- Tension on TLF will produce a force that exerts compression of abdominal contents – external corset

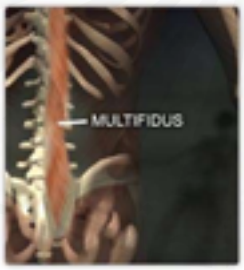
- Compress lumbosacral region and impart stability

2. Erector spinae

- Iliocostalis, longissimus spinalis
- Each having lumbar portion (pars lumborum) and thoracic portion (pars thoracis)
- Primary extensors of lumbar region when acting bilaterally
- Acting unilaterally, they are able to laterally flex trunk and contribute to rotation

3. Multifidus

- Not truly transverso spinales in lumbar region
- Run from dorsal sacrum and ilium in region of PSIS to spinous processes of lumbar vertebrae
- Line of pull in lumbar region is more vertical
- Greater cross sectional area
- Produce lumbar extension
- Add compressive loads to posterior aspect of interbody joints.



LATERAL MUSCLES

1. Quadratus lumborum

- Deep to erector spinae and multifidus
- Acting bilaterally: frontal plane stabilizer
- Also stabilization in horizontal plane
- Acting unilaterally, laterally flex spine and control rotational motion

- If lateral flexion occurs from erect standing, force of gravity will continue motion, and contralateral quadratus lumborum will control movement by contracting eccentrically.

- If the pelvis is free to move, quadratus lumborum will "hike the hip" or laterally tilt pelvis in frontal plane

ANTERIOR MUSCLES

1. Rectus abdominis

- Prime flexor of trunk
- Contained within abdominal fascia; separates rectus abdominis into sections and attaches it to aponeurosis of abdominal wall.
- Abdominal fascia also has attachment to aponeurosis of pectoralis major.
- These fascial connections transmit forces across midline and around trunk.
- Provide stability in a corset type of manner around trunk.

2. Abdominal wall

- External oblique, internal oblique, transversus abdominis muscles
- Forms "hoop" with TLF posteriorly
- Stability to lumbo-pelvic region

3. Psoas major

- Runs from lumbar transverse processes, anterolateral vertebral bodies of T12 to L4, lumbar intervertebral disk to lesser trochanter of femur
- Distal tendon merges with that of iliacus.

- Flexion of hip
- At lumbar spine, buttress forces of iliacus, which, when activated, cause anterior ilial rotation and thus lumbar spine extension
- Also provides stability to lumbar spine during hip flexion activities by providing great amountsof lumbar compression during activation
- Some anterior shear is also produced when it is activated

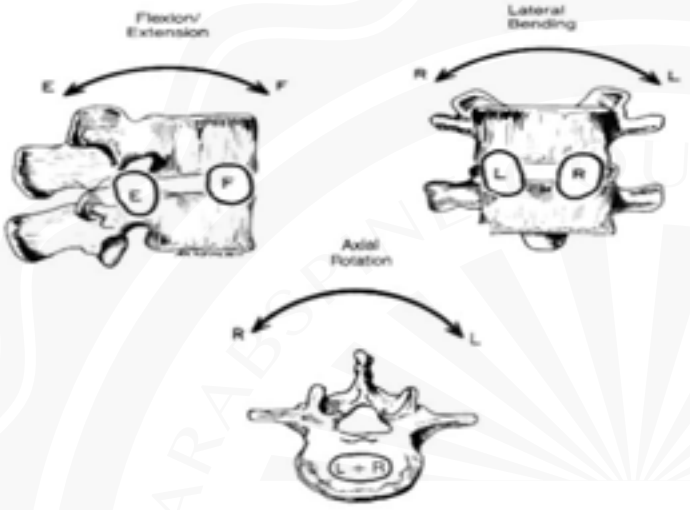
KINEMATICS

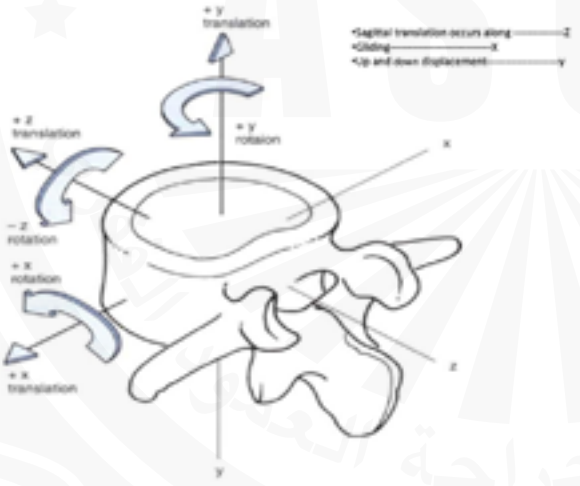
Movements available: flexion, extension, lateral flexion, and rotation.

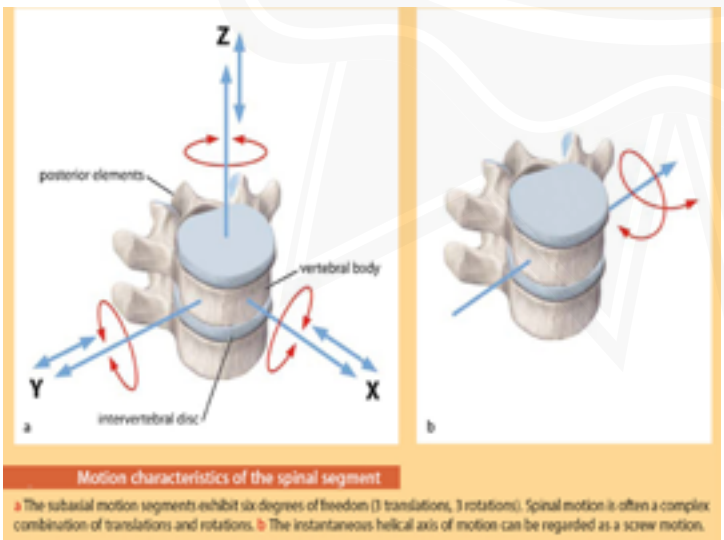
- Gliding- anterior to posterior, medial to lateral and torsional
- Tilt- anterior to posterior, lateral directions
- Distraction and compression

Kinematics is a branch of biomechanics that studies the motion of rigid bodies without consideration of influencing forces.

Each can occur in three orthogonal plains in the spine-----6 coupled motions can occur







Motion characteristics of the spinal segment

a The subaxial motion segments exhibit six degrees of freedom (3 translations, 3 rotations). Spinal motion is often a complex combination of translations and rotations. b The instantaneous helical axis of motion can be regarded as a screw motion.

Lumbar Range of Motion

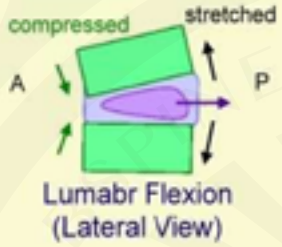
Flexion: 50
Extension: 15
Axial rotation: 5
Lateral flexion: 20

Donald A. Neumann

1. Lumbar flexion

- More limited than extension
- Maximum motion at lumbosacral joint
- Anterior tilting and gliding of superior vertebra occurs
- Increases diameter of intervertebral foramina

- Flexion generates compression forces on anterior side of disc tending to migrate nucleus pulposus posteriorly

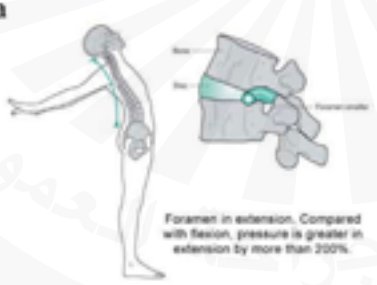


Lumabr Flexion
(Lateral View)

- Limited by tension in posterior annulus fibrosus and posterior ligament system

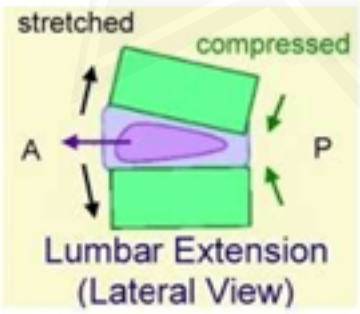
2. Lumbar Extension

- Increase in lumbar lordosis
- Posterior tilting , gliding of superior vertebra
- Lumbar extension reduces the diameter of intervertebral foramina



- Fewer ligaments checks extension

- During lumbar extension nucleus pulposus displaces anteriorly



Lumbar Extension
(Lateral View)

3. Lateral Flexion

- Superior vertebra laterally tilts, rotates and translates over vertebra below
- Annulus fibrosus is compressed on concavity of curve and stretched on convex side
- Nucleus pulposus migrate slightly towards convex side of bend

4. Spinal Rotation

- Rotation causes movement of vertebral arch in opposite direction
- Ipsilateral facet joints go for gapping and contralateral facet joints for impaction
- Axial rotation to right, between L1 and L2 for instance, occurs as left inferior articular facet of L1 approximates or compresses against left superior articular facet of L2.

- Limited due to shape of zygapophyseal joints
- Also restricted by tension created in stretched capsule of apophyseal joints and stretched fibres within annulus fibrosus
- Amount of rotation available at each vertebral level is affected by position of lumbar spine.

- When flexed, ROM in rotation is less than when in neutral position
- The posterior anulus fibrosus and PLL limit axial rotation when spine is flexed
- The largest lateral flexion ROM and axial rotation occurs between L2 and L3

SPINAL COUPLING

- Kinematic phenomenon in which movt of the spine in one plane is associated with an automatic movt in another plane
- Most consistent pattern involves an association between axial rotation and lateral flexion
- With lateral flexion, pronounced flexion and slight ipsilateral rotation occurs
- With axial rotation, however, substantial lateral flexion in a contralateral direction occurs

Lumbo-pelvic rhythm

- The kinematic relationship between lumbar spine and hip joints during sagittal plane movements

- Bending forward- lumbar flexion (40°) followed by anterior tilting of pelvis at hip joint (70°)
- Return to erect- posterior tilting at pelvis at hips followed by extension of lumbar spine

- Integration of motion of pelvis about hip joints with motion of vertebral column:
  - increases ROM available to total column
  - reduces amount of flexibility required of lumbar region
- Hip motion:
  - eliminates need for full lumbar flexion,
  - protecting anulus fibrosus and posterior ligaments from being fully lengthened

KINETICS

General biomechanics

Deformation of tissue in response to applied load usually is displayed by means of a stress-strain graph.

Stress is a standardized measure of applied load in a particular direction (load divided by area of specimen.

strain is a standardized measure of the deformation in a specified direction (elongation divided by original length for direct strain, and shear deformation divided by specimen thickness for shear strain).

The elastic range is the range of deformation from which complete recovery is possible after unloading.

After the elastic limit, plastic deformation can occur. After a specimen that has been taken into the plastic range is unloaded, a permanent, plastic deformation remains.

After the ultimate or maximum stress is passed, failure occurs.

An example of time-dependent behavior is the decline in force magnitude in Harrington instrumentation that occurs over a period of hours after the operation

KINETICS

COMPRESSION

- Lumbar region provides support for weight of upper part of body in static as well as in dynamic situations
- Lumbar region must also withstand tremendous compressive loads produced by muscle contraction

- Lumbosacral loads in erect standing posture inrange of 0.82 to 1.18 times body weight
- During level walking in range of 1.41 to 2.07 times body weight
- Changes in position of body will change location of line of gravity (LOG) and thus change forces acting on lumbarspine
- Lumbar interbody joints share 80% of load, Zygapophyseal facet joints in axial compression share 20% of total load.

- This percentage can change with altered mechanics: with increased extension or lordosis, Zygapophyseal joints will assume more of the compressive load
(degeneration of lumbar facets in dorsal kyphosis).

- Also, with degeneration of intervertebral disk, Zygapophyseal joints will assume increased compressive load.

SHEAR

- In upright standing position, lumbar segments are subjected to anterior shear forces caused by:
  - lordotic position
  - body weight
  - ground reaction forces

- Resisted by direct impaction of inferior zygapophyseal facets of the superior vertebra against superior zygapophyseal facets of adjacent vertebra below

PATHOMECHANICS

1. EXAGGERATED LORDOSIS

- Abnormal exaggeration of lumbar curve
- Weakened abdominal muscles
- Tight hip flexors, tensor fasciae latae, and deep lumbar extensors
- ↑ compressive stress on posterior elements
- Predisposing to low back pain

2. SWAY BACK

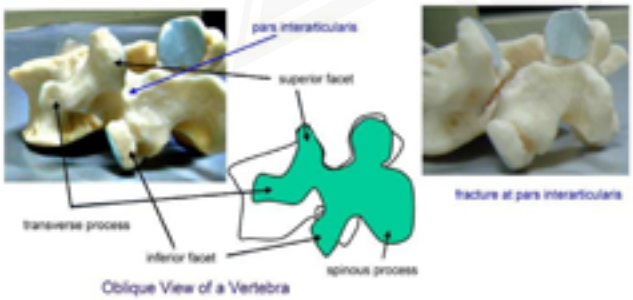
- Increased lordotic curve and kyphosis
- Weak : lower abdominals, lower thoracic extensors, hip flexors
- Tight : hip extensors, lower lumbar extensors, and upper abdominals

3. FLAT BACK POSTURE

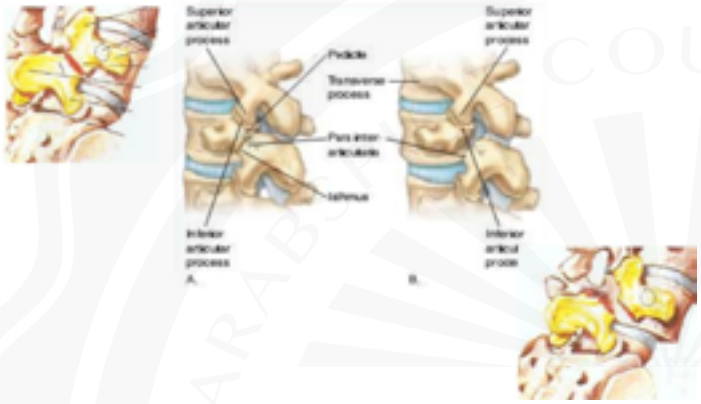
- Relative decrease in lumbar lordosis (20°),
- COG shifts anterior to lumbar spine and hips

4. PARS INTERARTICULARIS FRACTURES

- Region between superior and inferior articular facets
- Weakest bony portion of vertebral neural arch



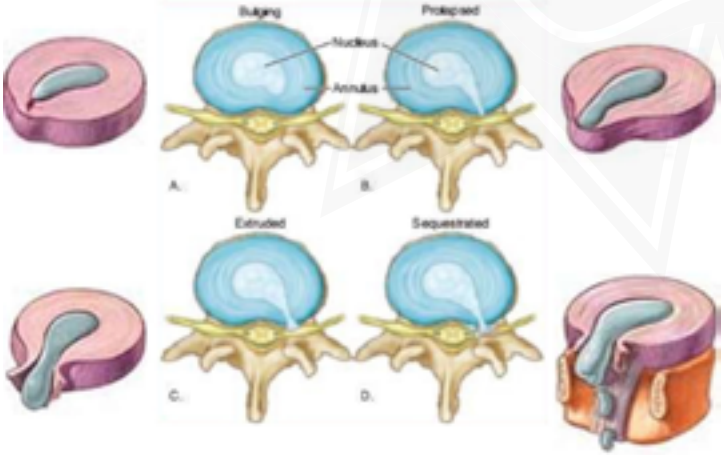
Spondylolysis ↔ **Spondylolisthesis**



- Common at L5-S1 and L4-L5

5. INTERVERTEBRAL DISC PROLAPSE

- Common site: L4-L5 & C5-C6



6. LUMBAR CANAL STENOSIS

- Narrowing of lumbar canal
- Congenital OR Acquired

7. LUMBAR FACET PATHOLOGY

- Subluxation or dislocation of facet, Facet joint syndrome (i.e. inflammation), Degeneration of the facet (i.e., arthritis)

8. LUMBAR CONTUSIONS, STRAINS, AND SPRAINS, FRACTURES AND DISLOCATIONS

- 75 to 80% of population experiences low back pain stemming from mechanical injury to muscles, ligaments, or connective tissue

Pathophysiology of Axial Low Back Pain

AHRQ Technology Assessment
Agency for Healthcare Research and Quality

"In the majority (>85%) of patients with low back pain, symptoms cannot be attributed to a specific disease or spinal pathology."

AHRQ Technology Assessment
Agency for Healthcare Research and Quality

"In the majority (>85%) of patients with low back pain, symptoms cannot be attributed to a specific disease or spinal pathology."

- Consensus statement from the 1970's
- Pre-dates MRI and modern diagnostic injection techniques

Spine Pain Differential Diagnosis

- Disc herniation
- Annulus fibrosis tear
- Radiculopathy
- Discitis
- Tumor
- Meningitis
- Z-joint pain
- Muscle pathology
- SI joint pain
- Atlanto-axial pain
- Atlanto-occipital pain
- Spinal stenosis
- Spondylolysis
- Spondylolisthesis
- Spondylosis
- Vertebral compression fracture
- Pars defect
- Charcot spine
- Diffuse idiopathic skeletal hyperostosis (DISH)
- Myelopathy
- Tethered cord
- Trauma with fracture
- Neck sprain/whiplash
- Musculotendinous strain
- Dural tear
- Cauda equina
- Pott's fracture
- Osteomyelitis
- Osteoarthritis
- Hematoma
- Sacroiliitis
- Retroperitoneal abscess
- Epidural abscess
- Arachnoiditis
- Multiple myeloma
- Meningioma
- Ulcerative colitis
- Psoriatic arthritis
- Reactive arthritis
- Ankylosing spondylitis
- Spina bifida
- Syringomyelia

Spine Pain Differential Diagnosis
Axial Low Back Pain
"Big Four"

- Disc
- Facet
- Sacro-Iliac
- Hip

What Is the Source of Chronic Low Back Pain and Does Age Play a Role?

156 patients underwent diagnostic procedures until putative source of pain identified

- SIJ anesthetic block
- Medial branch block (dual, facet)
- Provocation discography
- Interspinous ligament anesthetic
- Percutaneous augmentation

What Is the Source of Chronic Low Back Pain and Does Age Play a Role?

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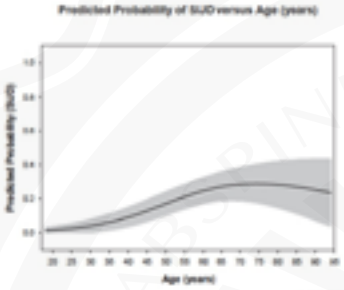
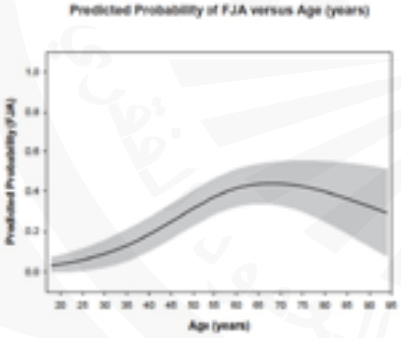
Overall prevalence:
- Disc 42%
- Facet 31%
- SIJ 18%

Does Age Play a Role? - DePalma

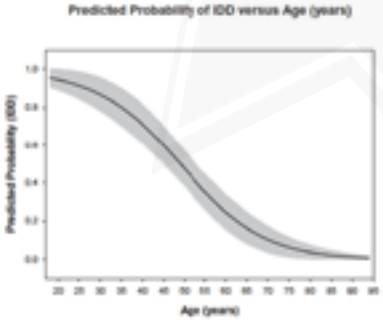


Pain Medicine 2011; 12: 224–233
Wiley Periodicals, Inc.

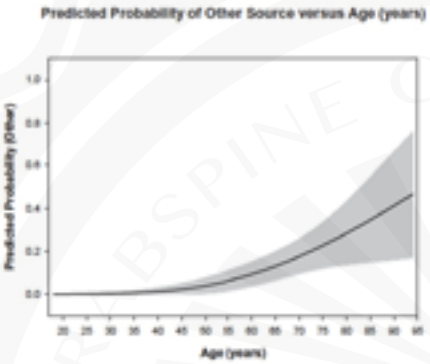
Facet



Intervertebral Disc



OTHER

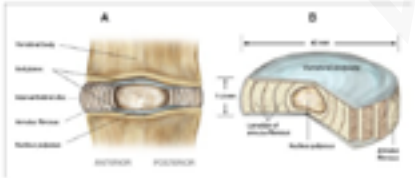


Prevalence

- Lumbar facet:
  - 10% (Schwarzer) - 31% (Depalma)
- Intervertebral Disc
  - 42%
- Hip
  - 88/100,000 per year of symptomatic hip OA in general population
  - 9% of population
- SIJ
  - 20-45%

Intervertebral Disc

- Nucleus Pulposis
  - Proteoglycan and water gel (type II collagen)
  - Supports compressive load, Cannot expand, transfers load
- Annulus Fibrosis
  - Type I collagen in circular layers
  - Run oblique and alternating to each other, resistant to tensile strength
- Avascular



Degenerated Intervertebral Disc

- Nucleus:
  - More fibrotic
  - Desiccation
  - Fragmentation
- Annulus:
  - Tear
  - Loss of structural integrity
- Causative factors:
  - ? Nutritional deficiency
  - Enzymatic activity (load related?)

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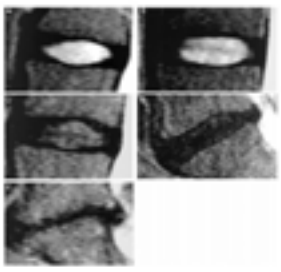
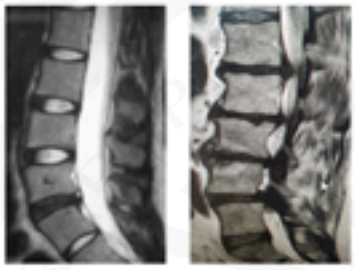
Pfirrmann Degeneration



SPINE Volume 26, Number 17, pp 1873–1878
©2001, Lippincott Williams & Wilkins, Inc.

- Grade 1: Homogenous, hyperintense nucleus, preserved height
- Grade 2: Structure is inhomogeneous
- Grade 3: Intermediate gray signal, loss of distinction between NP & AF, slightly decreased height
- Grade 4: Hypointense signal, loss of distinction, moderately decreased high
- Grade 5 – disc space is collapsed

Degenerated Intervertebral Disc



Lumbar Disc Pain – History

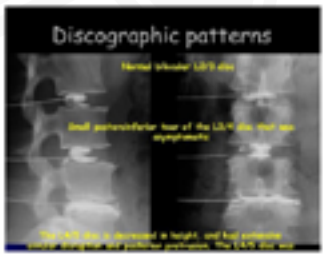
- Severe disabling episodic nature to the LBP
- Minimum of 3 days duration with periods of remission between the episodes of at least one month
- Typically flexion based pain

Lee D, Carragher D, Horn S, Levin J. Is a History of Severe Episodic Low Back Pain an Indicator of a Discogenic Etiology? Pain Med 2017 [available online ahead of print].

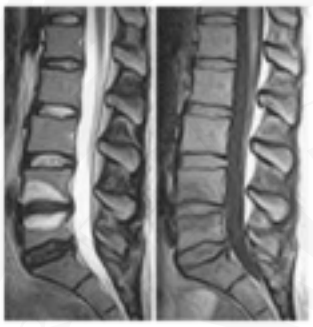
Degenerated Intervertebral Disc

Provocation Discography

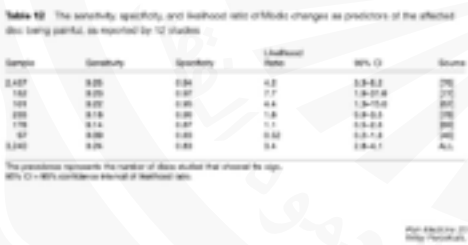
- Contrast is injected
- Reproduction of pain
- Normal Control Disc
- Assess for morphology
- Complications concerns



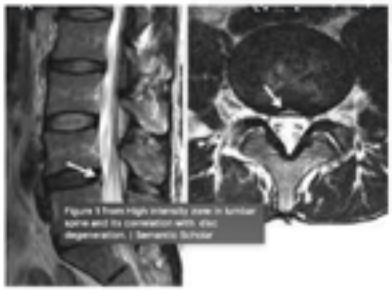
Degenerative Endplate Changes (Modic changes)



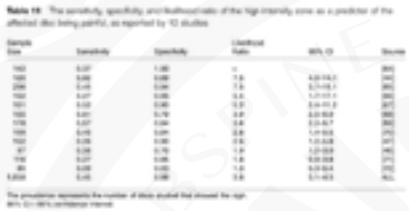
Intervertebral Disc – Modic Changes



Annular Tear

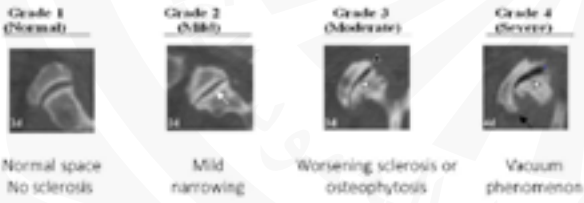


Intervertebral Disc – High Intensity Zone



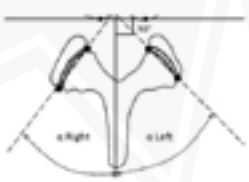
Facet Pain

- True diarthrodial synovial joint
  - Synovial reaction, Cartilage degeneration, Osteophytes formation.



Spine (Phila Pa 1976). Author manuscript; available in PMC 2014 January 15.

Facet Pain Predisposing Factors



- Rheumatologic conditions (Synovitis)
- Tropism
  - Asymmetry between right and left (on more sagittal)
  - Possible association with facet OA
- Orientation
  - Angle of joint in transverse plane relative to sagittal plane

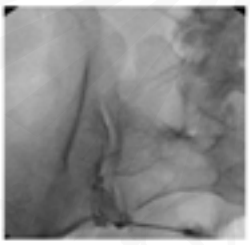
Facet Pain

History and Exam

- No single feature (or combination) proven to be valid and reliable
  - Schwarzer in 1995, Hancock in 2007
- Injections as the gold standard
  - Evidence strongest in support of MBB
  - High false positive (17-41%)

Sacroiliac Joint Degeneration

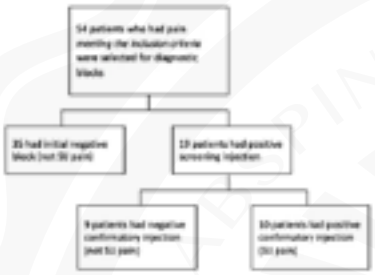
- Max. rotation: 2-2.5 degr., translation of 0.7 mm
- Large surface area ~ 1000 mm²
- Stability of SIJ; posterior sacral ligaments, (ossify ~60 years)
- Involved in most spondyloarthropathy
- Hypermobile;
  - Pregnancy (Relaxin)
  - Collagen Disorders
  - Post Lumbar Fusion (fused lumbar)



Sacroiliac Joint Degeneration

- In general, history does not predict response to diagnostic injection

SIJ Pain: Diagnostic block



- < 20% had SIJ pain
- 22% false positive

	+ SIJ Pain	- SIJ Pain
Positive 1st block	10	9
Negative 1st block	7	337

- *Maigne JY, et al. Results of sacroiliac joint double block and value of sacroiliac pain provocation tests in 54 patients with low back pain. Spine 1996;21:1889-92.*

Conclusions

- Low back pain is usually not "non-specific"
- Common anatomic causes include IVD, SIJ, facet
- Prevalence of these changes with age
- Diagnosis of discogenic pain – history and imaging
- Diagnosis of SIJ and facet largely dependent on diagnostic injections
  - Be ware of false positive responses

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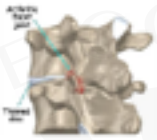
Spinal Alignment and Balance: The Role of the Lumbar Spine

Aging factors

Degenerative Cascade

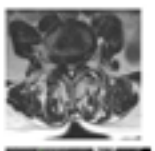
- Disc dehydration, degeneration
- Disc height collapse
- Facet degeneration
- Ligamentous laxity

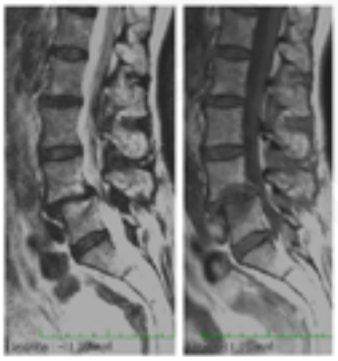


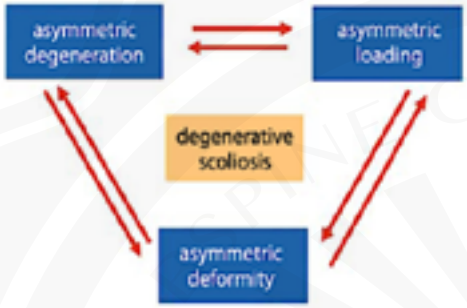
Degenerative deformities

- Degenerative changes:
  - Disc
    - Loss of disc height
    - Loss of anterior opening of the disc
    - Asymetric discopathy
    - Rotatory Dislocation
  - Facets
    - Subluxation
    - Synostosis
  - Muscles
    - Fatty degeneration
    - Poor neuro-muscular control

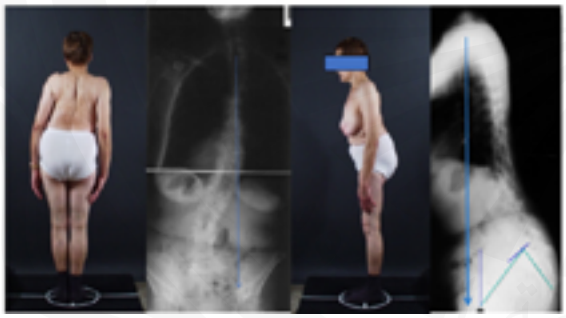
Primary (de novo) degenerative scoliosis results from segmental degeneration



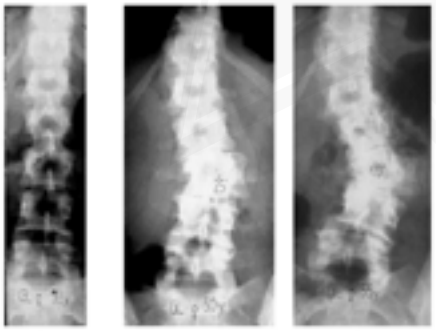




Coronal and Sagittal Imbalance



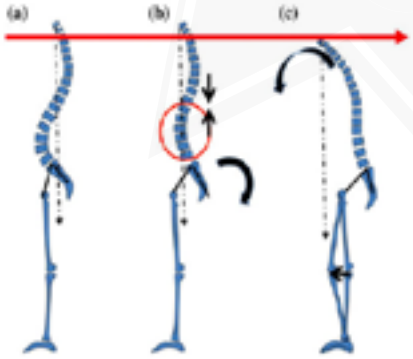
Primary (de novo) degenerative scoliosis results from segmental degeneration

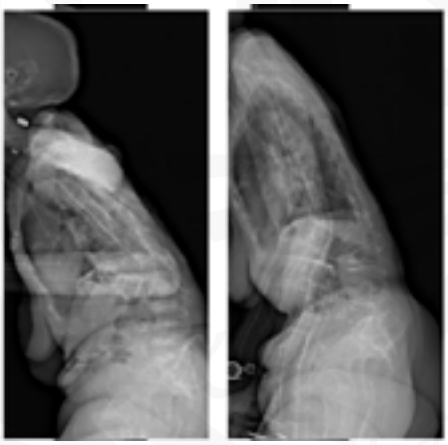


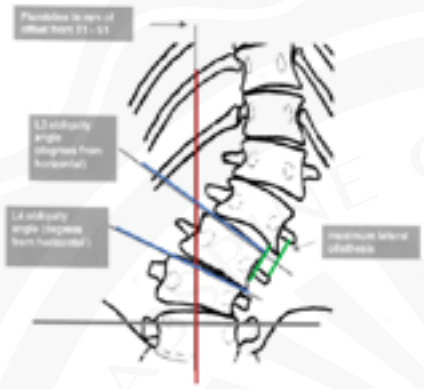
Aging Population

- Prevalence of ADS
- 68% >60y
- Mean Age : 70.5y
- Lumbar spine
- Coronal cobb >10°
- Apex L3
- Fractional curve L4S1

Effect of aging on sagittal alignement of the spine

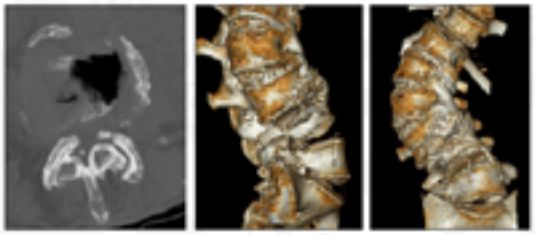


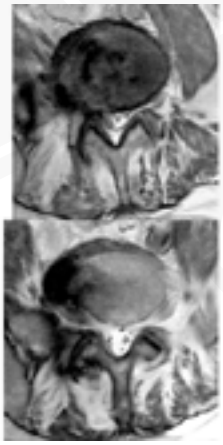


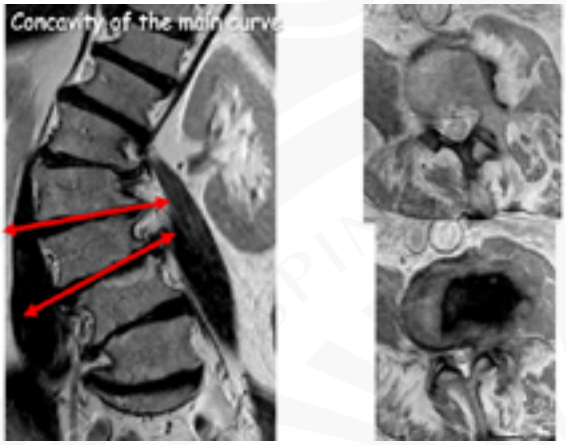


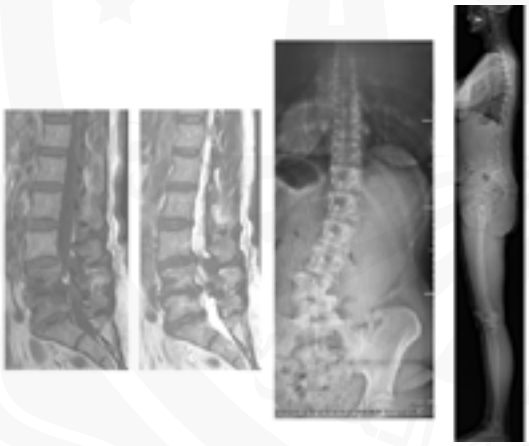
Neural canal consequences

Canal/Foramen stenosis







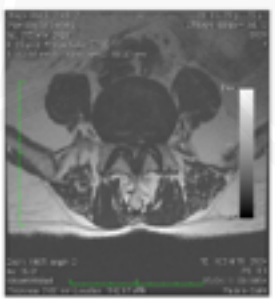


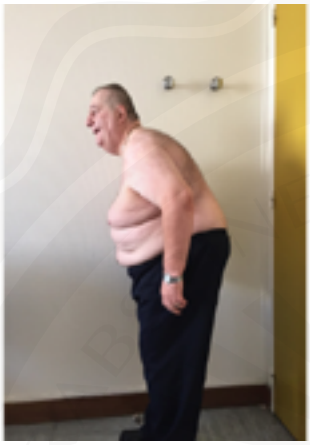
Iatrogenic factors

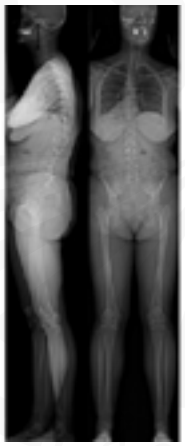
- Flat back: hypolordotic instrumentation
- Post laminectomy instability

Aging spine

- Sagittal aging profile
  - Cv Plumbline anteriorly displaced
  - Lumbar kyphosis
  - Prevalence 68% > 65yrs
- QoL & Sag Profile
- **Lumbar stenosis**
- Osteopenia/osteoporosis
  - Risk of adjacent Fractures
  - Implants hold !!!!







- 54 y Old F
- L1 Fracture
- Pseudarthrosis, Hardware fracture
- Removal of the hardware
- Post operative kyphosis (4y)
- Back pain ODI 46%

Conclusion

- Asymetrical disc degeneration/collapse
- De Novo adult scoliosis (coronal & sag def.)
- Risk factors of deteriortaion
- Foraminal and canal stenosis
- Sag deformity & QoL

Understanding Spinal Instability

Spinal instability definition

- **Stability** of the spine is that quality by which the vertebral structures maintain their cohesion in all physiological positions of the spine
- **Instability** is a pathological process that can lead to displacement of vertebrae beyond their normal physiological limits.

- Spinal instability and Low back pain : widely misunderstood
- Segmental joint Laxity : Loss of mechanical integrity

- Degenerative disc disease (loss of the disc height, loss of the mechanical support)
- Facet joint laxity
- Spondylolisthesis
- Segmental and global deformities
- Iatrogenic instabilities : (laminectomies, pars defect, muscles and ligaments disruption)

Instabilty as a source of back pain
Myth or reality?

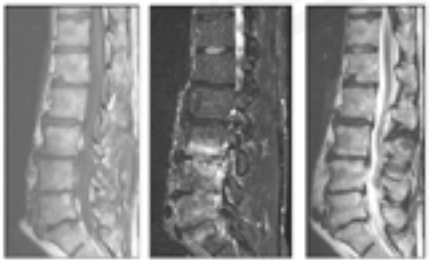
Hypothesis

- Spinal instability = Mechanical low back pain ?
- Stabilisation surgery = neutralisation of segmental instability ?
- Results of fusion on low back pain ?
- Correlation of radiographical fusion on back pain ?
- Determination of the pain generators ? (that might exceed the segmental instability)
- Scientific evidence?

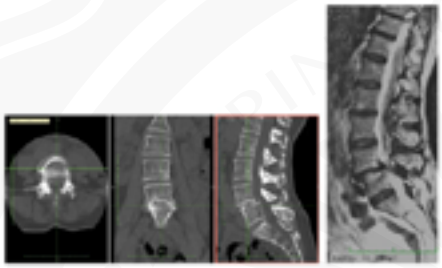
Clinical aspects of spinal instability

- 1950's the concept of **spinal instability**
- Mechanical Back Pain
- Instability might be vertical, translational, rotational or complex
- Abnormal motion (under physiological loads) is a source of pain
- Abnormal motion might be associated to back pain but not necessary causative!

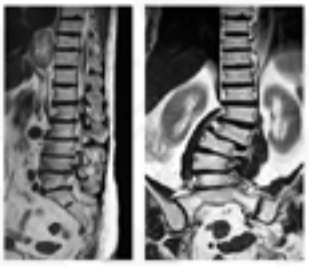
Lumbar instabilty (vertical)
Degenerative disc disease



Lumbar instabilty (translational) spondylolisthesis



Lumbar instabilty (rotational) segmental deformity



Lumbar instabilty (Iatrogenic)

- Post discectomy
- Post laminectomy

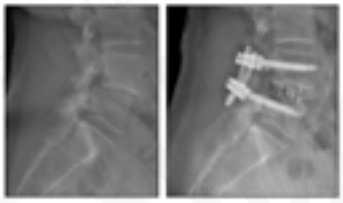
- Pseudarthrosis

- Hypolordotic instrumentation, adjacent segment pathologies

Surgical treatment
Rational

Fusion

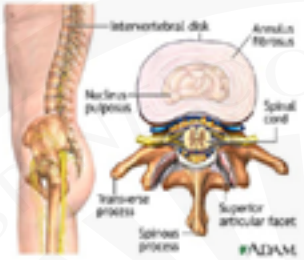
- Restoring disc height
- Restoring segmental lordosis
- Restoring regional alignment
- Indirect decompression (Foramen, canal)
- Durable stabilisation: 360° arthrodesis



Role of Intervetebral Discs in Low Back Pain

Basic Intervertebral Disc Composition

- Components:
  - Nucleus Pulposus
  - Annulus Fibrosus
  - End plates
- Function:
  - Absorb and dissipates loads on the spinal column and allows smooth movement of the spine



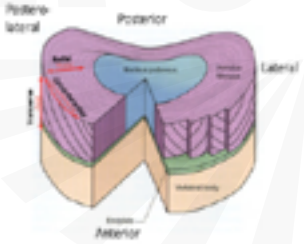
Basic Intervertebral Disc Form & Function

Unique structure

- Inner gelatinous Nucleus (type II collagen)
  - PG heavy
  - High water content
    - Maintains disc height
    - Dissipates loads
- Surrounded by Outer Annulus which contains concentric lamellae of collagen fibers (type I collagen)
  - Collagen heavy
  - Tensile strength

Loading Changes

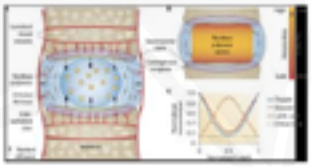
- Bending and compression loading
  - Disc bulging, endplate changes
- Torque or rotation
  - Disrupts annulus



Basic Intervertebral Disc Form & Function

Vascular supply

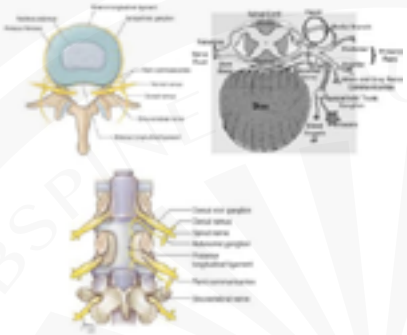
- Healthy disc: peripheral/segmental
- End plates above and below provide channels for diffusion of nutrients into the disc
  - Microcapillaries



Basic Intervertebral Disc Form & Function

Nerve supply

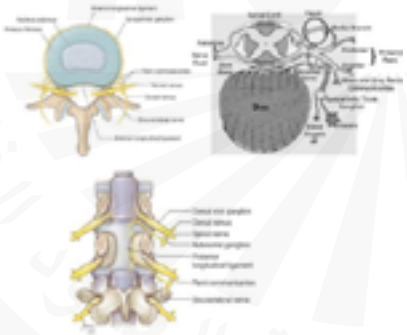
- Sinuvertebral nerve - Disc
  - comes off ventral root and gray rami communicantes
  - innervates PLL, ventral dura, posterior annulus
- Dorsal Root Ganglia - Pain
  - abundant blood supply
  - highest density of glutamate receptors ~~and associated with nociceptors~~
  - disc bulges closer to DRG more likely to trigger pain



Other Important Innervation

Innervation

- Facet Joints
  - Medial branch of dorsal primary rami course around SAP — facet capsule
  - Medial descending branch innervates facet joint, ligaments, muscles for level below
  - Each joint has two sources of innervation



Process

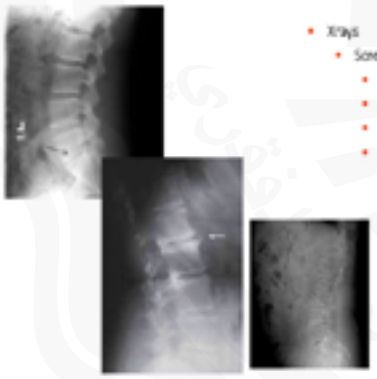
- After the age of 25, degenerative changes begin to occur:
  - Loss of hydration within nucleus
  - Loss of PG structure and viable cells within nucleus
  - Inner layers of annulus expand
  - Outer annulus remains same
  - Overtime the nucleus and inner annulus turn into stiffer fibrocartilaginous material
  - Calcification of cartilaginous endplates eliminates blood supply

Clinical

Low Back Pain

Known vs. Unknown

Known



- X'rays
  - Screening tool for degenerative changes
    - Osteophytes
    - Endplate sclerosis
    - Loss of disc height/narrowing
    - Vacuum disc phenomenon

Known

- MRI
  - Degeneration - loss of hydration signal on T2 image
  - Annular tearing
  - Loss of disc height
  - End plate changes
    - Modic Changes

Modic changes:
Type I : dec T1, inc T2 (vascular bone)
Type II: inc T1, iso T2 (fat)
Type III: dec T1, dec T2 (sclerotic)

Are those findings responsible for low back pain?

Abnormal Magnetic-Resonance Scans of the Lumbar Spine in Asymptomatic Subjects

67 asymptomatic patients

> 60 yo, 57% had abnormal findings

60-80 yo: almost all had degeneration or bulging disc

DON'T JUST TRUST THE MRI. CLINICAL CORRELATION WARRANTED.

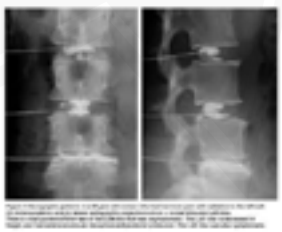
Can you even explain low back pain from Degeneration?

Theory

How can you prove that a degenerated disc is causing low back pain?

Discography

- Provocative study to elucidate symptomatic discs
  - 4 key components:
    - Low pressure injection
    - Dye extravasation – abnormal disc
    - Reproduction of pain (subjective)
    - Control level with no pain
- Historical debate - subjectivity high
- Reliability of study results questionable
  - Poor surgical results in those with positive discogram
- Carragee Studies



Discography

- It's a painful test
- Is it really reliable?
- Post discectomy patients
- Asymptomatic - experimental group
- Symptomatic - control
- Similar proportions of these patients had painful discs at injection
  - normal psych testing
- When abnormal psych testing, higher percentage of painful discs

Carragee EJ, Chen Y, Tanner CM, Truong T, Lau E, Brito JL. Provocative discography in patients after limited lumbar discectomy: A controlled, randomized study of pain response in symptomatic and asymptomatic subjects.

Spine (Phila Pa 1976). 2000 Dec 1;25(23):3065-71.

Discography

Prospective Controlled Study of the Development of Lower Back Pain in Previously Asymptomatic Subjects Undergoing Experimental Discography

- 50 asymptomatic controls
- Underwent discography and followed to see if those who were painful were predictors of future onset of low back pain

Discography

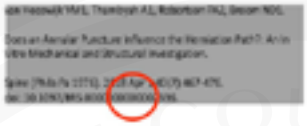
2009 ISSLS Prize Winner: Does Discography Cause Accelerated Progression of Degeneration Changes in the Lumbar Disc: A Ten-Year Matched Cohort Study

Compared to matched controls

- accelerated disc degeneration
- disc herniation
- loss of disc height and signal
- development of reactive endplate changes

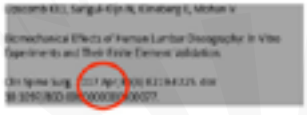
Size of the puncture matters biomechanically:

- The risk of acute herniation through the puncture site is dependent on the needle diameter used
- compared 18 gauge and 25 gauge
- posterolateral puncture
- no herniation seen with 25 gauge



Experimental & FEA

- Confirms degeneration
- Nucleus pressure decreases, annulus stress increases



2019

Effect of needle diameter, type and volume of contrast agent on intervertebral disc degeneration in rats with discography

Can control the degeneration encountered:

- smaller needle size, reduced degeneration
- minimize volume contrast agent
- use non-ionic contrast agent

Experimental subject: Rats

How can you prove that a degenerated disc is causing low back pain?

?? Discography ??

What does our surgical database tell us?

Clinical Presentation - Discogenic Back Pain

- Constellation of symptoms
  - LBP: benign to excruciating
  - Waistline pain
    - May radiate to the PSIS
  - Absence of radicular pain/neurogenic claudication
    - Unless end stage with foraminal height loss
  - Risk factors: Jobs with
    - Heavy lifting
    - Heavy machinery / jackhammering
    - Extended operation of motor vehicles

Surgical Strategies

OR

Fusion

Systematic review/Meta analysis of RCTs

- Fusion vs. Nonop for chronic discogenic low back pain
- Pooled data show no significant difference
- ODI in fusion improved

Disc Replacement

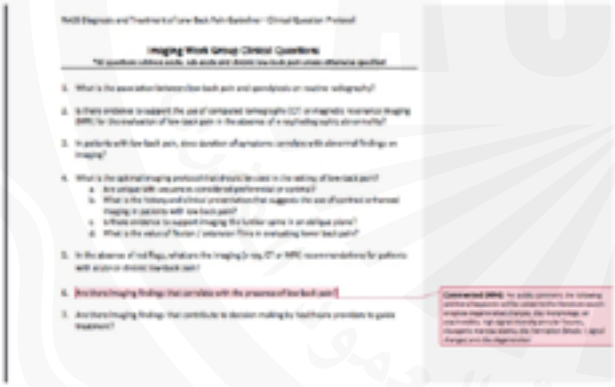
Systematic literature review

RCT TDR versus any other intervention

- "Although statistically significant, the differences in clinical improvement were not beyond generally accepted boundaries for clinical relevance."
- Low quality of evidence for improved ODI in TDR compared to fusion

Are there any guidelines for how to approach Discogenic Low Back Pain?


NASS
Clinical Guidelines
NASS Guidelines
Current Under Development:



IDET (Intradiscal Electrothermal Therapy)

- Heating of a catheter introduced into the posterior annulus
- Thickens collagens
- Closes tears
- Nerve ending cauterization

Freeman BJ1.

IDET: a critical appraisal of the evidence.

Eur Spine J. 2006 Aug;15 Suppl 3:S448-57. Epub 2006 Jul 26.

"The evidence for efficacy of IDET remains weak and has not passed the standard of scientific proof"

May need to step back and reassess.

First Validate low back pain coming from the disc

Dudli S1, Fields AJ2, Samartzis D3, Karppinen J4, Lotz JC2

Pathobiology of Modic changes.

Eur Spine J. 2016 Nov;25(11):3723-3734. Epub 2016 Feb 25.

Spectrum of Modic changes

Represent stages of a pathological process

Intradiscal steroid injections
anti-TNF-α antibody
antibiotics
bisphosphonates

Attempts to target Modic pathway

Change clinic features?

Intervertebral disc as a source of pain

Sandeep Kaur FRCA FFPMRCA
Hinchard Mulay FRCA FFPMRCA

Degeneration process **4 stages**:

- Dehydration
- Fissuring
- Neovascularization &
- Bony changes

With Neovascularization,

SENSORY NERVE ENDINGS spread into the inner layers of annulus, the Nucleus Pulposus and the end plates.

This is believed to be the key process of **DISCOGENIC PAIN.**

Treatment of DISCOGENIC PAIN:
90% pain relief spontaneously

Conservative treatment; Medications , PT, Rehabilitation and behavioural education

Interventions:
.Epidural injections
.Modulating intradiscal pain generators:
RF
IDET (Coagulation of the NERVE ENDINGS in the target tissues and decrease the DISC VOLUME)
.Block and destruction of the ramus communicans.

SURGERY.

Intervertebral Disc Degeneration and Low Back Pain: Molecular mechanism and Stem cell Therapy.

Anna Mellona, Nurrani Mustika, Andi Wijaya.

Understanding the pathogenesis and Treatment of LBP at the Molecular and Genetic levels.
CYTOKINES as matrix metalloproteinases, Phospholipase A2, Nitric Oxidase, TNF are thought to contribute to the Development of LBP.

Mesenchymal Stem Cells (MSCs) transplant to CARTILAGE like cells :
secrete extracellular Matrix
Encourage NP cell activity and inhibit NP cell apoptosis and some chemical mediators.
Safe and 7/ Effective new strategy for IDD treatment and regeneration.

Future of Discogenic Pain

- Continues to be studied
- Room for improvement
- Complex biochemical and biomechanical pathways potentially leading to generation of Low Back Pain
- Future: Targeting of steps along the pathway to diagnose and to treat
  - Common problem is delivery
  - Chemical mediator pathway interruption
  - Stem cells
  - Nucleus replacement

Interventional Treatment of Discogenic Low Back Pain

Intervertebral Disc

- Avascular fibrocartilaginous structure (largest in the human body)
- Supports (principal load bearing structure of the motion segment), and allows movement between vertebral bodies
- Outer annulus fibrosus – dense layers of collagen fibers
- Inner nucleus pulposus – collagen and elastin fibers, proteoglycan gel
- 40% of low back pain, tend to be in younger patients

Discogenic Low Back Pain

- Bogduk & others
  - Lumbar discs were innervated
- Reviews of the literature established that this had been known since 1959, but had somehow been ignored
- No longer a defense that lumbar discs could not hurt because they lacked a nerve supply

Discogenic Low Back Pain

- Dissection and histological studies
  - Nerve endings exist throughout the outer third of the annulus fibrosus
  - Branches of:
    - Sinuvertebral nerves
    - Grey rami communicantes
    - Ventral rami
- Histochemical studies in human and animal material
  - Intradiscal nerves contain peptides such as CGRP, VIP and substance P, which are characteristic of nociceptive, nerve fibers

Interventional Treatment options

- Regenerative Techniques
  - PRP, Stem Cell Injections
- Intradiscal Eletrothermal Therapy (IDET)
- Biaculoplasty
- Grey Ramus Communicans Ablation
- Basivertebral Nerve Ablation

Intervertebral Disc - History

- 1964: Nucleolysis with chymopapain
  - Proteolytic enzyme made from the latex of papaya
  - Catalytes hydrolysis of proteins in the nucleus pulposus
  - Decreases affinity for H2O by proteoglycans
  - Causes disc desiccation
    - Reduces disc pressure – relieves tension on nerve root

Intervertebral Disc - History

- 1964: Nucleolysis with chymopapain
  - Early comparative results positive
    - Wittenburg 2003: 100 patients chymopapain vs collagenase (12% allergic reaction)
    - Nordby, Javid 2000: 3000 patients – 82-87% success
    - Guha 2006: Prospective observational study – 149 patients, 5 yrs: 83% good to excellent
    - Gibson – Cochrane review 2007: Superior to placebo in 5 RCTs
  - Severe complications – anaphylaxis (1.5-2%), paraplegia, death
  - No longer manufactured

Intradiscal Injections

- Simmons 1992: 80% no improvement steroids, 90% no improvement marcaine
- Khot 2004: 2 RCT Intradiscal steroids : 120 pts, no difference
- Cohen 2007: Intradiscal Cytokine inhibitors: no difference
- Peng 2010: RCT for Methylene blue - placebo controlled, 2 year follow-up, 90% success
  - Kalleward: Prospective follow-up study with 15 patients – 40% had 30% pain relief

Regenerative Medicine: Definition

NEJM March 2018:

"Field that involves replacing, engineering, or regenerating human cells, tissues, or organs to establish, restore, or enhance normal function"

Broad scope:

Cell therapies, therapeutic tissue engineering products, human and cell tissue products, and combinations such as scaffolds

Intradiscal Platelet Rich Plasma

- Autologous injectate from whole blood
- Centrifuged to yield injectate concentrated with platelets, growth factors
  - Transforming growth factor b (TGF-b)
  - Insulin like growth factor 1 (IGF 1)
  - Basic fibroblast growth factor (bFGF)
  - Platelet derived growth factor BB (PDGF)
  - Vascular endothelial growth factor (VEGF)
- Supply and release supraphysiologic amounts of growth factors and cytokines to provide a regenerative stimulus that augments healing and promotes repair

Growth Factors

- Non-disc:
  - Some good animal and human results in clinical studies for elbow, knee, and shoulder tendons, and knee cartilage
- Rabbit and rat model *in vivo* experimental degeneration demonstrate protective effect:
  - preservation of disc signal and height and increased expression of mRNA for collagen type 2 and proteoglycan
- Disc:
  - animal and human in vitro cultured disc cells: some positive on survival, annulus cell proliferation, proteoglycan and collagen synthesis and inhibition detrimental inflammatory effect of TNF-alpha and Interleukin-1 on human nucleus pulposis cells

Intradiscal Platelet Rich Plasma - Evidence

2 prospective outcome trials

- Levi D, Horn S, Tyszko S, Levin J, Hecht-Leavitt C, Walko E. Intradiscal Platelet-Rich Plasma Injection for Chronic Discogenic Low Back Pain: Preliminary Results from a Prospective Trial. Pain Med. 2016;17(6):1010-22.
- Akeda K, Ohishi K, Masuda K, Bae WC, Takegami N, Yamada J, Nakamura T, Sakakibara T, Kasai Y, Sudo A. Intradiscal Injection of Autologous Platelet-Rich Plasma Releasate to Treat Discogenic Low Back Pain: A Preliminary Clinical Trial. Asian Spine J. 2017;11(3):380-389.

1 Randomized controlled trial

- Tuakli-Wosornu YA, Terry A, Boachie-Adjei K, Harrison JR, Gribbin CK, LaSalle EE, Nguyen JT, Solomon JL, Lutz GE. Lumbar Intradiskal Platelet-Rich Plasma (PRP) Injections: A Prospective, Double-Blind, Randomized Controlled Study. PM R. 2016;8(1):1-10.

SPINE SECTION

Intradiscal Platelet-Rich Plasma Injection for Chronic Discogenic Low Back Pain: Preliminary Results from a Prospective Trial

David Levi, MD,* Scott Horn, DO,* Sara Tyszko, PA,* Josh Levin, BS,† Charles Hecht Leavitt, MD,‡ and Edward Walko, DO*

- Design: Prospective trial n=22
- Single intradiscal injection: 1.5ml of autologous PRP
- 9 single level, 10 two level, 2 three level, 1 five level
- F/U: 1, 2, and 6 months post-treatment.
- Categorical success rate was defined as at least 50% improvement in VAS accompanied by a minimum of 30% improvement in ODI at 1, 2 and 6 months.

SPINE SECTION

Original Research Article

Intradiscal Platelet-Rich Plasma Injection for Chronic Discogenic Low Back Pain: Preliminary Results from a Prospective Trial

David Levi, MD,* Scott Horn, DO,* Sara Tyszko, PA,* Josh Levin, BD,† Charles Hoehl Lisanti, MD,† and Edward Wolko, DO*

No significant complications reported

Criteria: 50% improvement in VAS accompanied by a minimum of 30% improvement in ODI

- 1 month follow up: 3/22, 14% (95% CI 0% – 29%).
- 2 month follow up: 7/22, 32% (95% CI 13% – 52%).
- 6 month follow up: 9/19, 47% (95% CI 25% – 70%). (Post publication data to 24 pts: equivalent results)

Akeda K, Ohishi K, Masuda K, Bae WC, Takegami N, Yamada J, Nakamura T, Sakitokbara T, Kasai Y, Sudo A. Intradiscal Injection of Autologous Platelet-Rich Plasma Releasate to Treat Discogenic Low Back Pain: A Preliminary Clinical Trial. Asian Spine J. 2017;11(3):380-389.

Design: Prospective trial n=14

Single Intradiscal 2ml of autologous PRP.

Patients selected by discography and disc block (2% lidocaine)

4 - 48 week f/u VAS and Roland Morris

Imaging:

X-rays baseline, 2,4,6,8,10,12 months)

MRI (Baseline 3 and 12 months)

Akeda K, Ohishi K, Masuda K, Bae WC, Takegami N, Yamada J, Nakamura T, Sakitokbara T, Kasai Y, Sudo A. Intradiscal Injection of Autologous Platelet-Rich Plasma Releasate to Treat Discogenic Low Back Pain: A Preliminary Clinical Trial. Asian Spine J. 2017;11(3):380-389.

n=14, beyond 6 months had significant dropout

- *1 patient had repeat injection at 3 months*
- *L4/5 disc in 11 cases and L5/S1 in 3 cases*

Results

- At 1 month: 10/14 (70%) had >50% relief
- At 6 months 8/14 (57%,[illegible]) had > 50% relief
- Statistically significant change in mean VAS and RM at all time periods
- X-Ray: No change in disc height, No change in angle of Lordosis
- MRI: No change in qualitative T2 signal at 3 mo or 12 mos

Lumbar Intradiskal Platelet-Rich Plasma (PRP) Injections: A Prospective, Double-Blind, Randomized Controlled Study

Yetsa A. Tuakli-Wosornu, MD, MPH, Alan Terry, MD, Kwadwo Boachie-Adjei, BS, CPH, Julian R. Harrison, BS, Caitlin K. Gribble, BA, Elizabeth E. LaSalle, BS, Joseph T. Nguyen, MPH, Jennifer L. Solomon, MD, Gregory E. Lutz, MD

- 47 patients, randomized to intradiscal PRP or contrast
- Pain (Numeric Rating Scale), Function (Functional Rating Index), Short Form Health Survey (SF-36) and pt satisfaction (NASS Outcome Questionnaire)
- 1 week, 4 weeks, 8 weeks (6 months, and 1 year)
- At 8 weeks only, PRP group had improved FRI score, NRS Best pain (no difference in current pain, worst pain, SF-35 pain, or SF-36 Function scores)
- Followed PRP group Longitudinally for 6 months, 1 year = improvements from baseline, 6mo, and 1 year for NRS worst Pain, FRI, and SF-36

Issues

- Compared control group followed only after 8 weeks (crossover option)
- Differences seen only at weeks

Summary Intradiscal PRP

- Preclinical data in vitro and animal models is promising.
- 3 clinical trials
  - all with design issues
  - results are modest but encouraging

Intradiscal Electrothermal Therapy (IDET)

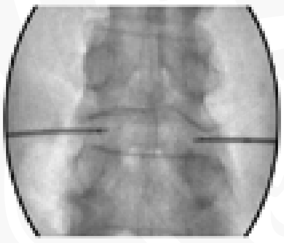
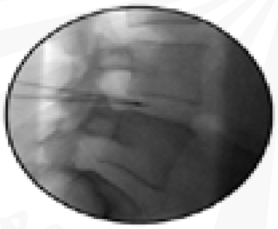
- Intradiscal Electrothermal therapy (IDET)–
  - –Introduced by Saal brothers, preliminary report in 2000
  - –Several prospective cohort, retrospective studies (Saal & Saal, Derby)
    - •Karasek and Bogduk – 12 months, and at 24 months – 54% had 50% relief
  - –Two RCTs
    - •Pauza 2004 – improvements in VAS vs sham, 40% had 50% improvement
    - •Freeman 2005 - randomized, double blind, controlled trial 57 patients – no benefit over placebo at 6 weeks or 6 months

Percutaneous Radiofrequency Neurotomy of the Ramus Communicans

- Oh WS, Shim JC. A randomized controlled trial of radiofrequency denervation of the ramus communicans nerve for chronic discogenic low back pain. *Clin J Pain.* 2004;20:55-60.
  - 63 patients with + discogram, failed conservative treatment and IDE, MBB negative, underwent a diagnostic block of the ramus communicans
  - At 4 months, benefit in the radiofrequency neurotomy group in VAS pain (7.1-3.8 vs. 7.0-6.3, p<0.05,) SF-36 bodily pain, and SF-36 physical function (43.7-58.9 vs. 44.1- 46.5, p<0.05.)
  - 77% of patients in the percutaneous radiofrequency neurotomy group discontinued or decreased analgesic medication consumption.
  - 58% of patients in the percutaneous radiofrequency neurotomy group were highly satisfied and 23% were moderately satisfied
  - No further trials

Biaculoplasty

- Bipolar needles

A Prospective, Randomized, Multi-Center, Open-Label Clinical Trial Comparing Intradiscal Biacuplasty to Conventional Medical Management for Discogenic Lumbar Back Pain.

Desai MJ, Kapural L, Petersohn JD, Vallejo R, Menzies R, Creamer M, Gofeld M

- N: 67, 63 treated
- Statistically significant improvement in pain @ 1, 3, & 6 months
- Trends indicating functional improvement
- 50% vs 18% Responder rate (2 point/30% decrease in VAS)
- 42% reported >50% decrease in pain
- *Conclusion: Superior performance of IDB with respect to all study outcomes suggests that it is a more effective treatment for discogenic pain than CMM-alone.*

Kapural, L., et al. Pain Medicine

- N = 64 enrolled, 59 treated in 1:1 randomization scheme
  - Biacuplasty (n = 29)
  - Sham Procedure (n = 30)
  - 1-2 level disease included
- All patients had positive pain discography
- 1, 3, & 6 month follow up
- Outcomes include SF-36, NRS, ODI
- 6 month follow up for all patients
- Study unblinded at 6 months & sham patients allowed to cross over to treatment

Kapural, L., et al. Pain Medicine

- Results:
- No procedure-related complications
- Statistically significant improvements in pain and function @ 6 months
- 16 mg reduction in daily opioid use

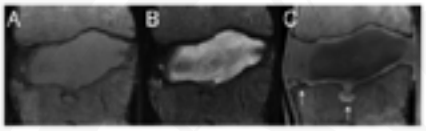
Conclusions

- Evidence for intradiscal treatments for discogenic LBP, including radiofrequency ablation, and injections, is very limited
- There may be a small subset of patients that may benefit from these treatments, however that appears difficult to define
- Carragee 2010:
  - "Modern discography techniques using small gauge needle and limited pressurization resulted in accelerated disc degeneration, disc herniation, loss of disc height and signal and the development of reactive endplate changes compared to match-controls"

Afterthought: Is it the disc?

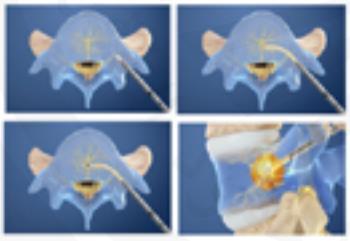
The Role of the Vertebral End Plate in Low Back Pain

J. C. Lotz[1] A. J. Fields[1] E. C. Liebenberg[1]



On the horizon

- Treatment of endplate pain with basivertebral nerve ablation



The Spine Journal 19 (2019) 1028–1037

A prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain

Jad G. Khalil, MD[a,*], Matthew Smuck, MD[b], Theodore Koreckij, MD[c], John Kerr, MD[d], Douglas Beall, MD[e], Bradly Goodman, MD[f], Paul Kalapos, MD[g], Dan Nguyen, MD[h], Steven Garfin, MD[i], on behalf of the INTRACEPT Trial Investigators[j]

- 140 patients across 20 institutions in the US
- Intraosseous radiofrequency ablation of the basivertebral nerve
- Oswestry Disability Index, VAS, SF-36 at three months
- Significant improvements in RF group – ODI -25.3 points vs -4.4

Surgical Indications for Axial Low Back Pain and Degenerative Disc Disease

Introduction

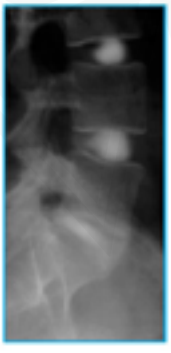
- Evaluation
- Surgical options
  - Fusion
  - Arthroplasty
- Evidence that surgery improves outcomes
- Conflicting evidence that surgery is better than non operative care

Diagnosis

- MRI
  - Least invasive and most sensitive. Gold standard.
  - High incidence of asymptomatic DDD
    - Boden S. JBJS. 1990
    - Borenstein D. JBJS. 2001
    - Jensen, M. NEJM. 1994

Diagnosis

- Discography
  - Morphology and provocation
  - Controversial
    - Eck J. JNS, Spine. 2014.
    - Willems P. Acta Orthop Suppl. 2013.
    - Manchikanti L. Pain Physician. 2009



Fusion

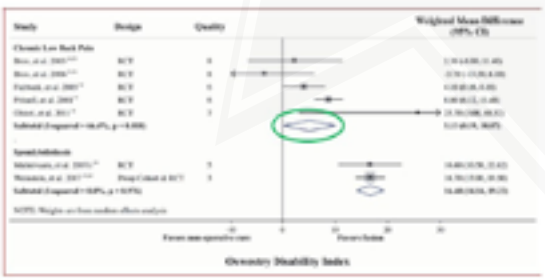
- Inconclusive
  - Eck J. JNS Spine. 2014. (Review)
  - Chou R. Spine. 2009. (Review)
    - Variation explained by non op treatment.
- Fusion better than non op treatment
  - Fritzell P. Spine. 2001
  - Hedlund. TSJ. 2016
    - 13 year f/u of Swedish Lumbar Spine Study
  - Ohtori S. Spine. 2011
- Fusion and non op treatment similar
  - Brox J. Spine. 2003
  - Fairbank J. BMJ. 2005

Fusion

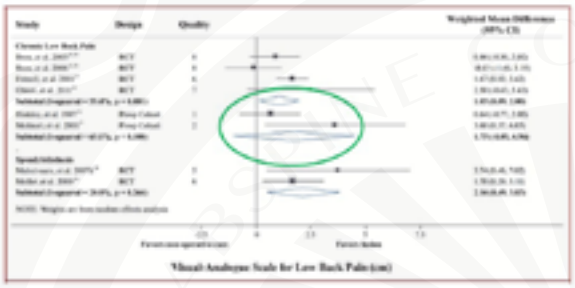
Lumbar Fusion for Degenerative Disease:
A Systematic Review and Meta-Analysis

BACKGROUND: Due to uncertain evidence, lumbar fusion for degenerative indications is associated with the greatest measured practice variation of any surgical procedure.

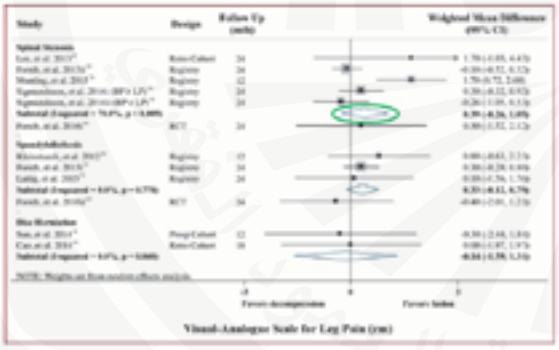
Yavin, el. 2017



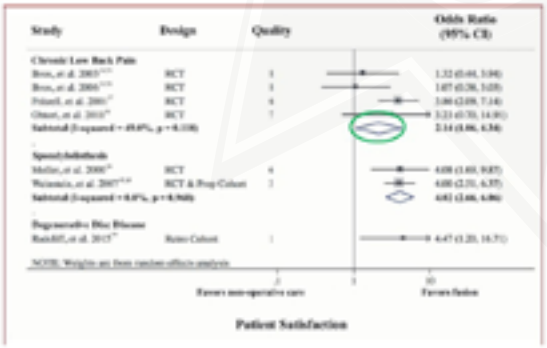
Yavin, el. 2017



Yavin, el. 2017



Yavin, el. 2017



Fusion

- No clear benefit of one type fusion over another
  - » Fritzell P. Spine. 2002
  - » Carreon L. TSJ. 2008
- Disc can be painful with solid posterior fusion
  - » Weatherly C. JBJS, Br. 1986



Arthroplasty

- No studies reported comparing LDA to non op treatment
- Several Cases series show benefit for LDA with no comparison group

Fusion vs. Arthroplasty

- No difference in outcome
  - » Yajun W. ESJ. 2010. (Review)
  - » Van den Eerenbeemt K. ESJ. 2010. (Review)
  - » Blumenthal S. Spine. 2005.
  - » Zigler J. Spine. 2007.
  - » Chou R. Spine. 2009. [Review]
  - » Jacobs W. Cochrane Review. 2013.

Prognostic Factors

- Smoking
- Obesity
- HIZ
- Modic changes
- Single level disease
- Psychologic factors
- Work injury/litigation

- DeBerard M. Spine. 2001
- LaCaille R. TSJ. 2005
- Hagg O. EST. 2003
- Hagg O. Spine. 2002
- Modic M. Radiology. 1988
- Aprill C. Br J Radiol. 1992
- Ricketson R. Spine. 1996

My Preference

- Mechanical symptoms by history
- Failed 1 year non op treatment ***
- No smoking
- BMI under 30
- Off narcotic pain medication
- Degenerative disease on MRI
- Discogram rarely
- Psychometric evaluation?
- One level disease. Rarely two.

My Preference

- Include discectomy
- L5,S1 - anterior
  - LDA
    - Minimal to no facet disease
    - Disc space narrowing (50%)
    - Bone density
  - ALIF
- L4,5 TLIF or LLIF
- Above L4,5 - LLIF

Fusion Options For Lumbar Degenerative Disease

- Spinal fusion is performed for degenerative disc disease in patients who have failed conservative care.
- The goal of fusion procedure is to eliminate motion at the affected spinal segment.
- Arthrodesis can be accomplished through a posterolateral fusion (PLF), an interbody technique after removal of the IVD, or a combined approach (360degree).

Interbody approaches include:

- ALIF, through either an abdominal or a retroperitoneal approach.
- Transforaminal lumbar interbody fusion (TLIF), through the facet and neuroforamen.
- Posterior lumbar interbody fusion(PLIF),via canal decompression.
- Fusion from the side (extreme lateral lumbar interbody fusion [XLIF]), via a transpsoas approach.
- Presacral approach (percutaneous axial lumbar interbody fusion [AxiaLIF]).

Posterolateral fusion

- Performed through a traditional midline approach.
- Exposure of the posterior spinal elements, disruption of the facet joints at the fusion levels, and decortication of the transverse processes, pars, and facets to stimulate fusion.
- Autograft or allograft bone is placed over the decorticated areas and fusion may be augmented with bone substitute.
- Instrumentation is placed to provide segmental stability to increase the success of fusion.

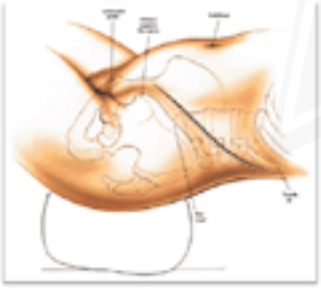
Interbody fusion

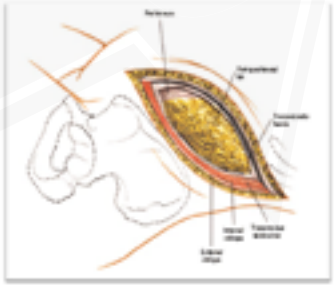
- The lumbar vertebral body represents 90% of the surface area and supports 80% of the load within the spine. The greater amount of compressive force anteriorly and the larger surface area leads to a greater potential for fusion.
- Interbody fusion is an effective technique in cases of sagittal and coronal deformity as loss of lumbar lordosis secondary to disc collapse or postlaminectomy kyphosis.
- The disc material itself may be a pain generator, which interbody fusion directly addresses by discectomy.

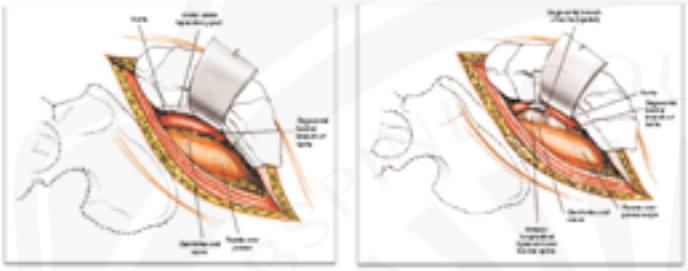
indications of Interbody fusion include:

- Spondylolisthesis, degenerative scoliosis, and spinal stenosis associated with instability.
- Recurrent lumbar disc herniation, where extensive bony removal is necessary for exposure of the disc fragments.
- Failed previous lumbar fusion.
- Discogenic low back pain.

Anterior Lumbar Interbody Fusion

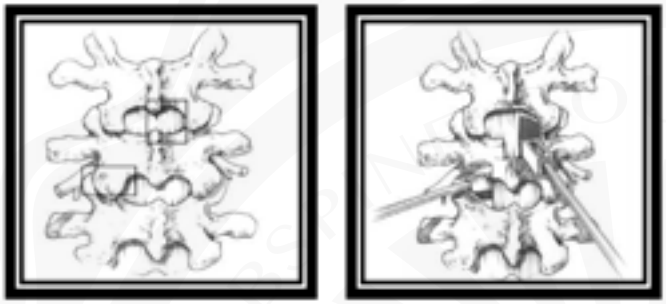






- Performing annulotomy and complete discectomy.
- Reconstruction with autograft bone, allograft bone, or a cage device.
- Allows for placement of a larger graft compared with the PLIF/TLIF procedures.
- Complications associated with the surgical approach, include ileus, injury to the abdominal contents or vasculature, incisional hernia, muscular atony, and retrograde ejaculation in men secondary to injury to the autonomic plexus.

Posterior Lumbar Interbody Fusion	Transforamenal Lumbar Interbody Fusion
The posterior spinal elements are removed to expose the traversing nerve root and lateral extent of the disc space.	Resection of the inferior articular process of the superior vertebra and the superior articular process of the inferior vertebra, exposing the intervertebral foramen.
The thecal sac and traversing nerve roots are mobilized and retracted to the midline.	Exposure of the posterolateral portion of the disc space.



Grafts

- The aim of interbody graft is to:
  - Restore disc height.
  - Create lordosis through the segment.
  - Distract the neuroforaminal space.
  - Restore anatomical weight bearing within the anterior column.
  - Promote fusion across the space.

- Interbody devices include:
  - Local autograft.
  - Iliac crest autograft.
  - Allograft bone.
  - Threaded cylindrical cages made of titanium.
  - Rectangular or trapezoidal cages made of titanium, carbon fiber reinforced, or plain PEEK polymers, and bioabsorbable polymers (i.e., polylactic acids).

- The modulus of elasticity of titanium is much greater than that of bone. The titanium cage may subside through the vertebral body endplates (especially in patients with osteoporosis).

- Use of metal cage prevents adequate radiographic demonstration of fusion.

- The modulus of elasticity of bone is closely approximated by nonresorbable polymers such as carbon fiber and PEEK.

- This allows for true load sharing and less stress shielding between bone and device, leading to more rapid and higher fusion rates.

Updates in the Use of Bone Grafts

Type	
Autograft	Gold standard / iliac crest(donor site morbidity) and local autograft.
Allograft	Slow incorporation / disease transmission./ freeze dried.
DBM	Osteoconductive with some osteoinductivity.
Synthetic substitutes (ceramics)	coralline hydroxyapatite, β-tricalcium phosphate, silicate-substituted calcium phosphate, calcium sulfate / osteoconductive / non-immunogenic / brittle low tensile strength.
BMP	Relatively soluble requiring carrier.(ceramics and synthetic polymers).
Growth factors	platelet-derived growth factor (PDGF) and transforming growth factor (TGF-β)
Bone Marrow Aspirate	osteoinductive and osteogenic / used with a structural graft.

Extreme Lateral Lumbar Interbody Fusion

- This procedure involves an anterolateral interbody fusion performed through a transpsoas approach to the lateral aspect of the IVD.
- The greatest risk during the procedure involves the dissection through the psoas, with risk of injury to the lumbar nerve roots and the lumbar plexus, most specifically the genitofemoral nerve.

Avoiding & Managing Complications Lumbar Fusion

Disclosures

David A. Wong MD, MSc, FRCS(C)

FDA Device/Drug Status:

- Charité, Infuse, Pedicle screw systems, Allograft tissue – Approved;
- Other Disc Arthroplasty, Bone morphogenic proteins – Investigational.
- Presenter Conflict of Interest:
  - c2, e2, k2 – Stryker;
  - e2, k2 – Cervitech;
  - k2 - Zimmer.

Outline

- Setting the Stage
  - Fusion numbers increasing
  - Complex/More instrumentation
- Complications
  - Patient selection/anesthesia
  - Wrong level
  - Approach issues
    - Neuro or vascular compromise
  - Instrumentation accuracy
    - Pedicle screws/cages
  - Deformity correction
  - Non union
  - Adjacent level disease

Increased Expenditures: Lumbar Fusion

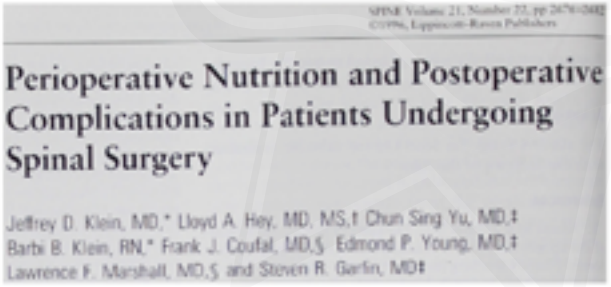
- Deyo R et al. United States Trends in Lumbar Fusion Surgery for Degenerative Conditions. Spine 2005; 30:1441-1445
- Nationwide Inpatient Sample(NIS) – AHRQ 1990-2001
  - 1990 – 32,701
    - 19.1/100,000 population
  - 2001 – 122,316
    - 61.1/100,000
  - 220% ↑

Martin B, Mizra s et al. Trends in Lumbar Fusion Procedure Rates and Associated Hospital Costs for Degenerative Spinal Diseases in the United States, 2004 to 2015. Spine 2019; 44:369-376.

- (1990 37,701 Sx- 19.1/100k pop)
- 2004 122,679 Sx-60.4/100k pop
- 2015 199,140 Sx-79.8/100k pop
- Greatest increase
  - Over age 65 138.7% volume
  - Dx Scoliosis 186.6%
  - Dx spondylolisthesis 111%
- Hospital Cost up 177%
  - $10 billion+/ >$50k/admit

Anesthesia Risk Issues Magnified in Older Patient

- Medical Factors
  - Nutrition
  - Cognitive Function
  - Immunocompromise
    - Diabetes
    - Rheumatoid Arthritis
  - Obesity
  - Hypertension
- Surgical Factors



Perioperative Nutrition and Postoperative Complications in Patients Undergoing Spinal Surgery

Jeffrey D. Klein, MD,* Lloyd A. Hey, MD, MS,† Chun Sing Yu, MD,‡ Barbi B. Klein, RN,* Frank J. Coufal, MD,§ Edmond P. Young, MD,† Lawrence F. Marshall, MD,§ and Steven R. Garfin, MD‡

- Patients undergoing lumbar spine surgery
  - 25% poor nutrition
    - Serum albumin <3.5g/dl = visceral protein mass
    - Total Lymphocyte count <1.5-2000 c/mm^3 = immune competence
  - 42% older patients > 60yr
  - Part I-27 patients Dx osteomyelitis
    - 24/26 complications in undernourished
  - Part II- 20 patients Dx spinal cord injury
    - 17/17 complications in undernourished

British Journal of Anaesthesia 100 (2): 165–83 (2008)
doi:10.1093/bja/aem380

Anaesthesia in the prone position

H. Edgcombe[1], K. Carter[1] and S. Yarrow[2]*

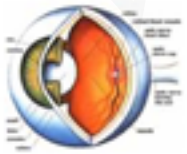
- Analysis multiple OR frames
- Discuss Several Issues/Complications
  - Cardiac Index(stroke volume) ↓24%
    - Anesthesia Considerations
  - Perioperative Blindness
    - Intra occular pressure-direct/indirect
    - Posterior Ischemic Optic Neuropathy (PION)
    - American Society of Anesthesiologists

Prone Position
Cardiac Index ↓ 24%

- Intra-op Hypotension
- Anesthesia Options
  - Phenylephrine
    - Vasoconstriction
      - No effect stroke volume
      - Potential negative peripheral circulation
      - Acidosis → coagulopathy
  - Ephedrine /Dopamine=Best
    - Cardiac stimulant

Peri-Operative Blindness

- Roth S et al – U Chicago
  - 2008 ASA Ann Mtg-abstr A1013
  - National Inpatient Sample '96-'05
    - Cardiac surgery-0.086%
    - Spinal Fusion-0.03%
      - 140/465,345
      - Lum 57%/Thor 35%/Cerv 8%
      - Posterior 83% (116/140)
    - Hip surgery-0.019%
    - Knee surgery-0.011
    - Laminectomy-0.010



Peri-Operative Blindness

ASA Practice Advisory 2012

- High Risk
  - Surgery > 6.5 hrs
  - Blood loss > 45%
  - Prone (spine surgery)
- Operative Management
  - Avoid direct eye pressure
  - Arterial line
  - BP within 24% baseline
    - 84 mm systolic minimum
  - Hct > 28%/Hb > 9.4

Clinical Study

Effect of the degree of reverse Trendelenburg position on intraocular pressure during prone spine surgery: a randomized controlled trial

- Mean intra-ocular pressures were:
  - 58% higher with Trendelenberg of 10 deg.
- 10 deg . f pressure

d the %!

Cognitive Function at Risk

- Advanced Age greater than 70 years
- Multiple medical comorbidities including sepsis, metabolic disturbances
- Poor nutritional status
- Alcohol and/or Drug Abuse
- Existing Neurologic or Psychiatric disorder
- Neurovascular disease, history of CVA or TIA
- Peripheral Vascular Disease
- Mild Cognitive Impairment

Delirium

- Acute Confusional state accompanied by cognitive impairment
- Delirium frequently occurs without surgery
- However delirium is the most common post-operative cognitive morbidity
- Incidence is 15-55% post surgery
- Prevalence approach 100% among those requiring an ICU stay
- Surgical postoperative delirium occurs postoperative days 2-7
- Not related to Anesthesia techniques but some meds are implicated

Silverstein J et al. Central Nervous System Dysfunction after Non-Cardiac Surgery and Anesthesia in the Elderly. Anesthesiology 106:622

Wrong Site Surgery (WSS) "Never Happen to Me!"

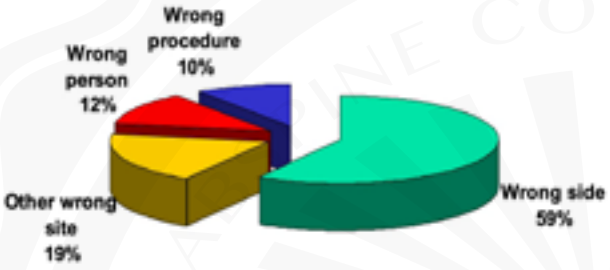
- AAOS Task Force WSS
  - Review closed claims data
  - Calculate individual risk
- 300 cases/yr. X 35 yr.
  - 9,150 cases in career
  - 1 WSS per 36,600 cases
- 25% chance of an Orthopaedic Surgeon perform WSS/career

"WSS" Cases by Anatomical Site

Anatomical Site	% ('95-'03)	% ('04-'05)	% ('06)	Anatomical Site	% ('95-'03)	% ('04-'05)	% ('06)
Knee	17	13	3	Abdominal cavity	2	6	4
Foot/ankle	10	4	5	Breast	2	2	0
Hand/wrist	9	6	5	Kidney	2	1	5
Spine	8	5	10	Skin/subcutaneous	2	2	3
Cranium	6	8	4	Shoulder/arm/forearm	2	0	0
Hip	6	4	4	Eye	2	6	5
Hernia	5	5	3	Urethra/bladder/ureter	2	1	1
Chest	5	6	10	Heart	1	0	0
Male genitalia/prostate	5	4	4	Peripheral nerve	1	4	14
Mouth/pharynx/larynx	5	12	7	Ear/nose/sinus	1	2	3
Uterus/ovaries/tubes	3	1	1	Neck	1	0	4
Peripheral vascular	3	6	5				

Courtesy Dr. R. Croteau-JCAHO

Types of Wrong Site Surgeries



World Health Organization-WHO Safe Surgery Saves Lives

- WHO Surgical Checklist
  - Chair:Atul Gawande/Harvard
    - Reduce medical errors
    - Promote team communication
- Sign In / Briefing
  - Prior to Induction
- Time Out
  - Prior to Skin Incision
- Sign Out / Debrief
  - Prior to Drape Removal

Web Resources

- American Academy of Orthopedic Surgeons (AAOS)
  - www.aaos.org
    - Sign Your Site (SYS)
      - Checklist
      - Background articles
- North American Spine Society (NASS)
  - www.spine.org
    - Sign,Mark and X-ray(SMaX)
      - Patient Brochures
      - Background articles

Lumbar Stenosis

- Wang et al. *Neurosurg Focus* 14(2):e7, 2003
  - Complications associated with lumbar stenosis surgery in patients older than 75 years of age (Retro, Level IV)
  - N= 88 (40 = f, 48 = m), Mean Age 78.5 y (75-88)
  - 52 treated with lumbar fusion, last follow up 21 mo
  - Preop back pain, 89% pts.
    - Postop, 76% complete or partial relief
  - Preop leg pain, 98% pts.
    - Postop, 85% complete or partial relief
  - Systemic and wound complications (18%, 14%)
    - Operative time and Charlston Co-Morbidity Index Associated with increased complications.

Christensen A, Bunger C. TLIF vs posterolateral instrumented fusion: cost utility... Eur Spine J 2014; epub ahead print

- 100 patients- RCT
  - TLIF 51/PLF 49
- Oswestry/SF-6D – 2 yr F/U
- Cost – national registry data
  - TLIF incur more cost (bed days) - 2,554€
  - TLIF higher cost productivity loss - 1,915€
- No Significant Difference TLIF vs PL
- Cost equivalent technologies
  - Author opinion-TLIF not an alternative to PLF

Courtesy Choll Kim

INSTRUMENT FAILURE
Risk Factors

- Osteopenia
- Large Correction
- Absent Anterior Column Support
- Stopping fusion/ instr at Kyphotic area
- Poor Sacral Fixation
- Poor Saggital/Coronal Plane Balance

Pedicle Screw Based Systems

- Korovessis Spine 2004
  - 45 pts dynamic /rigid/semi-rigid
  - 2 screw loosening/ 1 break
  - Average F/U 47 mo.
  - No adjacent level disease
    - X-Ray criteria -Any group
- Beastall Spine 2007
  - Positional MRI
  - No hypermobility adjacent levels

Kosmopoulos V, Schizas C. Pedicle Screw Placement Accuracy: A Meta Analysis. Spine 2007;32: E111-120.

- 130 studies 37,337 screws
  - Both in vivo and cadaver
  - 34,107(91.3%) accurate overall
    - In vivo navigation assist 95.2%
    - No navigation 90.3%
    - Navigation improved accuracy lumbar but not thoracic

Laudato P et al. Pedicle Screw Insertion Accuracy Using O-Arm, Robotic Guidance, or Freehand Technique. Spine 2018;43: E373-378.

- 84 patients 569 pedicle screws
  - Post op CT/2 observers/4 grades
- 11 patients (64 screws) robotic
  - 78.8% good/4.7% misplaced
- 25 patients (191 screws) O-arm
  - 69.6% good/4.2% misplaced
- 48 patients(314 screws) freehand
  - 70.4% good/6.4% misplaced
- Concl:NSD between techniques

Wound Infection Incidence - Overview

Procedure	Incidence
Discectomy	<1%
Posterior Fusion -Uninstrumented	1-4%
Posterior Fusion-Instrumented	2-13% (6%)
Scoliosis - Neuromuscular	25%

- Abbey DM, J Spinal Disord 8:278–281, 1995
- Glassman SD, Spine 21:2163–2169, 1996
- Keller RB Orthop Clin North Am 3: 99–111, 1972
- Roberts FJ, Spine 23:366–370, 1988

Infection Rates?

- Rovner J, Schwender J et al. Comparison of Infection Rates in MIS vs Open TLIFS. TSJ 2008;S1;191-192S.
- RCT Open Vs MIS
  - Return to OR for washout
- 251 Open
  - 9 infections = 3.6%
- 196 MIS
  - 0 infections = 0%

Wound Infection Incidence SRS

- SRS Morbidity & Mortality Comm 2010
  - 108,419 cases -2.1% overall
  - Degenerative 1.4%

Spine Deformity

Rates of Infection After Spine Surgery Based on 108,419 Procedures

A Report from the Scoliosis Research Society Morbidity and Mortality Committee

Justin S. Smith, MD, PhD,* Christopher I. Shaffrey, MD,* Charles A. Sansur, MD,† Sigurd H. Berven, MD,‡

WHO SSI Prevention Guidelines 2016 CDC SSI Guidelines 2017

GLOBAL GUIDELINES FOR THE PREVENTION OF SURGICAL SITE INFECTION

SSI GUIDELINES: CDC

- World Health Organization-WHO
  - https://www.who.int/gpsc/ssi-prevention-guidelines/en/
- Centers for Disease Control-CDC
  - Berrios-Torres S. JAMA Surg

Wound Infections Risk Factors

- Patient/Systemic
  - Nutrition-Garfin Spine 1996;21:2676
    - Albumin<3.5/lymphocyte<1.5-2,000
    - 25% pts/ 42% >60 yr
  - Diabetes
  - Obesity
  - Immune compromise
    - RA/Chemo/XRT/Steroids
  - UTI/Previous SSI
- Environmental/Procedural
  - Skin prep/ABX/Air Xchg/sterile proc

Risk Factors for Surgical Site Infection Following Orthopaedic Spinal Operations

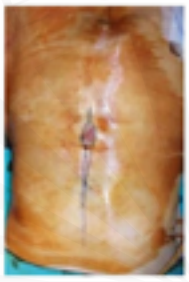
By Margaret A. Olsen, PhD, MPH, Jeffrey J. Nepple, MD, K. Daniel Riew, MD, Lawrence G. Lenke, MD, Keith H. Bridwell, MD, Jennie Mayfield, BSN., MPH, CIC, and Victoria J. Fraser, MD

J Bone Joint Surg Am. 2008;90:62-9 • doi:10.2106/JBJS.F.01515

- 2316 Sx/46 infec=2%

Risk Factor/Odds Ratio

- Diabetes-Odds Ratio 3.5
- Timing pre-op ABX 3.4
- BS pre>125/post>200-3.3
- Obesity-Odds Ratio 2.2



Wound Infections Risk Factors: Perioperative Diabetic Control

Glucose Level* (mg/dL [mmol/L])	No. of Patients with Surgical Site Infection/ No. Tested (%)	No. of Uninfected Patients/ No. Tested (%)	Odds Ratio (95% Confidence Interval)	P Value
Preoperative† >125 (>6.9)	20/39 (51)	30/182 (16)	5.3 (2.5, 11.2)	<0.001
Postoperative >200 (>11.1)	14/35 (40)	21/111 (19)	2.9 (1.2, 6.5)	0.011
Preoperative >125 or postoperative >200	25/45 (56)	45/215 (21)	4.7 (2.4, 9.3)	<0.001

- Suggest
  - Pre-op Blood Sugar <125
  - Post-op Blood Sugar <200

Prophylactic Antibiotics: Single vs. Multiple Doses (? Day SX)

SPINE Volume 28, Number 21, pp E413-E415 ©2003, Lippincott Williams & Wilkins, Inc.

Single *Versus* Multiple Dose Antibiotic Prophylaxis in Lumbar Disc Surgery

Matthew A. Dobzyniak, MD, Jeffrey S. Fischgrund, MD, Steve Hankins, MD, and Harry N. Herkowitz, MD

- 635 pts HNP surgery
  - 201 single pre-op dose
  - 434 pre-op + 3 doses x 24h
- Infection
  - 3/201 single = 1.49%
  - 5/435 multiple=1.15%
- No Significant Difference

Wound Infection Treatment Algorithm

Spine Unstable

- Debridement
- Remove necrotic tissue/ bone graft
- Deep Cultures
  - Appropriate IV ABX
- Repeat Sx prn
- Consider VAC
- Retain Implants
- >6 wks re-bone graft

Spine Stable

- Deep Cultures
  - Appropriate IV ABX
- Debridement
  - Necrotic tissue/bone graft
  - ?Remove implants
- Repeat Sx prn
  - VAC if difficult close
  - ? Flap/plastic surgeon
- 6-12 wks re-instr/graft

Implant Survival-Debride + ABX Nunez S ESJ 2011

- 44 pts Acute SSI
  - 15 lumbar degenerative
  - 13 Scoliosis
  - 10 fractures
  - 6 tumor
- Implant Survival
  - 85% at 6 months
  - 83% at 12 months
  - 73.4% at 24 months
  - 67% at 3 & 4 yrs

Does Wound Drain Prevent Hematoma

Clin Orthop Relat Res (2010) 468:2690–2694
DOI 10.1007/s11999-010-1235-6

CLINICAL RESEARCH

Is Closed-suction Drainage Necessary for Single-level Lumbar Decompression?

Review of 560 Cases

Masahiro Kanayama MD, Fumihiro Oha MD, Daisuke Togawa MD, Keiichi Shigenobu MD, Tomoyuki Hashimoto MD

- 560 patients – 1 level discectomies
- Retrospective review
- Split groups
  - prior 7/03 = drain 298 patients
  - Post 7/03 = no drain 262 patients
- Hematomas
  - 0.7% (2/298) drain
  - 0% (0/262) no drain
- 0% infections
- No difference hematoma/infection

Spine
SURGERY

Intrawound Vancomycin Decreases the Risk of Surgical Site Infection After Posterior Spine Surgery: A Multicenter Analysis

Clinton J. Devin, MD,* Silky Chotai, MD,* Matthew J. McGirt, MD,† Alexander R. Vaccaro, MD, PhD,‡ Jim A. Youssef, MD,§ Douglas G. Orndorff, MD,§ Paul M. Arnold, MD,¶ Anthony K. Frempong-Boadu, MD,‖ Isador H. Lieberman, MD, FRCSC, MBA,** Charles Branch, MD,†† Hirad S. Heidayat, MD,‡‡ Ann Liu, BS,†† Jeffrey C. Wang, MD,†† Robert E. Isaacs, MD,§§ Eric E. Radcliff, MD,¶¶ Joshua C. Patt, MD,‖ and Kristin R. Archer, PhD, DPT*‡‡

- 2056 pts/7 centers
  - Av levels 3.6
  - AV LOS 5 D (±4.7)
  - 1695 (82%) incl fusion
  - 1628 (79%) instrument
  - 434 (21.1%) ICU post op
- 996 (47%) vanco pdr
  - SSI 2.2%/returnOR 0.7%
- 1090 (53%) no vanco
  - SSI 5.1%/returnOR 3.9%
- Risk factors
  - # levels/post op ICU
  - ↑ B NSD DM/Obese/Renal

NASS Clinical Guideline Antibiotic Prophylaxis Spine Sx

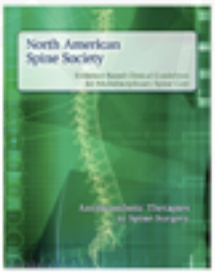
Avoiding Venous Thromboembolism

Chemoprophylaxis

- Recommendations from NASS Guidelines

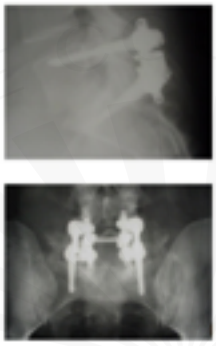
"Most commonly performed elective spine surgeries done through a posterior approach are associated with a very low risk of VTE. In this instance chemoprophylaxis may not be warranted"

"Recommend LMWH be used cautiously prior to routine, elective spinal surgery and withheld unless there are other risk factors for thromboembolism"



Adjacent Level Disease Lumbar Fusion

- Cheh- Spine 2007
- 188 Pts/pedicle screws
- F/U min 5 yrs (Av 7.8)
- X-Ray Adjacent Level Dis
  - 42.6%
- Clinically Significant
  - 30.3%

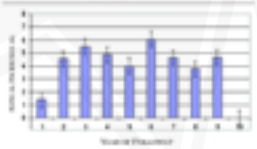


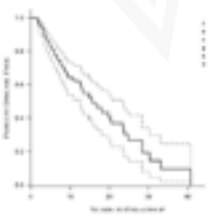
Risk Factors Adj Level Degen Lumbar Fusion

- Age > 50yr.
- Longer fusion
- Upper lumbar levels
  - L1-3 > L4-S1
- Facet Tropism
- *NOT* Risk Factor
  - Post Lat vs. 360

Kaplan Meier Survivorship Analysis

- Ghiselli JBJS 2004
- 215 pts posterior fusion
  - 51% instrument/49% non
- F/U average 6.7yr
- Survivorship
  - 3.9% per year
  - 36.1% @ ten years





Degenerative Spondylolysthesis

- Sears et al. *Spine J* 5:170-179, 2005
  - PLIF for degenerative spondylolisthesis: restoration of sagittal balance using insert-and-rotate interbody spacers (Prospective, Level II)
  - N= 34, (f=23, m = 11) Mean Age 65 y (35-82)
  - Follow up 21 mo (12-32)
  - VAS Pain improved significantly (p<0.001)
  - SF-12 PCS and MCS improved significantly (p<0.001)
  - 97% considered surgery worthwhile, , 88% would have surgery again
  - 8/34 (23%) operative complications (7 were dural laceration)
  - 9/34 (26%), early or late complication (4 ileus)
  - Only 1 patient required reoperation (2.9%)

XLIF
Extreme Lateral Interbody Fusion

- L2-5 Best
  - L1-2 – ribs obstruct
  - L5-S1 – iliac crest obstruct
- Thru Psoas Middle–Ant 1/3
  - Ant – Genitofemoral Nerve, Ureter, Vessels
  - Post – Lumbar Plexus
  - No consistent safe corridor
- Use EMG/Dilator/Retractor

XLIF Complications
Rodgers, Spine J 2008

- 300 Pts
  - 21 complications/6.9%
- 4 Neuro
  - 2 Quad weak-1 persist>6wk
  - 2 tibialis anterior weakness
- 1 wound hernia
- 1 end plate #
- 1 Cage # on insertion

Is there a Role for XLIF in Thoracolumbar Spinal Deformity Treatment?

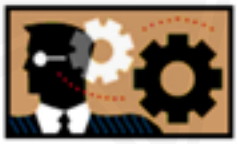
David A. Wong MD, MSc, FRCS(C)
Past President North American Spine Society
Director Advanced Center Spinal Microsurgery PSL Denver

- Laudato P et al. Pedicle Screw Insertion Accuracy Using O-Arm, Robotic Guidance, or Freehand Technique. Spine 2018;43: E373-378.

Who, What and How

Who to Report to

- Manufacturer
  - Mechanism, Procedures and process
    - Unclear and variable
- Prof Liability Insurance
- Food and Drug Administration (FDA)
  - Clear and specific
  - FDA IDE Trials
    - Mandatory
  - Post Marketing/Approval
    - voluntary



What to Report
Sample Statistics

- Post Market Surveillance 6/93-7/94-14,357 reports
  - Drugs
    - 9,879
  - Devices
    - 2,648
  - Biologics
    - 337
  - Medical Food
    - 88
  - Veterinary Medical
    - 8

What to Report

- Adverse Event
- Undesirable experience
  pt has using medical product
  - Serious
    - Death
    - Life Treatening
    - Initial or Prolonged Hospitalization
    - Intervention requ'd prevent damage
    - Congenital Anomaly
  - "Concern about quality, performance or safety "

What to Report

- "Physicians should report when there is a suspicion that the drug or device may be related to a serious AE; they are not expected to establish the connection or even wait until the evidence seems compelling"
  - Kessler D. JAMA ?1995

Courtesy A. van Ooij

What to Report

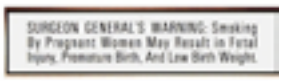
- Patient Identity
  - Confidential
  - Legally Protected
- Reporter Identity
  - May be shared with manufacturer
  - Unless reporter request otherwise
- 1 Form (down from 5)
  - FDA 3500
  - → Central Triage →Appropriate Ctr

How to Report

FDA Post Marketing Surveillance Program: "Medwatch"

- www.fda.gov/medwatch
- 1954 AMA
- 1963 FDA
  - 6/93-7/94 reports
  - 14,357 total
    - 9,879 drug AE's
    - 2,448 device AE's
    - 1,406 drug quality
    - 337 Biological AE's
    - 88 Food
    - 8 Vetrinary

FDA Actions



- Labeling Changes
  - New info add to Package Insert
- Boxed Warnings
  - Serious AE's
  - Warnings prominent on package
  - Restrict marketing
- Product Recall/Withdrawls
  - Remove product from market
- Medical & Safety Alerts
  - Info to Med Prof/Industry/Media-NASS/AAOS Alerts

NASS/AAOS Patient Safety Alerts

- Life or Limb Threatening
  - E-mail
  - Blast fax
- Routine
  - Label status
  - Indications/complications
    - NASS Spineline
    - AAOS Bulletin
    - Websites
      - Approx 40 notices up

Patient Safety Alerts

- Cefazolin
  - 379,975 Vials
  - Nationwide Distribution
  - *Bacillus pumilus, Staphylococcus hominis, Propionibacterium acnes, Micrococcus luteus*
- Allograft Bone
  - 5 Tissue Banks
- ICON Pedicle Screw

Chicago Tribune FINAL

THURSDAY, FEBRUARY 2, 2006 NORTH SHORE

Transplant warning issued

Tissue linked to N.Y. cadaver scandal used in local hospitals

- Sunday New York Times Editorial
  - Black Shrouds and Black Markets
  - Sunday, March 5, 2006
  - Susan Cooke Kittredge-Alistair Cooke's Daughter

ABC Nightline 3/10/06
People 3/13/06

Allograft Tissue Advisory Statement

- Revisit AATB accreditation
- AAOS Biological Implants Com
  - Scott Boden
- AAOS Allograft Tissue TF
  - Gary Friedlander
- Criminal charges-owners
  - Biomedical Tissue Services (BTS), Fort Lee, NJ
  - Brooklyn NY Funeral Homes
  - Forged tissue donor consent
  - Alter death certificates
    - Age
    - health

TDR for Degenerative Lumbar Disease

Is it still Usefull ?

Disapointments

- LBP: Challenging pathology
- No radiographical or biological « indicators »
- No evidence (class I or II)
- Failures scenari, revisions
- Cost-effectiveness / Reimbursement

Trends

- Marketing era 2000- 2006
  I have a degenerated disc could you replace it?

- Evidence era 2006-00
  ...Disc replacement? would you warantee?

What are the patients thinking ?

Not only do I work at an Orthopedic Hospital that has many excellent spinal surgeons, but I also had a lumbar L4 discectomy done 3 weeks ago. I had ruptured a disc and was actually in a wheelchair for a month.

Without the surgery I would have remained a cripple unable to stand or walk. Now I am walking 2 miles a day and after I see my doc on the 30th I hope to begin cycling again.

I want to caution you about the disc replacements. From what the surgeons I work with say, its good when its good but when its bad its a big problem. The artificial disc's are really difficult to remove.

Good luck and let us know how its going.

Ward

Disc replacement update

Can you update us on lumbar and cervical disc replacement surgery for DDD in Canada? What are the outcomes so far? Is anyone doing it in Canada yet?

Question submitted by Monique Moreau, MD Alliston, Ontario

Spinal arthroplasty (cervical and lumbar disc replacement) has been widely used in Europe for over three decades to treat degenerative disc disease (DDD), but only recently in selected Canadian centres, including Vancouver, Calgary, London, Toronto and Montreal.

Over 90% of European patients with lumbar arthroplasty with follow-up of more than a decade report satisfaction and pain relief.

Spinal arthroplasty has been widely used in Europe for over three decades.

Limitations of arthroplasty

- Only a very small, specific subgroup of patients with DDD may be candidates.
- The offending disc has to be the primary pain source.
- It is a complex surgery with serious potential complications.
- Arthroplasty mimics spinal connections, but does not reproduce them.
- Cost effectiveness has not yet been addressed.
- Long-term durability is not known (only 10 to 15 years for hip implant).

What are doctors saying?

- Are these technologies reliable?
  - "…. Only time will tell…"
- What would you prefer for yourself
  - 7% disc replacement
- What would you choose for your pat.
  - 47% spine fusion
  - 47% Chronic pain management
- Why not a disc replacement
  - 59% long term durability?
  - 36% disc over used
  - 9% Complications

Non fuser portfolio

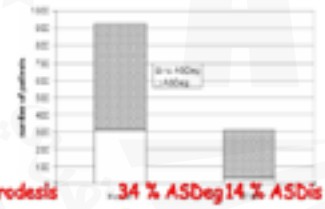
- Adjacent disc Disease ?
- AS Degeneration vs AS Disease
- Natural history ASdeg 3 to 4 % per year (Hassen and al)

Lumbar Adjacent Segment Degeneration and Disease After Arthrodesis and Total Disc Arthroplasty

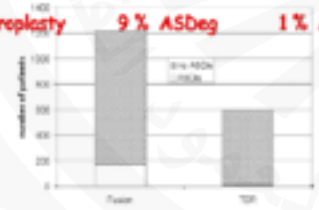
James S. Harrop, MD,* Jim A. Youssef, MD,† Mitch Maltenfort, PhD,* Peggy Vorwald, BS,‡ Pascal Jabbour, MD,* Christopher M. Bono, MD,‡ Neil Goldfarb, BS,§ Alexander R. Vaccaro, MD,* and Alan S. Hilibrand*

Study Design. Systematic review of published incidence of radiographic adjacent segment degeneration (ASDeg) and symptomatic adjacent segment disease (ASDis) after arthrodesis or total disc replacement.

1996-2006
"lumbar spine,"
"adjacent level degeneration,"
"adjacent level deterioration,"
"adjacent level disease,"
"spinal fusion,"
"total disc arthroplasty,"
"artificial disc"



Arthrodesis ..34 % ASDeg14 % ASDis



Arthroplasty 9 % ASDeg 1 % ASDis

Patient selection for lumbar arthroplasty and arthrodesis: the effect of revision surgery in a controlled, multicenter, randomized study

Fred H. Geisler, M.D., Ph.D.,[1] Richard D. Guyer, M.D.,[2] Scott L. Blumenthal, M.D.,[3] Paul C. McAfee, M.D.,[4] Andrew Cappuccino, M.D.,[5] Fabien Reyes, M.D.,[5] and John J. Regan, M.D.[6]

... clinical outcomes of patients enrolled in the CHARITÉ IDE trial who underwent revision surgery after primary TDR with CHARITÉ or ALIF...

The 7.1% of patients who underwent a secondary stabilization procedure had poor clinical improvement. This finding may indicate that if the alternative treatment had been the initial treatment, these patients would not have benefited, and further implies a 7.1% rate of imprecision in preoperative evaluation

Loss of integrity of the disc cause LBP

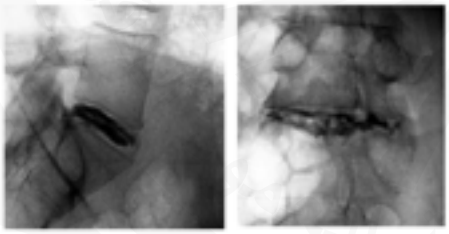
A degenerated disc might be the source of pain

Supra segmental control of the Pain !

Multimodal evaluation & treatment

2009 ISSLS Prize Winner: Does Discography Cause Accelerated Progression of Degeneration Changes in the Lumbar Disc

A Ten-Year Matched Cohort Study



- Discography using modern small needle disc puncture resulted in accelerated disc degeneration over 10-year follow-up compared to matched controls.
- Qualitative MR findings of new disc herniation, new endplate changes, and progression of disc degeneration grade were all found more frequently in discs exposed to disc injection.
- Quantitative MR findings of disc height loss and nuclear signal loss were also greater in the discs exposed to disc injection.
- New MR findings for disc herniation were disproportionately found on the side of the disc injection compared to the contralateral side.
- Careful consideration of risk and benefit should be used in recommending procedures involving disc puncture for diagnostic or therapeutic interventions.

Age
BMI
Multidisciplary evaluation
Conservative treatments
Facet evaluation (CT)
Patient's consent

Discogenic Lumbar pain

Treatment Goal:

- Resect the pain source
- Reconstruct the segment
  - Rigid reconstruction: Fusion
  - Dynamic reconstruction: Arthroplasty

Rationale for arthroplasty

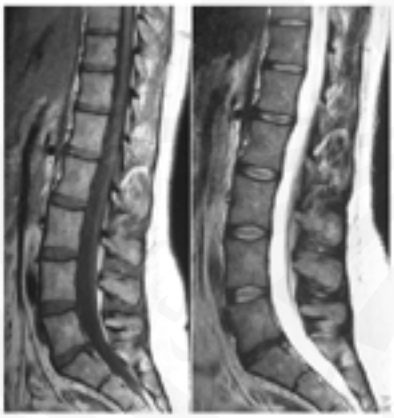
- Avoids stress being transmitted to AS
- Counteracts early degeneration of AS

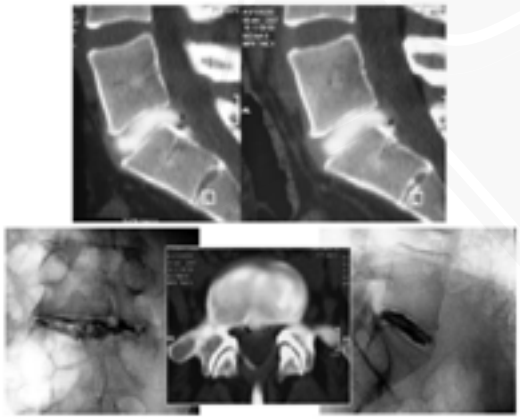
Older
Total segment disease
Segmental deformity
No access morbidity

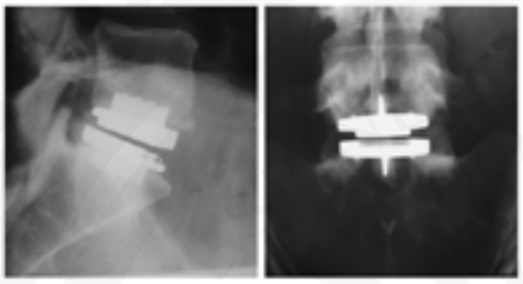
VS

Younger
Disc disease
No Segmental deformity
No access morbidity

Ideal candidate

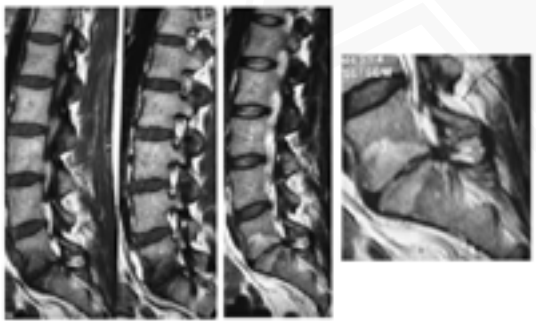


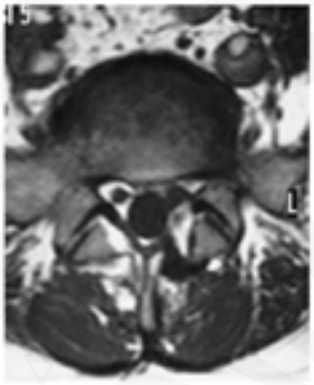


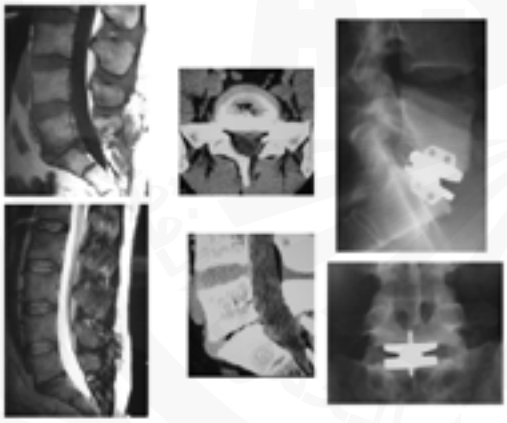


Controversies

Post discectomy syndrome
Multilevel TDR



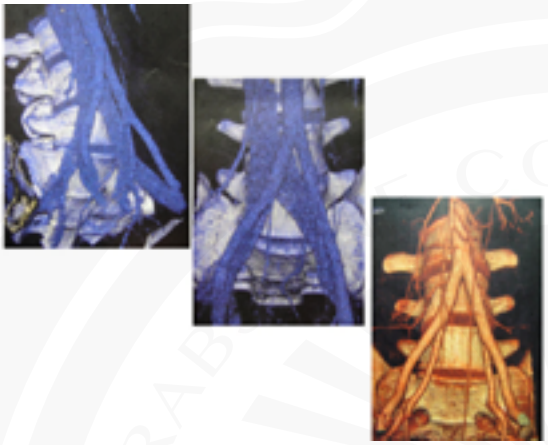


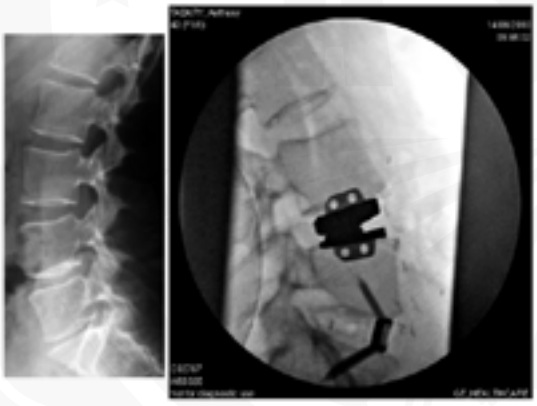


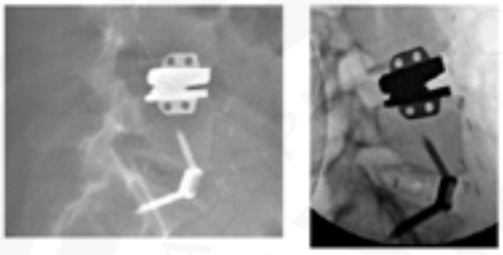
TDR in post-discectomy syndrome ?

Yes
if there is no radiculopathy

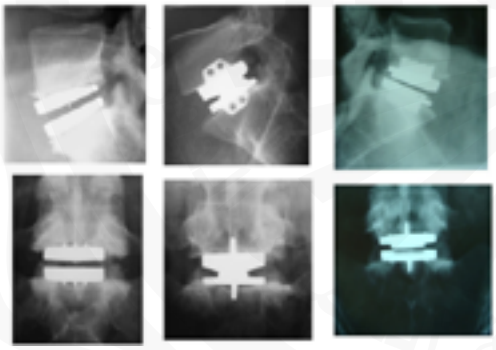
Multilevel disc disease







Choice of the Prosthesis



Lumbar Arthroplasty For Symptomatic Disc Disease: 24 Months Results Of An International Multicenter Prospective Observational Study

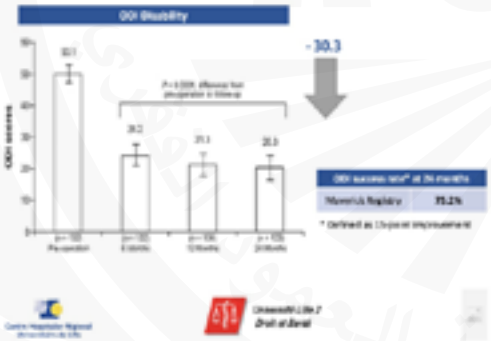
B Assaker*, K Ritter-Lang, D Vardon, S Litrico, S Fuentes, JC Le Huec**,

Maverick total disc replacement in a real-world patient population: a prospective, multicentre, observational study.

Patient Accountability and baseline characteristics

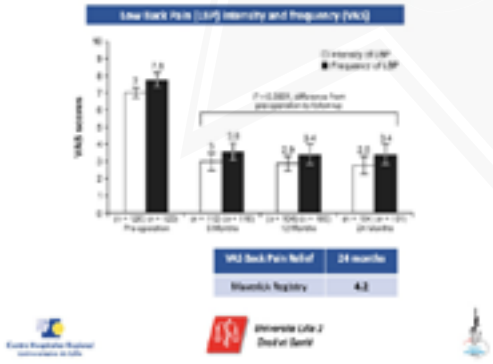
ODI Disability Reduction

Primary endpoint: ODI Disability at 6 months



VAS Back Pain Relief

Secondary endpoint: Vas Back pain relief at 6 months



Adverse Events

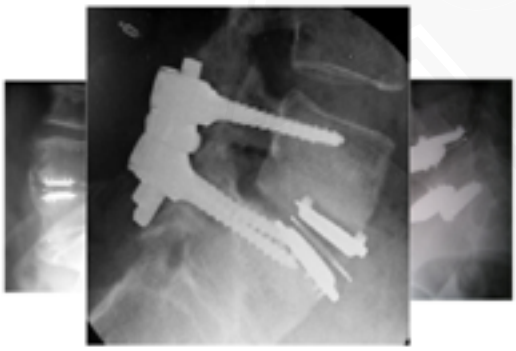
Adverse Event Category	Early AEs (up to 1mo)	Late AEs (after 1mo)
Abdominal wall	9	-
Ileum - Access-related	11	-
Ileum - Late non-specific (not access-related)	-	14
Vascular	6	-
Visceral - Ileum or Peritoneum	5	-
Visceral - Genito-Urinary tract	5	-
Late ileus / Impaction	5	-
Foreign body reaction	-	3
Early non-specific low BP	5	-
Late non-specific low BP	-	6
Other	9	14

One patient was explanted after 13 months due to foreign body reaction with first clinical symptoms reported at 12 months.

Conclusions

- This international prospective observational study shows a statistically significant improvement in disability (ODI) and pain (VAS) scores at 6, 12 and 24 months follow-up in patients treated with a total disc replacement for degenerative lumbar disc disease
- 75.2% patients had successful outcome according to the criterion for success defined by the FDA (≥15 point improvement in ODI)
- This is providing the first evidence of the effectiveness of TDR in real-world clinical settings across countries and patient populations, with an acceptable rate of perioperative complications.
- The similar outcomes of this registry compared to those from RCTs support the use of registry data for assessing interventions

Failures and revision surgery



Conclusion

- Patient's selection
- TDR could be an option (20% of DBP)
  - Discogenic, modict, no facet arthritis, no deformity
  - Socio psychological parameters
- Don't think fusion vs TDR !
- Surgeon part of multidisciplinay team
- Patient has to deserve the surgery !

Avoiding & Managing Complications Lumbar TDR

Rationale for TDR

- Adjacent disc Disease ?
- AS Degeneration vs AS Disease
- Natural history ASDeg 3 to 4 % per year
  (Hassett and al)

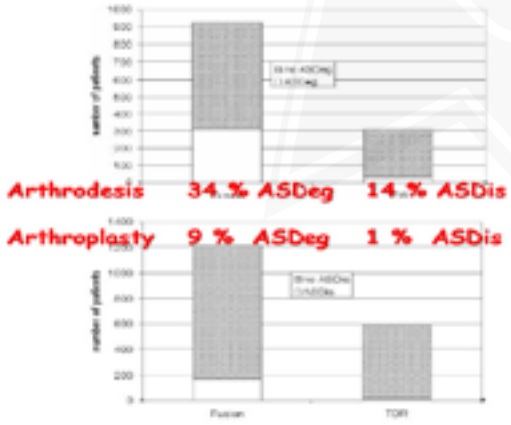
SPINE Volume 33, Number 10, pp 1701–1707
©2008, Lippincott Williams & Wilkins

Lumbar Adjacent Segment Degeneration and Disease After Arthrodesis and Total Disc Arthroplasty

James S. Harrop, MD,* Jim A. Youssef, MD,† Mitch Maltenfort, PhD,* Peggy Vorwald, BS,†
Pascal Jabbour, MD,* Christopher M. Bono, MD,† Neil Goldfarb, BS,§
Alexander R. Vaccaro, MD,* and Alan S. Hilibrand*

Study Design. Systematic review of published incidence of radiographic adjacent segment degeneration (ASDeg) and symptomatic adjacent segment disease (ASDis) after arthrodesis or total disc replacement.

1996–2006
"lumbar spine,"
"adjacent level degeneration,"
"adjacent level deterioration,"
"adjacent level disease,"
"spinal fusion,"
"total disc arthroplasty,"
"artificial disc"



Arthrodesis 34 % ASDeg 14 % ASDis

Arthroplasty 9 % ASDeg 1 % ASDis

J Neurosurg Spine 8:13–16, 2008

Patient selection for lumbar arthroplasty and arthrodesis: the effect of revision surgery in a controlled, multicenter, randomized study

Fred H. Geisler, M.D., Ph.D.,[1] Richard D. Guyer, M.D.,[2] Scott L. Blumenthal, M.D.,[3] Paul C. McAfee, M.D.,[4] Andrew Cappuccino, M.D.,[5] Fabien Bitan, M.D.,[5] and John J. Regan, M.D.[5]

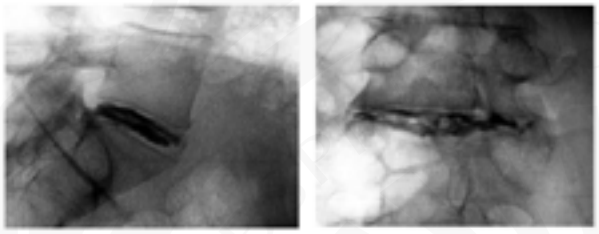
...clinical outcomes of patients enrolled in the CHARITÉ IDE trial who underwent revision surgery after primary TDR with CHARITÉ or ALIF...

The 7.1% of patients who underwent a secondary stabilization procedure had poor clinical improvement. This finding may indicate that if the alternative treatment had been the initial treatment, these patients would not have benefited, and further implies a 7.1% rate of imprecision in preoperative evaluation

Loss of integrity of the disc cause LBP

A degenerated disc might be the source of pain

Supra segmental control of the Pain !



SPINE Volume 34, Number 21, pp 2338–2345
©2009, Lippincott Williams & Wilkins

2009 ISSLS Prize Winner: Does Discography Cause Accelerated Progression of Degeneration Changes in the Lumbar Disc

A Ten-Year Matched Cohort Study

Eugene J. Carragee, MD,* Angus S. Don, FRACS,* Eric L. Hurwitz, DC, PhD,† Jason M. Cuellar, MD, PhD,‡ John Carrino, MD,§ and Richard Herzog, MD¶

- Discography using modern small needle disc puncture resulted in accelerated disc degeneration over 10-year follow-up compared to matched controls.
- Qualitative MR findings of new disc herniation, new endplate changes, and progression of disc degeneration grade were all found more frequently in discs exposed to disc injection.
- Quantitative MR findings of disc height loss and nuclear signal loss were also greater in the discs exposed to disc injection.
- New MR findings for disc herniation were disproportionately found on the side of the disc injection compared to the contralateral side.
- Careful consideration of risk and benefit should be used in recommending procedures involving disc puncture for diagnostic or therapeutic interventions.

Age
BMI
Multidisciplary evaluation
Conservative treatments
Facet evaluation (CT)
information

Discogenic Lumbar pain

Treatment Goal:

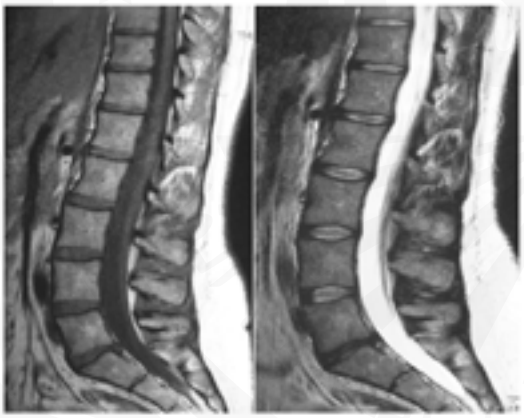
- Resect the pain source
- Reconstruct the segment
  - Rigid reconstruction : Fusion
  - Dynamic reconstruction: Arthroplasty

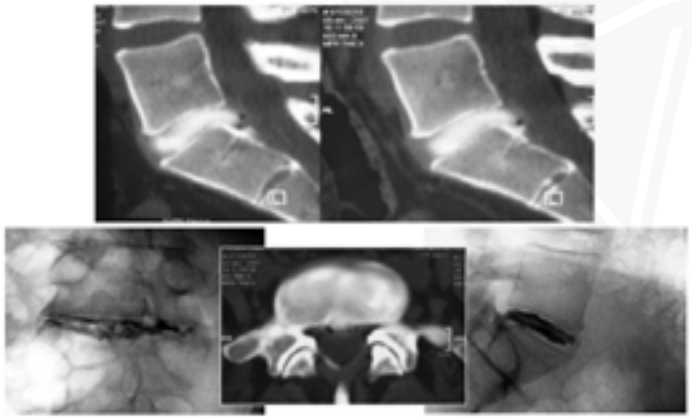
Rationale for arthroplasty

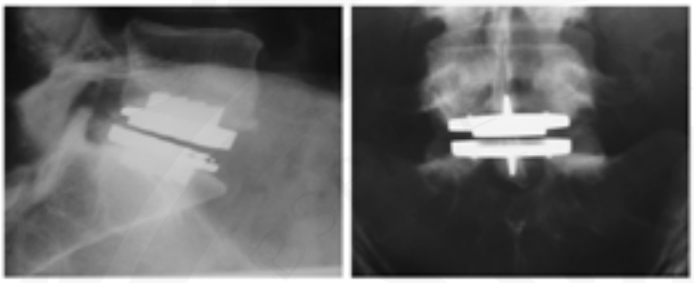
- Avoids stress being transmitted to AS
- Counteracts early degeneration of AS

VS

Ideal candidate

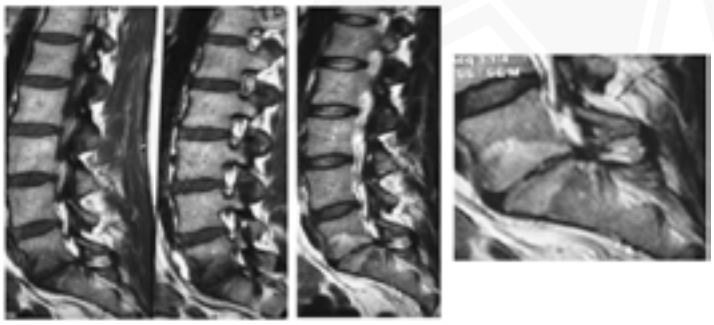


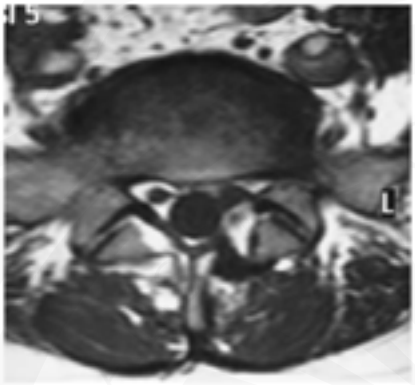


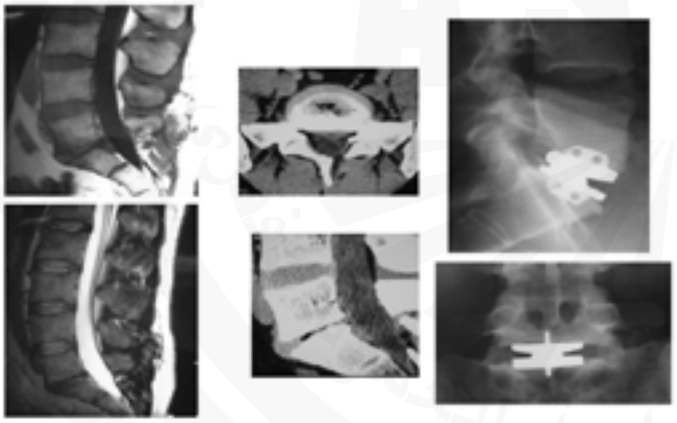


Controversies

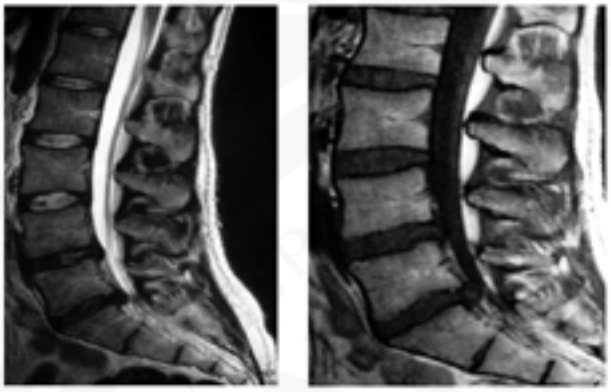
Post discectomy syndrome
Multilevel TDR

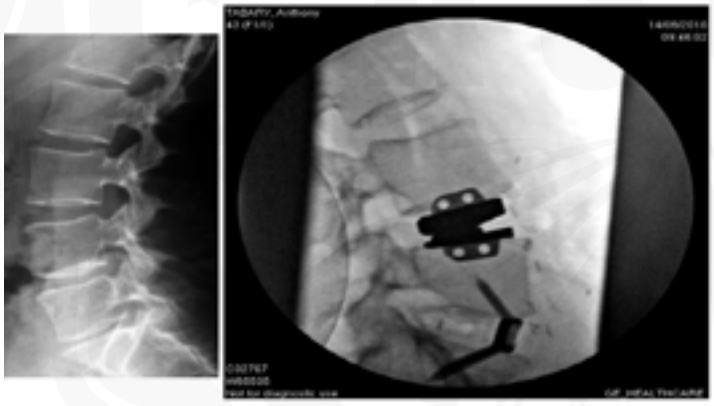






Multilevel disc disease





Lumbar Arthroplasty For Symptomatic Disc Disease: 12 Months Preliminary Results Of An International Multicenter Prospective Observational Study

Richard Assaker*, Jean-Charles Le Huec, Dominique Vardon, Karsten Ritter-Lang
*Neurosurgery, Lille, France

Thursday, October 3rd, 2013
8:30-10:00
Quickfire session QF15 EuroSpine

Conclusion

- Patient's selection
- TDR could be an option (20% of DBP)
  - Discogenic, modic1, no facet arthritis, no deformity
  - Socio psychological parameters
- Don't think fusion vs TDR !
- Surgeon part of multidisciplinay team
- Patient has to deserve the surgery !

SI Joint Pain, Diagnosis & Medical Management

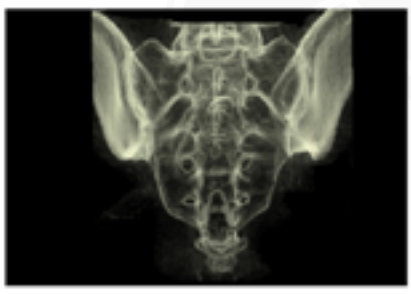
Overview

- Prevalence
- Physical Exam of the SIJ
- Diagnosis
- Conservative care

Sacroiliac joint

- Articulation between the sacrum and pelvis
- Wide, flat L or C shaped synovial joint
- Getting branches from S1, S2, S3, +/- L5 (8%) S4 (4%)
- Has many interlocking grooves and ridges – high coeffient of friction

The SIJ joint



Sacroiliac joint: Function

- Weight bearing joint
- Articulation between sacrum and pelvis
  - Translates force in transverse and longitudinal planes from spine to pelvis.
  - Passive joint – no direct muscular activity

Sacroiliac Joint: Anatomy

- Hyaline cartilage at sacral surface
- Fibrocartilage at iliac surface
- Synovial space is relatively low volume" 1.1-2.5cc, Average 1.5 CC (Fortin, Dreyfuss)

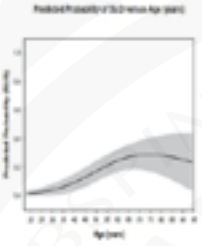
SIJ pain – Prevalence

Prevalance in patients with chronic axial pain

Schwarzer (Spine 1995) 16-30%
Maigne (Spine 1996): 19%
Cohen (Anes Analg 2005): 15-25%
DePalma (Pain Med 2011): 18%.

Post fusion:
Longo (British Medical Bulletin)
9 studies, 32-43% prevalence

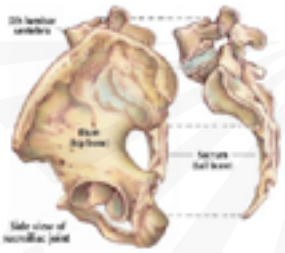
SIJ pain – Prevalence



Depalma, 2011, Pain Medicine

Sacroiliac joint - presentation

- Pain over PSIS, sometimes referred pain into groin, buttocks, posterior thighs
- Below L5



SACROILIAC JOINT HISTORY

- In general, history does not predict response to diagnostic injection
  - pain above L5 which rarely seen in patients with positive SIJ injection
  - Groin pain only thing discriminating between (+) and (-) diagnostic SIJ injection ($p<0.01$)

Positive vs Negative Block

Clinical Diagnosis

- History and pain referral are non-specific
  - What about physical exam?
  - Provocative maneuvers: Distraction, Compression, Sacral Thrust, Gaenslan's.

The value of medical history and physical examination in diagnosing sacroiliac joint pain.

- Patients referred for sacroiliac joint blocks
- 85 consecutive patients enrolled
- Also with pain principally below L5
- Underwent 12 Physical Exam maneuvers by chiropractor and physician
- Injection of anesthetic and steroid
  - Positive was considered 90-100% relief
- No historical feature or PE maneuvers demonstrated "worthwhile" diagnostic value

Correlation of clinical examination characteristics with three sources of chronic low back pain

Sharon Young, PT, Cert. MDT[a,*], Charles April, MD[b], Mark Laslett, PT, Dip. MT, Dip. MDT[c]

Usually unilateral

Association of 3 or more positive tests with positive intra-articular block. Odds ratio = 27.3

Unilateral pain below L5, 3 positive tests: 74% SI Joint

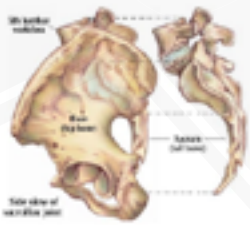
Diagnosis of Sacroiliac Joint Pain: Validity of individual provocation tests and composites of tests

Mark Laslett[a,*], Charles N. April[b], Barry McDonald[c], Sharon B. Young[d]

- Are 3 PE maneuvers better than 1?
- 62 patients underwent 6 PE maneuvers
- 48 also underwent fluoroscopic SIJ injection
  - + was considered 80% relief
  - 16 with positive block

Sacroiliac joint

- 2015 Systematic Review: Kennedy, MacVicar et al
  - 45 articles
  - No single physical exam maneuver is predictive of those that will respond to a diagnostic injection
  - With at least three physical exam findings sensitivity and specificity increases when compared with single diagnostic injections.



39 consecutive patients, each underwent provocative testing pre-and post SIJ injections.

- No association between positive tests and positive blocks
- Either singularly or in combination

Physical Exam?

- For any specific maneuver, very poor sensitivity and specificity when using anesthetic as a reference standard
- Laslett study suggests this can be overcome by using combination of 3 PE maneuvers
- More recent smaller studies did not show association

Conservative care

- Activity modification
- Medications
- Bracing
- Physical Therapy
- Chiropractic care
- Complementary and Alternative Medicine (CAM)

Medications

- NSAIDs or acetaminophen
  - short term for acute or chronic LBP
  - Systematic reviews of patients with OA consistently found NSAIDs superior to acetaminophen for pain relief
- Muscle relaxants
  - Short course (2 wks max) for acute LBP (cyclobenzaprine, methocarbamol)
  - Avoid carisoprodol and diazepam (high addiction potential and no benefit over less addictive meds)

Bracing – SIJ belt

- Small studies have reported improvements in self-reported disability and pain have been reported with the use of sacroiliac joint belts (pelvic belts)

Physical Therapy

- Limited evidence as a standalone treatment
- Therapy should be considered as part of a comprehensive treatment plan

Complementary and Alternative Medicine

- Limited evidence confirm the efficacy for treating SI joint pain utilizing CAM intervention

Interventional Procedures for SIJ pain – to be discussed in a separate lecture

- SI joint injections
- Radiofrequency Ablation
- Peripherall stimulation

SI Joint Interventional Options

The SIJ joint

Sacroiliac joint

- Articulation between the sacrum and pelvis
- Wide, flat L or C shaped synovial joint
- Getting branches from S1, S2, S3, +/- L5 (8%) S4 (4%)
- Has many interlocking grooves and ridges – high coeffient of friction

Sacral Ligaments

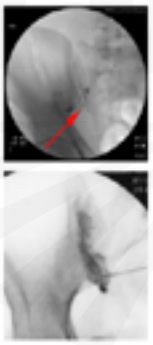
- The stability of the joint is in large part due to the posterior sacral ligaments.
  - sacrotuberous ligament, sacrospinous ligament, anterior sacroiliac ligament, posterior sacroiliac ligament, and the interosseous sacroiliac ligament.
- By 55 years of age, these ligaments tend to ossify, further limiting movement at the SIJ complex (Rosatelli, Agur, and Chhaya 2006)
- Make significant contributions of to the sacroiliac joint complex and its biomechanics

Interventional Procedures for SIJ pain

- SI joint injections
- Radiofrequency Ablation

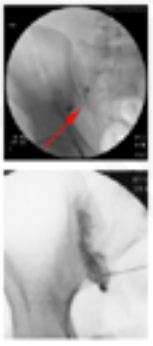
Sacroiliac Joint Injection Technique

- Patient lies prone & Area prepped and draped
- Inferior SI Joint Targeted
  - Caudal Tilt (SI joint has a curved orientation)
  - Contralateral Oblique Tilt (to align the joint)
- Skin and Subcutaneous tissue are anesthetized



Sacroiliac Joint Injection Technique

- Spinal Needle advanced toward the inferior joint line
- Lateral views confirm depth
- Contrast (limit volume)
- Local Anesthetic + Steroid
  - 2-2.5 cc total volume



Sacroiliac joint injections

- Overall evidence for therapeutic SIJ injections is **moderate**

Pain Medicine

Review Article

Fluoroscopically Guided Diagnostic and Therapeutic Intra-Articular Sacroiliac Joint Injections: A Systematic Review

39 studies of diagnostic SIJ injections
15 studies of therapeutic SIJ injections
7 systematic reviews

Caveats

- Real time fluoroscopy is essential, intra-articular (IA) delivery must be documented
- Ultrasound is insufficient for an IA injection
- Limited volume is essential < 2.5ml

Pain Medicine

Review Article

Fluoroscopically Guided Diagnostic and Therapeutic Intra-Articular Sacroiliac Joint Injections: A Systematic Review

Diagnostic Injections

Prevalence 20-30% (dual blocks, 75% relief) in clinically suspected population, increasing with age

No data on general population

False positive rates for single blocks: 19% (Maigne), 20% (Laslett)

Failure of joint access 4-20% (likely higher)

GRADE analysis of IA injections as a diagnostic test- ability to predict response to a therapeutic injection, is not possible with current evidence

Pain Medicine

Review Article

Fluoroscopically Guided Diagnostic and Therapeutic Intra-Articular Sacroiliac Joint Injections: A Systematic Review

David J. Kennedy, MD,* Andrew Engel, MD,† D. Scott Kreiner, MD,‡ Devi Nampiaparampil, MD, MS,§ Belinda Duszynski, DO,¶ and John MacVicar MBChB, MFamMed‖

Therapeutic Injections

2 RCTs in spondyloarthropathy patients:

Maugers 1996- explanatory trial, RCT fluoroscopically guided injections [steroid vs saline] effect greater than placebo. 1 month, few subjects, outcomes measures non-validated. 5/6 patients with >70% improvement in pain ($p<0.05$).

Kim 2010- pragmatic trial, 6 month outcomes. Heterogeneous treatment protocol

3 observational studies, combined results: >70% relief from dual blocks, 43-67% had > 50% pain relief for 4-6 weeks

GRADE of evidence for therapeutic IA injections: **moderate quality**

Posterior Complex Pain

Pain can also come from the supporting ligaments (interosseous [IO], dorsal SI ligaments [DSIL])

Lateral branch blocks (LBB) were developed to intercept nociceptive pathways from L5 dorsal ramus and S1-S3 lateral branches as they course to the SI Joint and supporting ligaments

Dreyfuss P, Snyder BD, Park K, Willard F, Carreiro J, Dogulu N. The ability of single site, single depth sacral lateral branch blocks to anesthetize the sacroiliac joint complex. Pain Med 2008; 9 (7): 844-50.

Pain Medicine

PAIN MEDICINE

The Ability of Multi-Site, Multi-Depth Sacral Lateral Branch Blocks to Anesthetize the Sacroiliac Joint Complex

Paul Dreyfuss, MD,* Troy Henning, DC,† Nikkole Malladi, MD,‡ Barry Goldstein, MD,§ and Nikolai Dogulu, MD, PhD¶

Sacral lateral branches are not consistently on periosteum, but within substance of the ligaments

Multi-site, multi-depth LBB had a 91% accuracy in cadaveric study

Multi-site, multi-depth LBB were physiologically effective in blocking nociception from the interosseus and dorsal SIJ ligaments in 70% of subjects

Only 20% of subjects were protected from IA pain (capsular distention): IA innervation is not solely dorsal

Intra-articular blocks – joint pain; Lateral branch blocks – posterior ligament/complex pain

Diagnosis and Treatment of Posterior Sacroiliac Complex Pain: A Systematic Review with Comprehensive Analysis of the Published Data

Diagnosis: Multi-site, multi-depth blocks:

GRADE evidence: **moderate quality**

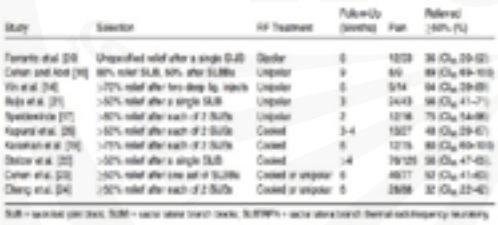
Treatment: Radiofrequency neurotomy of lateral branches

2 explanatory studies

13 supportive observational trials

GRADE evidence: **moderate quality**

Diagnosis and Treatment of Posterior Sacroiliac Complex Pain: A Systematic Review with Comprehensive Analysis of the Published Data



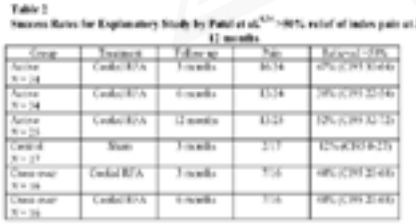
Observational Trials

Significant heterogeneity in patient selection and RF technique

A randomized, placebo-controlled study to assess the efficacy of lateral branch neurotomy for chronic sacroiliac joint pain. Patel Pain Med 2012; 13 (3): 383-98.

Patient selection: > 75% relief from dual sacral LBB

N=51, 2:1 randomization treatment: control



Cohen SP, Hurley RW, Buckenmaier CC, 3rd, Kurihara C, Morlando B, Dragovich A. Randomized placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac joint pain. *Anesthesiology*. 2008;109(2):279-288.

Success Rates for Exploratory Study by Cohen et al.[9] >50% relief of index pain at 6 months

Group	Treatment	Follow-up	Pain	Returned >50%
Active N = 14	Control RFA	6 months	8/14	57% (CI 34–81%)
Control N = 14	None	6 months	0/14	0%
Cross-over N = 11	Monopolar RFA	6 months	4/11	36% (CI 11–61%)

Alison Stout, DO,[1] Paul Dreyfuss, MD,[1] Nathan Bardin, DO,[1] Shannon Roberts, BA,[1] Dillon Lutz, BS,[1] and Amee Agur, PhD[2]

Proposed Optimal Fluoroscopic Targets for Cooled Radiofrequency Neurotomy of the Sacral Lateral Branches to Improve Clinical Outcomes: An Anatomical Study

Pain Medicine 2017; 0: 1–8
doi: 10.1093/pm/pnx287

- 20 Cadavers
- 40 Sacroiliac joints
- Proposed targets for lesion sites which minimized miss rate:
  - Right: 4:30 and 6:00 for S1
    2:30, 4:00, and 5:30 for S2
    1:00 and 2:30 for S3
  - Left: 6:00 and 7:30 for S1
    6:30, 8:00, and 9:30 for S2
    9:30 and 11:00 for S3.

Figure 7 All lesion targets from all specimens in overlay with clockface and S1–S3 sacral sites.

Sacral Radiofrequency Ablation: Summary of Evidence

- 27 Studies (at least)
- 2 sets of single-site, single-depth, anesthetic blocks of the sacral lateral branches and L5 dorsal ramus with at least 75% relief required for progression to SLBRFA. (Patel et al. 2012)
- Single set of single-site, single-depth SLBB with 50% relief in order to progress to SLBRFA. (Auch et al. 2017)
- 2 comparative intra-articular and/or deep interosseous ligament injections(Jung et al. 2007)(Mitchell et al. 2015). >70% relief with two comparative injections into the deep interosseous ligaments with anesthetic and steroid(Yin et al. 2003)
- 22 studies intra-articular sacroiliac joint block (SIJB)
  - more than half injections including steroid and local anesthetic.

Summary

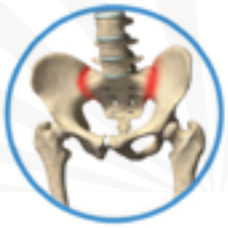
Intra-articular pain:
Intraarticular injection

Dorsal complex pain: Multi-Site, Multi Depth lateral branch blocks & RF neurotomy

SI Joint, Fusion Options and Percutaneous Technique

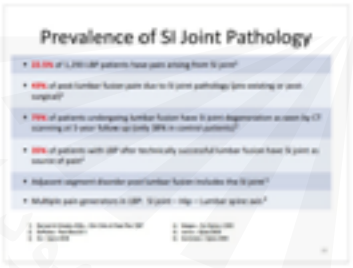
Prevalence of SI Joint Pain

- 13-30% incidence of SIJ Pain in LBP Patients
  (Schwarzer AC. Spine 1995)
- 18.5% incidence of SIJ Pain in LBP Patients
  (Maigne JY. Spine 1996)
- 15-25% of patients with axial LBP have SI Joint Pain
  (Cohen SP. Anesth Analg 2005)
- 27% incidence of SIJ pain in LBP Patients
  (Ylinin RW. AM J Physical Medicine & Rehabilitation 2007)



The Dilemma

- Is the SIJ a pain generator?
- Are current tests reliable in dx the problem?
- Are current treatment modalities effective in managing SIJ dysfunction?



Diagnostic Challenges

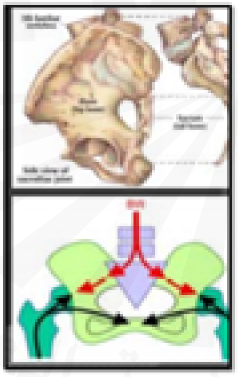
SIJ Pain

- Historically SIJ pain is difficult to diagnose
  - Multiple targeted P/E manuvers described in the literature
  - Diagnosis more likely if history and constellation of exam findings are positive (3+/7)
- Current accepted gold standard for diagnosis is injections with documented relief of greater than 50% (3)

References:
1. [illegible]
2. [illegible]
3. [illegible]

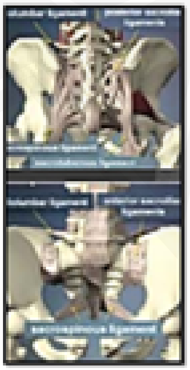
SIJ Anatomy

- True Diarthrodial Joint
  - Ant- synovial
  - Post- syndesmosis
- Joint space 1-2 mm wide
- C shaped joint – 2 lever arms interlock at the 2nd sacral vertebra
- Provides stability and minimal motion (< 1 deg)
- Stability provided by ligaments and ridges



SIJ Ligaments

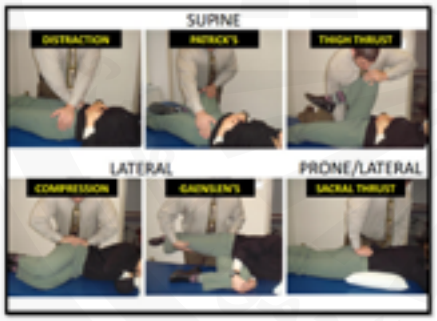
- Robust ligaments anteriorly and posteriorly
- Stabilize sacrum to pelvis



SIJ Innervation

- Complex coming from multiple spinal levels
- Dorsal rami play a primary role
- Possible ventral innervation

Physical Examination

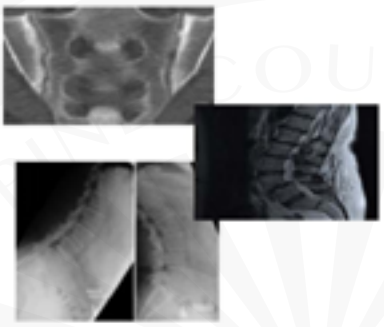


Evidence for Provocation Tests

- Weak in general
- High inter-observer variability
- Unreliable

SIJ Imaging

- X-rays
- CT scan
- MRI
- No diagnostic value in differentiating a painful SIJ

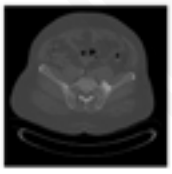


SIJ Injection

- Considered gold standard
- Fluoro control

SIJ Injections

- SI joint space is only 1-2 mm wide
- Potential space
- Variable anatomy
- ~20-30% false positive rate
- Still have not defined the pain generators in the SIJ



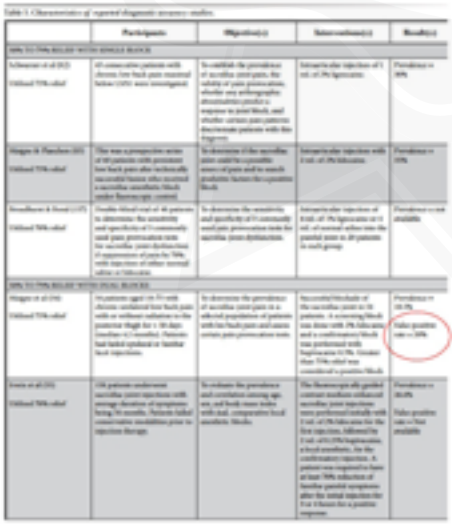
Evidence Supporting Diagnostic Injections

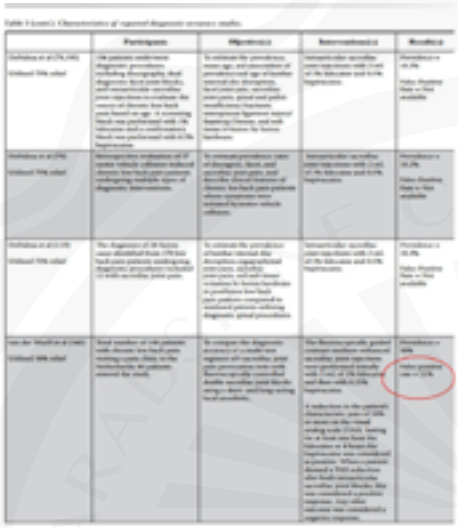
- Present gold standard is to perform these under fluoro control; even this technique leads to significant miss rates
- Blind injections only ~12% accurate
- CT guided ~22% accurate

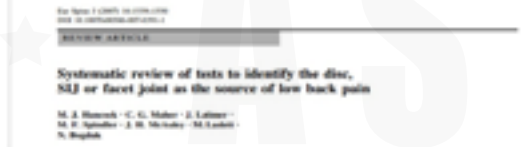
Systematic Review

A Systematic Evaluation of Prevalence and Diagnostic Accuracy of Sacroiliac Joint Interventions

- There continues to be considerable controversy utilizing diagnostic injections surrounding the use of diagnostic local injections in the SIJ
- Only fair to good evidence supporting the use of dual injections







Systematic review of tests to identify the disc, SIJ or facet joint as the source of low back pain

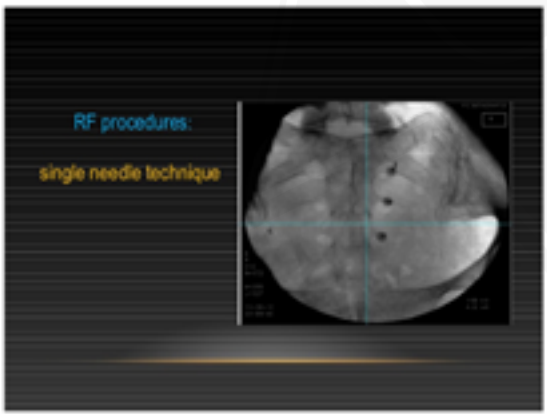
- The aim of this systematic review was to determine the diagnostic accuracy of tests available to clinicians to identify the disc, SIJ, or facet joints as the source of low back pain
- Eligible studies compared index tests with an appropriate reference test in pts with LBP
- Discography, facet blocks, SIJ blocks

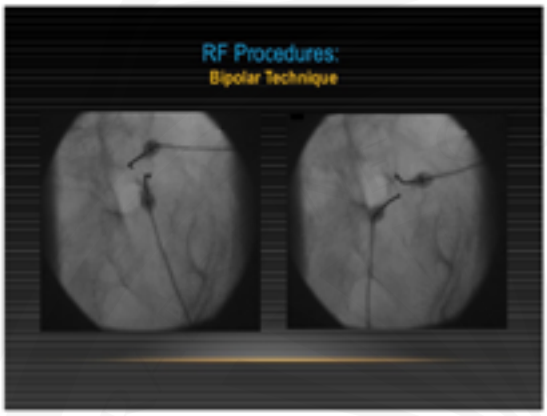
Systematic review of tests to identify the disc, SIJ or facet joint as the source of low back pain

- Tests do exist that change the probability of the disc and SIJ as a source of LBP
- However the usefulness of these tests is small to moderate at best
- The usefulness of these tests in clinical practice particularly for guiding treatment selection remains unclear

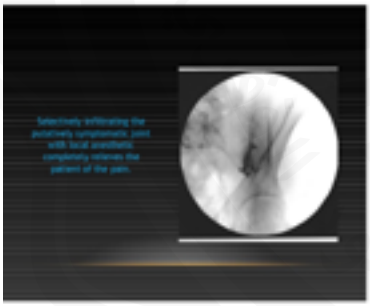
The Dilemma

- Patient selection





SURGICAL ALGORITHIM



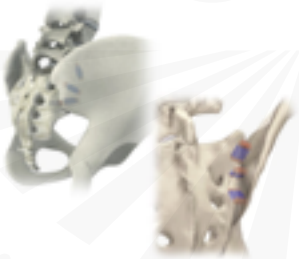
- SYMPTOMS/EXAM CONSISTENT WITH SI PATHOLOGY
- FAILED SI INJECTION (SHORT TERM RELIEF ONLY)
- FAILED TRIAL OF RFA SHORT TERM IMPROVEMENT)
- SUCCESSFUL OUTCOME WITH EXPAREL INJECTION(NO STEROID)
- SURGICAL CANDIDATE?

Surgery

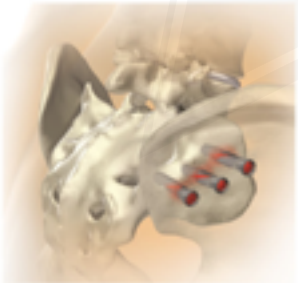
- Open dorsal
- MIS posterior approach
- MIS lateral approach

WHICH ONE.....WHAT APPROACH??

- Posterior approach into the plane of the joint allowing Direct Visualization of the joint space.
- Three allograft implants placed at opposing angles provide stability and promote fusion across the joint.



Lateral Approach



Lateral Approach

- Screw-based implant
- Self-Harvesting & Self-Filling Feature
- Implant uses patient's own bone (Autograft bone)
- Decortication Device (optional)
- Case studies show CT images of significant bone growth 3 months after surgery

Posterior Approach

- Minimal Blood Loss
- Less morbidities
- Anti-migration teeth to resist graft dislocation
- One piece tri-cortical allograft bone for immediate resorption
- Extrusion on proximal end to facilitate instrument engagement
- Patented titanium inserts to verify placement of bone graft correctly into joint

Preoperative Radiographs

Patient Name _____ Date _____

Address _____

CT scan of the Pelvis: Bone and Soft Tissue windows, special attention to the SI Joints

(Evaluate bone and soft tissue structures of pelvis)

Thin cut bone windows to include all of the SI joint on all views (1 – 2 mm):

1. Sagittal cuts, align from lateral aspect left ilium to lateral aspect right ilium
2. Coronal cuts, parallel to the posterior sacral wall of SI (include entire sacrum)
3. Axial cuts, align perpendicular to the coronal cuts (include entire sacrum)
4. 3D reconstruction

DX _____

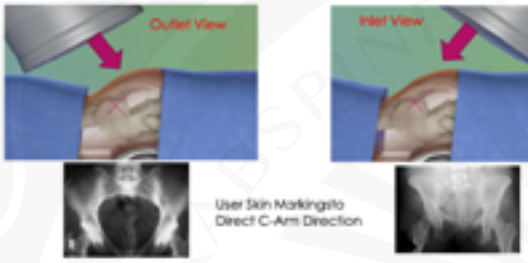
_____ _____

Physician Name (printed) *Physician Signature*

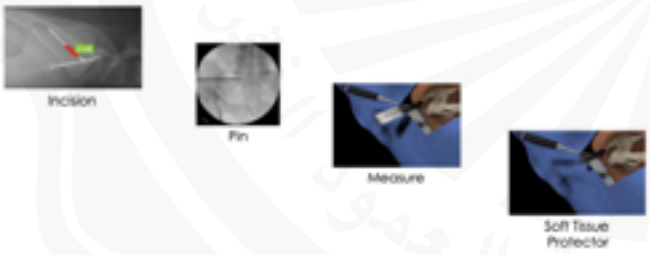
Patient Positioning

- Flat Jackson Table
- Prone Position
- RolledBlanket Under Chest, Pelvisand Ankles

C-Arm Positioning

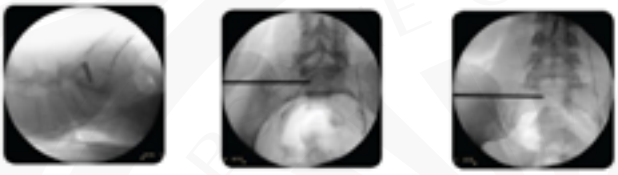


SI Fusion Procedure



SI Fusion Procedure

Fluoroscopic View Pin Placement



Final Implant Positioning

SIJ Dysfunction

- 2008- introduction of MIS SIJ fusion
- > 20,000 MIS cases done to date using technology from a single company

What Is the Frequency of Minimally Invasive Sacroiliac Joint Fusion

Summary of Results

- Total number of estimated SI joint fusion procedures increased from 189 in 2001 to 3,900 in 2012.
- MIS SI joint fusions accounted for an increasing percentage of the total, ranging from 0% in 2008 to 76% in 2011, with an estimate of 85% for 2012.

Literature Review

- PubMed search
- SI joint
- 4960 citations
- 46 pertinent studies

Duhon et al IJSS April 2016; Triangular Titanium implants for SIJ fusions; 2 year followup from a prospective randomized study

- 172 pts, 149 2 yr f/u
- 26 US sites
- 1,3,6,12,18,24 eval
- VAS, ODI, SF-36, EQ-5D

Duhon et al IJSS April 2016; Triangular Titanium implants for SIJ fusions; 2 year followup from a prospective randomized study

- VAS; 79 to 26 at 24 months
- ODI; 55 to 30 at 24 months
- Significant improvements in SF-36 and EQ 5D
- Opioid use decreased from~76% to 55% at 24 months

1. Postoperative complications in patients undergoing minimally invasive **sacroiliac fusion**. Schwell K, Buser Z, Jakoi A, Pham M, Patel NN, Hsieh PC, Liu JC, Wang JC.

Spine Journal: Official Journal of the North American Spine Society. 2016 Jun 24. [JOURNAL ARTICLE]

- Investigate the safety of MIS SI fusion
- Used a large nationwide sample group
- Identify complication rates of MIS SI fusion

1. Postoperative complications in patients undergoing minimally invasive **sacroiliac fusion**. Schwell K, Buser Z, Jakoi A, Pham M, Patel NN, Hsieh PC, Liu JC, Wang JC.

Spine Journal: Official Journal of the North American Spine Society. 2016 Jun 24. [JOURNAL ARTICLE]

- MIS SI fusions from 2007-2014
- Pearl Diver patient records database
- Records reviewed to reveal incidence of complications

1. Postoperative complications in patients undergoing minimally invasive **sacroiliac fusion**. Schwell K, Buser Z, Jakoi A, Pham M, Patel NN, Hsieh PC, Liu JC, Wang JC.

Spine Journal: Official Journal of the North American Spine Society. 2016 Jun 24. [JOURNAL ARTICLE]

- 469 patients
- Overall complication rate of 13.2%
- Infection, pain, osteomyelitis, joint derangement, UTI,
- Higher incidence of complications than previously reported

Summary

- Need more information
- Better diagnostic tests which are reliable and reproducible
- Longer term studies independent sources

CONCLUSIONS

- METICULOUS PATIENT SELECTION
- I HAVE DONE MANY WITH GREAT SUCCESS WITH THIS AND OTHER TYPES OF IMPLANTS
- WHAT ARE THE SALVAGE STRATEGIES
- THERE ARE SOME NEWER IMPLANTS WITH ALTERNATVE APPROACHES THAT CAN BE CONSIDERED BUT THERE IS NOT A GREAT DEAL OF EXPERIENCE WITH THESE OPTIONS YET

Studies

- X-RAYS
- CT SCAN
- MRI
- SPECT BONE SCAN

- UNFORTUNATELY FREQUENTLY NON-DIAGNOSTIC

SIJ Dysfunction

- 1921- Smith Peterson
  - SIJ suspected of causing LBP
- 1934- Mixter and Barr
  - Lumbar HNP
- 1987- Waisbrod, Krainick et al
  - SIJ pain reemerges

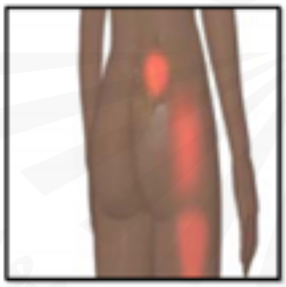
Pertinent Anatomy and Biomechanics

Biomechanics

- 2008 - Three-Dimensional Movements of the Sacroiliac Joint: A Systematic Review of the Literature and Assessment of Clinical Utility
- Rotation
  - X axis: -1.1 to 2.2 degrees
  - Y axis: -0.8 to 4 degrees
  - Z axis: -0.5 to 8 degrees
- Translation
  - X: -0.3 to 8 degrees
  - Y: -0.2 to 7.0 degrees
  - Z: -0.3 to 6 degrees

Presentation

- LBP (72%)
- Gluteal pain (94%)
- Groin pain (14%)
- Radicular pain (50%)
- Estimated ~25% of LBP presentation is pain related to SIJ pathology



Differential Diagnosis

- Inflammatory arthritis
- Postpartum syndrome
- Adjacent OA (Hip)
- Paget's disease
- Trauma
- Adjacent segment degeneration (lumbar spine)

THE BEGINING

MARK RILEY MD

- Re-Live is a mini-open procedure for achieving a true arthrodesis of the sacroiliac joint. The surgical procedure is performed under fluoroscopic guidance.
- The standard of care includes a decortication of the joint with placement of autograft and allograft in the joint. SI–Fixation of the joint is achieved with three precision-machined Multi-Point Structural Allograft implants.
- Using fluoroscopic guidance and a specifically designed series of instruments, this mini open procedure provides access to the joint with safety and control. The posterior approach provides a superior level of safety for this standard of care fusion technique, including decortication of the joint with grafting.

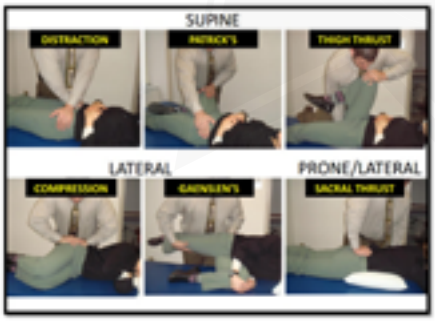
Treatment

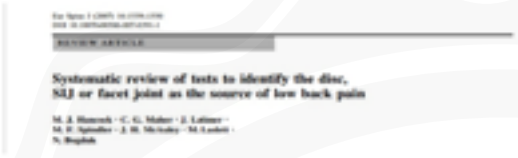
- Physical therapy, Chiropractic
- Medications
- Sacral belt
- SI injections
- RFA

The Dilemma

Diagnosis

Provocation Tests





Systematic review of tests to identify the disc, SIJ or facet joint as the source of low back pain

- Positive likelihood ratios >2 or negative likelihood ratios <2 were considered informative
- 41 studies of moderate quality were included
- 7 studies investigated the SIJ

- Schwarzer et al; none of the SIJ examination procedures tested could differentiate reliably from other sources of LBP
- Simpson and Gimmell; no single exam finding can reliably dx SIJ dysfunction
- Berthelot et al; clinical signs and manuvers are unreliable in dx SIJ dysfunction, low sensitivity and specificity; SIJ injections are unreliable as well

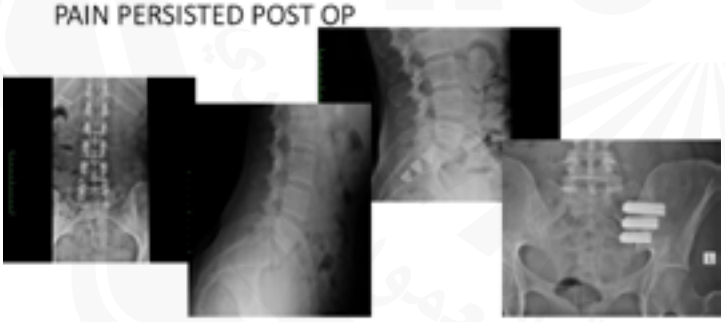
A Systematic Evaluation of Prevalence and Diagnostic Accuracy of Sacroiliac Joint Interventions

Pattern of Spine Technology

BMJ 2001;323;1477

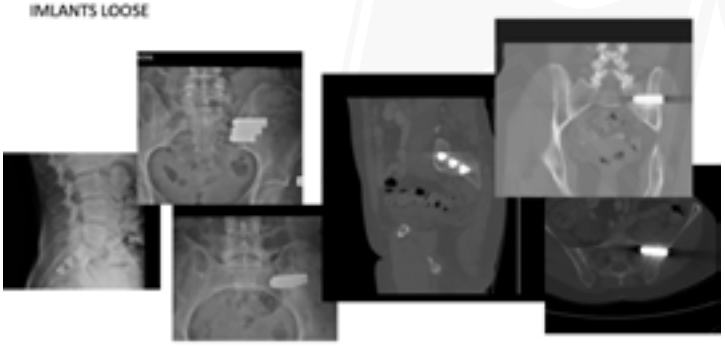
MIS SIJ Fusion

DC 45 Y/O FEMALE SI PAIN ATHLETIC RUNNER
COMPLETED PRE-OP ALGORITHIM
PAIN PERSISTED POST OP



DC 2015
PERSISTENT PAIN
IMLANTS LOOSE

TREATED WITH PT FURTHER INJECTIONS LIMITED SUCCESS
SPARSE FOLLOW-UP



DC 9/2018 RE-APPEARS WITH PAIN RESOLVED

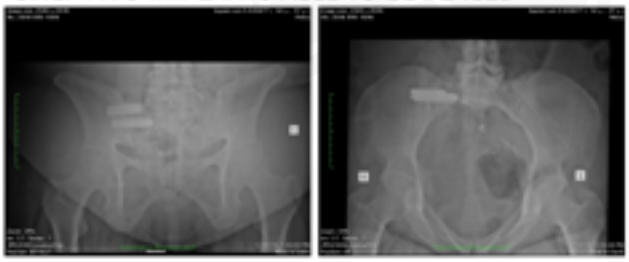
LUCENCY AROUND IMPLANTS HAVE RESOLVED 4 YEARS POST-OP

INITIALLY SURGERY FAILED TO ADDERESS SYMPTOMS

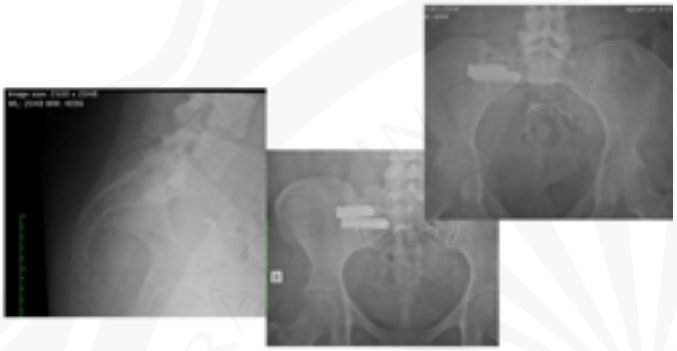
WHAT ARE POST-OP STRATEGIES FOR PERSISTENT POST-OP

LI 52 Y/O FEMALE SEVERE PAIN IN SI JOINT CHRONIC
FAILED CONS CARE
MET ALGORITHIM
OFFERED SURGERY
STUDIES 12/2013

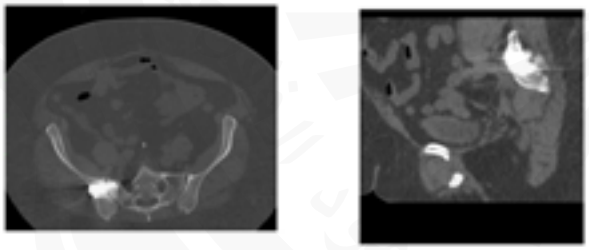
POST-OP SURGERY JAN 2014
SYMTOMS RESOLVED
ONLY TWO IMPLANTS ABLE TO BE PLACED



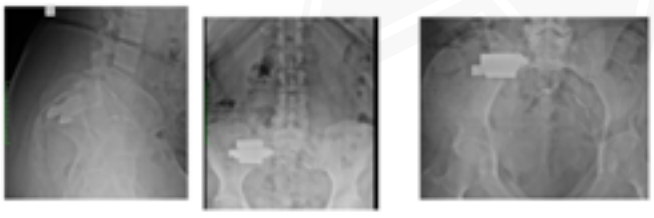
RETURNS AFTER TRIPPING OVER HER DOG
PAIN HAS RETURNED
JULY 2015
NO CHANGE IN XRAYS

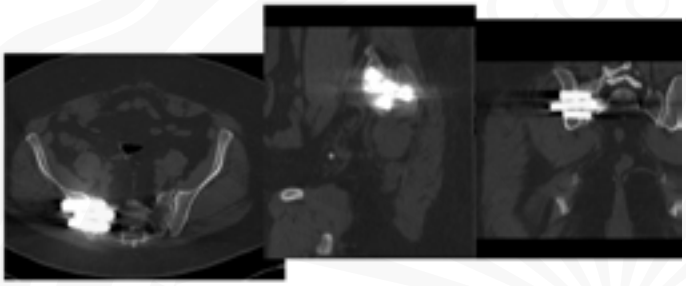


CT AUGUST 2015
NO FRACTURES OTHERWISE NOT HELPFUL
TREATED CONSERVATIVELY
PT INJECTIONS
NOT HELPFUL
CONSIDERED REVISION OPTIONS



CONSIDERED POSTERIOR APPROACH OR REVISING TO DIFFERENT IMPLANT BUT OD ARE ALL VERY CLOSE
ATTEMPTED REFERRAL TO TRAUMA SURGEON. OFFERED NO OPTIONS
ULTIMATELY SEEN BY ANOTHER SURGEON WHO AGREED TO A REVISION JAN 2018
SHE NOW HAS 5 IMPLANTS STILL HURTS!
NOW WHAT?



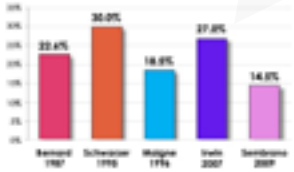


Indications

- Severe Degenerative Sacroiliitis
- Post-traumaticSacroiliacDegeneration
- Adjacent level SI Joint Degenerative Arthritis
- SI Joint Osteolysis withInstability

Prevalence of SI Joint Pain

15-30% Component of Low Back Pain



32-43% Post Lumbar Fusion SI Joint Pain

Katz 2003	32%
Maigne2005	35%
De Palma2011	43%
Liliang 2011	40%

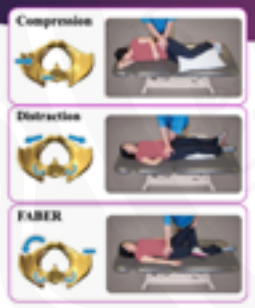
ISAP SI Joint Pain Diagnosis Criteria

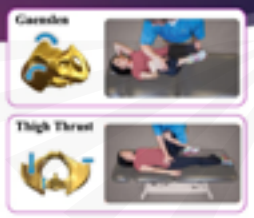


Merskey, H, 1994/2002, ISAP Guidelines

IASP
International Association for the Study of Pain

SI Joint Provocative Tests





3 out of 5 PositiveTests Confirm SI Joint as Pain Generator

Pain Distribution

- Pain at or Lateral to PSIS
- Pain in Buttock
- Pain in PosterolateralThigh
- Ocassional Pain in Proximal Posterolateral Calf

Implant System

- Triangular TitaniumImplant
- InterferencePress-fit
- Decreases Rotational Instability
- Porous Coating
- 20,000 Cases performed

Level I Study

- Prospective, multicenterrandomized controlled trial
  - 19 centers in US
  - 148 patients
  - Enrollmentfrom January 2013 to May 2014
- Sponsored by device manufacturer (SI-BONE, Inc., San Jose, CA)

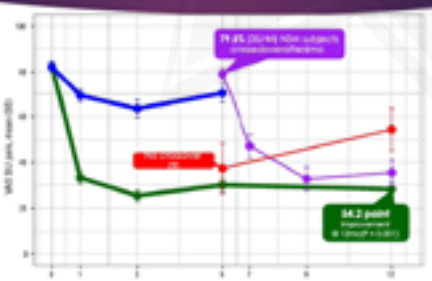
Non-Surgical Management (NSM)
(n=46)
NSAIDs
Physical Therapy
Steroid Injections
Radio frequency Ablation

MIS SI Joint Fusion
(n=102)

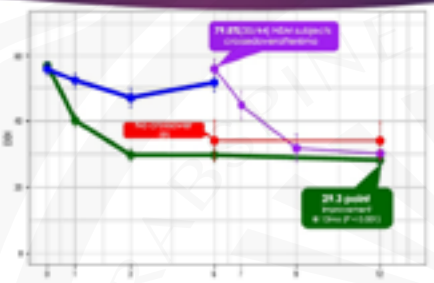
SI Joint Fusion

ClinicalTrials.gov ID
NCT01681004

VAS Comparison



ODI Comparison



Summary

- Patient Selection Continues to be the Most important Predictor of a Good Prognosis
- Physical Examination with ProvocativeTesting Critical
- Patient Positioningand FlucroscopicAlignment will Decrease Intraoperative Complications
- Still Remains the Treatment of Choice for Intractable SI Joint Pain that is Resultingin a Poor Quality of Life and an Inability to CompleteActivities of Daily Living.

FUSION

- OPEN
- MIS
- POSTERIOR
- LATERAL
- IMPLANT TYPE?

Treatment Options

Non-Surgical Treatment:

- Anti-inflammatory medications
- Limited Physical Activity
- Braces / Sacroiliac Belt
- Physical Therapy / Chiropractor
- SI Joint Injections
- Radiofrequency Ablation

Minimally Invasive Surgery

- Surgical procedure to stabilize the SI joint by eliminating motion

SI JOINT

- 6 times more resistant to lateral forces than lumbar spine
- 1/20 resistance to forces in axial compression
- 1/2 resistance to rotational forces compared to lumbar spine

Role of Facet (Z-joints) in Low Back Pain

Lumbar Facet Pain

- 1911 Goldwaith proposed z –joints as cause of LBP
- 1994 Schwarzer et al. describing prevalence of lumbar facet pain
  - Younger patients chronic LBP injured prevalence 15%
  - Elderly patients prevalence 40%
- Prevalence in literature ranges between 10-40%

Facet Joints

- Zygapophyseal Joints (Z-joints)
- Synovial joints
- Formed by the superior and inferior articulating process of adjacent vertebrae
- 10-40% pain – more frequent in older patients (age>65)
- Alignment/direction determines direction of movement

Facet Joint

- Dual innervation from medical branch of the nerve root and at the level above
- L4-5 facet is innervated by the L3 and L4 medial branches
- Primarily axial pain
- Typical referral patterns

Nomenclature: Punctuation Matters

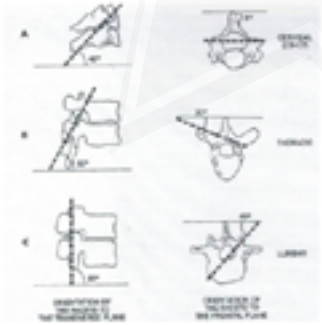
Let's eat, Grandma!

Let's eat Grandma!

Nomenclature: Punctuation Matters

- Joints/discs designated using a hyphen
  - Indicates a conjunction – joining two parts
    - L4-5 z-joint; L5-S1 intervertebral disc
- Nerves designated using a comma
  - Indicates a sequence
  - L4, 5 medial branches innervate the L5-S1 z-joint
  - L4, 5 MBB indicates block of L4 and L5 MB's
- L4-5 block is non-specific

Variable planes of facet joints



Facet Joint Orientation

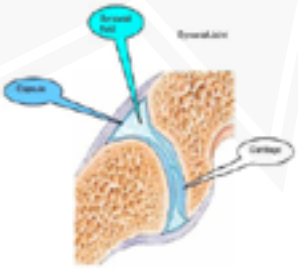
- Cervical: coronal plane, resists flexion
  - Flex-ext greatest at C5-6 and C6-7
  - Lateral bending greatest at C3-4 and C4-5
- Thoracic: intermediate
- Lumbar: sagittal plane, resists rotation (except L5-S1: nearly coronal in orientation)
  - Flexion/Extension: greatest at L4-5

Spondy-what??

- Spondylosis
  - degenerative condition of the spine. Often, age-related changes
- Spondylolysis
  - defect in the pars interarticularis of the neural arch, that portion of the neural arch that connects the superior and inferior articular facets
- Spondylolisthesis
  - Slippage of one vertebral body with respect to the one beneath it

Zygapophyseal Joint Pain

- True synovial joints with mechanoreceptors and nociceptors
- Like any other joint, has joint space, hyaline cartilage, synovial membrane, fibrous capsule
- Capsule is lax - prone to rupture in hyperflexion



Zygapophyseal Joint Pain

- Wide range of reported prevalence among chronic pain patients: 4%-75%
- Using controlled blocks: 4%-15% (Jackson, Carrette, Schwarzer) with one study showing up to 40%. (Schwarzer Ann Rheum Dis 1995)
- 90% at L4-5 & L5-S1 (Schwarzer)
- Documented degenerative changes in cadaveric studies as early as third decade of life (NASS 2008)

Zygapophyseal Joint Pain

- How do we know who has it??
- No pathognomonic history or symptomatology
- No pathognomonic physical exam findings for diagnostic specificity or sensitivity
- No consistent imaging findings
- Continued controversy about prevelance, diagnosis, and treatment

Imaging

- Unless there is a joint fx or subluxation, routine imaging cannot detect injury to facet joint
- Xrays: range of findings, from none to severe degenerative changes
- Nuclear imaging: will detect inc. uptake, but cannot say if symptomatic
- Neither radiography, CT or MRI are reliable indicators of facetogenic pain (Shwarzer et al, Spine 1995)

Imaging – Facet arthropathy

- Marked osteophytosis in lumbar facet joints

- Osteophytosis extending into lateral recesses bilaterally and causing nerve root compression

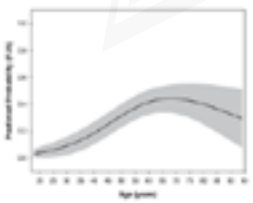
Pain Medicine

What Is the Source of Chronic Low Back Pain and Does Age Play a Role?

- Depalma, Pain Medicine 2011
  - CLBP: underwent diagnostic injections until pain generator was identified
  - Intervertebral disc: 42%
  - Facet Joint 31%
  - Sacroiliac Joint 18%

Pain Medicine

What Is the Source of Chronic Low Back Pain and Does Age Play a Role?

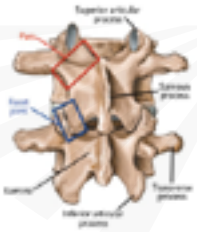


Initial Treatments for Facet Mediated Pain

- Medications: NSAIDs, Tylenol
- Physical Therapy/Home exercise program
- Ice/Heat
- Alternative/Complementary: Acupuncture, chiropractic care, inversion
- TENs unit
- Yoga/Pilates
- Time
- Reassurance

Interventional Treatments for Facet Mediated Pain – Up Next

- Intra-articular Injections
- Medial Branch Blocks
- Radiofrequency Neurotomy



Interventional Treatments for Facet-Mediated Pain

Interventional Treatments for Facet Mediated Pain

- Intra-articular Injections
- Medial Branch Blocks
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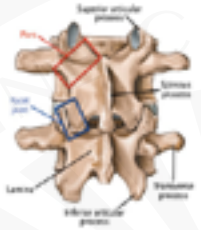


History

- 1983 Bogduk describes the innervation of the lumbar facet joints via the medial branch of the dorsal ramus
- 1990s filled with mixed results of attempts at RFA due to developing techniques/patient selection
- 1997 Dreyfuss demonstrates validity of anesthetizing the medial branches (MBB)
- 1998 Kaplan demonstrates that MBB blocks experimentally induced facet pain

History

- 2000 first study with modern technique and patient selection via MBB showing RFA is effective
- Last 15 years:
  - Strong body of evidence
  - Continued Debate

Patient Selection

Increased Likelihood of Success

- Advanced Age
- Pain with palpation over paraspinals
- Pain maximal in low back
- Most common level L4-L5 followed by L5-S1

Decreased Likelihood of Success

- Younger Age
- Pain with flexion
- Pain with palpation over spinous process
- Pain below the knee
- Normal radiology

Intra-articular Injections

- 2015 systematic review: outcome measures at short term (6 months), long term (1 year)
  - 21 RCTs, 5 observational studies
  - Level III for lumbosacral intraarticular injections
  - Level IV for cervical intraarticular injections

Results (Kennedy and Schneider)

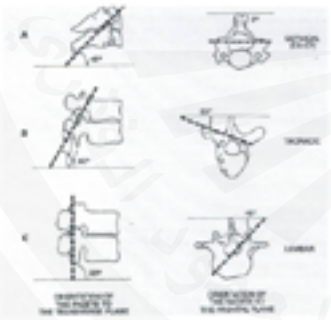
	Need RF (Fail)	No RF (Success)
Triamcinolone	16	8
Saline	15	7

	Time to RFA	p-value
Triamcinolone	6.0	0.82
Saline	6.5	

Intra-articular Facet Joint Injections

- Facet volume is ~ 1cc
- Rx of Facet Joint cysts causing compressive neuropathy and/or stenosis (aspiration or rupture)
- Risks
  - Worsening of pain, Infection, Bleeding, Nerve Damage,
  - Needle can damage the articular cartilage as it is passes into the joint space

Intra-articular Facet Joint Injections



Intra-articular Facet Joint Injections: Lumbar

- Technique
  - Fluoroscope is adjusted to align the margins of the SAP and IAP
    - Lumbar Facets
      - Oblique 15
      - Joints are vertically angled with various degrees of obliquity
  - Small amount of contrast is added to confirm placement
  - Injection of local anesthetic and steroid

Intra-articular Facet Joint Injections: Lumbar

Lumbar Medial Branch Block

- Diagnostic procedure anesthetizing the medial branch of dorsal ramus to identify lumbar facet joint as causative source of low back pain

Diagnostic block

- Diagnostic medial branch blocks should be done prior to RFA
- Proceed with RFA if pain relief concordant with time frame of diagnostic block

Medial Branch Diagnostic Blocks

- Cervical and Lumbar Spine Intervention Society (SIS) and North American Spine Society (NASS) recommend radiographically guided medial branch blocks
- Single diagnostic lumbar z joint blocks can false positive 38% of the time.
- Blocks are usually repeated

Lumbar Medial Branch

- Medial Branch courses between the SAP and the transverse process
- Mamillo-Accessory Ligament holds nerve in place

Lumbar Medial Branch Block - Technique

- Oblique fluoroscopy so that the facet joint lines and the junction with the SAP and transverse process is well visualized
- Spinal Needle is directed toward the junction of the SAP and transverse process until bony contact is made
- Bevel is oriented so that it faces bone
- Aspiration and then injection of a small (0.5 mL) volume of concentrated local anesthetic (2% lidocaine or 0.5% bupivacaine)

Skin Wheal?

Chen et al., Procedural Pain During Lumbar Medial Branch Blocks With and Without Skin Wheal Anesthesia: A Prospective Comparative Observational Study, Pain Medicine, 2019

80% relief is ideal

Some use 50%

Injections as a Predictor of Treatment

- MBB not only diagnosis lumbar facet pain, it predicts response to RFA
- Study by Dreyfuss:
  - At least 80% relief following two controlled diagnostic MBBs
  - 60% of patients experienced at least a 90% reduction in pain
  - 87% had at least a 60% reduction in pain lasting 12 months
- Multiple other studies show that less rigorous diagnostic criteria result in less robust response to RFA

Radiofrequency Ablation

- Minimally invasive treatment for FACET MEDIATED low back pain
- Can provide 6 months to two years of relief in carefully selected patients
  - Average relief 15 month
- Perform medial branch anesthetic blocks prior to the procedure (MBB)
- Only those patients who get significant relief from medical branch blocks are candidates for RFA

Radiofrequency ablation

- Level I evidence for medial branch blocks for diagnostic accuracy in the lumbar spine, level II evidence in the cervical spine
- Several studies: after appropriate diagnostic blocks, RFA leads to significant and sustained pain relief

Radiofrequency Outcome Studies

- Lord 1996 :
  - prospective, double blind, controlled RFA vs. Sham in chronic cervical facet joint pain
  - Median time for pain to return to 50% pre-procedure levels
    - RFA group: 263 days
    - Sham: 8 days
- Dreyfus 2000: the first prospective study to treat only patients with lumbar facet pain diagnosed via dual diagnostic MBB
  - 1 yr 90% had at least 60% pain relief, 60% had 90% relief
- No reports of long-term adverse side effects secondary to facet joint RF neurolysis

Radiofrequency Ablation for SIJ pain

- 2008 – RCT Cohen: 28 patients
  - L4 and L5 primary dorsal rami and S1-3 lateral branch RF ablation
  - 1,2,6 months
  - 79% (1 mo), 64% (2 mos), 57% (6mos) >50% relief vs 14% and 0 in control at 1, 2 mos
- 2012 – RCT Patel: 51 patients
  - L5 primary dorsal rami and S1-S3 lateral branch ablation
  - Treatment group showed improvements at 3 months, with benefits beyond 9 months

MacVicar J, Bogduk et al. May 2013. Pain Med. Lumbar medial branch radiofrequency neurotomy in New Zealand.

- 106 patients, selected on the basis of complete relief of pain following controlled, diagnostic, medial branch blocks, were treated with RFN.
- Successful outcome was defined as complete relief of pain for at least 6 months, complete restoration of ADLs, no need for any further health care, and RTW.
- Results: In the two practices, 58% and 53% of patients achieved a successful outcome. Relief lasted 15 months from the first RFN and 13 months for repeat treatments. Allowing for repeat treatment, patients maintained relief for a median duration of 17-33 months, with some 70% still having relief at follow-up.

Radiofrequency Ablation

- Success for lumbar RFA ranges from 60-90%
- 21% had complete pain relief and 65% reported mild to mod pain relief
- Other studies
  - 60% of patients at least 80% relief at 12 months
  - 80% percent at least 60% percent relief at 12 months

Systematic Review of the Effectiveness of Lumbar Medial Branch Thermal Radiofrequency Neurotomy, Stratified for Diagnostic Methods and Procedural Technique – Schneider et al

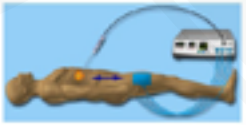
- At six months, 26% of patients selected via single medial branch block with 50% pain relief and treated via perpendicular technique achieved at least 50% pain relief
- 49% of patients selected via dual medial branch blocks with 50% pain relief and treated via parallel technique achieved at least 50% pain relief.
- The most rigorous patient selection and technique—two diagnostic medial branch blocks with 100% pain relief and parallel electrode placement—resulted in 56% of patients experiencing 100% relief of pain at six months

Outcomes: Summary

- Pain relief 6mos-2 years (reinnervation)
  - Average is 15 months
- Can be repeated
- Early studies done under poor technique - poor outcomes

Radiofrequency Principles

- Complete circuit between electrode and grounding pad
- Electrical field is established around the electrode tip
- With alternating RF current oscillating movement of ions in the tissue
- Movement causes friction in tissue surrounding the catheter tip which produces heat
- Monitoring the catheter tip temp therefore adequately measures tissue temperature



Radiofrequency Principles

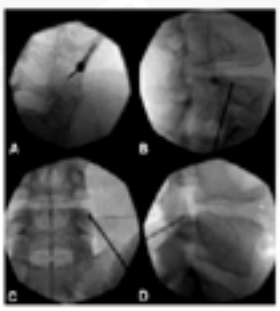
- RF current is low energy, high frequency (100,000-500,000 hz)
- RF lesions do not selectively destroy nociceptive afferents
- Temperature and size of probe determine the size of the lesion
- Cells become damaged at temps 42 to 45 degrees Celsius.
- Temps of 60-100 degrees Celsius there is near instantaneous induction of protein coagulation, leading to cell death

Radiofrequency Principles

- Temperature
  - most lesions at 80 degrees
- Impedance
  - Changes imply entry into different medium i.e. fluid to tissue or vice versa
- Electrical Stimulation
  - Sensory confirms proximity to the target
  - Motor confirms safe distance to motor fibers

Radiofrequency Principles

- Electrical stimulation: 50 hz
  - sensory stimulation less than 1 V if electrode is placed correctly.
  - Debatable if necessary
  - adjusting the electrode position to minimize the threshold for evoked activity does not improve outcome, and takes time
  - Radiological confirmation of electrode placement is essential
- Motor stimulation: 2 hz
  - contraction of ipsilateral paraspinal muscles below 2.5 V but without limb contracture.



Technique

- RF electrodes coagulate transversely
- If placed perpendicularly may fail to coagulate the nerve
- Electrodes placed parallel to the nerve - most reliable coagulation

Technique: Lumbar RFA

- Pt is awake and in prone position
- Caudal tilt
- Radiofrequency cannula with 5-10mm active tip
- Start approx 1 level below, advance shallow angle toward the junction of the SAP and transverse process
- Cannula is walked off the superior margin of the transverse process

Technique

- Radiofrequency probe is then inserted into the cannula
  - The active tip delivers the most heat energy parallel to its location NOT at its tip
- Check impedance
- ? Sensory Stim and Motor Stim
- Anesthetize with local anesthetic (2% lidocaine)
- Thermocoagulation 80 deg C for 90 sec

Considerations

- RFA near bone or scar tissue have differences in impedance and conductivity
  - May result in irregular ablation pattern
- Pacemakers
  - Reference guidelines on safety and management of implanted device post procedure
- Spinal cord stimulators
  - Consider bipolar ablation

Complications

- Increased soreness, local pain esp. 3-5 days
  - Persistent pain less likely
- Itching, Burning, Hypersensitivity (typically subsides in 4-6 weeks)
  - Treat with gabapentin or TCA
- Thermal injury to skin/superficial tissue
- Extremely rare complications due to lesioning of incorrect nerve
  - Permanent limb weakness
  - Permanent sensory deficit

Complications

- Pneumothorax
- Ramus or nerve root injury.
  - Suggest motor stimulation prior to lesioning to prevent inadvertent ventral ablation
  - EMG should show denervation potentials after procedure indicating that destruction of the medial branch nerves.
  - If no denervation potentials, then facet RFA can be repeated
- Skin burns in thin patients

Repeat RFAs

- Repeat radiofrequency neurotomy for lumber facet pain
  - success and duration of relief remained consistent after each subsequent ablation.
- When repeat treatments have been applied, cumulative durations of complete relief of pain have exceeded 20 and 30 months
- the longest being >100 months
- median duration of 13 months per treatment

Hybrid Lumbar TDR and Fusion

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Introduction

- Cervical TDR has gained widespread acceptance and may be the new gold standard for painful cervical disc degeneration
- Strong data from a variety of study formats performed in various countries support TDR for 1- and 2-level pathology

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Introduction

- Receiving less attention has been the use of cervical TDR combined with ACDF for the treatment of multi-level symptomatic disc degeneration

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Rationale for Cervical Hybrid

- Many patients have painful degenerative changes at multiple levels in the cervical spine
- Fusion has often been the treatment to address these symptoms with good outcomes
  - However, ACDF brings with it the problems of mobility loss and accelerated degeneration of adjacent segments

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Rationale for Cervical Hybrid

- TDR has been shown to maintain motion and reduce ASD
  - However, not all degenerated levels are amenable to TDR
- Hybrid has the potential to provide ACDF to levels with more severe degenerative changes where TDR is not indicated and TDR at level(s) appropriate for this intervention

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- When used adjacent to ACDF, TDR function was not adversely affected
- A hybrid construct offers significant biomechanical advantages over 2-level ACDF in terms of reducing compensatory adjacent-level hypermobility and also loads required to achieve a predetermined ROM

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Biomechanics of Cervical Hybrid

- TDR maintained total flexion-extension ROM to the level of the intact controls when implanted adjacent to ACDF
  - No impact of ACDF being at level above or below TDR
- 2-level fusion significantly increased motion demands on the nonoperated segments compared to a hybrid

Lee et al, Spine, 2011

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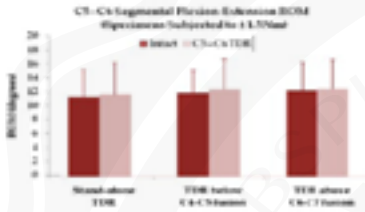
TDR ROM Similar with TDR Only vs. Above or Below ACDF



TDR function not compromised by placing device adjacent to ACDF

Lee et al. Spine. 2011

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- ACDF resulted in significant decreased in motion at the fused level and an increase in motion at the un-fused levels
- In the hybrid construct, TDR adjacent to ACDF preserved motion at arthroplasty level, thereby reducing demand on the other levels

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Indications for Hybrid Surgery?

- Hybrid not included in prospective RCTs / FDA trials with rigorously defined selection criteria
- Evaluate patients the same as if considering multi-level TDR
- Indications for TDR in hybrid are the same as for TDR
  - If TDR is contra-indicated at one of the levels, consider hybrid
  - In general, if patient is indicated at one level for TDR and not the other, hybrid appears to be good option

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- Records reviewed for 464 patients undergoing TDR or ACDF during a 5-yr period by 3 surgeons specializing in TDR
- Reason for performing ACDF vs. TDR were recorded

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Results

Reason not TDR	N	%
Anatomical	64	13.79%
Insurance	17	3.23%
Deformity/kyphosis	13	2.80%
Pseudo repair (prior ACDF)	3	0.65%
Osteoporosis	2	0.43%
High HO risk	2	0.43%

Percentages based on total of 464 patients
Guyer et al. Eur Spine J. 2020

Reason not TDR	N	%
Nickel allergy	1	0.22 %
Trauma w posterior element fx	1	0.22 %
TDR removal	1	0.22 %
Concern about artifact on future imaging	1	0.22 %
Benign osteoblastic bone	1	0.22 %
Did not think could get adequate surgical approach for TDR implantation	1	0.22 %

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When Elected to Do ACDF Rather Than TDR

- Most common reason for ACDF vs. TDR was anatomical (conditions that may not be adequately addressed with TDR and/or may interfere with device function)
  - Occurred in 64 of 464 patients (13.79%)
- 2nd most common reason was insurance denials/lack of coverage: n = 17; 3.23%
- Deformity/kyphosis not addressable with TDR: n= 13; 2.80%
- Other reason were: Pseudo repair in 3 patients (0.65%), osteoporosis in 2 (0.43%), high risk of HO in 2 others (0.43%)
- 1 case (0.22%) each of: nickel allergy, trauma with posterior element fracture, TDR removal, multiple prior cervical spine surgeries, concern about artifact on future imaging studies, benign osteoblastic bone, and limitation to adequate surgical approach for TDR

Guyer et al. Eur Spine J 2020

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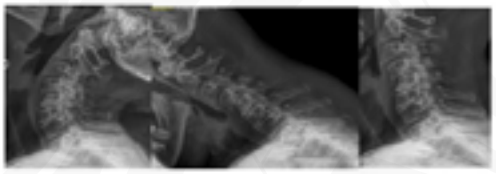
Case Example

- 57 yr old female with long history of neck pain (currently 7/10) and weakness in left upper extremity
- >10 cervical injections, PT, and chiropractic manipulation
- Prior doctors recommended 3-level ACDF, interested in TDR
- Stenosis C4-7, spondylolisthesis C4-5



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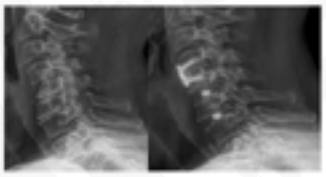
Case Example

- ACDF C4-5 to address instability and spondy
- TDR (Simplify disc) C5-7 to maintain mobility while increasing disc space height and related stenosis



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- 7 studies, 2 prospective, 5 retrospective; 2-yr follow-up
- Hybrid had statistically significantly greater NDI score improvement and trend for greater VAS pain score improvement (p=0.058)
- Total ROM (C2–C7) significantly greater with hybrid vs. ACDF (p<0.01)
- Compensatory increased ROM of adjacent segments significantly greater in ACDF vs. hybrid
- Hybrid is effective alternative for multilevel cervical spondylosis

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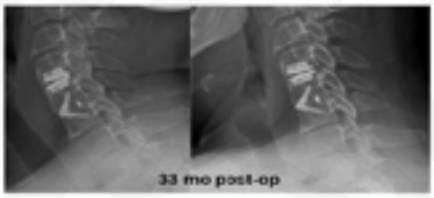
Hybrid with Motion at TDR Level and Fusion at ACDF Level



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- Registry for patients who underwent hybrid, TDR, or ACDF for symptomatic disc degeneration
- 439 hybrid patients, 976 TDR, and 27,480 ACDF
- For hybrid group, unplanned readmission rate was 0.7%, index surgery–related re-op rate was 0.3%, and nonroutine discharge rate was 2.1%
- Major and minor complications were also rare, with rates of 0.2% for each
- Conclusion: Hybrid was noninferior to ACDF and TDR in terms of early post-op outcomes

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- Hybrid superior to 2-level ACF based on better NDI recovery, less post-op neck pain, faster C2-C7 ROM recovery, and less adjacent ROM increase

ArabSpine Course Diploma

- 196 patients, primarily treated for radiculopathy and/or myelopathy receiving cervical hybrid for ≥2-level cervical DDD and spondylosis
- Mean follow-up 45.2 mo, range 24 to 102 mo
- Conclusion: Anterior cervical hybrid construction appears to be an acceptable option in the management of multilevel cervical degenerative disc diseases and spondylotic spinal stenosis

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Improvement in Arm Pain and NDI at 24 mo Follow-up

Yilmaz et al, J Orthop Surg Res, 2021

ArabSpine Course Diploma

Indications

- Similar indications described in a study involving hybrid, TDR, and ACDF and findings from flex/ex films
- TDR preferred at level without (at such levels ACDF is preferable):
  - Segmental instability (defined by movement of >3.5 mm or >15° angular motion)
  - Significant vertebral body spondylosis
  - Facet degeneration
  - Loss of segmental mobility

Yilmaz et al, J Orthop Surg Res, 2021

ArabSpine Course Diploma

- 48 hybrid pts, 43 ACDF patients; >2 yr follow-up
- Significant improvements in VAS neck and arm pain, JOA, and NDI in both groups, with no significant differences between groups
- Local lordosis improved significantly after surgery in both groups and was similar in the two groups
- ROM of the TDR level was maintained; global cervical ROM greater than in ACDF group
- Conclusion: For indicated patients, hybrid may provide an alternative for treating symptomatic 2-level DDD

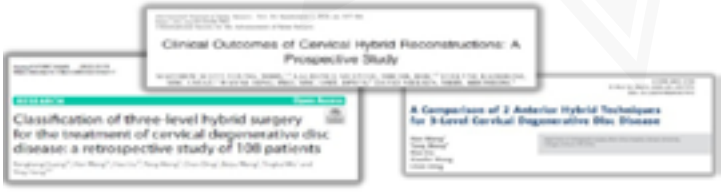
ArabSpine Course Diploma

- 50 patients; follow-up 5 yrs
- Significant improvements in NDI, VAS, SF-36, and JOA
- Mean disc height was restored in all cases
- Conclusions: Hybrid is an effective and safe procedure for the treatment of multilevel cervical degenerative disc disease

ArabSpine Course Diploma

Cervical Hybrid

- Typically hybrid is thought of as TDR at one level and ACDF at a 2nd level
- Several papers have described hybrid surgery involving 3 or even 4 levels



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Clinical Outcomes of Cervical Hybrid Reconstructions: A Prospective Study

- 151 patients, ≥12 mo follow-up (, median follow-up 2 years (range = 1-10 yrs)
- Included treatment at 2 (29.8%), 3 (49.0%), and 4 (12.1%) levels
- Improvement in pain and disability scores were both clinically and statistically significant ($P < .001$), and these improvements were sustained throughout the course of follow up
- Re-op rate: 1.5%
- Statistically and substantial clinical benefits can be achieved by cervical hybrid surgery in the treatment of cervical pathologies including radiculopathy and myelopathy. The key principles is to follow strict indications, and to match technology with the pathology

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Re-operations

- Preliminary data from TBI on cervical hybrids found that among 137 consecutive patients, beginning with first case experience in 2008 and at least 2 years post-op, the following re-ops occurred:
  - 2 (1.5%) TDR removals (1 for migration, 1 for subsidence)
  - 4 (3.0%) repeat ACDF for pseudo at the ACDF level
  - 1 (0.7%) multilevel decompression including hybrid levels
  - 7 (5.1%) additional TDR and/or ACF for adjacent segment degeneration (mean duration from implant to re-op 68 mo)

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Costs

- Reliable cost data not available to compare hybrid to TDR or ACDF
- In general, TDR is less expensive than ACDF
  - May apply to hybrid with respect to cost of fusion cage and graft material vs. TDR device

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Discussion

- Good biomechanical data supporting hybrid preferable to 2-level ACDF with respect to motion and reducing load on adjacent segments
- Indications for TDR in hybrid same as for TDR in general
- Many patients are good cervical TDR candidates; however, even among TDR specialists, ACDF may be preferred at levels where it is prudent to not take undue risks
- Literature supports hybrids produce good clinical outcomes with acceptable re-op rate

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Are There Best Levels for Hybrid?

- As with TDR and ACDF, hybrid most commonly performed at:
  - C5-6 and C6-7
  - Next most common levels are C4-5 and C5-6
- No particular "best levels" for hybrid compared with TDR or ACDF

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TDR or ACDF at Superior or Inferior Level?

- Decision based on indications at each level
  - If TDR is indicated, use TDR
  - If TDR is not indicated, use ACDF
- Also need to consider overall spinal alignment

Evidence Based Medicine

The Practice of Evidence Based Medicine

- Definition:
- EBM is the integration of the
  - best research evidence with
  - clinical experience and
  - patient values
- NASS online EBM Course 2/yr
  - Literature review
  - Evidence analysis
  - Clinical Guidelines
  - Identify "bias"

The Practice of Evidence Based Medicine

- EBM is the integration
  - best research evidence
    - Literature review
      - Evidence tables
  - clinical experience
    - Modified Delphi (clinicians score alternative treatment scenarios)
  - patient values
    - Most difficult to ascertain

Literature Review Levels of Evidence in Therapy

- 1a Systematic Review of RCTs Meta Analysis (homogeneity)
- 1b Individual Randomized Controlled Trial (RCT)

- 2a Systematic Review of Cohort (homogeneity)
- 2b Individual Cohort study (or low-quality RCT)

Levels of Evidence in Therapy

- 3a Systematic Review of case-control studies (homogeneity)
- 3b Individual Case-control study

- 4 Case series (and poor quality cohort and case-control studies)

- 5 Expert opinion

Literature Review Materials and Methods

- Explicitly state experimental question
- Frame study group
  - Inclusion/exclusion criteria
- Outline treatment cohorts
- Outcomes instruments
  - VAS/ODI
- Statistical analysis
- Economic Analysis

Literature Review Results

- Report Outcomes
  - Clinical outcomes instruments
  - Radiologic parameters
- Economic Outcomes
  - Relate to clinical instruments
  - Utility Measures used to calculate Quality Adjusted Life Years (QALY's)
    - Euroqual-5D (EQ-5D)
    - Health Utility Index
    - SF-6D
  - Historical Controls-Oswestry

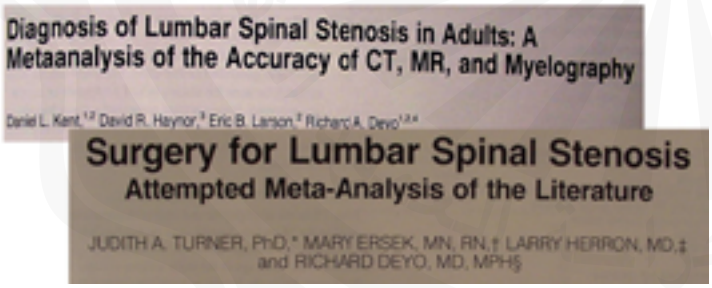
HighestLevel of Evidence 1a
Meta - Analysis

- Statistical method for combining data from RCT's
- Gives Increased statistical power
- Glass, 1976 Pres. Address American Ed. Res. Assoc.
- Randomized Controlled Clinical Trials Only
  - Homogeneity
    - Patient cohorts(inclusion/exclusion)
    - Treatment options
- Not a comprehensive literature review

Cautions in Literature Review Major Skepticism-Meta Analysis

Meta Analysis in Musculoskeletal Medicine

- Few RCT's/homogeneity of treatment cohorts poor
- Authors claim systematic review Literature =RCT Try to give paper misleading level statistical power



Cautions in Literature Review
RCT Methodology

- Inclusion/exclusion criteria match research question to avoid bias
  - e.g. HNP study exclude significant LBP
- Report 2-way analysis to be fair
  - Intent to treat
  - As treated
  - More confident in conclusions if both analyses reach same conclusion
- Post hoc analysis=potential bias

SPINE • VOLUME 8 • NUMBER 2 • 1983

1982 Volvo Award in Clinical Science

Lumbar Disc Herniation
A Controlled, Prospective Study with Ten Years of Observation

HENRIK WEBER, MD

- Classic RCT
  - Volvo Award
- Clinical Question
  - Sx vs non op
  - Sciatica/mild neuro deficit
- 288 pts/sciatica/HNP
  - 67 definite Sx
    - Pain/scoli/prog neuro/B&B
  - 126 randomized
    - Sciatica/SLR/muscle weak
  - 87 Non op

RCT Herniated Disc Weber

- Entire population not randomized
  - Worst patients operated on
  - Removed from randomized group
- Crossover
  - Initial randomization –non op
  - Ultimately operated on – did well
- ⇒Success non op Tx
  - Ultimately did well
- ?Failure of non op Tx?
  - Clinically poor – needed surgery

Effect of Crossover
Intent to Treat Analysis

- Weber
  - Crossovers to Sx/did well=non op success-intent to treat
- Bell – recalculate
  - Crossovers = failure non op Tx i.e. as treated

	Satisfactory
1 year	Non82/Sx91
4 years	Non90/Sx86
10 years	Non92/Sx93

Confirmed-Boos N, Spratt K. ISSLS 2003

Evidence Based Medicine
How Do We Use It

- AAOS Guidelines
- NASS Guidelines
  - Spinal Stenosis
  - Antibiotic Prophylaxis
- Colorado Workers Compensation Guidelines
- CMS MCAC Spine Fusion
- Beta Blockers for Anesthesia

Practicing EBM

- The practice of EBM requires 5 steps
  - Asking an answerable clinical question about a patient
  - Finding the best evidence to answer that question
  - Critically evaluating that evidence as to its validity, impact and applicability
  - Integrating the best evidence with the clinician's clinical experience and the patient's values
  - Evaluation of the effectiveness of decision

Bibliography

Guyatt G, Rennie D. Users' Guides to the Medical Literature: Essentials of Evidence-based Clinical Practice. American Medical Association, 2002.

Straus SE, Richardson WS, Glasziou P and Haynes RB. Evidence-Based Medicine: How to Practie and Teach EBM. Third Edition. Elsevier, 2005.

Sackett DL, Rosenberg W, Mc Gray JA, Haynes RB, Richardson WS. Evidence-based medicine: what it is and what it isn't. BMJ, 1996; 312: 71-2

Eddy DM. Evidence-based medicine: a unified approach. Health affairs (Project Hope), 2005; 24 (1): 9-17

NASS online Evidence Based Medicine Course twice per year available at: Evidence-Based Medicine Training (spine.org)

Clinical Guidelines

Outline

- Background
  - Call for development
  - History of Clinical Guidelines
- General Principles
  - Relation Guidelines to Standard of Care
  - Red flags-Issues Guideline not applicable
  - Evidence Analysis
    - Levels of Evidence
    - Strength of Recommendation
- Resources/Literature

Background History/ Call for Development

- Nachemson A, La Rocca H. Editorial Spine 1987; 12:427
- Waddell G. A New Clinical Model for Treatment LBP Spine 1987;12:632
  - Call for evidence based Treatment/more RCTs
- Hazard R, Goal Achievement Model for LBP. Spine 2013;38:1431-5
  - 1996-2005 Med expenditure LB/neck ↑65%
  - Social Security Disability Index LBP
    - 1996- 20.6%
    - 2005 – 25.4%

Evidence Based Clinical Guidelines vs. Standard of Care

- Clinical Guidelines
  - Summary for physicians
    - Literature/evidence
    - Treatment options/outcomes
  - NOT cookbook medicine
- Standard of Care
  - Analagous 3 lane highway
  - Guidelines = Middle lane
    - Compliance with Guideline = within standard of care
    - Guideline Does not include the entire standard of care

[Standard of Care]

Clinical Guidelines
Low Back Pain

- 1980's
  - NASS/AAOS
    - Algorithms
    - Consensus based
- 1994-AHCPR
- 2007-ACP/APS
- 2000's – Workers Comp
- 2000's NASS
  - Evidence based Clinical Guidelines
    - Coverage Recommendations(insurance)
    - Appropriateness Criteria(clinicians)

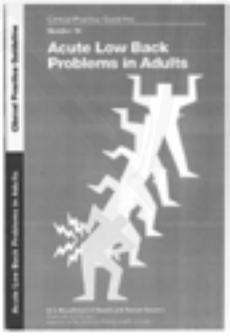
American Academy Orthopaedic Surgeons
North American Spine Society
1980's Algorithms /Red Flags concept

Critical Exclusionary Dx
(Red Flags)

- Cauda Equina Syndrome
- Severe Neuro Deficit
- Progressive Neuro Deficit
- Severe Progressive Symp
- Fracture
- Neoplasm
- Infection
- Previous Surgery-ongoing pain
- Chronic Pain Syndrome

AHCPR LBP Guideline 1994

- Forerunner Agency Healthcare Research & Quality (AHRQ)
- Federal Government Agency
  - Committee multiple special interest groups = agendas
- Treatment first 30 days
- Problems
  - Cover/title/press releases/conferences not reflect 30 days
  - Federal Govt/Leaders/please SIS's
    - Validate some (chiro) repudiate (surgery)



CLINICAL GUIDELINES

Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society

Roger Chou, MD; Amir Qaseem, MD, PhD, MHA; Vincenza Snow, MD; Donald Casey, MD, MPH, MBA; J. Thomas Cross Jr., MD, MPH; Paul Shekelle, MD, PhD; and Douglas K. Owens, MD, MS, for the Clinical Efficacy Assessment Subcommittee of the American College of Physicians and the American College of Physicians/American Pain Society Low Back Pain Guidelines Panel*

Recommendation 1: Clinicians should conduct a focused history and physical examination to help place patients with low back pain into 1 of 3 broad categories: nonspecific low back pain; back pain potentially associated with radiculopathy or spinal stenosis; or back pain potentially associated with another specific spinal cause. The history should include assessment of psychosocial risk factors, which predict risk for chronic disabling back pain (strong recommendation, moderate-quality evidence).

Recommendation 2: Clinicians should not routinely obtain imaging or other diagnostic tests in patients with nonspecific low back pain (strong recommendation, moderate-quality evidence).

Recommendation 3: Clinicians should perform diagnostic imaging and testing for patients with low back pain when severe or progressive neurologic deficits are present or when serious underlying conditions are suspected on the basis of history and physical examination (strong recommendation, moderate-quality evidence).

Recommendation 4: Clinicians should evaluate patients with persistent low back pain and signs or symptoms of radiculopathy or spinal stenosis with magnetic resonance imaging (preferred) or computed tomography only if they are potential candidates for surgery or epidural steroid injection (for suspected radiculopathy) (strong recommendation, moderate-quality evidence).

Recommendation 5: Clinicians should provide patients with evidence-based information on low back pain with regard to their expected course, advise patients to remain active, and provide information about effective self-care options (strong recommendation, moderate-quality evidence).

Recommendation 6: For patients with low back pain, clinicians should consider the use of medications with proven benefits in conjunction with back care information and self-care. Clinicians should assess severity of baseline pain and functional deficits, potential benefits, risks, and relative lack of long-term efficacy and safety data before initiating therapy (strong recommendation, moderate-quality evidence). For most patients, first-line medication options are acetaminophen or nonsteroidal anti-inflammatory drugs.

Recommendation 7: For patients who do not improve with self-care options, clinicians should consider the addition of nonpharmacologic therapy with proven benefits—for acute low back pain, spinal manipulation; for chronic or subacute low back pain, intensive interdisciplinary rehabilitation, exercise therapy, acupuncture, massage therapy, spinal manipulation, yoga, cognitive-behavioral therapy, or progressive relaxation (weak recommendation, moderate-quality evidence).

Ann Intern Med. 2007;147:478-491.
For author affiliations, see end of text.
www.annals.org

Low Back Pain Guidelines Analysis 2006

Eur Spine J (2006) 15: 543–555
DOI 10.1007/s00586-005-1027-y

REVIEW

Josep M. Arnau
Antoni Vallano
Anna Lopez
Ferran Pellisé
Maria J. Delgado
Nuria Prat

A critical review of guidelines for low back pain treatment

Low Back Pain Guidelines 2006 European Union Work Group

Eur Spine J (2006) 15 (Suppl. 2): S192–S300
DOI 10.1007/s00586-006-1072-1

O. Airaksinen
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On behalf of the COST B13 Working Group on Guidelines for Chronic Low Back Pain

Chapter 4 European guidelines for the management of chronic nonspecific low back pain

NASS Clinical Guidelines etc.
Available Products

- Clinical Guidelines
  - Clinical questions
  - Evidence analysis/tables
  - Strength of Recommendation
- Coverage Recommendations
  - Specific procedures
  - Evidence based
- Appropriateness Criteria
  - Formal consensus methodology
  - Rand/Modified Delphi

Levels of Evidence For Primary Research Question[1]
As Adopted by the North American Spine Society January 2005[2]

	Types of Studies			
	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model
Level I	• High-quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic Review[3] of Level I RCTs (and study results were homogeneous[4])	• High-quality prospective study[5] (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients) • Systematic review[3] of Level I studies	• Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[3] of Level I studies	• Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses • Systematic review[3] of Level I studies
Level II	• Lesser quality RCT (e.g., < 80% follow-up, no blinding, or inappropriate randomization) • Prospective[5] comparative study[6] • Systematic review[3] of Level II studies or Level I studies with inconsistent results	• Retrospective[7] study • Untreated controls from an RCT • Lesser quality prospective study (e.g., patients enrolled at different points in their disease or <80% follow-up) • Systematic review[3] of Level II studies	• Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[3] of Level II studies	• Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses • Systematic review[3] of Level II studies
Level III	• Case-control study[8] • Retrospective[7] comparative study[6] • Systematic review[3] of Level III studies	• Case-control study[8]	• Study of non-consecutive patients; without consistently applied reference "gold" standard • Systematic review[3] of Level III studies	• Analyses based on limited alternatives and costs; and poor estimates • Systematic review[3] of Level III studies
Level IV	Case Series[9]	Case series	• Case-control study • Poor reference standard	• Analyses with no sensitivity analyses
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

NASS Clinical Guidelines
Evidence Based

Grades of Recommendation for Summaries or Reviews of Studies

A:
Good evidence (Level I Studies with consistent finding) for or against recommending intervention.

B:
Fair evidence (Level II or III Studies with consistent findings) for or against recommending intervention.

C:
Poor quality evidence (Level IV or V Studies) for or against recommending intervention.

I:
There is insufficient or conflicting evidence not allowing a recommendation for or against intervention.

NASS Clinical Guidelines
www.spine.org

Evidence Based Guidelines/
Tech Reports

- Lumbar Disc Herniation
- Lumbar Spinal Stenosis
- Degenerative Lumbar Spondylolisthesis
- Adult Isthmic Spondylolisthesis
- Cervical Radiculopathy
- Antibiotic Prophylaxis
- Low Back Pain

NASS
Coverage Recommendations

- Cervical Epidural Steroid Injections
- Cervical Artificial Disc Replacement
- Cervical Fusion
- Cervical Laminoplasty
- Coccygectomy
- Electrical Stimulation Bone Healing
- Endoscopic Discectomy
- Laser Spine Surgery
- Lumbar Fusion
- Interspinous Device with/without Fusion

NASS Appropriateness Criteria
Formal Consensus/Rand Mod Delphi

- Cervical Fusion
  - Central Stenosis
  - Foraminal Stenosis
  - No Stenosis
  - Plate for ACDF
  - Posterior Decompression
  - Pseudoarthrosis
  - Soft Disc Herniation

NASS Resources

- NASS Clinical Guidelines available for members at: https://www.spine.org/Research-Clinical-Care/Quality-Improvement/Clinical-Guidelines
- Spine.org also has available
  - Clinical Guidelines Technical Documents
  - Coverage Recommendations
  - Appropriateness Criteria
  - Online Evidence Review Course
  - Online Course on most recent Clinical Guideline
    - Low Back Pain

References

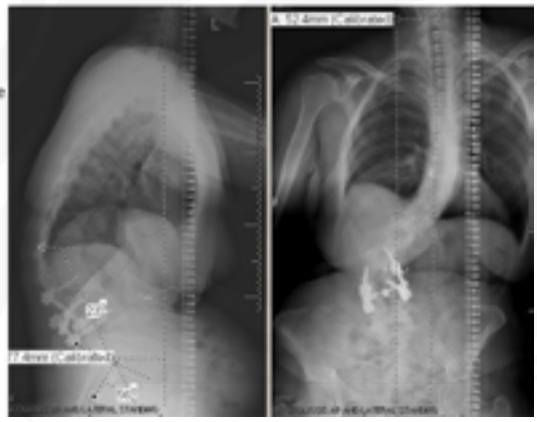
- Dept. of Clinical Epidemiology and Biostatistics, McMaster University. How to read clinical journals. V. To distinguish useful from useless or even harmful therapy. CMAJ 1984;124:1156-1162.
- Hernan MA et al. Observational Studies Analyzed Like Randomized Experiments. Epidemiology 2008;19:766-779.

Outcome Measures in Spine Patients

Case: 60 YOF with severe LBP

Radiology:

DLS
Coronal Cobb angle
Lumbopelvic parameters
SVA



Case: 60 YOF with severe LBP

Radiology:

DLS
Coronal Cobb angle
Lumbopelvic parameters
SVA

Aligned spine

What does it mean to the clinician?
What does it mean to the patient?

Outcome Measures

Up until recently the focus of most spine surgery literature has been based on clinical outcomes

- (something missing)!!!
- Ultimate outcome however, should be a combination of:
- Clinical
- Functional
- Health-related outcomes
- Satisfaction with care.

Cost-Effective Care

How Do We Know If Care Is Effective?

- Effective care maximizes probability of desired health outcomes
- Outcomes are markers of whether or not care is effective

The Era of Outcomes Assessment

- Outcomes in clinical practice provide the mechanism for:
  - The health care provider
  - The patient
  - The public
  - The payer

To assess the end results of care and its effect upon the health of the patient and society.

(Anderson & Weinstein, 1994)

What Are Health Outcomes?

- Traditional clinical endpoints
  - Death, disease occurrence, other adverse events
  - Clinical measures/biological indicators
  - Blood pressure
  - Blood hemoglobin level
  - Symptoms (e.g. fever)
- Health-Related Quality of Life

Outcome Meanings

- Health Care Customer - Meaning of Outcomes
  - Payers-purchasers — Cost containment
  - Regulators — HCP compliance
  - Administrators — Efficiency-low utilization
  - Clinical Researchers — Proof of a premise
  - Outcomes Experts — Patient's benefit
  - Health Care Providers — Clinical-Health Status

(Hansen DT, Mior S, Mootz RD & Yeomans SG: The Clinical Application of Outcomes Assessment, Stamford Connecticut, Appleton & Lange, 2000)

Outcomes Criteria

Utility	Is it useful?
Reliability	Is it dependable?
Validity	Does it do what it is supposed to?
Sensitivity	Can it identify patients with a condition?
Specificity	Can it identify those that do not have the condition?
Responsiveness	Can it measure differences Over time?

Outcomes Measures

- When outcome measures are appropriately used and integrated
  - into an evidence-based
  - patient-centered model of practice,
- there is accountability and quality assurance.

(Hansen DT, Mior S, Mootz RD in Yeomans SG: The Clinical Application of Outcomes Assessment, Stamford Connecticut, Appleton & Lange, 2000)

Subjective Questionnaires

- Subjective outcomes assessment information is gathered by the patient in self-administered questionnaires and scored by either the:
  - health care provider
  - staff members or
  - by a computer.

Subjective Questionnaires

- In spite of the definition associated with the term "subjective,"
- "pen-and-paper tools" have been described as very valid and reliable
  - in many cases more so than many of the "objective' tests that health care providers have relied upon for years.
    - (Chapman-Smith, 1992; Hansen, 1994; Mootz, 1994).

Classification of Outcome Assessment Tools

- **Subjective** -Functional
  (Patient Driven)
  - General Health
  - Pain Perception
  - Condition or Disease Specific
  - Psychometric
  - Disability
  - Patient Satisfaction
- **Objective** –Clinical
  (HCP Driven)
  - Union
  - Range of Motion
  - Strength - Endurance
  - Proprioception
  - Cardiopulmonary
  - Developmental

Clinical Outcome

- Clinician rated
  - - Focused on impairment measures
  - - These include findings like range of motion, muscle strength, and radiographic healing
  - - These findings have the advantage of being easy to measure
  - - Important for clinical decision making
    - - Treatment planning

Clinical Outcome

- Clinician
  - - Disadvantage is that they do not consider the patient's opinion of the success or failure of treatment

Functional Outcome

- Patient-based measures
  - - Evaluate the impact of injury on
    - - Patient's daily activity
    - - Work
    - - recreation
- The focus of outcomes assessment has now shifted to patient-based subjective assessments of outcome
- A combination of impairment and patient-based assessment is probably the ideal measure of outcome
- *Patient satisfactions is very important!*

Functional Outcomes HRQOL

- *Health-related* functions are the patient's perception of how they are functioning based on their overall health.

Health-Related Quality of Life is:

How the person FEELs (well-being)

- Emotional well-being
- Pain
- Energy

What the person can DO (functioning)

- Self-care
- Role
- Social

19

Targeted HRQOL Measures

- Designed to be relevant to particular group.
- Sensitive to small, but clinically-important changes.
- More familiar and actionable for clinicians.
- Enhance respondent cooperation.

HRQOL is Multi-Dimensional

Condition-specific Low Back

- Over 40 low back functional questionnaires exist with five identified by researchers as "gold standards" (Kopec and Esdaile, 1995).
  - - Sickness Impact Profile (Bergner et al, 1981)
  - - Roland-Morris Disability Questionnaire (Roland and Morris, 1983)
  - - Oswestry Low Back Pain Disability Questionnaire (Fairbank et al, 1980).
  - SF-36
  - - Million Visual Analogue Scale (Million et al, 1982).
  - - Waddell Disability Index (Waddell, 1984).

Roland-Morris Disability Questionnaire (RMQ)

- Total Possible Score = 24.
- "The best single study of assessing short-term outcomes of primary care patients with low back pain "(Von Korff and Saunders, 1996)
- Scores greater than 13 = Significant disability associated with an unfavorable outcome
  - (Von Korff and Saunders, 1996)
- Any change of less than 4 points is both too small to matter and too small to be reliable
  - a(Stratford et al, 1996)

Oswestry Disability Index

ODI - pain and function assessment

- 10 sections on various functions with 6 levels of assessment
- Physical and social functions that day
- Scores added (0-no disability to 100-maximum disability)
- Validated and reproducible instrument

Fairbank J, Pynsent P. Spine 2000; 25:2940-2953

Oswestry – Score Interpretation

0-20%	Minimal Disability
20-40%	Moderate Disability
40-60%	Severe Disability
60-80%	Crippled
80-100%	Bed Bound or Exaggerating

Outcome Measures - Pain

Pain Measurement

- SF-36 pain scale
- Visual analog scale (VAS)
- Brief Pain Inventory (BPI)
- Treatment Outcomes in Pain Survey (TOPS)

Outcome Measures - Satisfaction

Global Satisfaction

- Extremely, very, somewhat satisfied
- Mixed
- Somewhat, very, extremely dissatisfied

Outcome Measures - Satisfaction

Satisfaction Questionnaire (SQ)

- 14 item measure of satisfaction
- Includes items on
  - - interpersonal quality
  - - technical quality
  - - time spent
  - - cost of care
  - - satisfaction with care

Spinal Stenosis Questionnaire

- 18 items
  - - Symptom Severity : 7 Items
  - - Physical Function: 5 Items
  - - Satisfaction: 6 Items

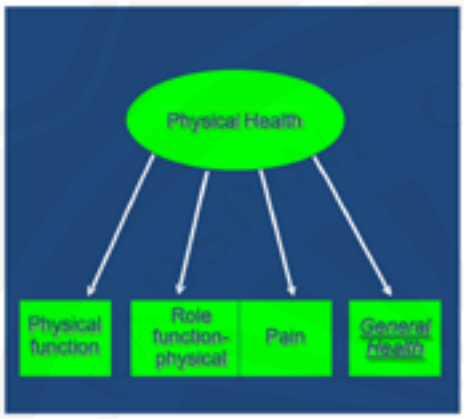
Spinal Stenosis Questionnaire

- "was found to be reproducible, valid, internally consistent, and responsive to clinical change in a geriatric spinal stenosis population pre and post-surgery" (Stucki et al, 1996).
- This measure is meant to be used in conjunction with other existing spine and health status instruments.

SF-36 Generic Profile Measure

- Physical functioning (10 items)
- Role limitations/physical (4 items)
- Role limitations/emotional (3 items)
- Social functioning (2 items)
- Emotional well-being (5 items)
- Energy/fatigue (4 items)
- Pain (2 items)
- General health perceptions (5 items)

SF-36 Physical Health



SF-36 Mental Health

Interpretation of Scores

- MCD: Minimal detectable change
  - - Associated with 2 administration of the measure
  - - Enable clinician to evaluate a patient's response to treatment
  - - Does not equate to change that is important to the patient

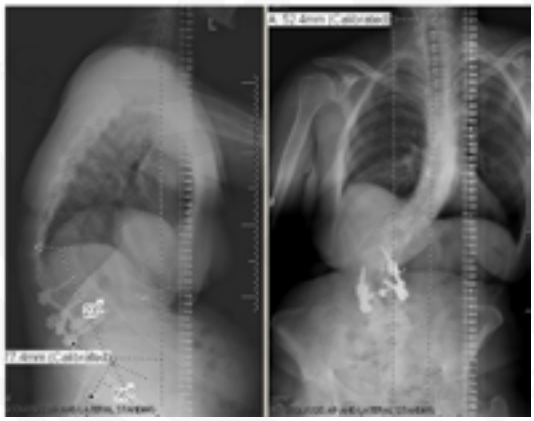
Interpretation of Scores

- MCID: minimal clinically important difference
  - Meaningful to the patient
  - Beneficial to the patient as an index of responsiveness
  - Value for each measure
    - An MCID for the ODI has been reported as 6% change
      Fairbanks, Spine 2000

Case: 60 YOF with severe LBP

Radiology:
DLS
Coronal Cobb angle
Lumbopelvic parameters
SVA

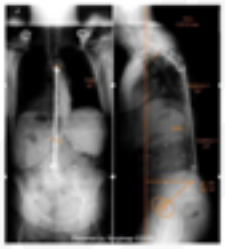
VAS 10
ODI 80



VAS 2
ODI 20

Radiology:
DLS
Coronal Cobb angle
Lumbopelvic parameters
SVA

X-rays and Patient Reported Outcomes



HRQOL Instruments
ODI
SF-12
SRS

Correlations ?
MCID?

4 Steps to Become Outcomes Based

- Utilize subjective/objective tools
- Score the tools at the initial visit to establish baseline measures
- Repeat the instrument after treatment in intervals to track the effects of treatment changes
- Base clinical decisions on the outcome results

"Medical Necessity"

- The fully developed clinical record defines the "medical necessity" of the case in the eyes of the insurer.

"Medical Necessity" Documentation

- Provider must document
  - - Etiology of complaint (onset, severity, frequency , duration
  - - Patient's health history
  - - Current subjective complaints
  - - Current objective clinical findings
  - - Diagnosis
  - - Treatment plan
  - - Measurements of patient improvement (outcome assessment)

Informed Consent

What is Informed Consent?

- The **process** of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention (American Medical Association 1998)
- ***…It's more than a signature on a piece of paper!***
- Failure to obtain informed consent renders any U.S. physician liable for negligence or battery and constitutes medical malpractice

Why Do We Need Informed Consent?

- The Short Answer:
  - It's the law
- Beyond the Law
  - It's the ethical thing to do
  - It's an access/diversity issue
  - It's a safety and quality of care issue
    - Patient identification
    - Procedure confirmation
      - Spine=Levels/Side(s)/approach/procedures

Why Do We Need Informed Consent?

- The Slightly Longer Answer:
  - Greater patient safety and satisfaction
  - Attainment of higher ethical standards and organizational morale
  - Closer adherence to legal requirements and reduced risk of litigation
  - Increased levels of institutional quality (e.g., compliance with accreditation standards)
  - Potential time and money savings (or offsets) related to reduced litigation

Who is Responsible for Informed Consent?

- The clinician has core responsibility... but...
  ... a team approach is required with contributions from:
  - entire clinical staff (clinician, nurse, technicians, pharmacist)
  - administrative and clinical leadership
  - legal counsel

When is Informed Consent Required?

- In most institutions, for:
  - surgery
  - anesthesia
  - other invasive or complex medical or radiologic procedures
- Laws vary from state to state & country about exactly when and how formal informed consent must be provided.

Why Do We Need to Improve Informed Consent?

- Even after signing a consent form, many patients still do not understand basic information about the risks and benefits of their proposed treatment options.
- Patient Factors:
  - Low health literacy
  - Limited Language proficiency
  - Cognitive impairments
  - Confusion about the purpose of consent process
  - Feeling of intimidation, and stress or time pressure

Why Do We Need to Improve Informed Consent?

- Even after signing a consent form, many patients still do not understand basic information about the risks and benefits of their proposed treatment options.
- Provider Factors:
  - Lack of time for up-front patient education
  - Overly complex or overly broad written materials
  - Lack of support with interpreters
  - Wrong assumptions about patient comprehension

Low Health Literacy — A Common Theme in Poor Clinician-Patient Communication

- "It is likely the almost everyone has been, at some time, put off by densely worded forms, and confused by complex medical regimens, conflicting health care advice, poorly worded instructions, and medical speak that few on the receiving side of health care can understand".

From "What Did the Doctor Say?: Improving Health Literacy to Protect Patient Safety" The Joint Commission, 2007 **www.jointcommission.org**

Low Health Literacy — A Common Theme in Poor Clinician-Patient Communication

- "Many leave the doctor's office with questions unspoken and unanswered..."
- "The communications gap between the abilities of ordinary citizens, and especially those with low health literacy and low English proficiency, and the skills required to comprehend everyday health care information must be narrowed".

From "What Did the Doctor Say?: Improving Health Literacy to Protect Patient Safety" The Joint Commission, 2007 **www.jointcommission.org**

What's the Evidence that the Informed Consent Process is Not Working Well?

- Braddock et al 1999
  ... found uninformed patients
- Audiotape recordings from 1057 physician-patient encounters:
  - Only 9% of decisions were completely informed
  - Only 20% to 38% of the encounters met less stringent criteria for completeness

What's the Evidence that the Informed Consent Process is Not Working Well?

- Manthous et al 2003
  ... found variability in use of informed consent
- National mailed survey of 117 intensivists and 56 internists:
  - Found heterogeneity in when physicians obtained informed consent
    - 74% to 93% for transfusion of blood products
    - 77% to 96% for common diagnostic procedures (e.g., lumbar puncture, paracentesis)
  - Many physicians used a "blanket" consent forms to cover invasive medical procedures

What's the Evidence that Informed Consent Forms are Poorly Written?

- Bottrell et al 2000
- Analyzed 540 informed consent forms from 157 hospitals:
  - Only 26% included all four elements (nature of procedure, risks, benefits, alternatives)
  - Less than half of the forms provided specific information about risks
  - Alternatives were noted only in 57% of forms

What are the Potential Consequences of Lack of True Informed Consent

- patient safety incident or medical error eg wrong site sx
- Increased chance for malpractice cases
- Violation of professional and ethical obligation to clinicians to communicate clearly

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- Manthous C et al. Informed consent for medical procedures: local and national practices. Chest 2003;124:1978-84
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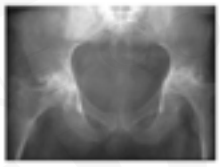
LBP and Systemic Disease

Is it the Spine???
Back & Buttock/Leg

- Hip
- SI Joint
- Vascular – AAA
- GI/GU
- Neoplasm/1º/mets
- Vascular Claudication
- Peripheral Neuropathy



Hip–Spine Syndrome

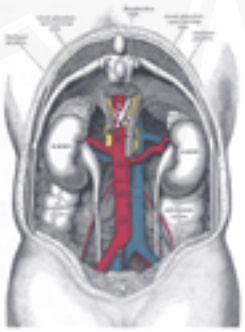
C. M. OFFERSEN, MD, and I. MACNAB, M.B., Ch.B.

Systemic Causes LBP

- I. Pathology outside the Spine
- II. Inflammatory conditions
- III. Metabolic disorders
- IV. Tumors of axial spine
- V. Spinal Infections

Systemic Causes LBP
I. Pathology Outside the Spine

- GI
  - Pancreatitis/Gallbladder/Diverticulitis
- GU/Kidney disease:
  - Nephrolithiasis
  - Pyelonephritis
- Vascular
  - Abdominal Aortic Aneurism
- Neurologic
  - Herpes Zoster



Systemic Causes LBP
II. Inflammatory Conditions

- Osteoarthritis
- Ankylosing Spondylitis
- Rheumatoid Arthritis
- Other Rheumatol & immune diseases
  - Psoriasis
  - Polymyalgia Rheumatica
  - Fibromyalgia

Ankylosing Spondylitis

- 0.1%-0.5% adults
- Esp men teens/20's
- SI/LBP
  - Joints/tendonitis
- X-Ray
  - SI
  - Bamboo Spine
- HLA- B27

Classification criteria for axial spondylo-arthritis (SpA) by: Spondylo-arthritis International Society (ASAS)

ASAS classification criteria for axial SpA

(in patients with back pain >= 3 months and age at onset < 45 years)

Sacroiliitis on imaging*
plus
>= 1 SpA feature**

or

HLA-B27
plus
>= 2 other SpA features**

** SpA features:
- Inflammatory back pain
- Arthritis
- Enthesitis (heel)
- Uveitis
- Dactylitis
- Psoriasis
- Crohn's disease/ulcerative colitis
- Good response to NSAIDs
- Family history for SpA
- HLA-B27
- Elevated CRP

* Sacroiliitis on imaging:
- Active (acute) inflammation on MRI highly suggestive of sacroiliitis associated with SpA
or
- Definite radiographic sacroiliitis according to mod. New York criteria

Sensitivity 82.9%, specificity 84.4%; n = 649 patients with chronic back pain and age at onset < 45 years.
Imaging arm (sacroiliitis) alone has a sensitivity of 66.2% and a specificity of 97.3%.
** Note: Elevated CRP is considered a SpA feature in the context of chronic back pain

Systemic Causes LBP
III. Metabolic disorders

- Osteoporosis/fragility fracture
- Ossification of the PLL (OPLL)
- Diffuse idiopathic skeletal hyperostosis (DISH)
- Calcium pyrophosphate arthropathy
- Amyloidosis
- Acromegaly

WHO Diagnostic Criteria

Classification	T-score
Normal	-1.0 and higher
Osteopenia	Between -1.0 and -2.5
Osteoporosis	-2.5 and lower
Severe osteoporosis	-2.5 and lower with history of fragility fracture

From Lewiecki E, AAOS online course

World Health Organization (WHO). Prevention and management of osteoporosis. Report of a WHO Scientific Group. http://whqlibdoc.who.int/trs/who_trs_921.pdf. Accessed December 26, 2011.

Osteoporosis Risk Factors
Medications

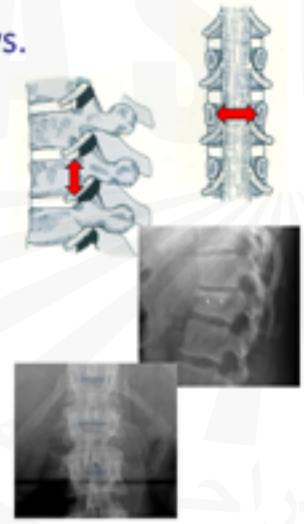
- Oral Steroids
- Cancer Treatments
  - Chemotherapy
  - Radiation
- Thyroid Medication
- Anti-Epileptic Meds
- Gonadal Hormone Suppression
- Immunosuppression

Compression Fracture vs. Burst

- Three Column Concept Stability
  - Anterior
  - Middle
  - Posterior
- Compromise
  - 1 Column – stable (compression #)
  - 2 Column – unstable (burst #)
  - 3 Column – unstable (Chance #)

Compression Fracture vs. Unstable Burst

- X-Ray Measurements
  - Vertical posterior body
    - Should be average of adjacent
    - Less = compress middle column
  - Interpedicular distance
    - Should be average of adjacent
    - Less = spread middle column
  - Less=possible burst/unstable #
    - Need CT look@ 1 vs. 2/3 column #

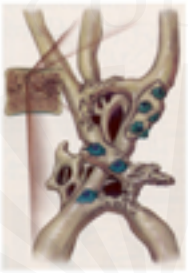


Pharmacologic Treatments Antiresorptive Agents

- Calcitonin
- Hormone replacement
- Selective Estrogen Receptor Modulators
  - Raloxifene
    - 62% less risk Ca Breast
    - No extra risk endometrial Ca
    - 3X risk DVT
  - Tamoxifen
    - Higher risk DVT
    - Endometrial Ca
- Bisphosphonates
  - Alendronate (Fosamax)
  - Risedronate (Actonel)
  - Ibandronate (Boniva)
  - Zoledronic Acid(Reclast)
- GI Ulceration
- Jaw osteonecrosis
- Adynamic Bone
  - Paradoxical decrease strength/resilience
  - Oversuppression turnover

Pharmacologic Treatments
Anabolic Agents

- Parathyroid Hormone (PTH)-Forteo
  - Teriparatide (PTH1-34) - Forteo
  - Enhance bone turnover
  - Increase bone mass 13% @ 2yrs
  - Contra-indications
    - Padgets/mets/bone radiation tx/open epiph
    - Osteosarcoma-1 human case/rat studies
  - Barriers
    - Daily subcutaneous
    - Cost - $600-700/mo (€485/mo)
    - Max 24 months lifetime



Systemic Causes LBP
IV. Tumors of Axial Spine

- Arch/Posterior Body
  - Osteoid Osteoma
  - Osteoblastoma
  - Aneurismal Bone Cyst-ABC
- Body
  - Metastases
  - Myeloma
  - Lymphoma
  - Eosinophilic Granuloma
  - Hemangioma
- Sacrum
  - Giant Cell
  - Chordoma

Spinal Neoplasm- Benign

	Age	Sex	Location	Characteristics
Osteoid **Osteoma**	<30	M > F	posterior	nidus/sclerosis
Osteoblastoma	<30	M > F	posterior	lucent
Osteochondroma	10-20	M > F	posterior	calcified
Aneurismal Bone Cyst ABC	<25	M=F	posterior	Lytic/**expansile**
Eosinophilic **Granuloma**	<20	M > F	body	Lucent/collapse
Giant Cell	>20	M > F	Body sacrum	lytic
Hemangiomas	>30	M < F	Body	Vertical trabeculae **Specling on CT**

Spine Neoplasm - Malignant

	Age	Locationn	Characteristics
Neuroblastoma	<3	Body	Rosette on histology
Osteosarcoma	10-20	body	Destructive
Chordoma	30-70	Sacrum/C1-2	Lucent/destructive
Chondrosarcoma	50-70	Body	Destructive/calcification
Lymphoma	>20	Body	Osteopenia
Multiple myeloma	>50	Body	Osteopenia
Metastases	>40	Body/pedicle	Destructive/Sclerotic Disc Spared

Spinal Neoplasm - Intraspinal

Intradural - Extramedullary

	Age	Sex	Characteristics
Neurolemmoma	30-40+	M = F	Schwannoma
Neurofibroma	30-40+	M = F	Dumbell or circular
Meningioma	50-60+	M > F	Thoracic 80%

Intradural Intramedullary

	Age	Sex	Characteristics
Ependymoma	20-60+	M > F	50% in filum terminale
Astrocytoma	20-50+	M > F	
Syringomyelia	> 20	M = F	Cystic
Arachnoid Cyst	> 20		Cystic esp Thoracic
Perineural Cyst	> 20		Cystic esp Sacrum/ Tarlov

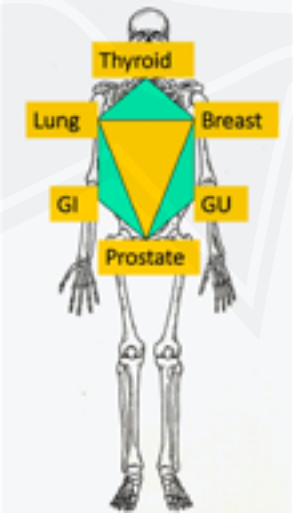
Skeletal Metastases

Hexagon

- Thyroid
- Lung
- Breast
- GI
- GU
- Prostate

Blastic

- Lung
- Breast
- Prostate



Systemic Causes LBP
V. Spinal Infections

- Discitis
- Spondylodiscitis
  - Septic
  - Ankylosing Spondylitis
- Spondylitis
- Epidural Abscess
- Septic facet arthritis

Systemic Causes LBP
V. Spinal Infections

- Delayed diagnosis (elderly)
- Progressive course
- Continuous pain exacerbating in night
- Fever and septic patterns might be absent
- Predisposing factors:
  - Diabetes,
  - Immunodeficiency
  - Peripheral infections,
  - Drug abusers,
  - Dialysis
- Most frequently found organisms are Staphylococcus aureus (30–55%), E. coli, Salmonella, Enterococcus, Proteus mirabilis, Pseudomonas aeruginosa (in 65% of drug abusers), Streptococcus viridans, and epidermatitis (especially diabetics)

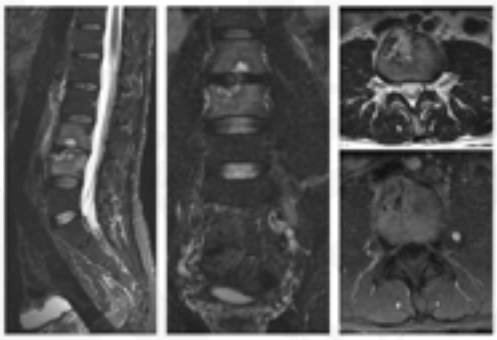
Septic Discitis

- Very painful upright/OK flat
- Systemic symptoms
  - Fever/chills
- Immune Compromise
  - Diabetes/Chemo/RA/IBS
- Imaging
  - Involve disc-T2 hyperintense/narrow
  - Endplate enhancement/erosion
  - Epidural/paraspinous/psoas abscess

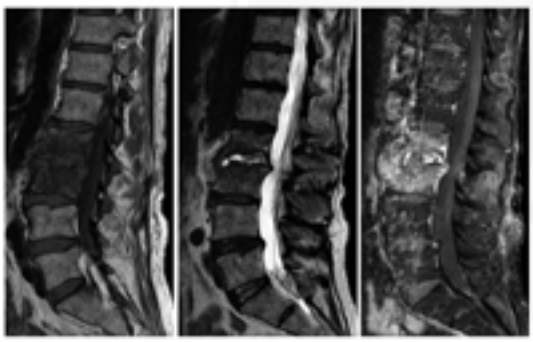
Spinal Tuberculosis-TB (Pott's)

- Children/young adults
- Most common extrapulmonary
- Start ant inf corner vert body
- Destruct disc sp/body
- Most common T/T-L
- Often spread mult levels
- Gibbus/ neurologic

Brucella Spondylodiscitis



Spondylodiscitis L2/3 – Candida Albicans



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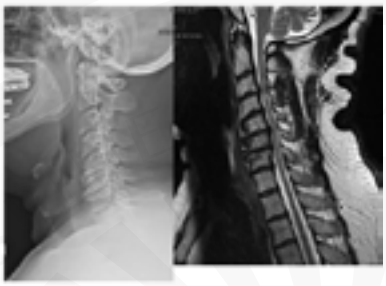
DVT Prophylaxis in Spine Surgery

Case

- 66 y/o male
- h/o chronic neck pain
- 4 month h/o progressive ataxia, hand numbness
- 3/5 hand intrinsics
- PMH remarkable for DVT in remote past



Case

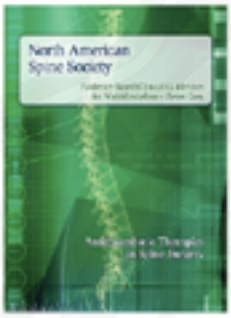
- Underwent C3-C7 laminectomy, posterior instrumentation and fusion C2-T2
- VTE prophylaxis consisted of IPC, LMWH started postop day 2

Case

- POD # 3 pt c/o increasing neck pain, dysthesias BUE
- Motor exam 3/5 diffusely BUE
- Pt underwent emergent I&D

Avoiding Venous Thromboembolism

Guidelines exist

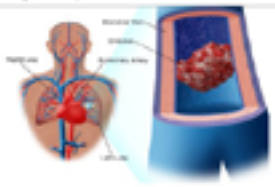


Thromboembolic?

- DVT
- PE

Thromboembolic?

- DVT
- PE How big a problem?



Avoiding Venous Thromboembolism

Natural History

Historically difficult to discern

- No studies of patients with no prophylaxis
- Diagnostic method between studies varies greatly
- Patient populations between studies varies widely

NASS Guidelines "unable to definitively answer" the question

Avoiding Venous Thromboembolism

Big data able to provide answer

Spine Journal 2017

Clinical Study

Risk factors and pharmacologic prophylaxis for venous thromboembolism in elective spine surgery

Ryan P. McLynn, BS, Pablo J. Diaz-Collado, MD, Taylor D. Driesen, BS, Nathaniel T. Ondeck, BS, Jonathan J. Cui, BS, Praveen Bovonratwet, BS, Blake N. Shultz, BA, Jonathan N. Grauer, MD*

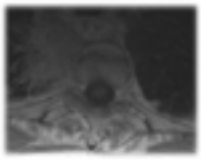
NSQIP studies

- 2005-2009 1.2% (0.4% PE, 0.8% DVT)
- 2004-2014 0.6%

Incidence varies

"High Risk"—trauma, cancer

- w/o prophylaxis:
  - Incidence difficult to estimate
- Higher than elective
- ↑↑ rate w/ SCI/neurologic deficit (Maynard et al., JBJS, 2009)



Avoiding Venous Thromboembolism

Efficacy of Prophylaxis

Mechanical Compression

- Two studies looking at mechanical prophylaxis
  - Compression comparable to compression with chemoprophylaxis (Rokkas et al, Spine 1996)
  - Foot pumps and calf pumps equally effective (Wood et al, J Spine Sur 1997)

Avoiding Venous Thromboembolism

Efficacy of Prophylaxis

Mechanical Compression

Conclusion

- Mechanical compression devices are suggested in patients undergoing elective spine surgery (Grade B evidence)
- Should start at the time of surgery
- Should continue until pt fully ambulatory

Avoiding Venous Thromboembolism

Chemoprophylaxis

- Recommendations from NASS Guidelines

"Most commonly performed elective spine surgeries done through a posterior approach are associated with a very low risk of VTE. In this instance chemoprophylaxis may not be warranted"

"Recommend LMWH be used cautiously prior to routine, elective spinal surgery and withheld unless there are other risk factors for thromboembolism"

Avoiding Venous Thromboembolism

Chemoprophylaxis

Despite this, many US centers REQUIRE it for ortho: spine is lumped in

≠

How long for chemoprophylaxis

- NASS guideline: Workgroup consensus
  - "...until patient is fully ambulatory is a reasonable practice."

ok for deformity
OK if can EVENTUALLY ambulate

How long for chemoprophylaxis?

- NASS guideline: Workgroup consensus
  - "...until patient is fully ambulatory is a reasonable practice."

Not OK if no hope of ambulating
e.g. complete SCI

When is it safe to start chemoprophylaxis?

Another unknown

- NASS Guideline: can start day of
- Boston Survey: wide range (for high-risk Pts)

Does chemoprophylaxis ↑ risk for Epidural hematoma?

Systematic review (Glotzbecker, Bono, et al, Spine, 2010)

- Estimated rates:
  - w/ chemoprophylaxis: 0-0.7%
  - w/o chemoprophylaxis: 0-1.0%

i.e. NO DIFFERENCE

Special circumstances

Bridge therapy

- E.g. patient w/ past h/o of DVT/PE
- Need to stop long-acting (e.g. warfarin, plavix) more than ½ life

- "Bridge" w/ short-acting (e.g. LMWH)
- Stop short-acting 12-24 h preop
- Restart long-acting post-op

Special circumstances

Tx of postop DVT or PE

- Worst case scenario
- Need to be therapeutic levels
- Balance actual risk vs. benefit
  - E.g. DVT below knee—need to be txd?

Special circumstances

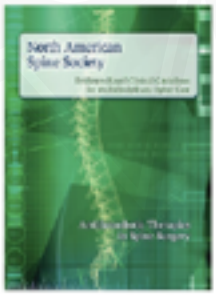
Patients w/ stent

- Fresh stent (<6 mos): postpone surgery (elective)
- Stent > 6 mos—stay on ASA through surgery
  - Bleeding? Not much different intraop, ↑ in drain (postop)

Avoiding Venous Thromboembolism

Wound Complications

- Does the use of chemoprophylaxis increase the risk of wound complications or neurologic decline from epidural hematoma?



Insufficient evidence to address the question

Avoiding Venous Thromboembolism

Takeaways from NASS Guidelines

- Literature is pure
- Incidence is low
- Mechanical prophylaxis should be used
- Chemoprophylaxis not necessary for routine, elective cases

Avoiding Venous Thromboembolism

American College of Chest Physicians

- Six randomized controlled trials
  - Chemoprophylaxis vs placebo
  - LMWH vs unfractionated heparin
  - Three mechanical with or without chemoprophylaxis

Avoiding Venous Thromboembolism

American College of Chest Physicians

Risk factors for VTE

- Combined AP surgery
- Multiple levels
- Pt related factors
  - Age
  - Prior VTE
  - Malignancy

Avoiding Venous Thromboembolism

Recommendation:

"For patients undergoing spinal surgery, we suggest mechanical prophylaxis, preferably with IPC, over no prophylaxis (Grade 2C), unfractionated heparin (Grade 2C), or LMWH (Grade 2C)"

Avoiding Venous Thromboembolism

Recommendation:

- "For patients undergoing spinal surgery at high risk for VTE...we suggest adding pharmacologic prophylaxis to mechanical prophylaxis once adequate hemostasis is established and the risk of bleeding decreases (Grade 2C)"

Avoiding Venous Thromboembolism

Recommendation:

- "For major trauma patients at high risk for VTE..., we suggest adding mechanical prophylaxis to pharmacologic prophylaxis (Grade 2C) when not contraindicated by lower-extremity injury"

Avoiding Venous Thromboembolism

Additional Findings

- There was a modest increase in major bleeding complications with chemoprophylaxis
- Venous ultrasound should not be used for periodic surveillance of VTE

Avoiding Venous Thromboembolism

Where does that leave us?

Summary from these guidelines

- All spine surgery patients should receive mechanical prophylaxis begun at the time of surgery and continued until d/c
- Patients at "high risk" should receive chemical prophylaxis as well when the risk of major bleeding has subsided
- Routine surveillance in asymptomatic patients with venous ultrasound is not recommended

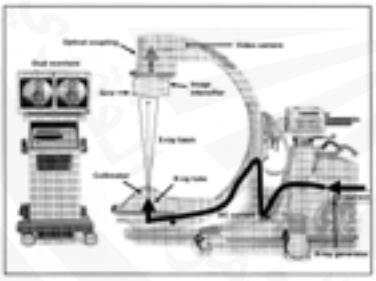
Radiation Exposure in Spine Surgery

Outline

- Patient
  - MIS SX – Minor/case
  - Pre Surgical Imaging
    - Plane Films
    - CT scan
- Surgeon
  - Measurement Units
  - Exposure Limits
    - Risk / Procedure
  - Safety Strategies

Surgeon Problem:

MIS Surgery=Indirect Visualization



The Concern:

Carcinogenesis

Dr. Edgar Dawson

- Past President SRS
- Chief of Staff UCLA Medical Ctr
  - First Fellow John Moe/Minneapolis
  - NASS/AOA/COSS
  - Golf
- 2004 - Thyroid Carcinoma
- Ortho Surg Sx lifetime cancer rate (Mastran
  G. Increased cancer
  risk...surgeons...Orthopaedic Hosp. Occ
  Med (Lon) 2005;55:498-500)

Measurement Units

Unit	Equivalent	Definition	Application
Gray (Gy)		1 joule/kg	Energy absorbed/mass
Rad -Old	1 Gy=100 rads		Absorbed Dose
Sievert (SV)			Equivalent dose Effect of absorbed dose based on organ senstivity = Absorbed dose x tissue factor (1=skin, 20=gonads)
Rem - Old	100 Rem=1Sv	Roentgen Equivalent Man	

Exposure Limits

(Equivalent Dose - Absorbed Dose x Tissue Factor)

Anatomic Area	Yearly Maximum	Effect
Total Body	5 rem (0.05 Sv)	Cancer
Cornea	15 rem (0.15 Sv)	Cataracts
Extremities (hands)	50 rem (0.5 Sv)	Burns

Table 21.4: Radiation dose limits

Annual	50 mSv	5 rem
Cumulative	10 mSv	1 rem × age
Annual dose limits for tissues and organs		
Lens of the eye	150 mSv	15 rem
Skin, hands, and feet	500 mSv	50 rem
Fetus		
Total dose equivalent	5 mSv	0.5 rem
Monthly dose equivalent	0.5 mSv	0.05 rem

From Gruber et al. 2000[9] with permission of Hanley & Belfus.

Giordano B, Radiation Exposure Issues in Orthopaedics JBJS-A 2011;93:e69/1-10

Radiation Exposure Issues in Orthopaedics*

Brian D. Giordano, MD, Jonathan N. Grauer, MD, Christopher P. Miller, MD, Thomas L. Morgan, PhD, CHP, and Glenn R. Rechtine II, MD

The topic of radiation exposure for patients, physicians, and staff has become prominent in the lay press. It seems that every week another story about radiation safety makes the evening news. For physicians and surgeons, the largest radiation exposures involve fluoroscopy use with either fixed or mobile units. For patients, fluoroscopy (c-arm), computed tomography (CT), and nuclear medicine studies constitute the vast majority of exposures. The use of each of these modalities has grown dramatically with changes in the practice of medicine.

C-arm use in orthopaedic surgery is increasing rapidly as surgery transitions to minimal-access surgery. With less direct ing in radiation safety". One questionnaire study of physicians showed that 4% did not know that ultrasound did not involve ionizing radiation and 27% did not know that magnetic resonance imaging (MRI) did not involve radiation at all". Approximately 90% of physicians underestimated the radiation exposure and risks from pediatric radiographs and CT scans". A single pediatric abdominal CT scan exposes the patient to more radiation than the seventy-one exposure from living in the vicinity of the Chernobyl accident". For a five-year-old patient who weighs 19 kg, a chest CT is the equivalent of 600 chest radiographs and a CT of the abdomen and pelvis is the same as 1400 chest radiographs".

Radiation Exposure

Giordano B, Radiation Exposure Issues in Orthopaedics JBJS-A 2011;93:e69/1-10

TABLE I Comparative Values of Sources of Radiation Exposure

Source	Radiation Exposure	Equivalent
Airport backscatter x-ray screen	0.05 μSv	1 index scan
Airline travel at 35,000 feet	5 μSv/hr	1.5 airport scans per minute in the air
Lumbar spine radiograph	1.5 mSv	30,000 airport scans
Lumbar computed tomography scan	15 mSv	300,000 airport scans

TABLE II Effective Doses and Fatal Cancer Risk for Selected Diagnostic Imaging Studies

Examination†	Adults: Avg. Effective Dose (mSv)	Adults: Risk Ratio‡
Radiography		
Skull (AP and lateral)	0.1	1 in 200,000
Cervical spine	0.2	1 in 100,000
Thoracic spine	1.0	1 in 20,000
Lumbar spine (AP and lateral)	1.5	1 in 13,300
Chest (PA and lateral)	0.1	1 in 200,000
Chest (PA)	0.02	1 in 1,000,000
Mammography	0.4	1 in 50,000
Abdomen	0.7	1 in 28,600
Pelvis (AP)	0.6	1 in 33,300
Hip	0.7	1 in 28,600

/Year
5 Rem
0.05 Sv
=50mSv

Comparative Exposure

- Lumbar spine radiographs (Richards)
  - 0.3 mSv (=0.0003 Sv) each for AP and lateral
- Whole body PET/CT (Bingsheng Huang; Radiology 2009):
  - 13 – 32 mSv (= .013 - .032 Sv) (annual allowed .05 Sv)
  - CA risk (National Academies' Biological Effects of Ionizing Radiation VII Report): 0.163% - 0.514%
    - Calculation method accounts for age/sex, etc variables
- Brenner D. Computed Tomography-An Increasing Source of Radiation Exposure NEJM 2007;357:2277
  - 62 Million CT scans/year in USA / 4 million children

Exposure – Surgeon

Rittenberg J. Radiation Safety for Spine Providers. Spineline 2006; 7:9

Surgical Procedure	Average Fluroscopy Time (seconds)	Equivlent Dose (mrems/min)	Maximum Procedures per year
L4-S1 pedicle screws	79	79	631
Vertebroplasty-1 level	120	42	592

Rittenberg J. Radiation Safety for Spine Providers. Spineline 2006; 7:9

Table 2. Number of Fluoroscopically Guided Spinal Procedures to Reach the Recommended Annual Hand Equivalent Dose Limit (50,000 mrem/year)

Procedure	Average Fluoro Time (seconds)	Equivalent Dose (mrems/min)	Case Load Allowable Per Year
L4-S1 pedicle screws (<150 lb patient)[7]	58	58 (unprotected) 39.3 (leaded glove)	859 1,311
L4-S1 pedicle screws (>150 lb patient)[7]	79	79 (unprotected)	631
Lumbar transforaminal epidural injection[18]	15	2.77 (unprotected)	71,429
Three level lumbar discography,[19] L3-4, L4-5, L5-S1[19]	172	4.03 (unprotected)	4,553
Vertebroplasty, one level[20]	120	42.2 (unprotected) 11.2 (leaded glove)	592 2,232

(Data adapted from raw data from references cited in table)

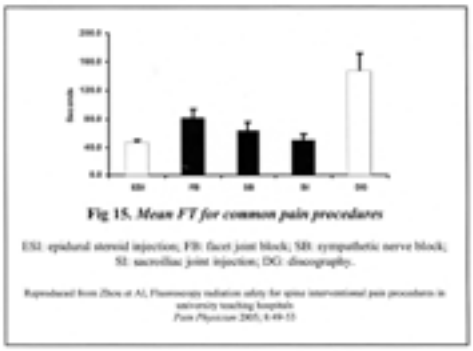
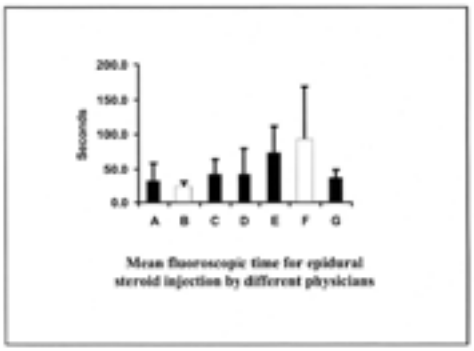


Fig 15. *Mean FT for common pain procedures*

ESI: epidural steroid injection; FB: facet joint block; SB: sympathetic nerve block; SI: sacroiliac joint injection; DG: discography.

Reproduced from Zhou et Al, Fluoroscopic radiation safety for spine interventional pain procedures in university teaching hospitals. *Pain Physician* 2005; 8:49-53



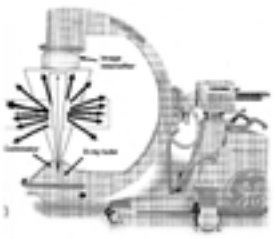
Mean fluoroscopic time for epidural steroid injection by different physicians

Operator Controls

- Milliamperage (mA)
  - 0.5-5 mA
  - Number of electrons
- Kilovoltage peak (kVp)
  - 50-120 kV
  - Accelerating force
- Good to use high kVp for useful contrast : brightness
- ALARA: as low as reasonably achievable

Collimation

- Collimation (radiopaque blades that move into x-ray beam
- Modifies size and shape of beam to conform to FOV
- Reduces scatter
- Improves image quality
- ALARA: as low as reasonably achievable



Rittenberg J. Radiation Safety for Spine Providers. Spineline 2006: 7:9

- Surgeon Risk
- Scatter Radiation
  - Highest closest to beam entrance point (tube)
  - Three times higher in lateral vs. AP projection

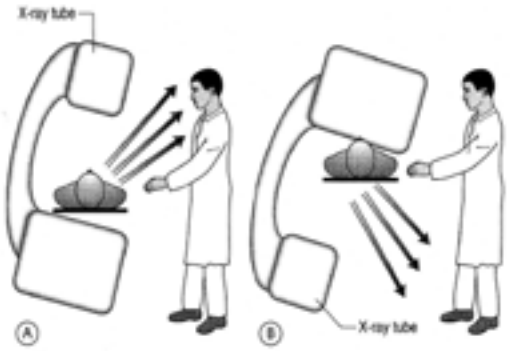
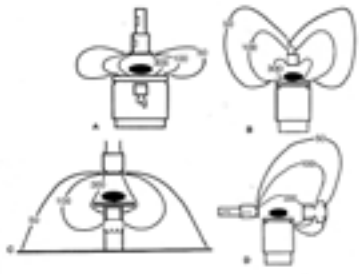
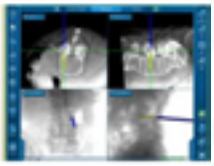


Fig. 21.7 The radiation exposure effects to the interventionist when improper radiation source positioning is used.



Intra-operative CT/ O-arm

- Abdullah K Spine 2012; 37: E1074-1078



Av Surg **Expose**	44.22 **uRem**
Dist **from O-arm**	4.56 m
Exposure time	19.6 seconds
Annual procedures	113,071

Distance

- Inverse Square Law
- Radiation exposure proportional to inverse square of distance from the source
- Old 6 ft rule/ New 20 ft. (Giordano B, Radiation Exposure Issues in Orthopaedics JBJS 2011;93:e69/1-10)

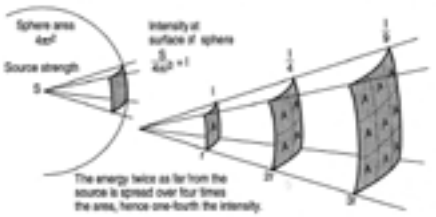


Fig. 21.4 Radiation deteriorates at the inverse square of the distance from the source.

Dose Reduction of Shielding

- Lead apron
- Thyroid shield: <75-85% Marshall BJR 1992
- Lead barriers at patient:
- Leaded gloves:
  - 1/3 reduction (Rampersaud - cadaver)
  - <70% (Synowitz – clinical)
- Leaded glasses: <87% Marshall

Surgeon Strategies

- X-Ray Source under the OR table
  - Jones D. Radiation exposure during fluroscopically assisted pedicle screw insertion... Spine 2000; 25:1538
- Stand same side as image intensifier
  - Rampersaud Y. Radiation exposure to the spine surgeon during fluroscopically assisted pedicle screw insertion. Spine 2000;25:2637
- Patient close to source (reduce air gap/scatter)
  - Giordano B. Patient and surgeon radiation exposure; comparison standard and mini C-arm fluroscopy. JBJS-A 2009;91:297
- Use collimation
- Reduce exposure time – NO LIVE FLURO
- Plane X-Ray/O-arm – 20 ft RULE (NOT 6 ft)
- ALARA: As Low As Reasonably Achievable
- Use barriers

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- END OF THE PROGRAM -

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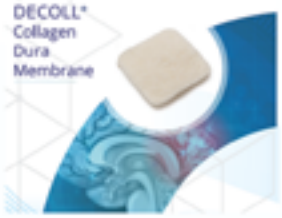

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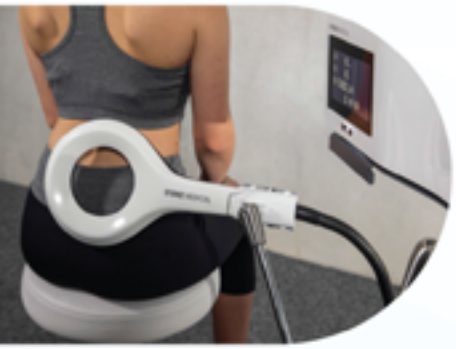

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