PaiNweek®

Minimally Invasive Spine Treatments

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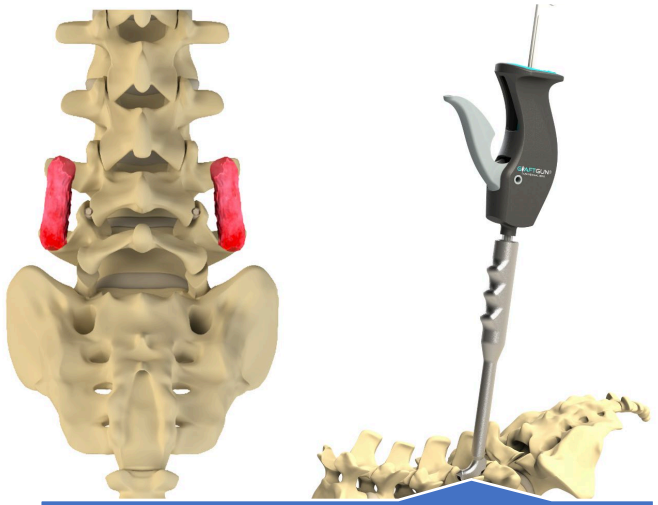
Disclosures

- ***Consulting Fee (e.g., Advisory Board):*** Abbott, Mainstay, Surgentec, Medtronic, PainTeq, SPR, Vertos, Nevro
- Stock Shareholder (Individual stocks/Stock ***options; diversified mutual funds do not need to be disclosed):*** PainTeq, Vertos, SPR

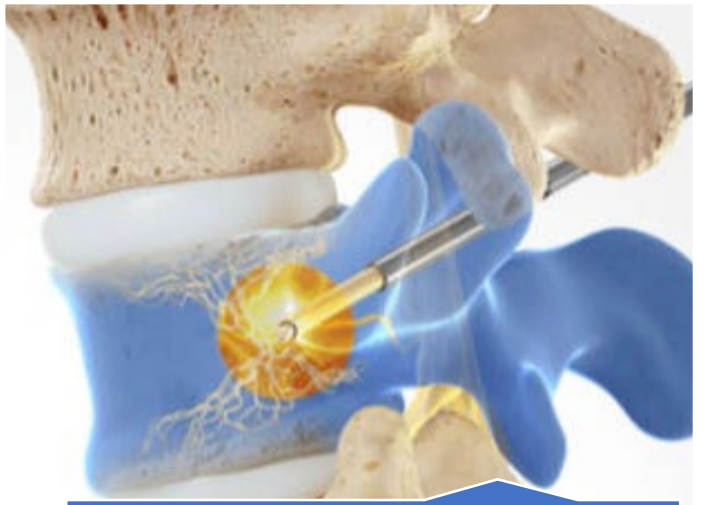
Learning Objectives

- Review emerging therapies in interventional pain medicine
- Describe appropriate patient selection for these therapies
- Describe safety and efficacy
- Discuss future direction

Neuromodulation

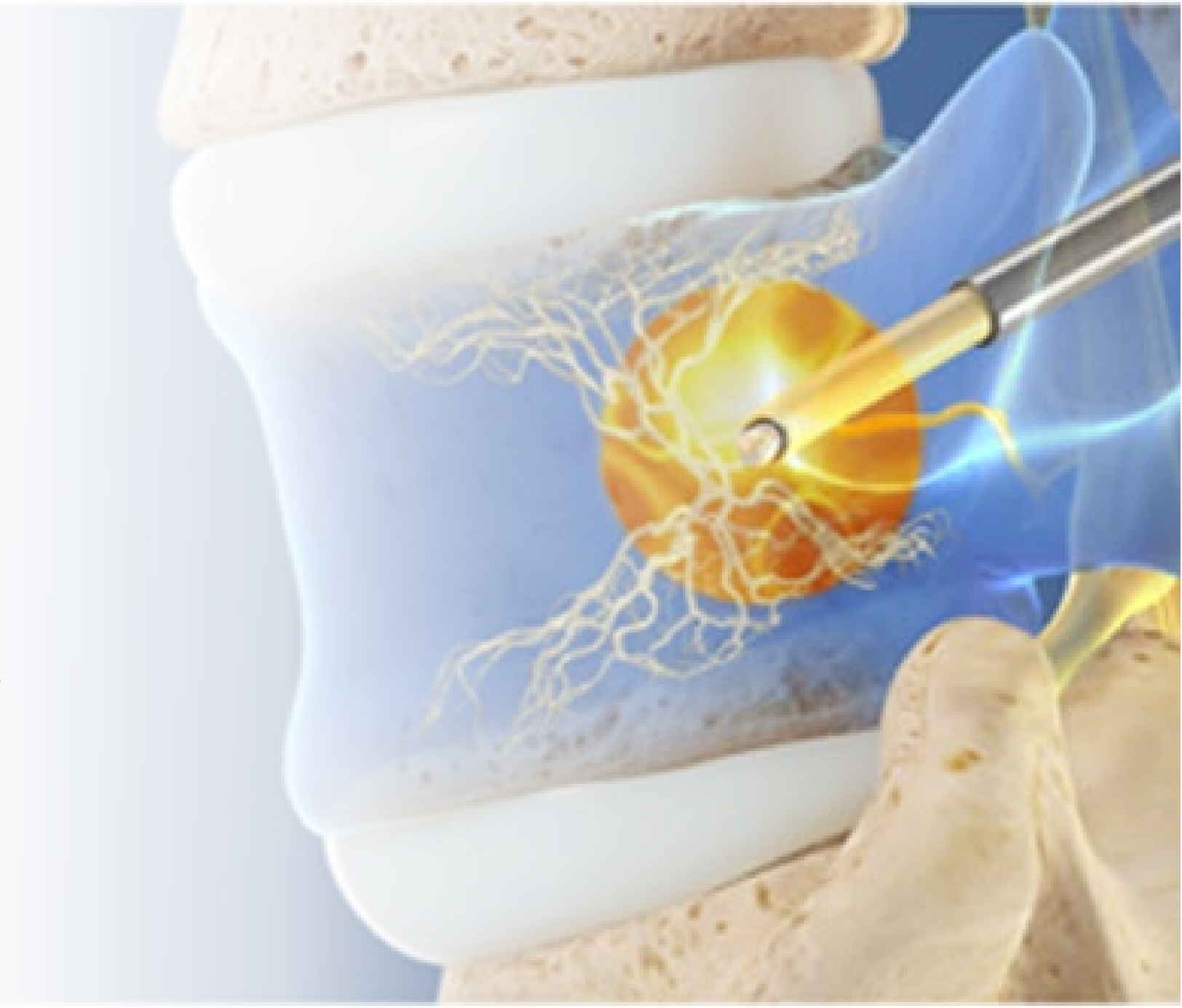


Minimally Invasive Surgery



Ablative

Basivertebral Nerve Ablation for Chronic Vertebrogenic Low Back Pain

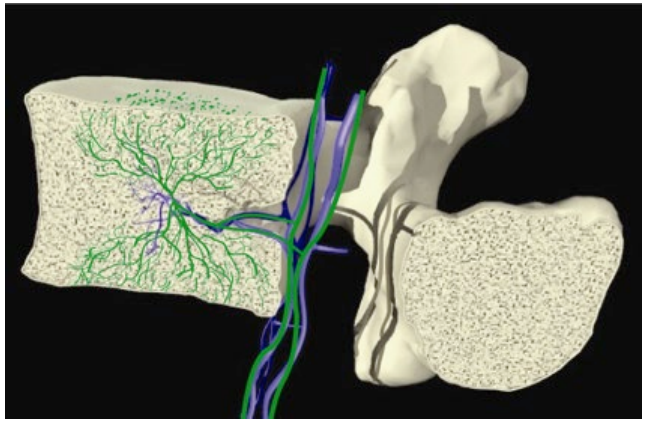


Vertebrogenic Pain is a Paradigm Shift in the Science of CLBP

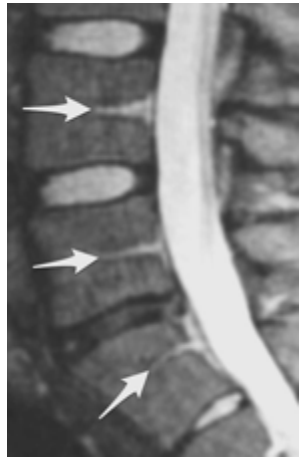
For decades, treatments ignored the endplates and focused on the disc

- Vertebral endplates are more innervated than intervertebral discs[1]
- PGP 9.5 positive nociceptors confirmed at the vertebral endplates
- Basivertebral nerve (BVN) innervates the endplates and transmits pain signals from the vertebral endplates to the CNS [2]

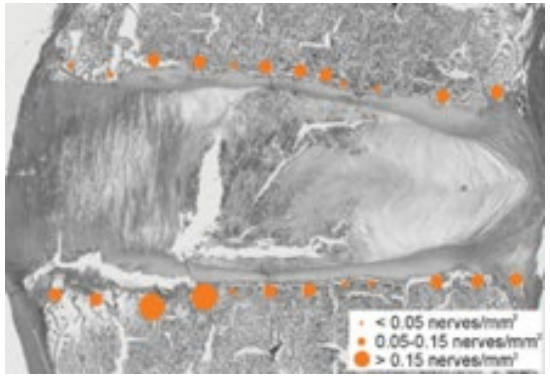
Distribution of the basivertebral nerve



Basivertebral Foramen



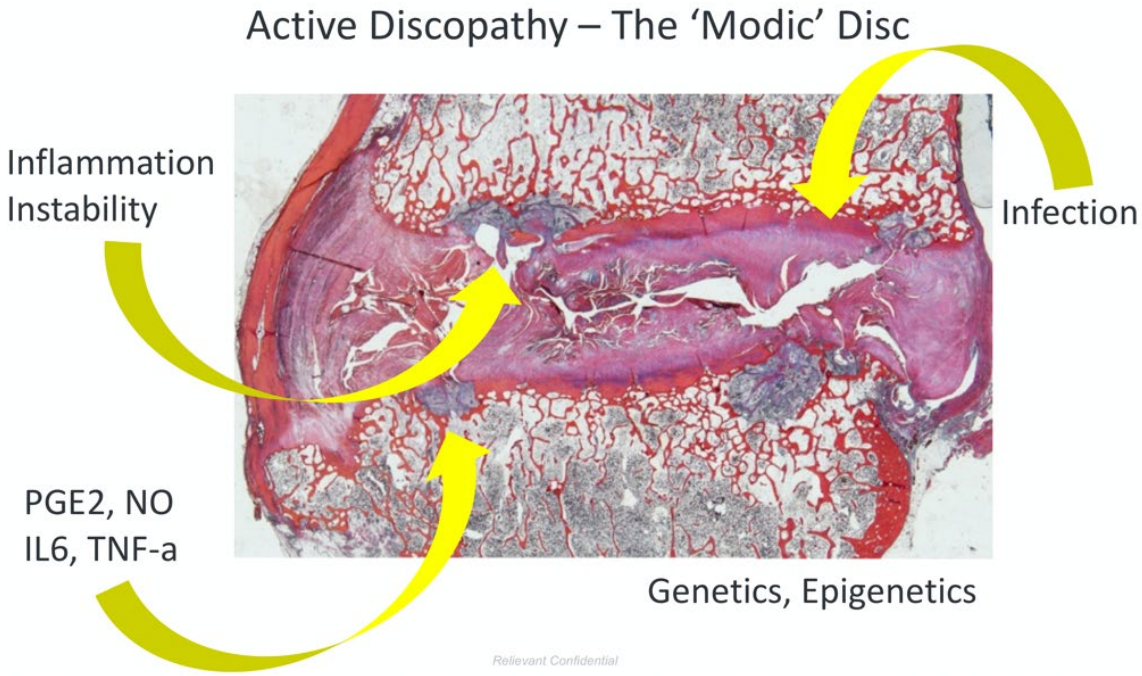
Distribution of PGP+ nerve fibers across endplate



[1]Fields AJ, Liebenberg EC, Lotz JC. The Spine Journal 2014;14(3):513-521.
[2]Bailey JF, Liebenberg E, Degmetich S, Lotz JC. Innervation patterns of PGP 9.5-positive nerve fibers within the human lumbar vertebra. Journal of Anatomy 2011;218(3):263-70.

Extensive Research Supports Pathobiology of Vertebrogenic Pain

- Endplate defects allow proinflammatory disc tissue to leak into the bone marrow, inciting an inflammatory response
- Chronic endplate inflammation leads to Modic changes (MC) on MRI
- Prevalence and density of endplate nociceptors higher in vertebral bodies with MC[1]



[1] Dudli S et al. ISSLS Prize Winner; 2017

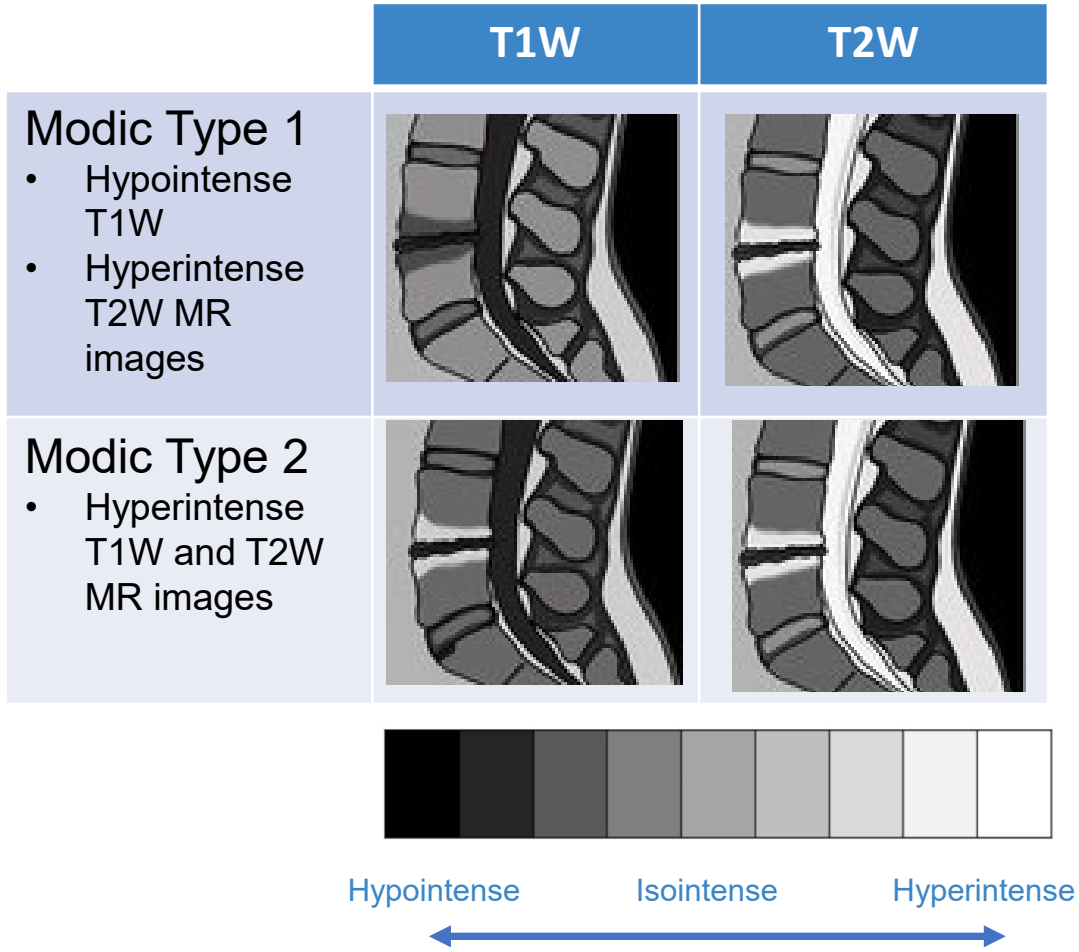
Modic Changes are Correlated with Severe CLBP

Research Findings:

Association between discography and moderate to severe Type 1 and Type 2 Modic changes[1]
- 38% sensitivity
- 88% specificity with moderate Modic 1 and 2
- 100% specificity with severe Modic 1 and 2

Modic Changes were associated with historical LBP, and with severity and duration of symptoms ($p<.05$)[2]

Patients with MC Type 1 seek care more often and have poor outcomes to conservative treatment[3,4]



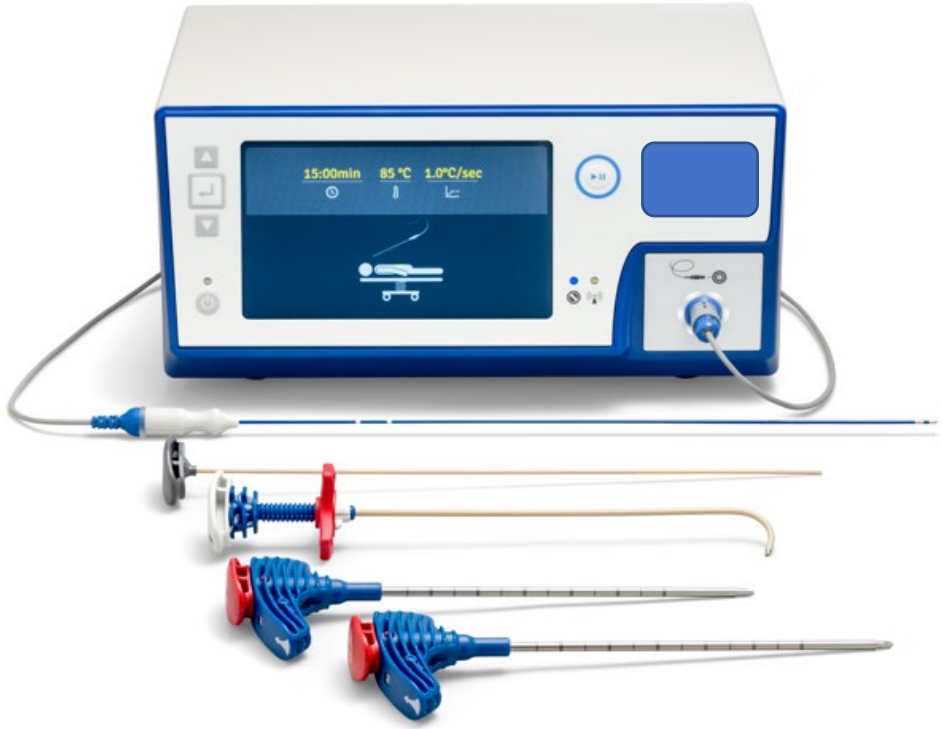
[1] Weishaupt D et al. Radiology; 2001
[2] Mok F et al. The Spine Journal; 2016
[3] Jensen OK et al. The Spine Journal; 2014
[4] Jensen RK et al. BMC Musculoskelet Disord; 2011

Patient Indications

- Chronic Low Back Pain of at least 6 months duration; and
- Failure to respond to at least 6 months of conservative care; and
- MRI changes consistent with Modic Type 1 or Type 2 at one or more levels from L3 to S1

BVN Ablation Procedure Summary

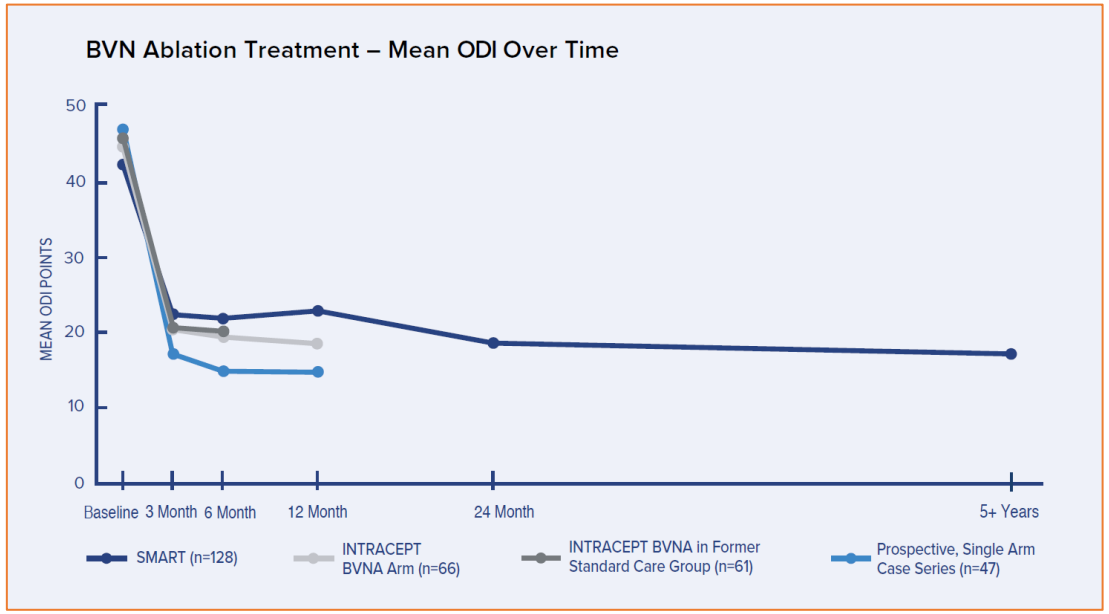
- Minimally invasive, outpatient procedure
- Unilateral transpedicular approach at each VB (L3-S1) with Modic Type 1 or 2 changes
- GA or MAC with patient prone
- 1 hour procedure time for 2 VBs
- 1 or 2 C-arms for intra-op fluoroscopy
- Recovery similar to multi-level lumbar facet RFA
- No implants; preserves all future treatment options

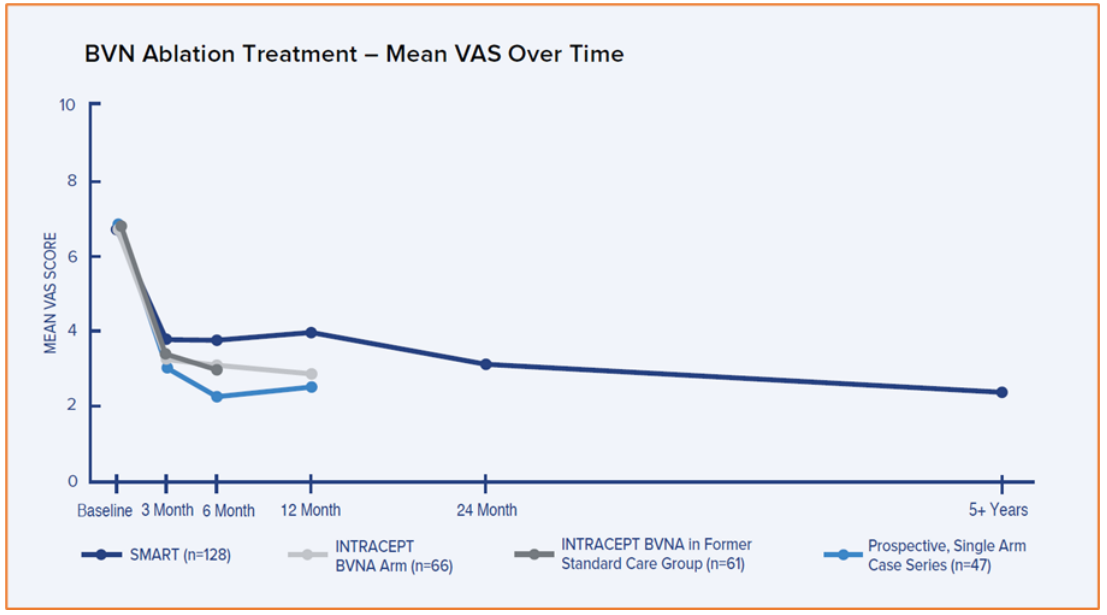


Strong Clinical Foundation Supporting the BVN Ablation

	Trial	Lead Author	# of Subjects	Publication
SMART	SMART Pivotal RCT vs Sham	Fischgrund	225 (147/78)	European Spine Journal
	SMART 2 Year Outcomes	Fischgrund	106	Int'l Journal of Spine Surgery
	SMART 5 Year Outcomes	Fischgrund	100 (n=US PP)	European Spine Journal
INTRACEPT	INTRACEPT Pivotal RCT vs Conservative Care	Khalil	140 (66/74) *Interim Analysis* 104 (51/53)	The Spine Journal
	INTRACEPT 1 Year Outcomes BVN Arm + 6 Mo Outcomes on crossover Arm	Smuck	127	Regional Anesthesia and Pain Management
Prospective Single-Arm Study	Prospective, Single-Arm Study 3 mo Clinical Results	Truumees	28	European Spine Journal
	Prospective, Single-Arm Study 12 mo Clinical Results	Macadaeg	47	NASSJ

Consistent Improvements in ODI and VAS Across Studies





Conclusion

- Research supports pathobiology of vertebrogenic pain
- Chronic endplate inflammation leads to Modic changes on MRI, which are correlated with chronic vertebrogenic low back pain
- Modic changes are a specific biomarker for vertebrogenic pain and primary indication for basivertebral nerve ablation
- BVN ablation is straightforward, implant-free and preserves all future treatment options
- Strong clinical foundation with two Level I Randomized Controlled Trials
  - SMART and INTRACEPT Trials
- Strong safety profile reported across clinical studies

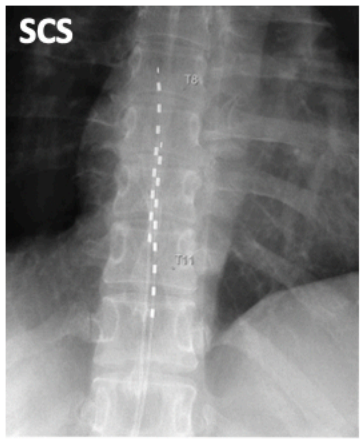
Restorative Neurostimulation for Mechanical Chronic Low Back Pain

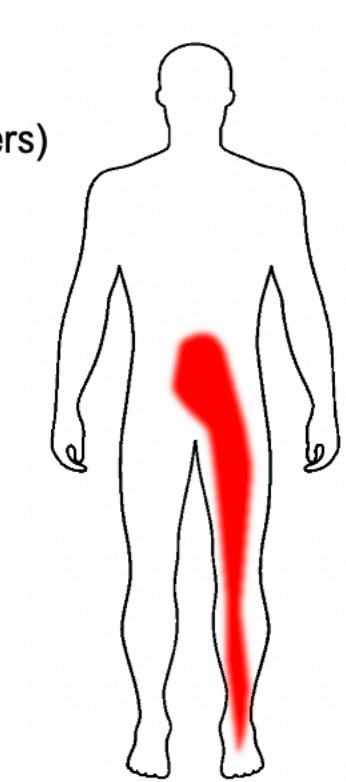
Radicular (Neuropathic)

- Often due to failed back surgery

SCS for radicular pain

- Palliative (stim. of sensory fibers)
- Leads within spinal canal



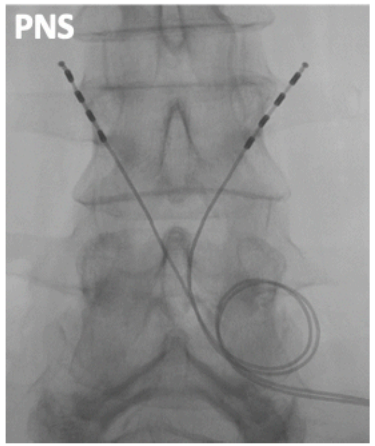


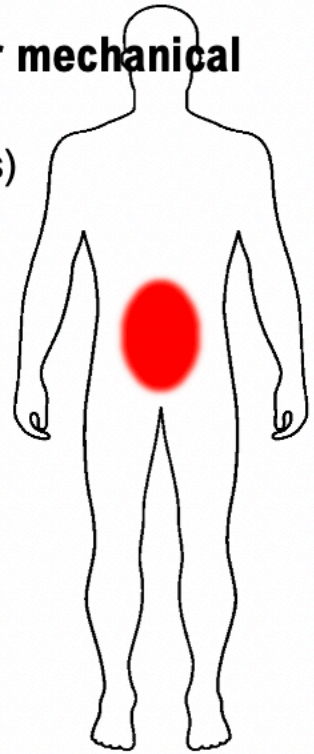
Mechanical (Nociceptive)

- Often due to impaired muscle control (Multifidus)
- Few therapeutic options, surgery rarely indicated

Medial Branch Nerve stim for mechanical pain

- Restorative (stim. of motor fibers)
- Leads outside spinal canal

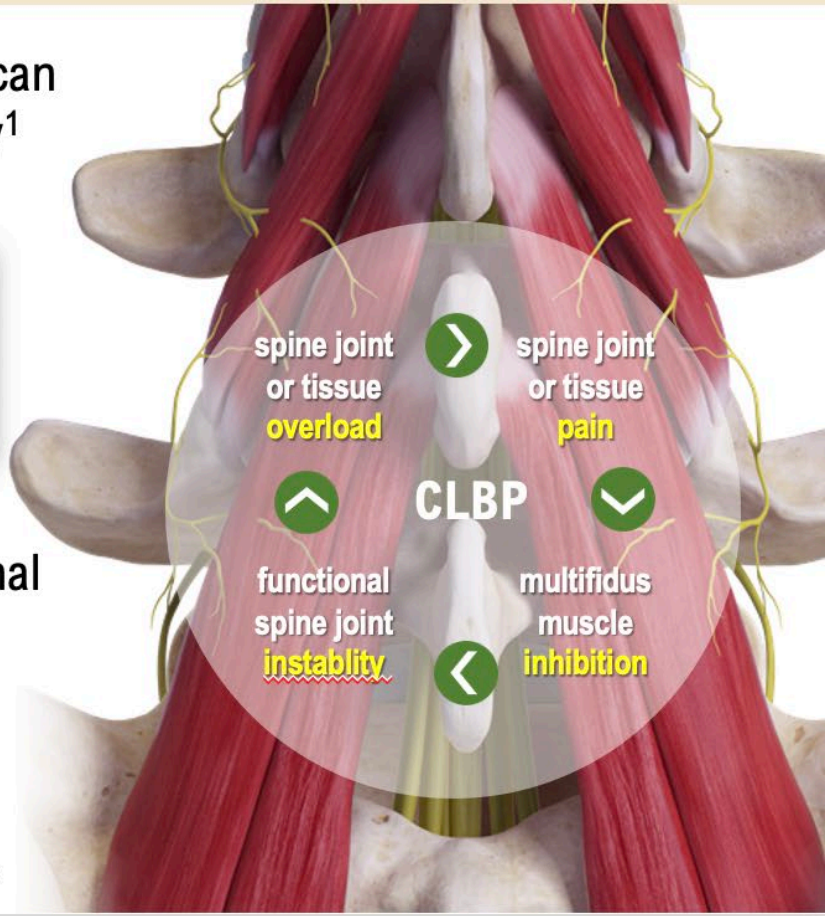




Root cause: Impaired neuromuscular control of segmental stabilizers

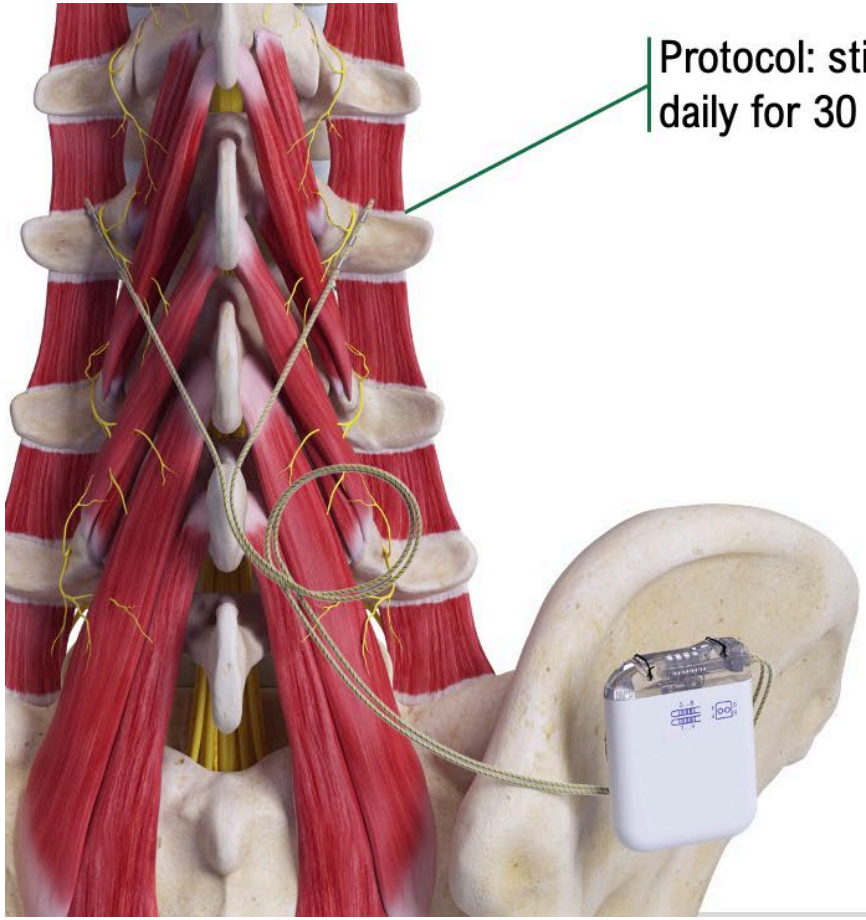
- Pain associated with non-neural structures can lead to impaired muscle control and atrophy[1]

- Impaired control → vicious cycle of functional instability and chronic pain[2,3]



1. Freeman, M. D., Woodham, M. A. & Woodham, A. W. The Role of the Lumbar Multifidus in Chronic Low Back Pain: A Review. PM R 2, 142–146 (2010).
2. O'Sullivan, P. B. (2005). Diagnosis and classification of CLBP disorders: maladaptive movement and motor control impairments as underlying mechanism. Manual Therapy, 10(4), 242–55.
3. Seminowicz, D. et al (2011). Effective treatment of CLBP in humans reverses abnormal brain anatomy and function. The Journal of Neuroscience, 31(20), 7540–50.

Restoration of neuromuscular control facilitates recovery



Protocol: stimulate the medial branch of the Dorsal Ramus 2x daily for 30 minutes to elicit episodic multifidus contractions to:

Override
underlying inhibition

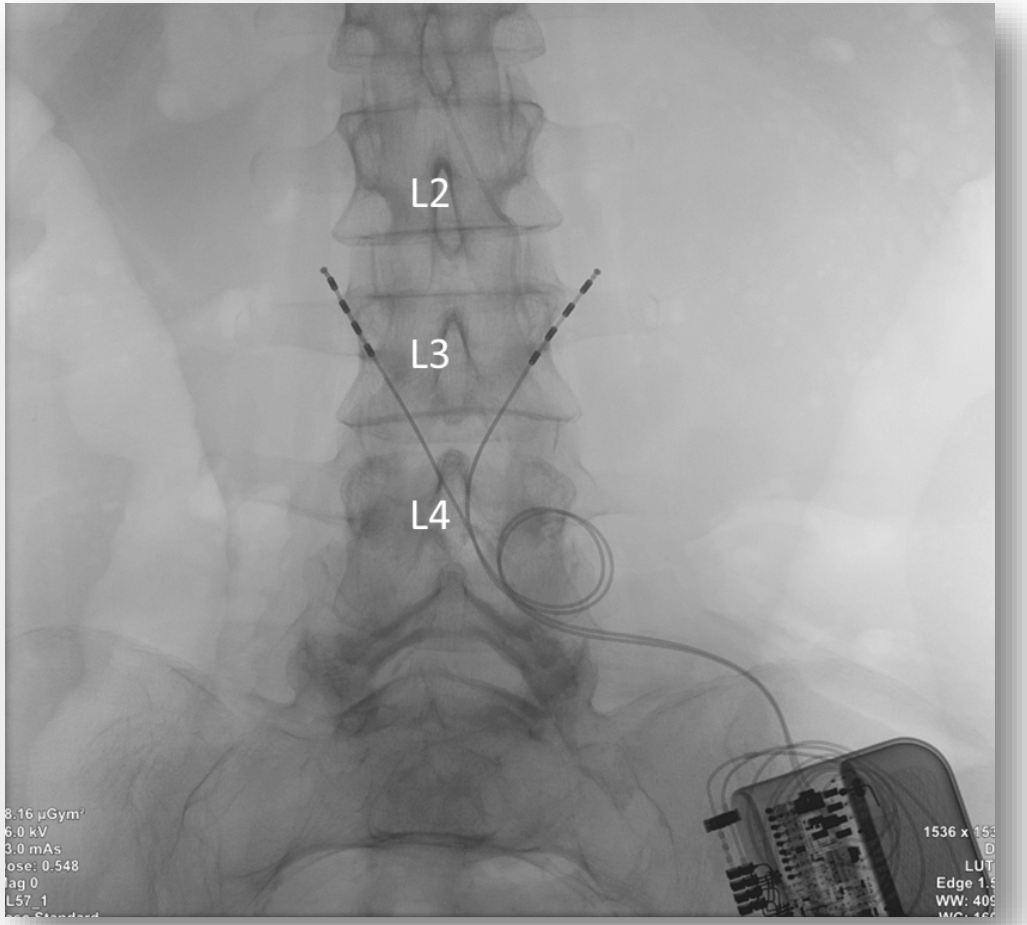
Elicit
afferent sensory input

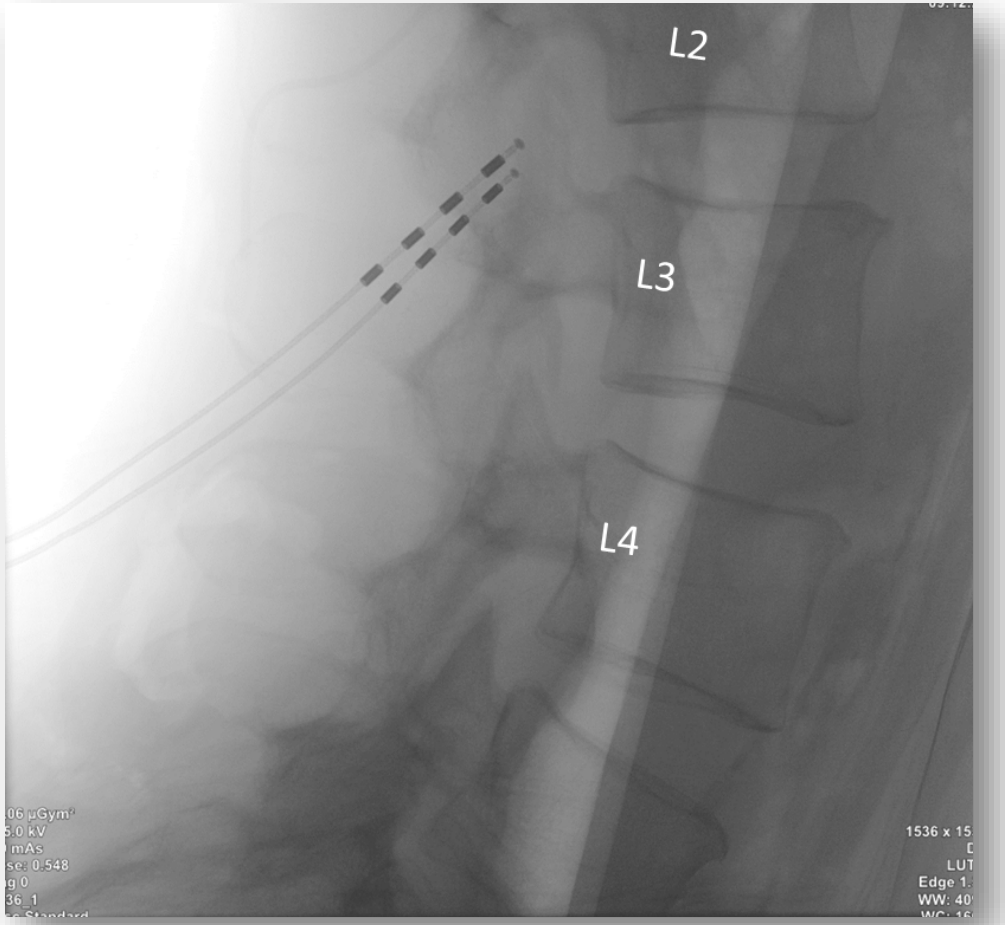
Reactivate
muscle control

Restore
functional spine stability

Reduce
pain

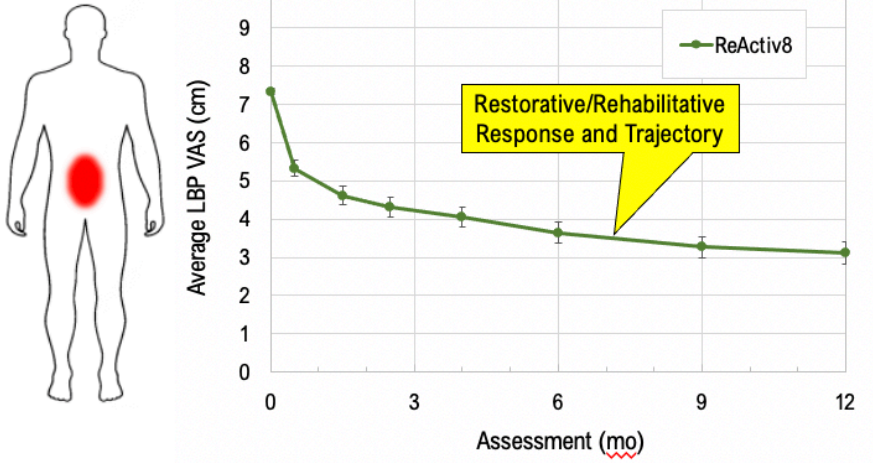
Surgical Technique: Implanted electrodes and pulse generator, NO TRIAL.



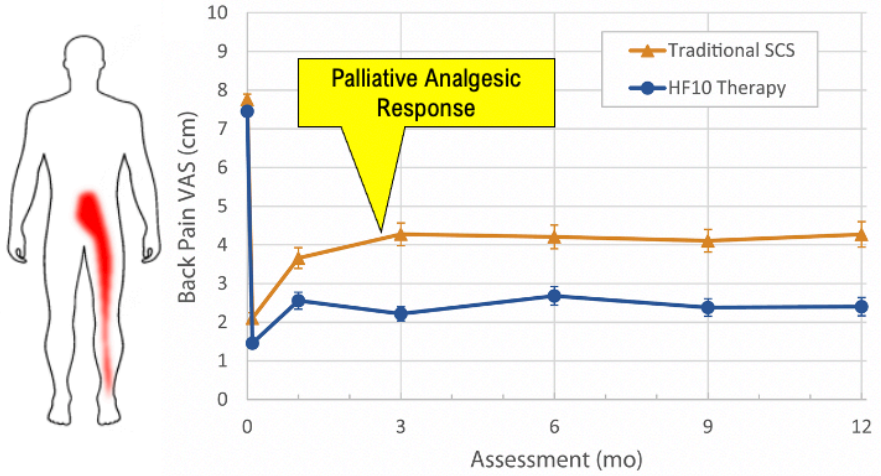


Different patients and mechanisms but comparable effect size

Restorative Neurostimulation



Spinal Cord Stimulation



Refractory mechanical (axial) CLBP

- Restorative treatment effect accrues over time and is durable
- Two 30-minute stimulation sessions daily

Refractory radicular CLBP

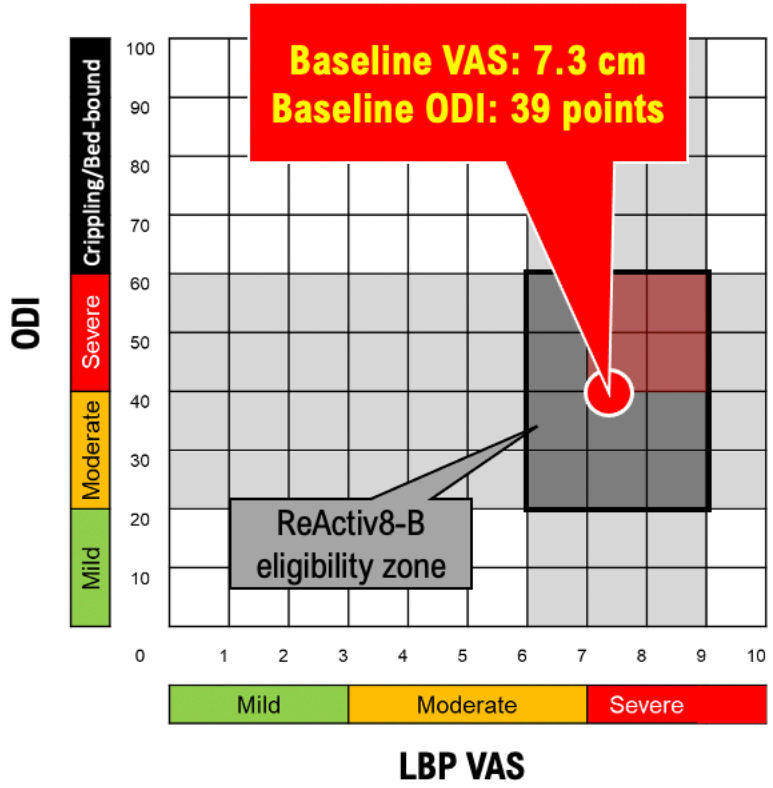
- Palliative analgesic effect maintained while stimulating
- Continuous stimulation (24/7)

Source: Kapural L, et al. *Anesthesiology*. 2015;123(4).

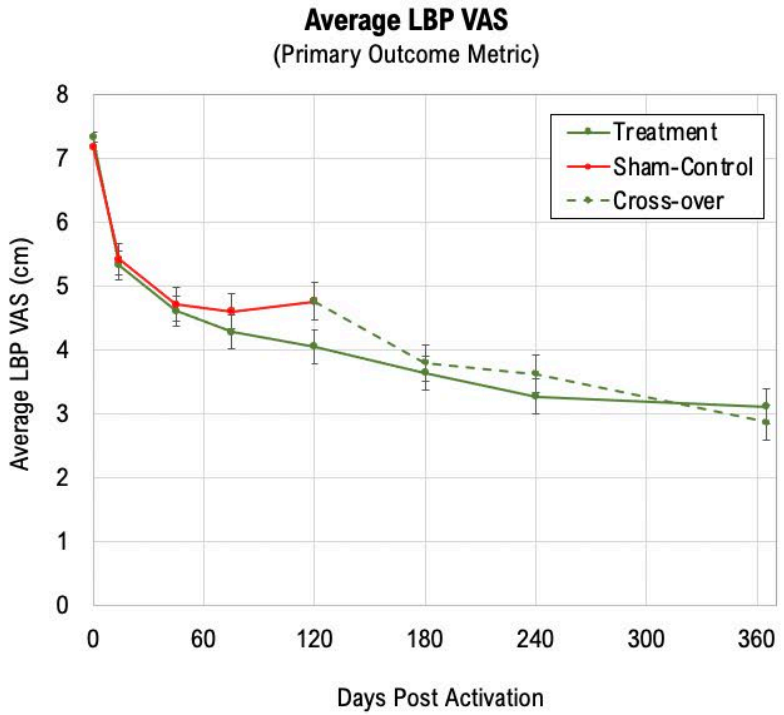
ReActiv8-B trial population reflects severe burden of disease

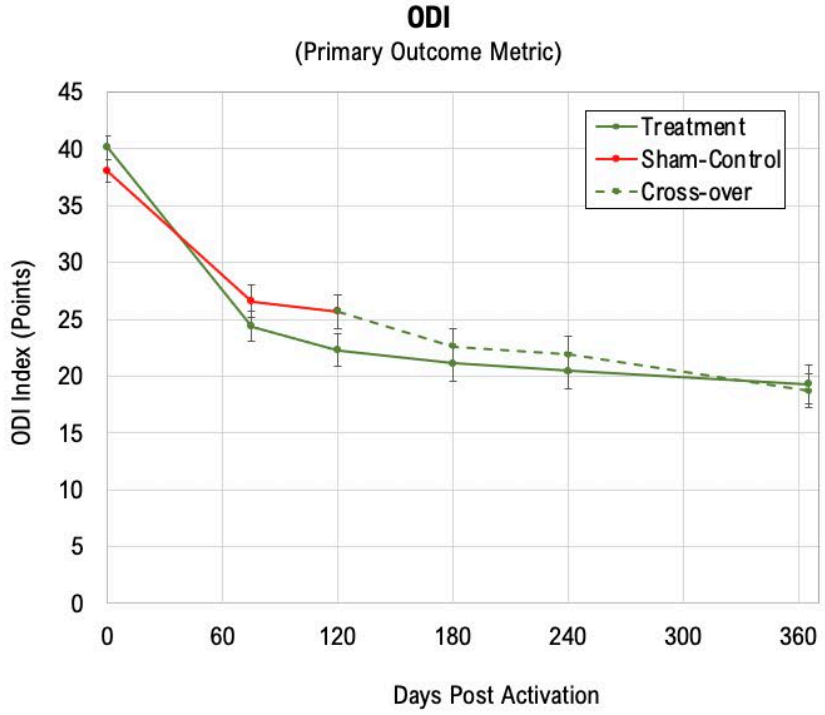
- **204 patients implanted:**
  - Relatively young (Avg. 47 years)
  - **14 years of low back pain**
  - **Pain on 97% of days in prior year**
  - 100% failed physical therapy (Avg. 31 sessions)
  - 100% failed pain medications
    - 37% on opioids at baseline
  - 52% failed interventional pain therapies

- **Excluded:**
  - ✘ Prior low back surgery or current indication
  - ✘ Leg Pain > Back Pain (neuropathic genesis)
  - ✘ Co-morbid Chronic Pain Conditions



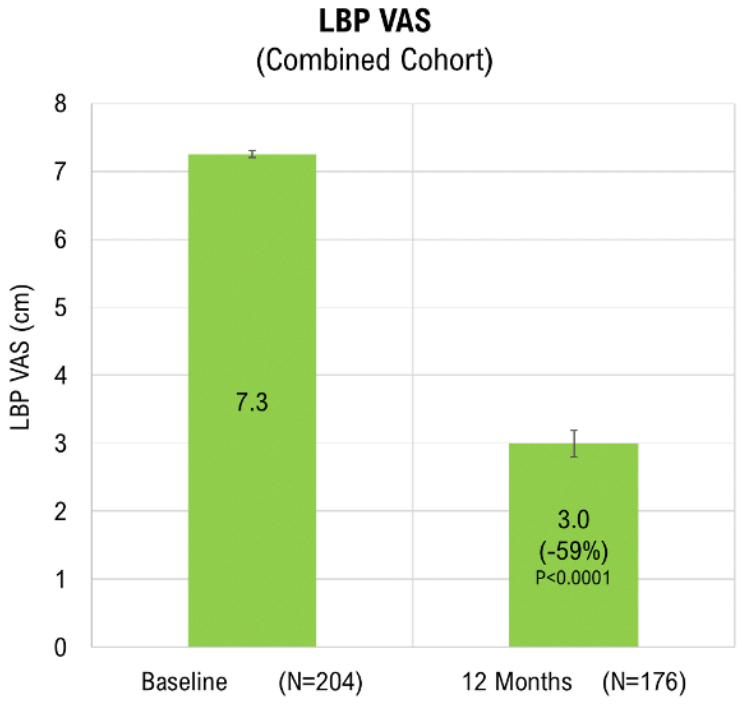
Improvements in pain and function accrue over time…

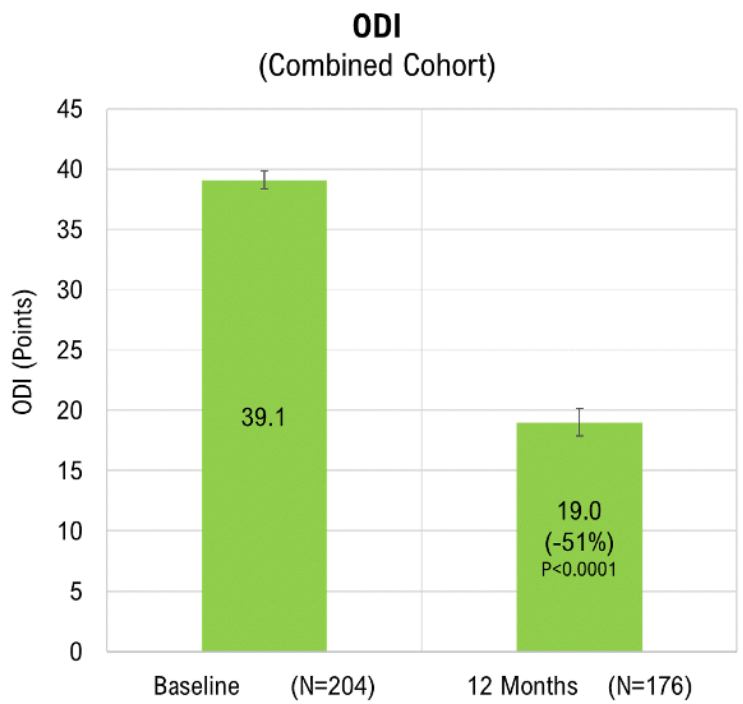




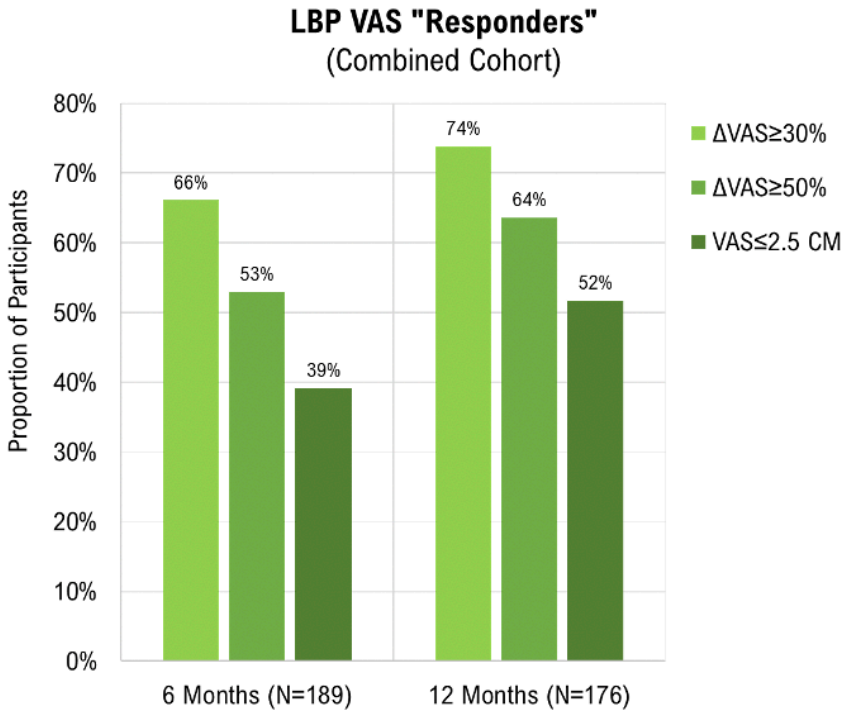
…consistent with restorative mechanism

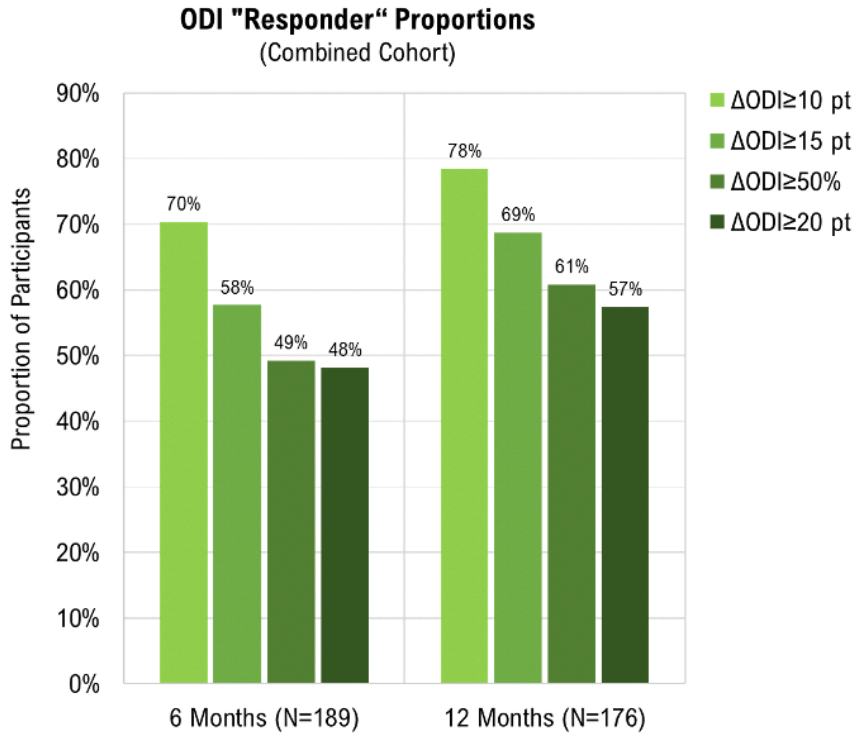
Substantial and durable improvements in pain and function at 1-year





Responder proportions in pain and function improve through 1-year





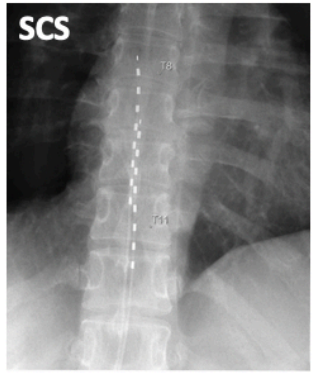
*24-Month data collection ongoing but delayed due to COVID-19

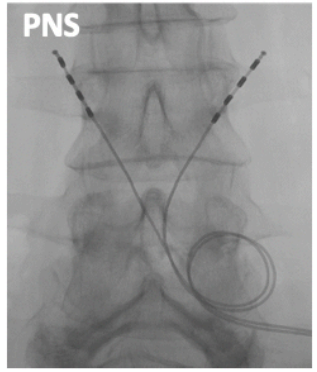
…consistent with restorative mechanism

Favorable safety profile compared to published data

ReActiv8 Safety Data Cumulative Through 12 Months Compared to Published SCS Safety Data			
	SCS (Hayek[1]) Multi-center Review 234 Subjects	SCS (Eldabe[2]) Literature Review >4000 Subjects	**ReActiv8-B Prospective RCT 204 Subjects**
Adverse Events			
Infection	4.3%	2.5-10%	**3%**
Implant Site Discomfort	11.1%	9-12%	**8%***
Lead Fracture/Malfunction	4.3%	0-10.2%	**2.5%**
Lead Migration	8.5%	2-27%	**0%**
Surgical Interventions	48%	0-47%	**13%**
System Explants	23.9%	NA[1]	**9%**
Lead Replacement	23.9%	NA[1]	**3%**

* 16/204 patients had implant site discomfort which required surgical intervention to reposition the IPG (6) or is ongoing (10).



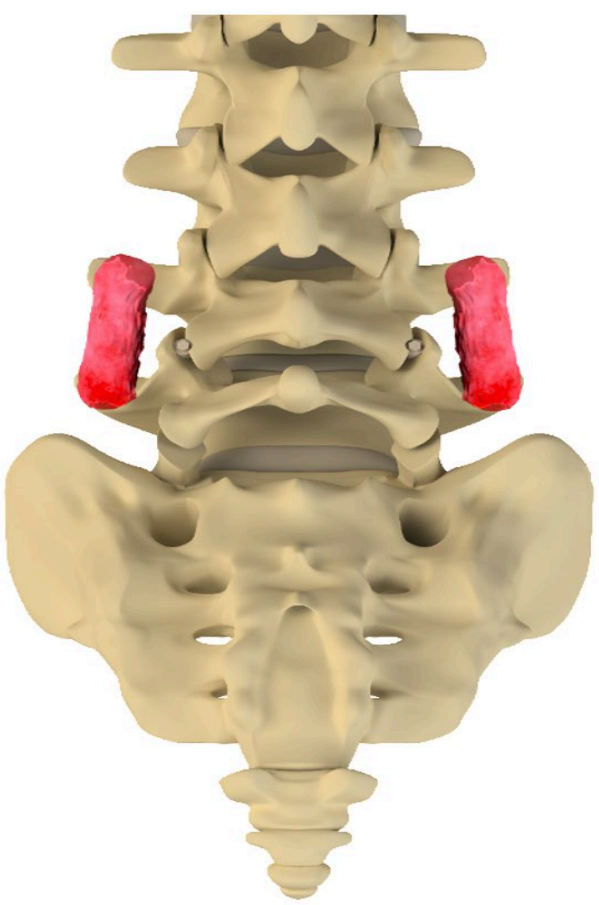


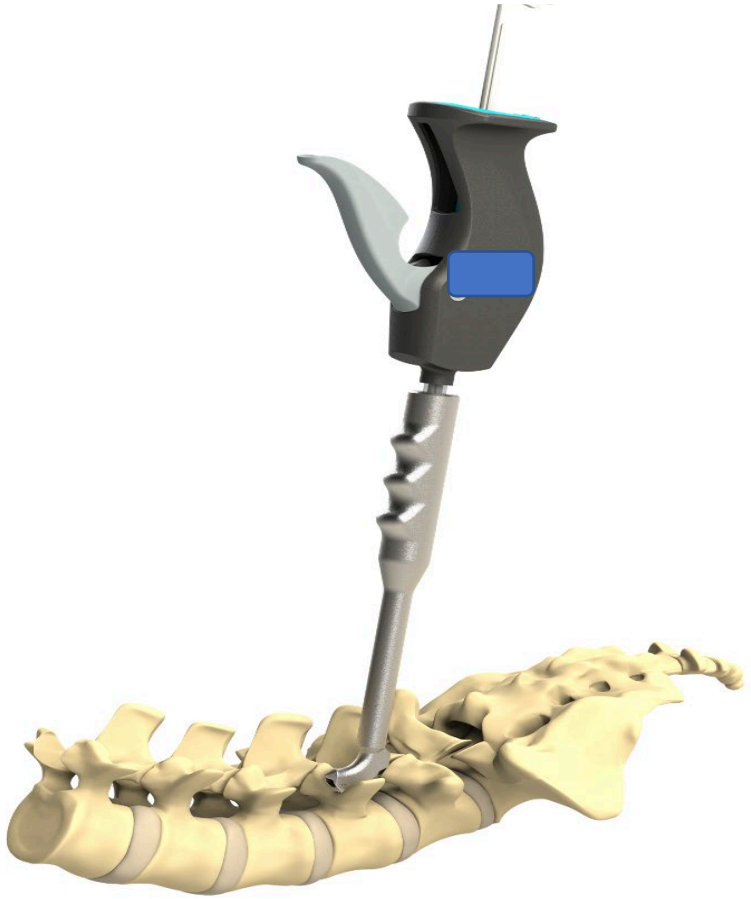
1. Hayek SM et al. Treatment-Limiting Complications of Percutaneous SCS Implants: A Review of Eight Years of Experience From an Academic Center Database. Neuromodulation [Internet]. 2015 18(7):603-8
2. Eldabe S et al. Complications of Spinal Cord Stimulation and Peripheral Nerve Stimulation Techniques: A Review of the Literature. Pain Med [Internet]. 2016 14;0:1–12.

Conclusions:

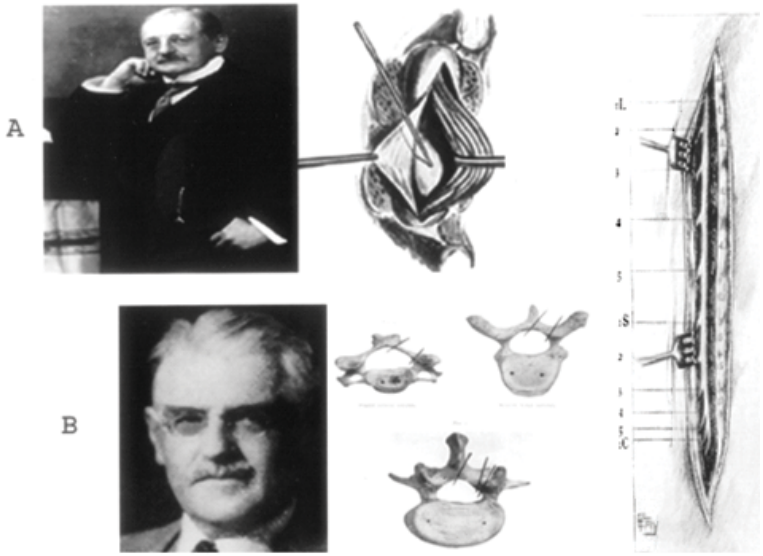
- Restorative Neurostimulation is a safe, effective and durable treatment for patients with refractory disabling mechanical CLBP
- Progressive long-term improvements in **pain** and **functional capacity** are consistent with the restorative mechanism of action
- Restorative Neurostimulation is complementary to SCS:
    - Targets different CLBP patients
    - Employs different (restorative/rehabilitative) mechanism of action
    - Similar treatment effect size

Minimally Invasive Posterolateral Lumbar Fusion



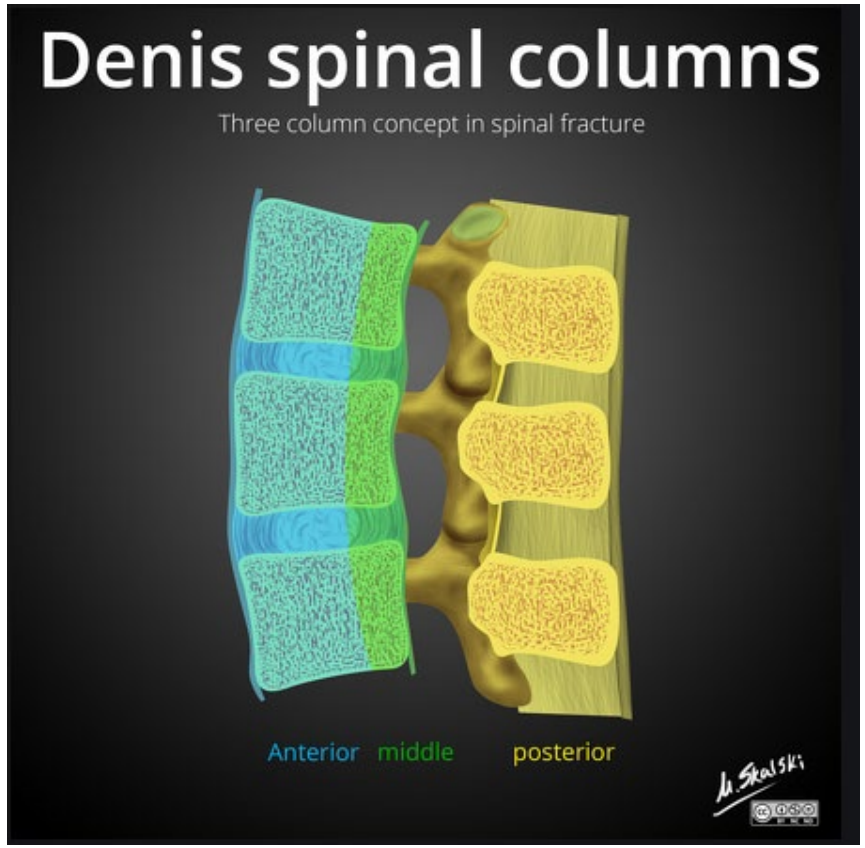


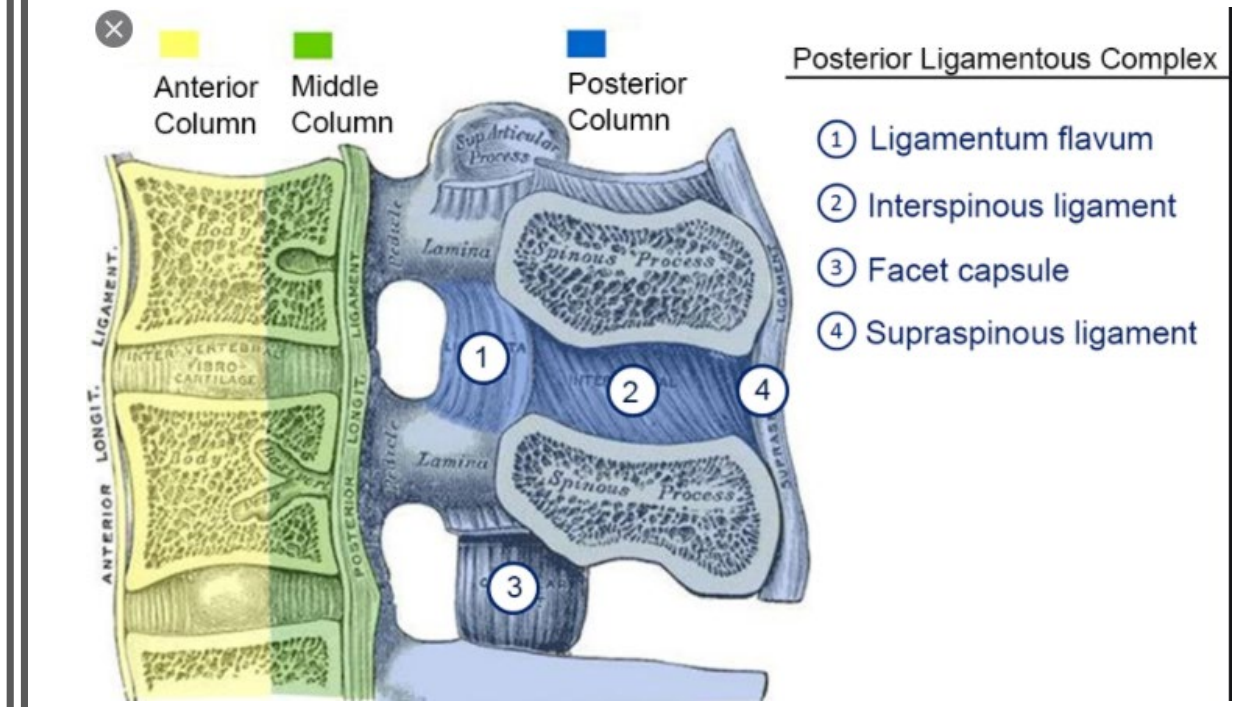
Evolution of Spine surgery



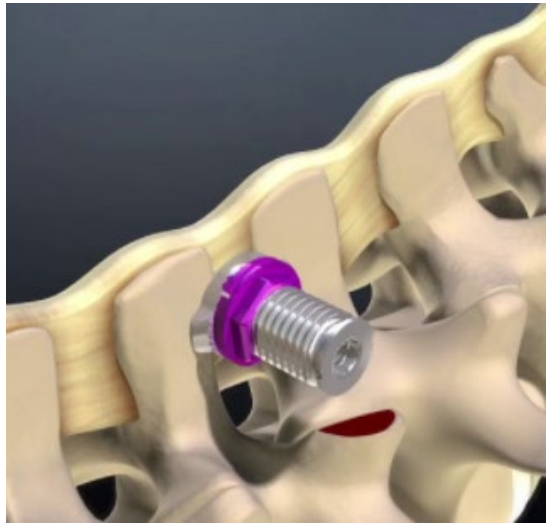
- <u>Posterolumbar/Intertransverse fusion dates back to the earliest forms of fusion</u>
- **1911**
  - A crude version of a posterolateral fusion (PLF) was developed by Albee. Bone was taken from the patient's tibia (autologous bone), chopped up (morselized) and packed between adjacent spinous processes.
- **1953**
  - The modern version of Posterior lateral fusion was pioneered by Watkins and Campbell, which involved fusion of the facet joints, pars interarticularis, and bases of the transverse processes.
- **Current Technique**: Surgeons dissect all the tissue (including fascia, ligaments and muscle) from the posterior elements of the vertebrae involved in the fusion . This includes the transverse processes of both vertebra and the lateral facet joints and maybe the lateral lamina.

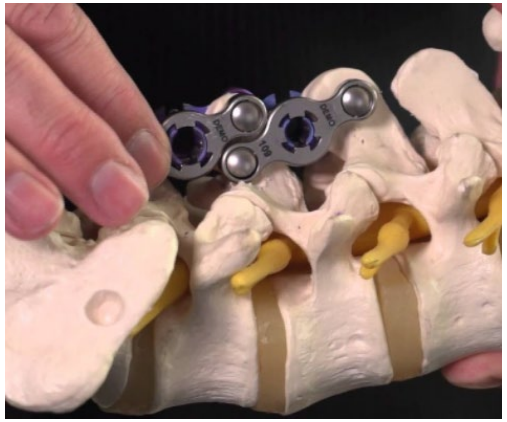
Biomechanics of the spine





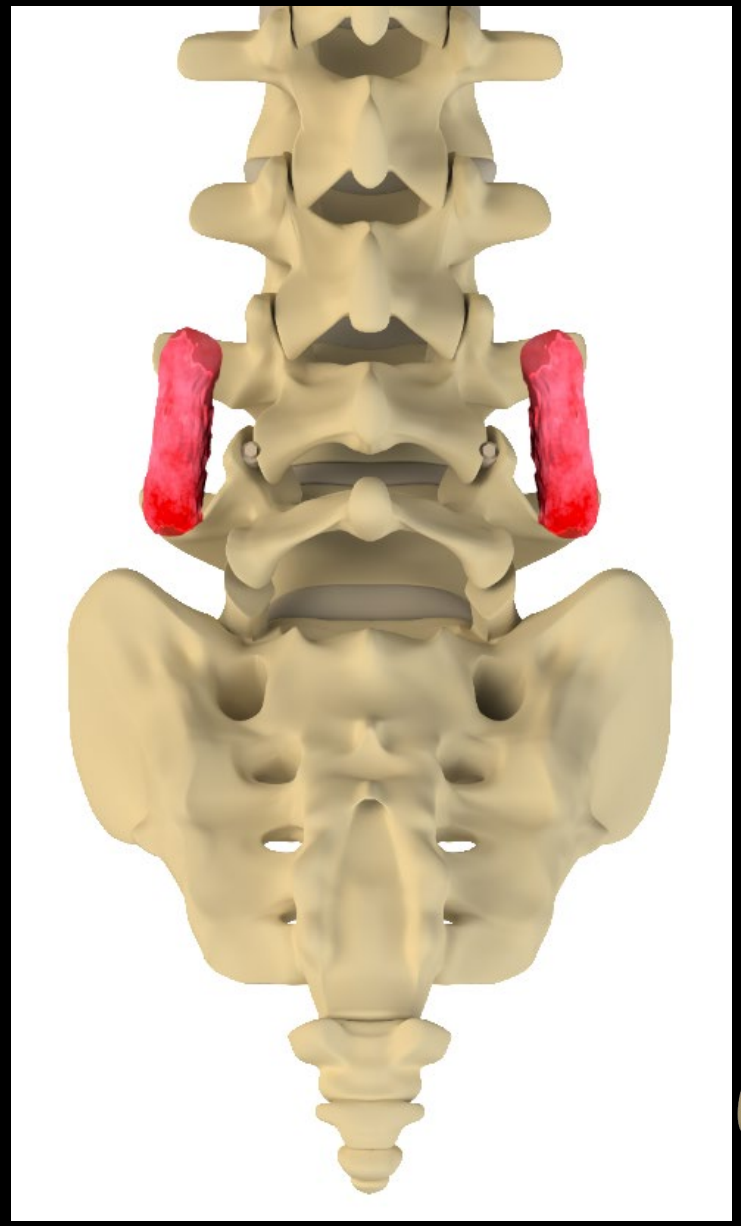
Current Products focusing on posterior column support





- Current FDA 510k indications: Non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion
- Helps prevent flexion/extension but NOT Lateral bending and axial rotation
- Biomechanics of Interspinous Devices:Paolo D. Parchi, [1,*] Gisberto Evangelisti, [1] Antonella Vertuccio, [1] Nicola Piolanti, [1] Lorenzo Andreani, [1] Valentina Cervi, [1] Christian Giannetti, [2] Giuseppe Calvosa, [2] and Michele Lisanti [1]

- Facet implant and minimally invasive graft system System Combination
- Instrument Overview
- Facet Surgical Technique
- Surgical Technique: Decorticate, Dilate, Deliver.



Facet implant + Novel Graft Rasp System Combination

- **Two standalone instrument sets that can be used together in a ”3D” (Dilate, Decorticate, Deliver) novel procedure**.

  - **Spondylosis**
  - **Lumbar DDD**
  - **Minor instability (1-2 mm listhesis)**
  - **Adjacent level disease**
  - **Mild foraminal stenosis**
  - **Mild canal stenosis**
  - **Posterior supplemental fixation to interbody fusion (ALIF, LLIF,TLIF, PLIF)**
  - **Adjunct to interspinous fusion**

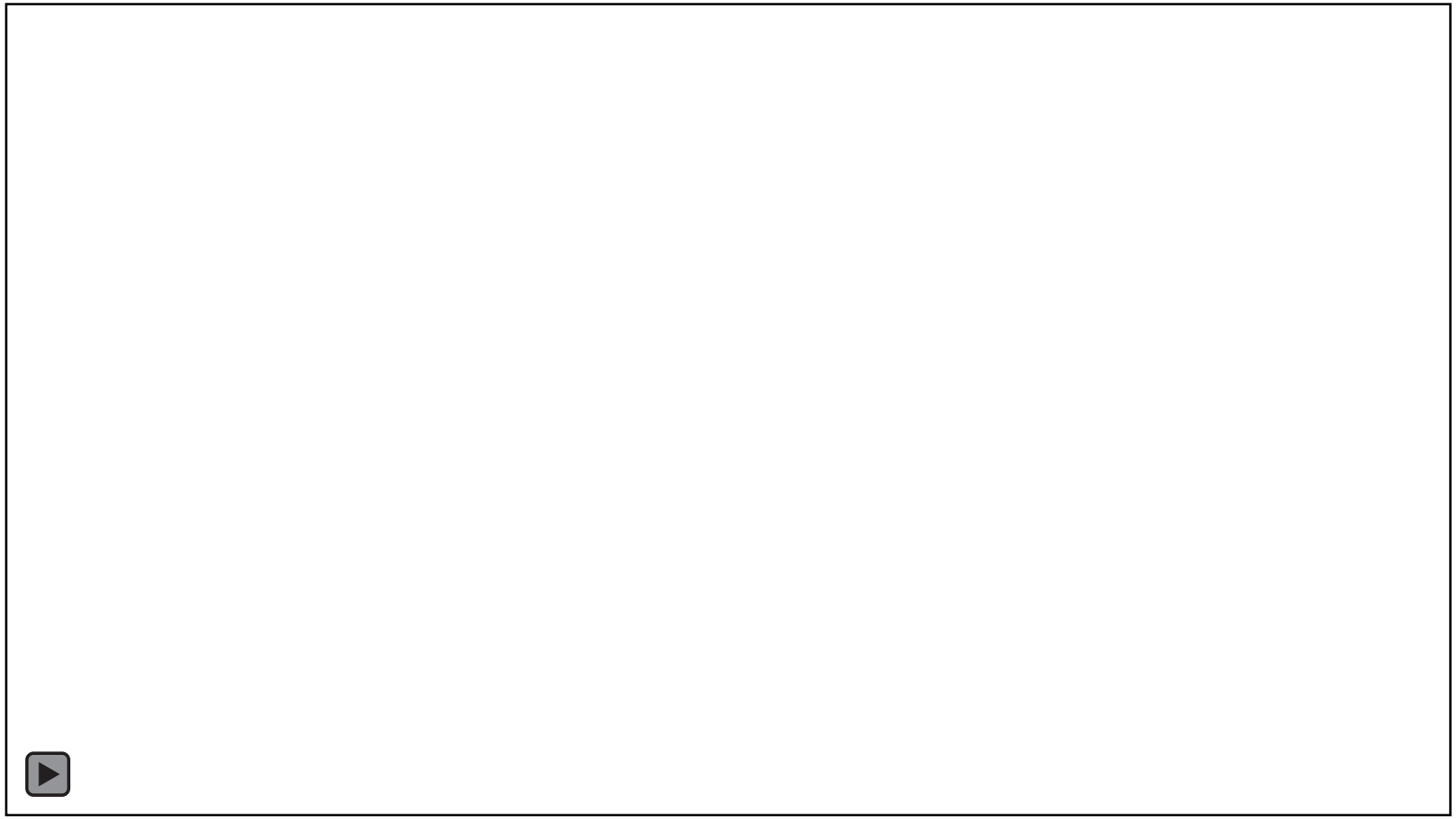
Advantages of MIS approach procedure vs open posterolateral fusion

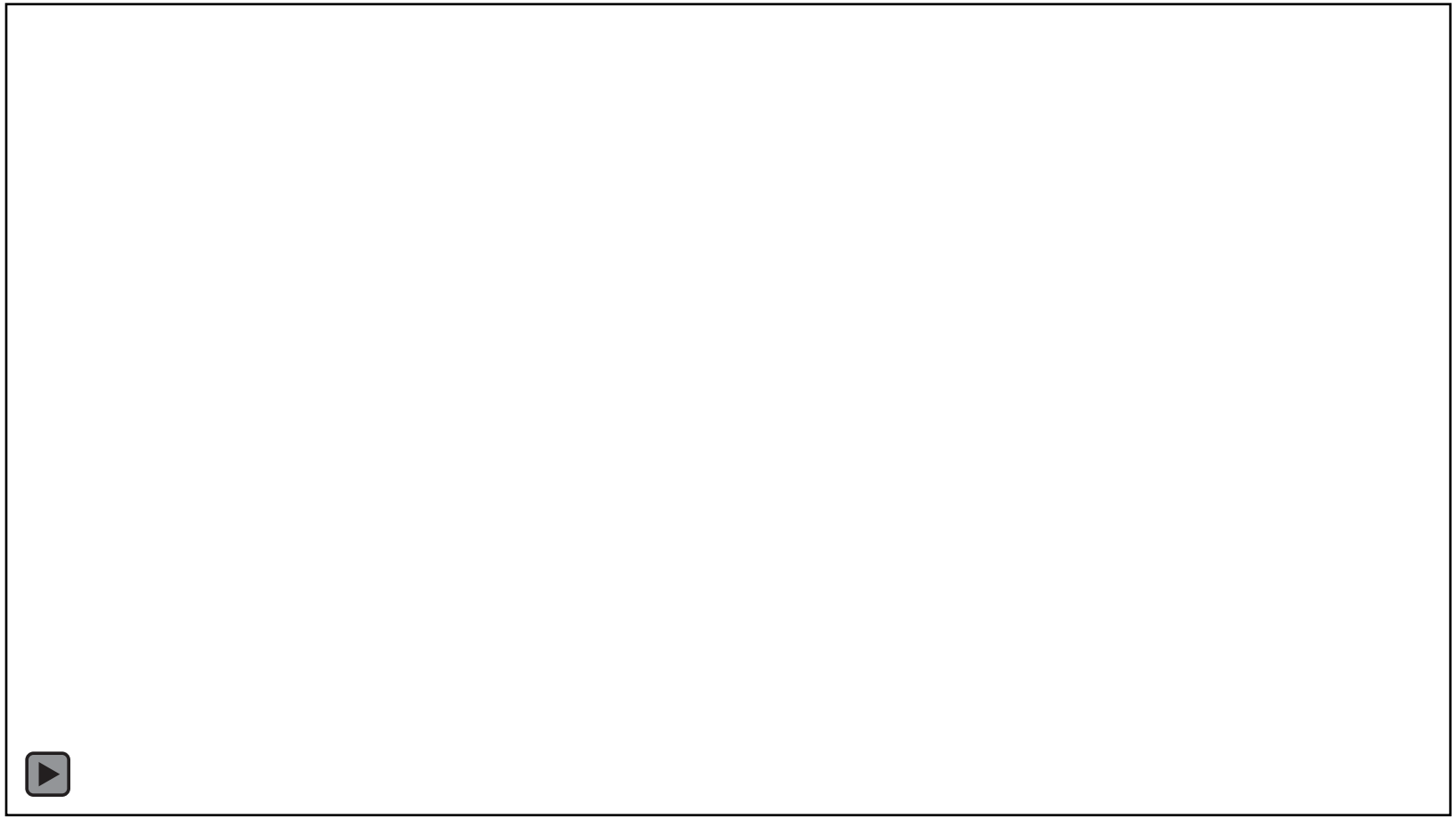
- **Decreased blood loss and scarring**
- **Decreased intrinsic muscle stripping and damage**
- **Reduced invasiveness and morbidity**
- **Decreased OR time**
- **Early recovery and discharge**
- **Motion preservation of disc space(micro-motion)**
- **Doesn't burn bridges if future surgery is needed**
- **No hardware necessary(No metallic implants is very marketable)**
- **Integration of allograft implants**
- **4 points of potential fusion(bilateral facets and bilateral TP's)**
- **Implants significantly less than hardware procedure(cages/screws)**

Traditional Procedure – 4-inch incision

VS

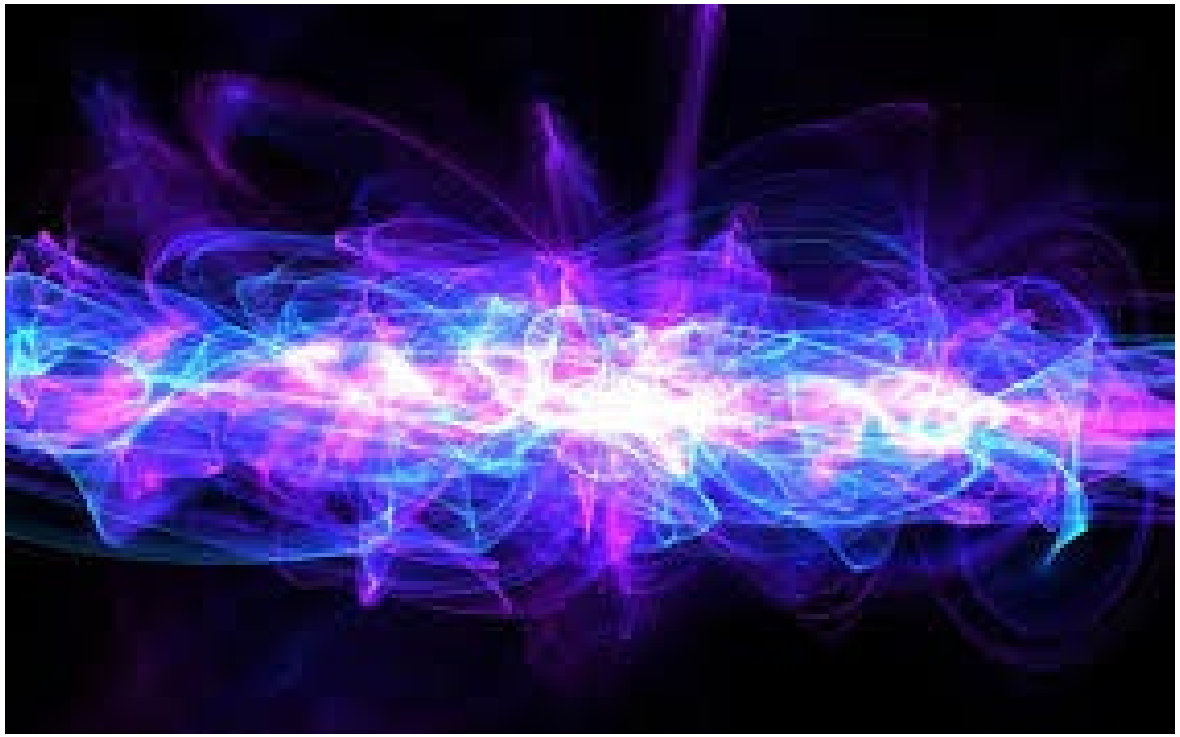
3D Procedure – 1-inch incision





Potential risks and Complications

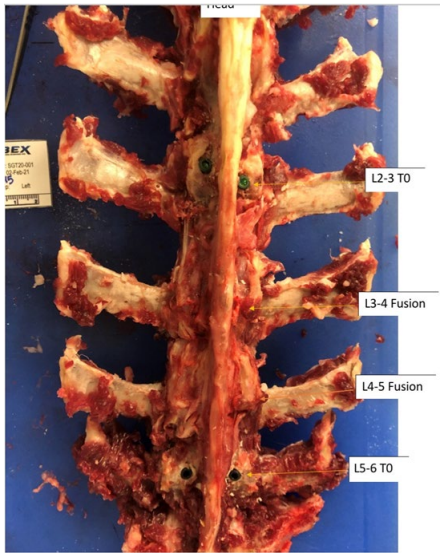
- **Anesthetic complications**
- **Infection**
- **Hematoma**
- **Worsening of pain**
- **Numbness or Weakness**
- **Nerve damage**
- **Need for further surgery**
- **Transverse Process Fracture**
- **Non-union**



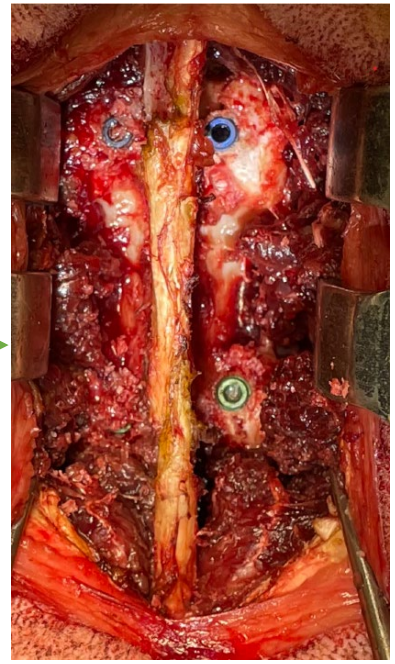
Future projects: Titanium Facet Implant

ANIMAL STUDY IMAGING

- Facet implants provide optimal surface texturing for bone integration
- 12-week sheep study demonstrated complete fusions after CT scans
- Implants were tested within facet joint and femur for back out and fusion
- Histology and biomechanical testing will be performed on the sheep spines

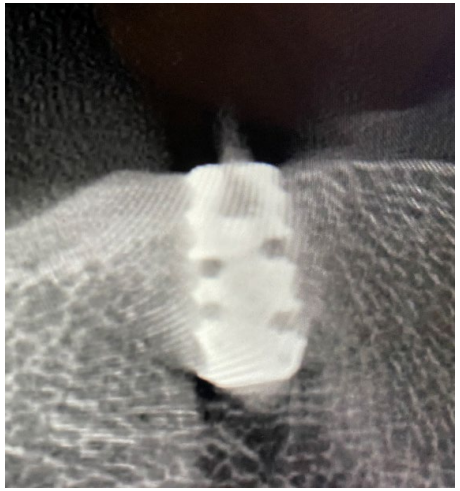


Facet implants placed intraop. During surgery →

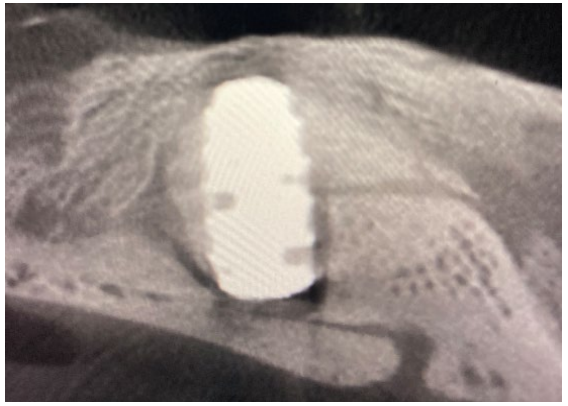


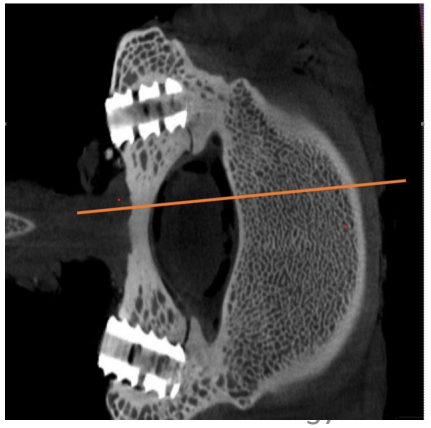
Implant time zero

Femur 12 weeks after implant

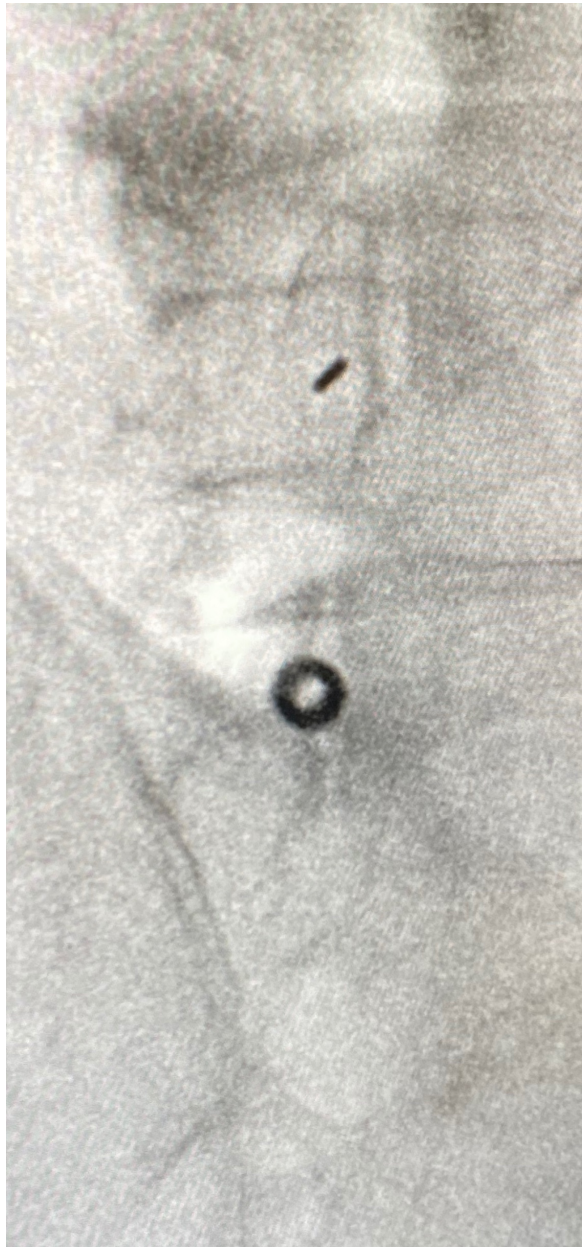


Facet Joint 12 weeks after implant



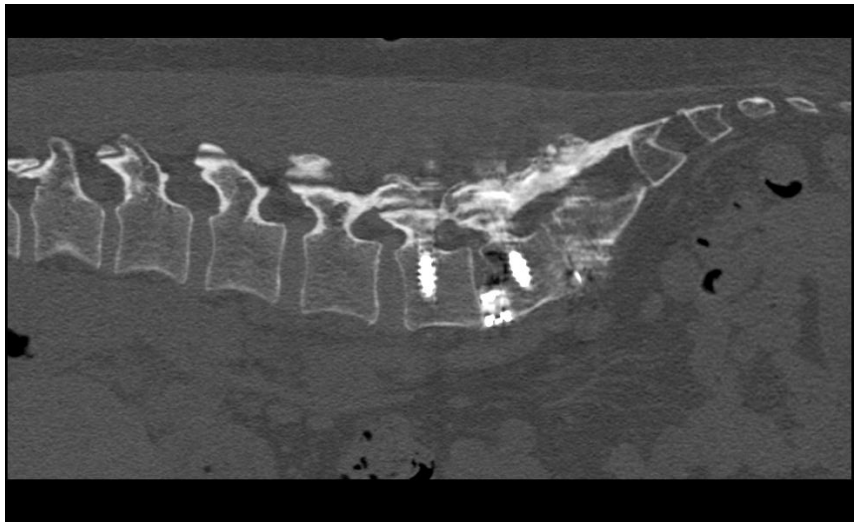


Titanium MIS Facet Screw at L5/S1



CASE SERIES

- Two year study on the use of the MIS Graft Rasping for MIS lumber fusion
- Three patients, from 46 to 64 years, that underwent single level and multilevel minimally invasive transforaminal lumbar fusions using the 3D GraftRasp System
- Results:
  - All three patients were released from the hospital within 24 to 48 hours with little to no pain and discomfort
  - Independent radiologists graded all three patients fused at 1 year and 2 years



A Novel Decortication and Graft Delivery Technique for Minimally Invasive Spine Fusion Surgery

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Abstract: Minimally invasive (MIS) lumbar fusion has become a popular alternative to traditional methods of lumbar decompression and fusion. When compared with the open technique, the minimally invasive approach can result in decreased pain and blood loss as well as a shorter length of hospitalization. However, the narrower working channel in the MIS technique increases the difficulty of decortication and bone grafting. This paper describes a novel set of instruments, the 3D GraftRasp System by SurGenTec, that physicians can use to help create an optimal environment to fuse the facet joints and lateral gutters during minimally invasive lumbar fusions. Retrospective clinical data from case reports are presented on 3 patients that underwent single level and multi-level MIS lumbar fusions utilizing the 3D GraftRasp System. The case reports show that the 3D GraftRasp System can provide a viable solution for physicians wanting to perform a minimally invasive procedure to achieve fusion while decorticating and packing bone graft around the facet joints and lateral gutters.

Study Design: Retrospective Case Reports

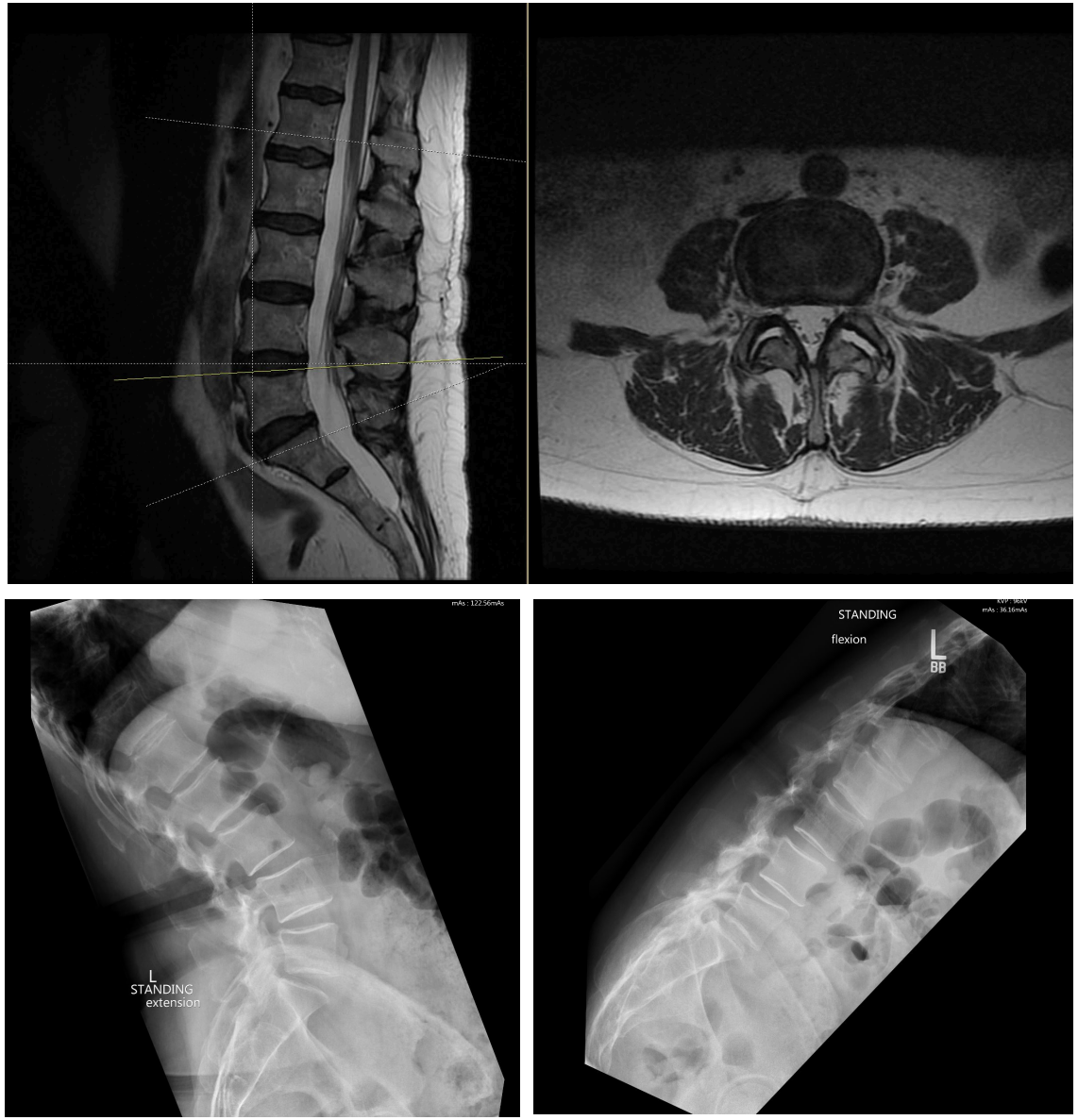
Keywords: Minimally Invasive, Spinal Fusion, Rasp, Bone Grafts, Decorticate, Non-union, Lumbar Fusion, Graft Delivery

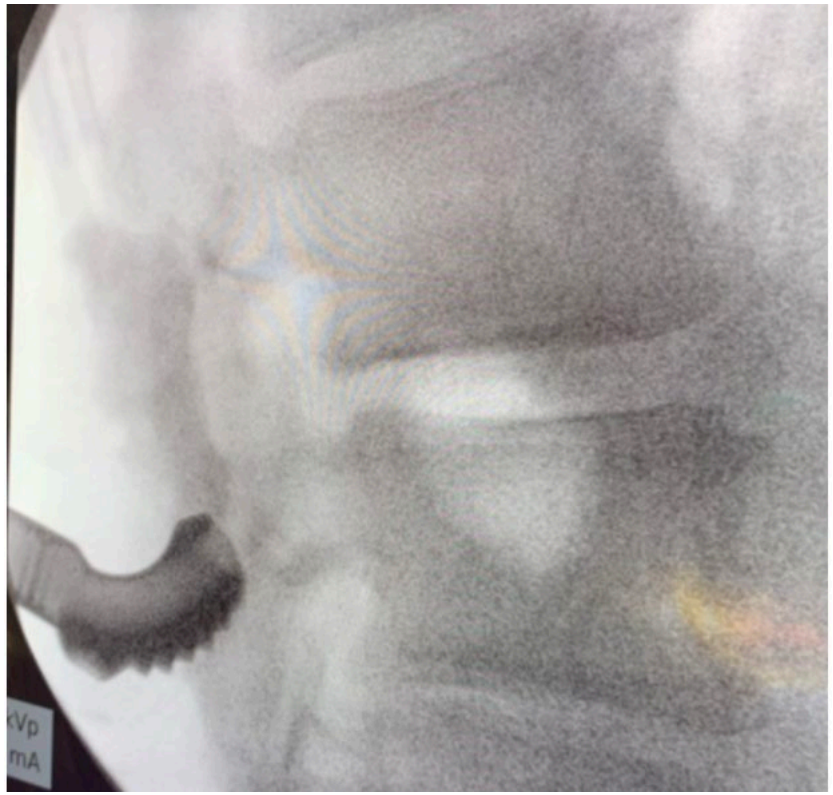
AMA CPT Code: 22612 (when applicable)- Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)

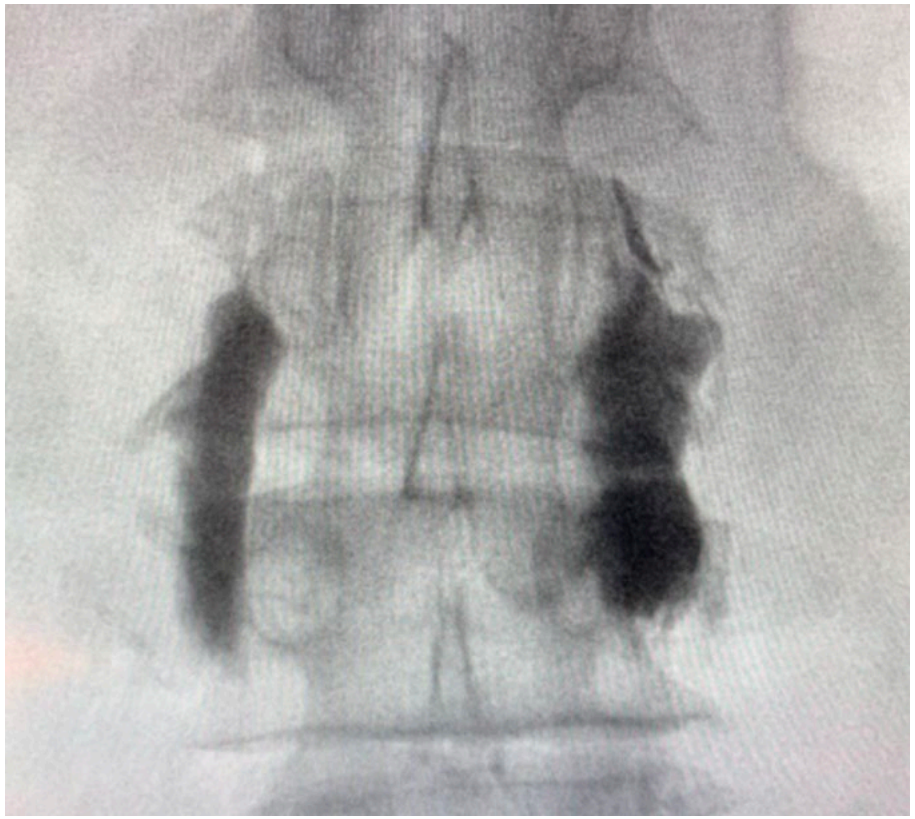
PATIENT SELECTION: CASE STUDY

Case Study

- **Patient Presented With:**
  - 74 year old female with 3 year history of lower back pain
  - No radicular symptoms/leg pain
  - Pain with standing and walking, mainly axial
- **Initial Treatments:**
  - ESI x 3, PT, Injections, RFA x 1 (relief), repeat RFA no relief.
- **Treatment Plan:**
  - Performed L4/L5 Posterolateral fusion/fixation
  - Minimal back pain/80-90% relief at 4 week follow-up.




KVp
mA



Conclusions

- Minimally invasive posterolateral fusion can be a less invasive technique to traditional approaches
- Minimal hardware and implants and no “bridges burned”
- Initial experience and case series are encouraging
- Second generation systems with more robust titanium implants/facet implants currently undergoing FDA testing for approval
- Prospective research will be critical to evaluate efficacy and safety