Non-surgical interventions for the non-operated back pain patient

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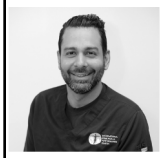
Mehul J. Desai, MD, MPH



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Disclosures

I have relevant financial relationships with the products and services, described, reviewed, evaluated or compared in the presentation.

- Abbott – Consultant
- Avanos – Consultant, Advisory Board
- SPR Therapeutics – Stock Options
- Smart Implant Systems – Stock Options

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Agenda

- Epidemiology and prognosis
- Treatment challenges and limitations of common therapies
- Newer minimally invasive interventions for virgin (non-operated) back pain
- Patient treatment preferences
- LBP treatment algorithm

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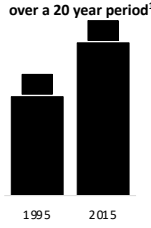
Impact of low back pain (LBP)

- #1 cause of global years lived with disability (YLD)[1]
- 7.3% global point prevalence (activity-limiting)[2]

80%
of adults have LBP at some point[3]

$200 B
Est. annual cost of LBP in U.S.[3]

54% increase in YLD over a 20 year period[1]



1. Vos *Lancet* 2016
2. Hartvigsen *Lancet* 2018
3. Rubin *Neurol Clin* 2007

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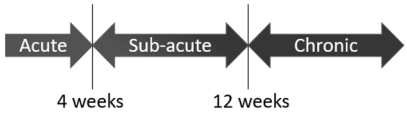
Prognosis in primary care

- 90% of acute LBP patients recover…
- …but recurrence is common!
- ~10% develop chronic back pain[1]



1. Meucci *Rev Saude Publica* 2015

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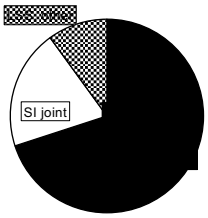
LBP Patients

Epidemiology is often unclear

- Axial pain is non-specific in ~70% of LBP patients
- SI joint pain occurs in ~20% of LBP patients[1]
- Lumbar Spinal Stenosis (LSS) occurs in ~10% of LBP patients and is more common in the elderly[2]



1. Cohen *Essentials of Pain Medicine* 2018
2. Ishimoto *Osteoarthritis Cartilage* 2013

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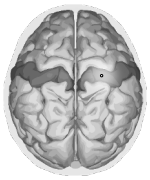
The urgency of treating pain

- Unchecked nociceptive inputs can change the CNS, resulting in hypersensitivity to pain (central sensitization)[1]
- Imaging reveals brain structures are involved[2]
- Potential for peripheral *and* central pain generators in LBP a present significant treatment challenges[3]
- Central Sensitization → Chronicity



1. Woolf *Pain* 2011
2. Kuner *Nat Rev Neurosci* 2017
3. Allegri *F1000Research* 2016

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LBP and the opioid crisis

- 20% of LBP patients still fill an opioid Rx[1]
- Little evidence of efficacy in chronic LBP[2]
- Non-pharma treatments needed for LBP
- Non-surgical interventions can reduce opioid intake

Opioids

1. Rosa *J Am Board Fam Med* 2020
2. Deyo BMJ 2015
3. Gilmore American Society of Regional Anesthesia and Pain Medicine November 2019.
4. Al-Kaisy Pain Med 2018

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Bottom Line

We need novel interventional treatments that are patient friendly and effective!

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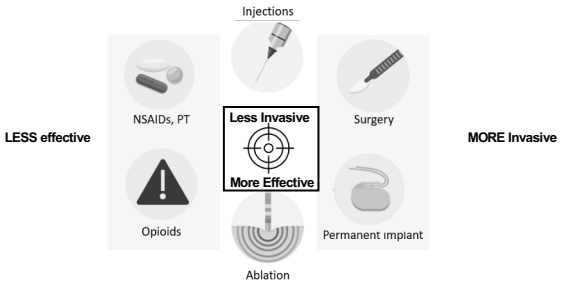
Conventional Treatments



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Long-standing Therapies: Injections

Pain Management Injection Therapies for Low Back Pain, AHRQ 2015[1]

Radiculopathy	Immediate, small, short-term, improvements common
Spinal Stenosis, facet joint pain	Evidence suggests that epidural/facet joint corticosteroid injections are not effective
SI joint pain	Insufficient evidence to evaluate effectiveness

Bottom Line: Low Risk, Minimal Benefit

1. Chou AHRQ 2015

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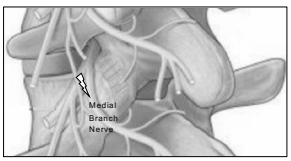
Long-standing therapies: RFA

- RFA = Radiofrequency Ablation
- Used for >20 years
- Denervates select peripheral nerves with heated needle probe
- Typically involves repeated procedures



Medial Branch RFA/Denervation

Adapted from: https://anatomia-fisioterapia.es/en/lumbar/articles/systems/musculoskeletal/spine/lumbar/analysis-of-the-posterior-ramus-of-the-lumbar-spinal-nerve-the-structure-of-the-posterior-ramus-of-the-spinal-nerve

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Meta-analysis of RFA for LBP[1]

- Provides minimal effect on VAS pain score
- Longer-term effectiveness is uncertain
- Can result in paraspinal muscle degeneration
- While medial branch is <1mm in diameter, lesion created is significant (up to ~600 mm^3) [2]

RFA guidelines[3] recommend discussing risk and alternative therapies with patients

	Trials	*n*	*Pain Reduction (10 point scale)*
RFA of facet joints			
1–3 mo	7	599	–0.56
6 mo	4	361	–0.66
12 mo	2	291	–0.72
RFA of sacroiliac joints			
1–3 mo	5	384	–1.53
6 mo	1	228	–0.28
12 mo	1	228	–0.19
RFA of intervertebral discs			
1–3 mo	4	200	–0.98
6 mo	3	127	–1.74
12 mo	1	20	–1.70

1. Chappell. *BMJ* 2020
2. Cedeño, et al Pain Physician 2017
3. Cohen Reg Anesth Pain Med 2020

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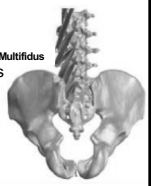
Healthy Multifidus, Healthy Back?

More than just an interesting correlation?
- Low back pain is non-specific in ~70% of LBP patients
- Lumbar multifidus muscle atrophy is present in ~80% of LBP patients



Potential benefits of a contracting multifidus:
- Proprioceptive cues from multifidus contractions may be important in maintaining low back health ("exercise is health")
- Many low back pain patients are unable (or unwilling) to perform low back exercises

Medial branch nerve provides:
- sensory innervation of facet joints
- motor innervation to multifidus, a core stabilizer of the spine

Should we wait to ablate?

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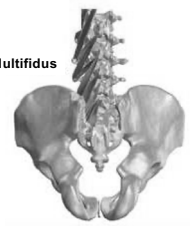
More info…Multifidus and Low Back Pain



- The prolonged absence of multifidus activity and contractility reduces proprioceptive central feedback
- The absence of proprioceptive feedback may cause pain to be centralized even after the original pain generator heals
- Centralization of pain may explain why LBP is so often non-specific
- Increasing healthy peripheral inputs from contracting muscle may increase proprioceptive inputs and reverse central sensitization

Injury/Onset of Pain → Arthrogenic Inhibition → Reduced Multifidus Contraction → Atrophy and Fatty Infiltration → Reduced Central Proprioceptive Feedback → Central Hypersensitivity and Centralization of Pain → Pain Becomes Non-specific

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Interventional Sub-indication Targets in LBP

	Lumber Spinal Stenosis (LSS)	Sacroiliac Joint Pain	Vertebrogenic Pain	Axial Pain
Symptoms	Pain in back/legs/buttocks when standing; relief when sitting	Pain over SI joint, often with leg pain: commonly aggravated by walking and stairs	Localized back pain, no leg pain; MRI indicates Type I/II Modic changes	Localized back pain, no leg pain
Causes	Ligamentum flavum hypertrophy, disc bulging or foraminal narrowing impinging on spinal cord nerves	Damage or injury to SI joints	Vertebral endplate damage	Evidence of clear pain generator may be unclear; central sensitization is common

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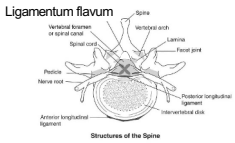
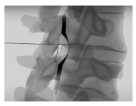
Lumbosacral Spinal Stenosis (LSS) Interventions

Approaches:

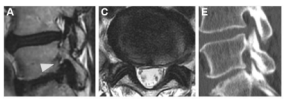
- **Debulk** hypertrophic ligamentum flavum encroaching on spinal cord nerves (PILD procedure)



Structures of the Spine


Hypertrophic Ligamentum Flavum Encroachment

- **Insert spinal spacers** to reduce stenosis associated with intervertebral foraminal encroachment upon extension



Koga, *Mini-invasive Surg* 2017;1:3-5

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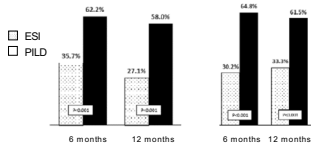
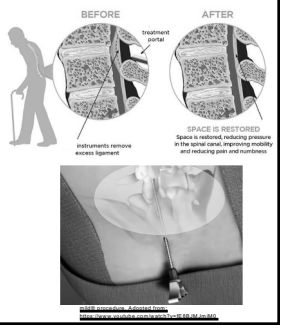
LSS Intervention: Debulking of Ligamentum Flavin

Improvements in Oswestry Disability Index (ODI) and Patient Satisfaction with Epidural Steroid Injections (ESI) Versus Percutaneous Image-guided Lumbar Decompression (PILD)



No difference in safety between PILD and ESIs

Champagne Pain Physician 2016



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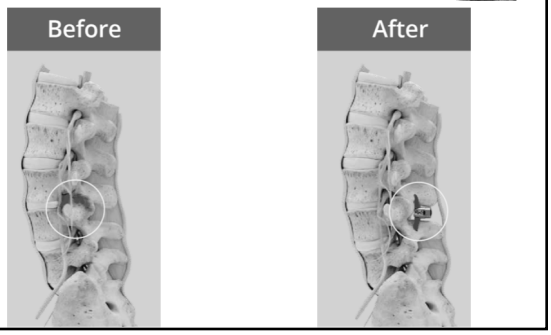
LSS Intervention – Interspinous Spacer Implant



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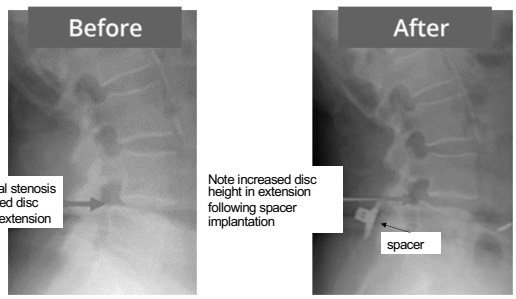
LSS Interventions– Interspinous Spacer Implant



1. Patel Spine 2015

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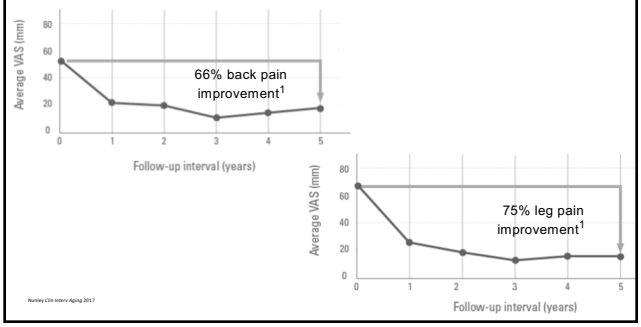
LSS Interventions– Interspinous Spacer Implant



Nursley Clin Interv Aging 2017

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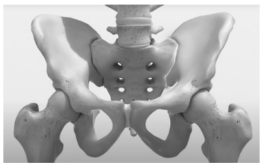
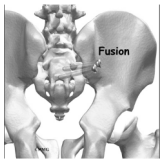
SI Joint Pain

- Feeling of weakness or instability is common
- Pain on provocative SI joint testing
- Goal of treatment is to stabilize the SI joint
- Several interventional options available, with or without graft material
- Guidelines do not yet recommend one technique or device over another



Sacroiliac (SI) Joint



Conventional Surgical Fusion

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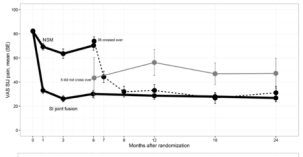
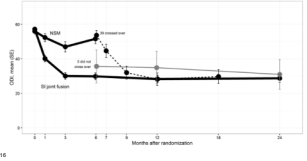
SI Joint Interventions: Fusion/Stabilization

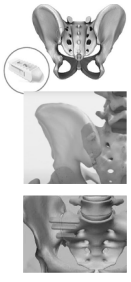
Pain: Non-surgical Management (NSM) vs Minimally invasive fusion



Disability: Non-surgical Management (NSM) vs Minimally invasive fusion



Multiple treatment options exist, some without long term data



1. Polly *Int J Spine Surg* 2016

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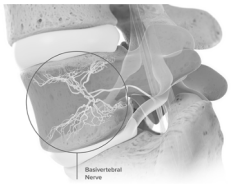
Vertebrogenic LBP



Intraosseous nerves within the vertebral body were first described in 1998

The vertebral endplates can be a source of pain

Pain is generally accompanied by Type 1 or Type 2 Modic changes on MRI

- Modic type I changes are related to bone marrow edema and inflammation signifying acute degenerative changes in the vertebral end plate.
- Modic type II changes signify fatty degeneration of the bone marrow.

Adopted from:
https://www.relievant.com/intraseat-procedure/

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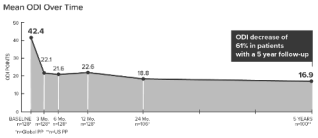
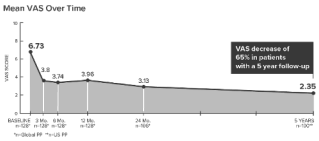
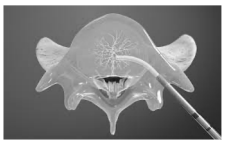
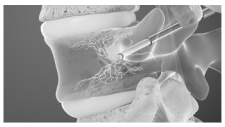
Axial LBP Treatments: Basivertebral Nerve Ablation









1. Fischgrund *Int J Spine Surg* 2020

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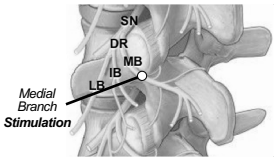
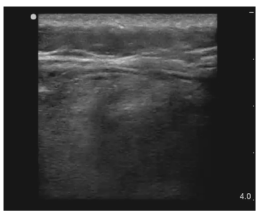
Axial LBP Intervention: 60-day Medial Branch PNS

Peripheral nerve stimulation (PNS) of the medial branch nerve





- Medial Branch PNS induces cycling tension within the multifidus muscle
- Multifidus contractions induce activation of afferent (sensory and proprioceptive) signals terminating in the cortex

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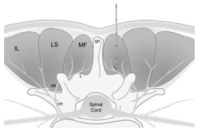
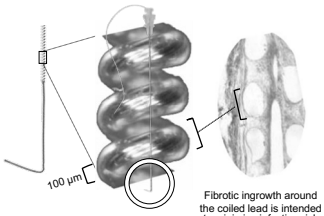
Axial LBP Intervention: 60-day Medial Branch PNS

Peripheral nerve stimulation (PNS) of medial branch nerve, for up to 60 days





Fibrotic ingrowth around the coiled lead is intended to minimize infection risk during the 60-day treatment period

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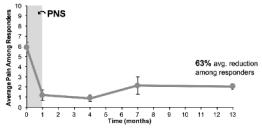
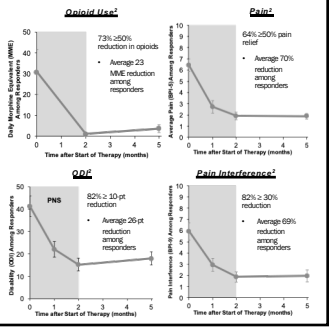
Axial LBP Intervention: 60-day Medial Branch PNS

Pain relief often endures well beyond treatment period[1]





1. Gilmore *Pain Pract* 2020
2. Gilmore ASPN 2019

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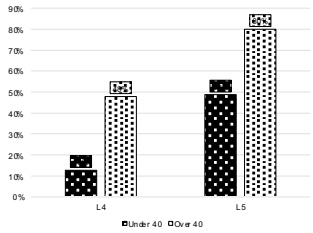
Considering PNS Versus RFA

When is multifidus preservation important?

A. In the younger patient to minimize multifidus atrophy?
B. In the older already atrophic patient?
C. A and B

It's in both populations, of course!

Percent of LBP Patients with Lumbar Multifidus Atrophy on MRI Under and Over 40 Years of Age



Ekin et al, Diagn Interven Radiol 2016; 22: 273-276

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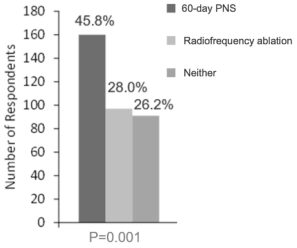
Patient Preference Survey (n=347)

- Survey of patients (aged 34–75) with activity-limiting moderate-to-severe axial back >6 months duration
- Potential complications include:
  - For RFA:
    - Multifidus denervation
  - For 60-day PNS:
    - Potential for 100-micron lead fracture
- **Patients overwhelmingly preferred PNS as a motor-sparing option**



*Gulati, et al. Rethink your Pain Strategy. Presented at: American Academy of Pain and Neuroscience webinar, August 2020.

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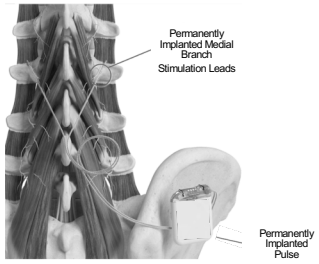
Axial LBP Intervention: Permanent PNS Implant

Medial branch stimulation delivered for two 30-minute sessions daily in which the patient is lying prone



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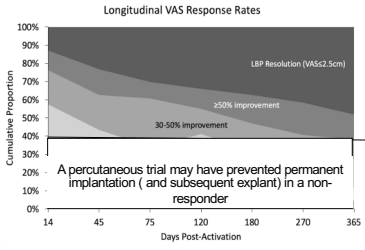
Axial LBP Intervention: Permanent PNS Implant



A percutaneous trial may have prevented permanent implantation (and subsequent explant) in a non-responder

62% of patients with >50% improvement or with mild pain <2.5/10

38% of patients with no or minimal improvement

- Temporary stimulation was not performed in these subjects prior to implanting the permanent system

As presented July 16, 2020 at INS NACC Webinar: The Right Device for the Right Patient - Case Presentations and Discussions

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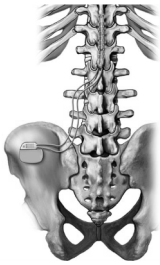
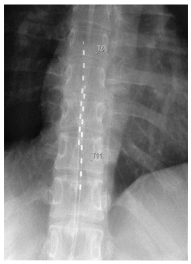
Axial LBP Intervention: Permanent SCS Implant





1. Al-Kaisy *Pain Med* 2018

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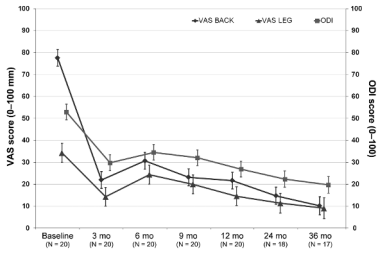
Axial LBP Intervention: Permanent SCS Implant



1. Al-Kaisy *Pain Med* 2018

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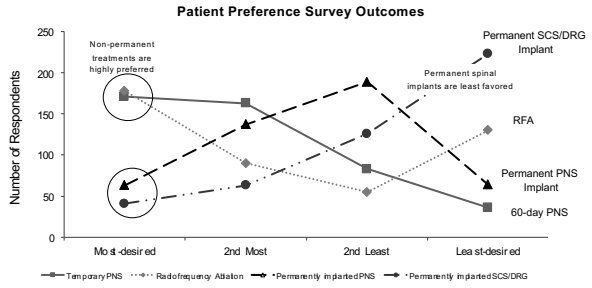
Patient Preference Survey (n=453)



Data on file, SPR Therapeutics

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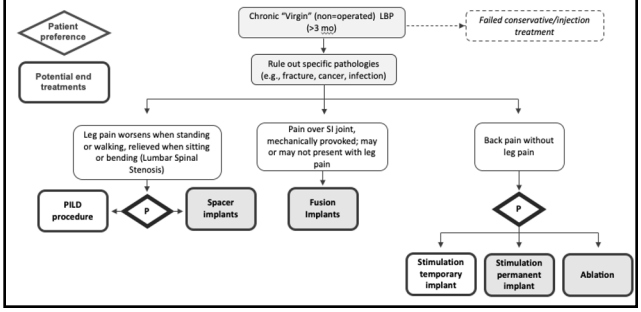
LBP Interventional Treatment Algorithm



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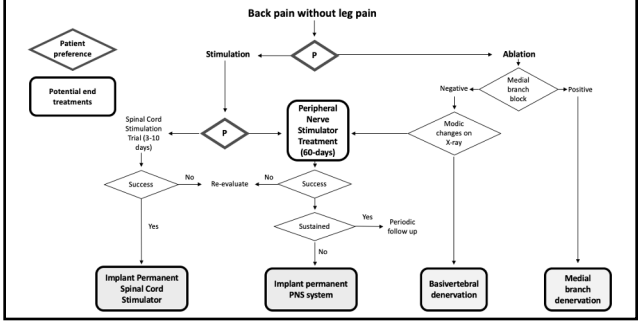
Axial LBP Interventional Treatment Algorithm



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LBP Interventional Treatment Safety Summary

	Debulking Intervention[1]	Interspinous Spacer[2]	60-day PNS[3]	Permanent PNS[4]	Spinal Cord Stimulation[5]
Serious Adverse Event* Rate (%)	0.0%	8.4%	0.0%	11.0%†	9.0%†

*Procedure - or device-related
†Rate of surgical interventions required

1. Champagne *Pain Physician* 2016
2. Patel *Spine* 2015
3. Gilmore *RAPM* 2019
4. As presented July 16, 2020 at INS NACC Webinar: The Right Device for the Right Patient - Case Presentations and Discussions
5. https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022b.pdf

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Summary

- LBP is the leading cause of global disability
- The opioid crisis has driven development and adoption of new FDA-cleared interventional treatment options for LBP
- Patients generally prefer treatments that do not involve permanent implants or motor impairment
- Check with your pain physician to better understand what interventions they are offering and trained to perform

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Thank you!

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