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TECHNOLOGY IN SPINE CARE

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Technology in Spine Care

Kathleen Fink, MD

February 12, 2020



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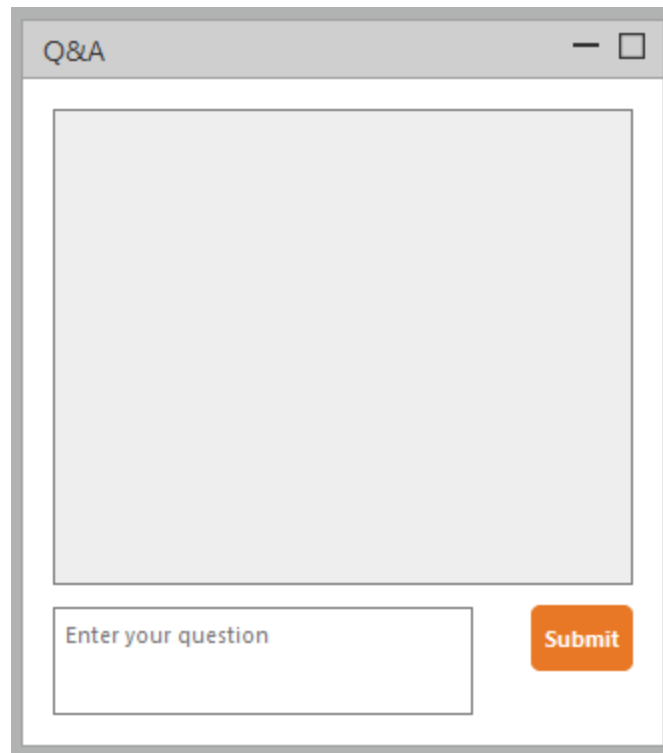
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Spine care – Why is it important?

Spine care – Why is it important?

- Most common cause of job-related disability and a leading contributor to missed work days
- A study ranking the most burdensome conditions in the U.S. in terms of mortality or poor health in 2010, put low back pain in third place, with only ischemic heart disease and chronic obstructive pulmonary disease ranking higher
- Global burden of disease 2015: 540 million people with activity limiting back pain
- 85% of back pain is considered non-specific



National Institute of Neurological Disorders and Stroke – Low Back Pain Fact Sheet <https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Low-Back-Pain-Fact-Sheet>

Mythbusters

Laser surgery is going to be the wave of the future



**Fact or
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**Fact or
Fiction?**

Present day management

CONSERVATIVE TREATMENT	SURGICAL TREATMENT	CHRONIC MANAGEMENT
<ul style="list-style-type: none">• Therapy• Medications• Injections• Percutaneous procedures	<ul style="list-style-type: none">• Open• Minimally Invasive (MISS)• Laser	<ul style="list-style-type: none">• Medications• Spinal cord stimulator (SCS)• Pumps

Therapy

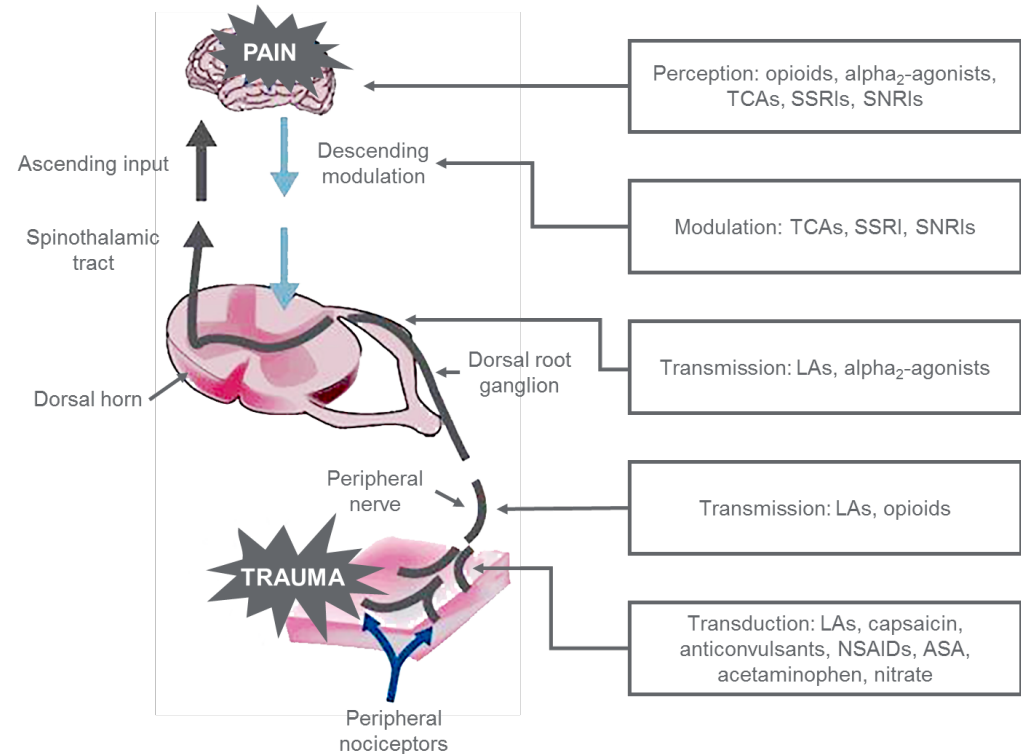
- Detailed, focused
- Limited based on functional gains
- Positional preference
- Manual therapy
- Traction
- Dry Needling
- Modalities

Pain pharmacology

Mechanistic approach

Address underlying problem

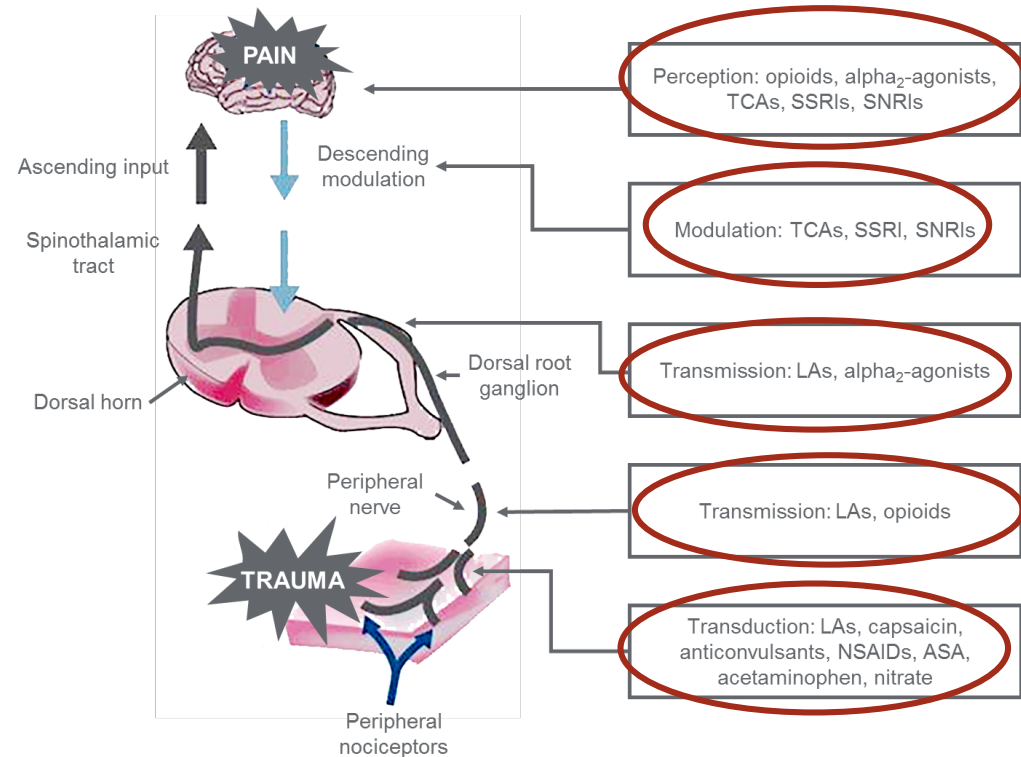
- Non-steroidal Anti-Inflammatory drugs (NSAIDs)
- Steroids



<https://reference.medscape.com/>

Adjuvants

- Antidepressants
- Anticonvulsants
- Local anesthetics
- Muscle Relaxants
- NMDA receptor antagonists

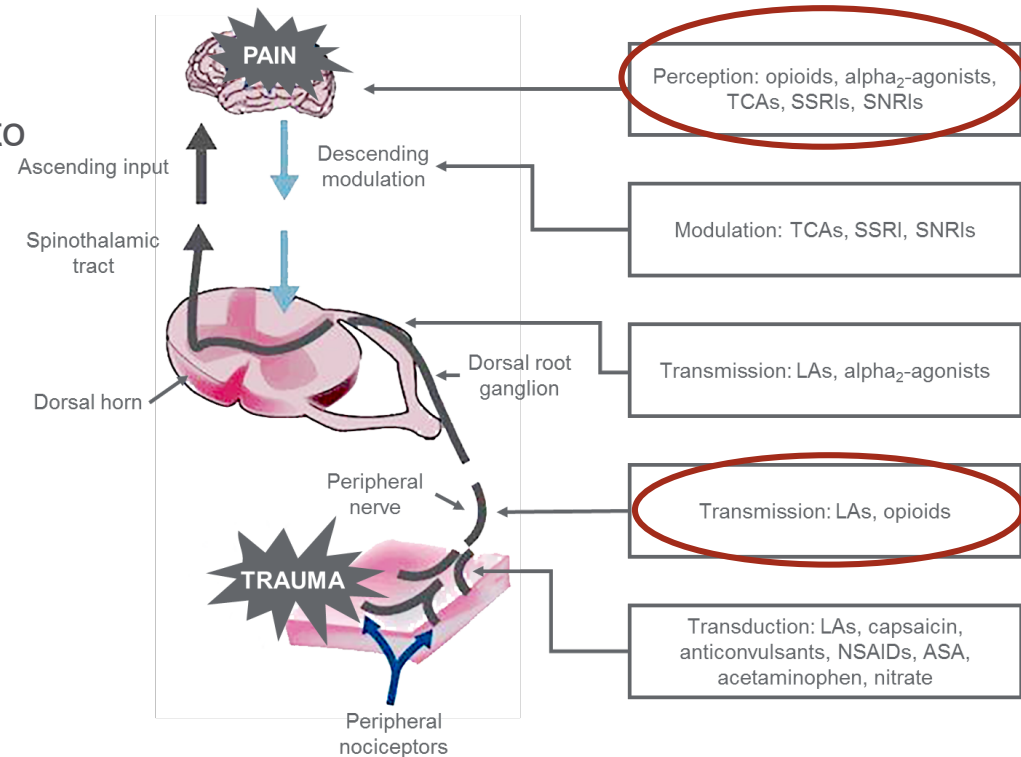


<https://reference.medscape.com/>

Opioids

Opioids - μ - receptor agonists

- Work along the brain and spinal cord to regulate pain
- Common examples
 - Oxycodone
 - Hydrocodone
 - Morphine
 - Hydromorphone
- Buprenorphine



<https://reference.medscape.com/>

Buprenorphine

- Mechanism – partial Mu agonist , kappa antagonist
- FDA indications
 - Opioid detoxification
 - Opioid maintenance
 - Pain management
- Safety
 - Ceiling effect due to partial activation
 - High affinity and slow dissociation
- Examples
 - Belbuca, Butrans, Suboxone (combined with naloxone)

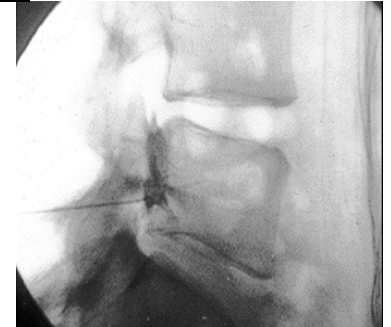
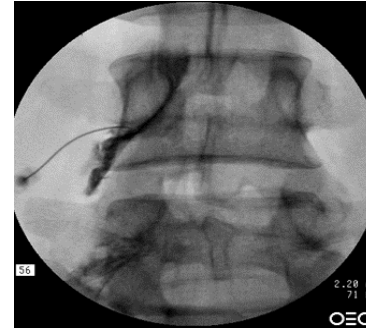
Interventional spine care

Evidence-Based Guidelines

- Pain Physician. 2013 Apr;16(2 Suppl):S49-283. **An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations.** Manchikanti et al.
- Pain Physician. 2007 Jan;10(1):7-111. **Interventional techniques: evidence-based practice guidelines in the management of chronic spinal pain.** Boswell et al.

Epidurals

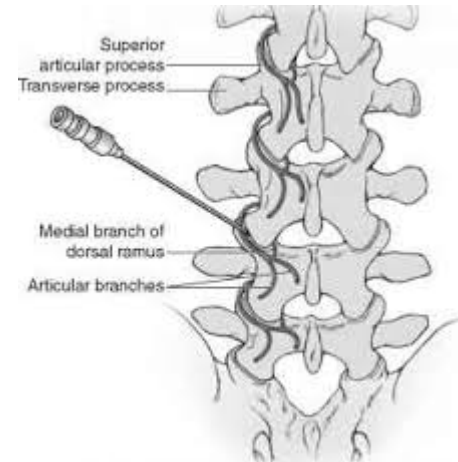
- Transforaminal usually best option
- Caudal best option for LBP(non-radic)
- Cervical Interlaminar best option



Deidentified patient x-rays provided by Kathleen Fink, MD

Facet injections

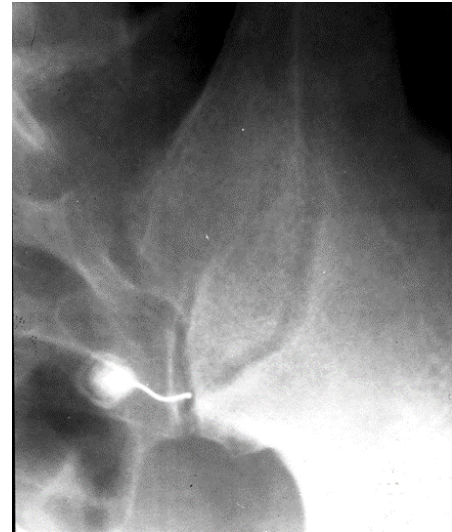
- Incidence 27-40% of chronic LBP
- Single diagnostic false positive rate at 33%
- Evidence Based Use
 - Diagnostically strong Cervical and Lumbar spine
 - Therapeutic moderate



<https://www.pharmacologicalsciences.us/pain-management-2/spine-injections.html>

Sacroiliac Joint Injections

- Incidence SIJ pain - 10-27% chronic LBP
- Evidence Based Use
 - Diagnostically moderate
 - Therapeutic moderate ST but limited LT



Deidentified patient x-rays provided by Kathleen Fink, MD

Compression fracture management

VERTEBROPLASTY

- Glue-like bone cement is then injected into the vertebral body space
- Complications with leakage
- Complications with fracture at adjacent levels

KYPHOPLASTY

- A special balloon is inserted and gently inflated to restore height to the vertebral structure and reduce spinal deformity
 - Contained and prevents leakage
 - Publicized to correct wedge deformity
 - Complications with fracture at adjacent levels
-

Implantable drug delivery system evidence based reviews

- Boswell 2007: Strong short term and Moderate long term relief
- Manchikanti 2013: Limited support
- Recent studies:
 - Hamza 2012. Prospective three-year follow up of low dose IT opioid for chronic non malignant pain (Total n=61)
 - Hamza 2015. Randomized bolus versus continuous infusion with no statistical difference between groups (Total n=40)

Spinal Cord Stimulator (SCS)

NON-WORKERS' COMPENSATION

- Manchikanti 2013: Fair for CRPS and FBS
- Boswell 2007: Strong for CRPS and FBS

WORKERS' COMPENSATION

Spinal cord stimulation for failed back surgery syndrome: outcomes in a workers' compensation setting. Turner JA, Hollingworth W, Comstock BA, Deyo RA *Pain*. 2010 Jan;148(1):14-25.

- No evidence for greater effectiveness of SCS versus alternative treatments in this patient population after six months
- 2011 Study on cost did not show any cost effectiveness in this population

Jury is still out

- Discogram: Provocative vs. Analgesic
- Annuloplasty
- Nucleoplasty
- Adhesiolysis

Surgery – Open or Traditional Approach

Standard incision. The large bands of muscles in the back are stripped free from their attachments to the spine and retracted off to each side.

PROS

- Better visibility
- Lower re-operation rates

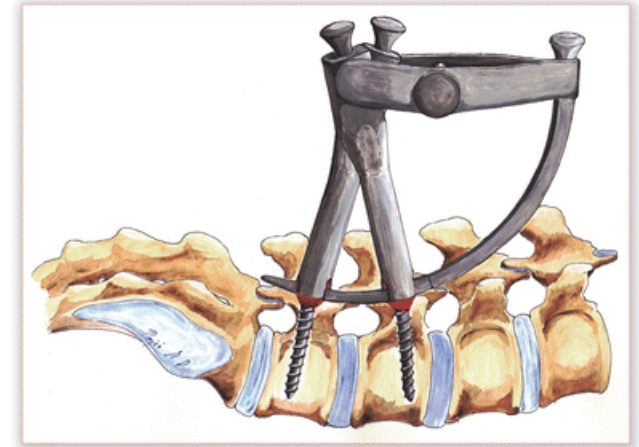
CONS

- Muscles disrupted
 - Considerable back pain from the muscle retraction
 - Large incision and scar including muscles
 - Longer recover
-

Surgery – MISS

Use of guidance to allow the surgeon to “see” the spine through the skin without making a large incision and an endoscopic port allows access.

Interlaminar and transforaminal



PROS

- Small incision
- Muscles not disrupted
- Shorter recovery time

CONS

- Less visibility

Two non-inferiority randomized controlled laser trials

Brouwer and Abrishamkar

- Percutaneous laser disc decompression (PLDD)
- Plasma laser nucleoplasty
- Reported pain relief at one year ranges from 60-84%

ABRISHANMKAR	BROUWER
<ul style="list-style-type: none">• Higher back pain and radicular pain versus open• Reoperation Rates: No statistical difference	<ul style="list-style-type: none">• Higher VAS leg pain at one year higher in PLDD versus Open• Reoperation Rates: 44% versus 16% conventional

Future trends

Future management

CONSERVATIVE TREATMENT

- Medications
- PRP
- Stem cell
- SCS Advancement

SURGICAL TREATMENT

- ADR
 - New Metal Alloys
 - 3D implants
 - Nano tech
 - Robots
-

Pain pharmacology: Future trends

- Pharmacogenetic testing
- Marijuana/CBD Products
 - Note: Marijuana has a Schedule I classification from the DEA and is lacking the essential quality control measures required to ensure safe prescribing.
- AT-121
 - Dual action at two opioid receptors – Mu and Nociceptin/orphanin FQ peptide (NOP) receptor

Regenerative medicine - PRP

- Animal studies: Restoring structural changes (IVD height) and improving the matrix by MRI and histology
- Only one double-blind randomized controlled trial
- All studies have indicated safe use
- PRP injections for sacroiliac joint-related pain are not accepted
- PRP injections for facet arthropathy – small prospective trials show possible benefit

J Pain Res. 2019 Feb 25;12:753-767. doi: 10.2147/JPR.S153085. eCollection 2019. **Platelet-rich plasma in the management of chronic low back pain: a critical review.**

Curr Pain Headache Rep. 2019 Jul 3;23(7):52. doi: 10.1007/s11916-019-0797-6. **Platelet-Rich Plasma for the Treatment of Low Back Pain: a Comprehensive Review**

Regenerative medicine – Stem Cells

Mesenchymal Stem Cells for Lumbar Degenerative Disc Disease

Study Type:	Interventional (Clinical Trial)
Estimated Enrollment :	24 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Intervention Model Description:	24 participants will be equally randomized into two groups; 12 Healthy controls subjects & 12 treatment subjects. The treatment group will then be sub-divided and randomized into 6 subjects receiving a low dosage treatment and 6 subjects receiving a high dosage treatment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Percutaneous Image Guided Delivery of Autologous Bone Marrow Derived Mesenchymal Stem Cells for the Treatment of Symptomatic Degenerated Intervertebral Disc Disease
Estimated Study Start Date:	June 2019
Estimated Primary Completion Date:	September 30, 2021
Estimated Study Completion Date:	September 30, 2022

ClinicalTrials.gov

SCS – Future Trends

- Burst wave forms
- High frequency
- DRG stimulation
- Wireless SCS trials
- Multicolumn surgical paddles

Surgery



Artificial Disc Replacement (ADR)

- Indications: One or Two Contiguous levels Cervical Spine
- Two studies of C-ADR for two-level disease
 - Statistically superior to fusion surgery for primary outcome (GRADE: Moderate).
 - Non inferior to fusion for perioperative outcomes, patient satisfaction, and health-related quality of life (GRADE: Moderate).
 - Superior to fusion for recovery and RTW, lower rates of re-operation (GRADE: Moderate)
 - Maintained motion at the index-treated cervical level (GRADE: Moderate)
 - Insufficient evidence on adjacent level surgery rates
 - Insufficient evidence to determine the long-term durability of C-ADR.

Cervical Artificial Disc Replacement Versus Fusion for Cervical Degenerative Disc Disease: A Health Technology Assessment. Published online 2019 Feb 19.

Artificial Disc Replacement (ADR)

- Indications: One Level Lumbar
- Articulating
 - Nonconstrained or semiconstrained
 - More constrained needs more precise placement and less forgiveness
 - Less constrained places more stress on posterior joints
- Nonarticulating
 - Needs to be more compressible, shock absorbing
 - Challenges: biocompatible materials, adherence, durability, debris

[Int J Spine Surg.](#) 2018 Apr; 12(2): 201–240. We Need to Talk about Lumbar Total Disc Replacement. Beatty, S.

Implants

- New Metal Alloys

- Molybdenum-Rhenium

- Stronger, more durable
- Less biofilm formation
- Less allergenicity

- Shape-memory Alloys or Smart Metals

- Alloys of nickel and titanium (NiTi) and copper-aluminum-nickel

- Return to that shape when the temperature is reached

- Bioceramic Implants

- Alumina and Zirconia - bioinert ceramic materials

- Examples - Vitoss Bone Graft Substitute (Stryker Corp.) and Vitrium® (Bio2 Technologies, Inc.)

Implants

Adaptive Spine Intelligence

- Initially utilized in deformity indications, UNiD ASI has been used in more than 5,000 cases and now being used in degenerative cases.
- Medicea announced 2/11/2020 that it received FDA clearance for UNiD IB3D Patient-Matched interbody cages, a 3D–printed titanium implant that allows for customization.

“Through 3D reconstruction of the spine, the engineers map out the exact anatomy of each vertebrae endplates. They then design the ideal cage to restore proper height and angulation but also to offer an optimized surface contact between the implant and the vertebrae endplates in order to improve stability of the instrumented segment and reduce subsidence.”

3D Implants

Currently in use

- Cranial surgery and models for complex surgical planning

Benefits

- Uses less material since it is constructed in add on fashion
- Allows for greater personalization
 - Adjustable pore size can be based on bone quality
- Animal studies show better ingrowth in sheep

Nano Tech

- Applications with fusion, regeneration, drug delivery
- Being combined with polyetheretherketone (PEEK)
- Nanotopographies and nanoroughness that enhance bone growth
- Example: PEEKplus® Nanotextured surface, concavities of 20-50 nanometers are created by the impact of argon atoms.
 - Nanotexturing below 100 nanometers has been shown to be beneficial to osteoblast functions that are necessary to grow bone and promote fusion
- Can be coated with antibiotics

World Neurosurg. 2019 Mar;123:142-155. **Nanotechnology in Spine Surgery: A Current Update and Critical Review of the Literature**

Robots

- Currently being used to assist with instrumentation
- Future AI performance of laminectomies, discectomies, and fusions
- Surgeon supervision virtually, augmented reality or endoscopically

Robots example

Mazor X is a robotic guidance system that combines advanced software, robotic technology and instrumentation for a more precise minimally invasive spinal procedure.

- The Mazor X Stealth Edition was cleared by FDA in November 2018
- Preoperative 3D imaging - converting 2D to volumetric 3D images
- Cross Modality Image Registration – pairs pre opt CT and intraoperative fluoro
- Intraoperative surgical planning
- Robotic-guidance for pedicle screw placement

Case studies



Case #1

- 45-year-old male
- Fell from scaffolding
- Emergency room evaluation with X-rays showed no fracture
- Pain in radicular pattern into the lower extremity

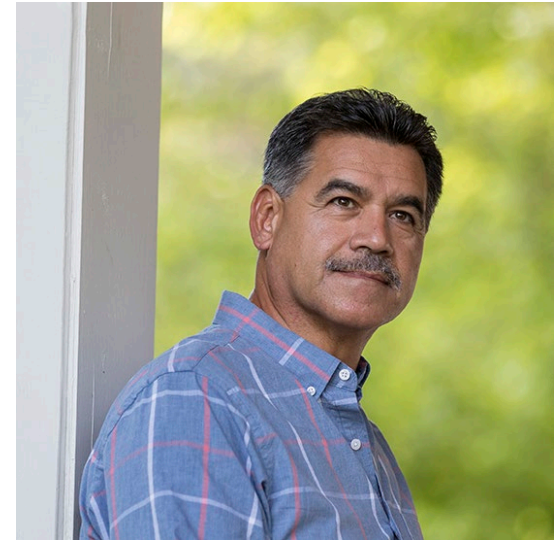


Management

PRESENT DAY	FUTURE
<ul style="list-style-type: none">• NSAIDs/Steroids, muscle relaxants, etc.• Physical therapy 8 sessions• MRI with disc herniation• Epidural injection with relief but return of symptoms• MISS surgery at L5S1• Ongoing back pain• Facet – Diagnostic block and RFA	<ul style="list-style-type: none">• Initial treatment• Surgery – possible non articulating disc• Continued back pain• Facet arthropathy - PRP

Case #2

- 56-year-old male, Police officer
- Injured in line of duty
- Imaging with degenerative changes and scoliosis L3-S1
- Pain is predominantly axial



Management

PRESENT DAY	FUTURE
<ul style="list-style-type: none">• Conservative treatment• MRI with degenerative changes, spondylolithesis at L45 and L5S1• Flex/Ext films with movement/instability noted• Steroid injection into facet joints• Fusion 2 level• Ongoing pain<ul style="list-style-type: none">– Hardware issues and needs revision after two years• SCS trial and possible medication management	<ul style="list-style-type: none">• Initial treatment• Surgery<ul style="list-style-type: none">– Mazor or UNiD• Continued back pain• SCS DRG stimulation

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Laser surgery is going to be the wave of the future

Spine implants will be made from a 3D printer

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