Identifying the Right Patients for BVN Ablation with the Intracept Procedure

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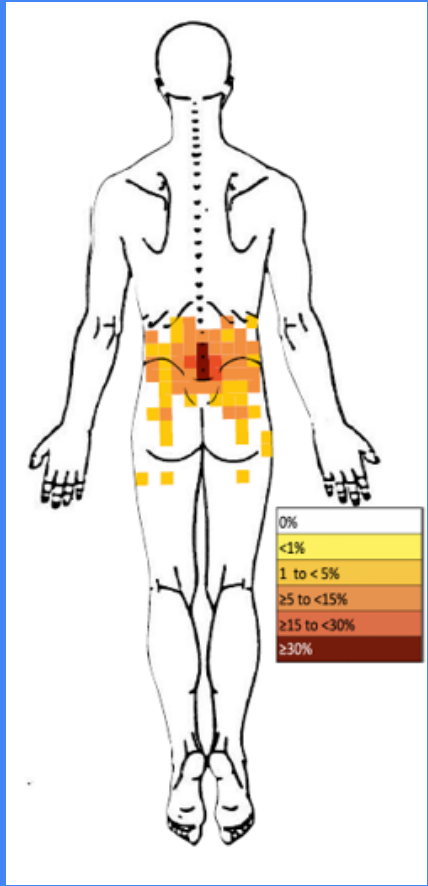
Disclosures

Consultant for Relievant and Abbott

Who is an ideal patient for basivertebral nerve ablation?

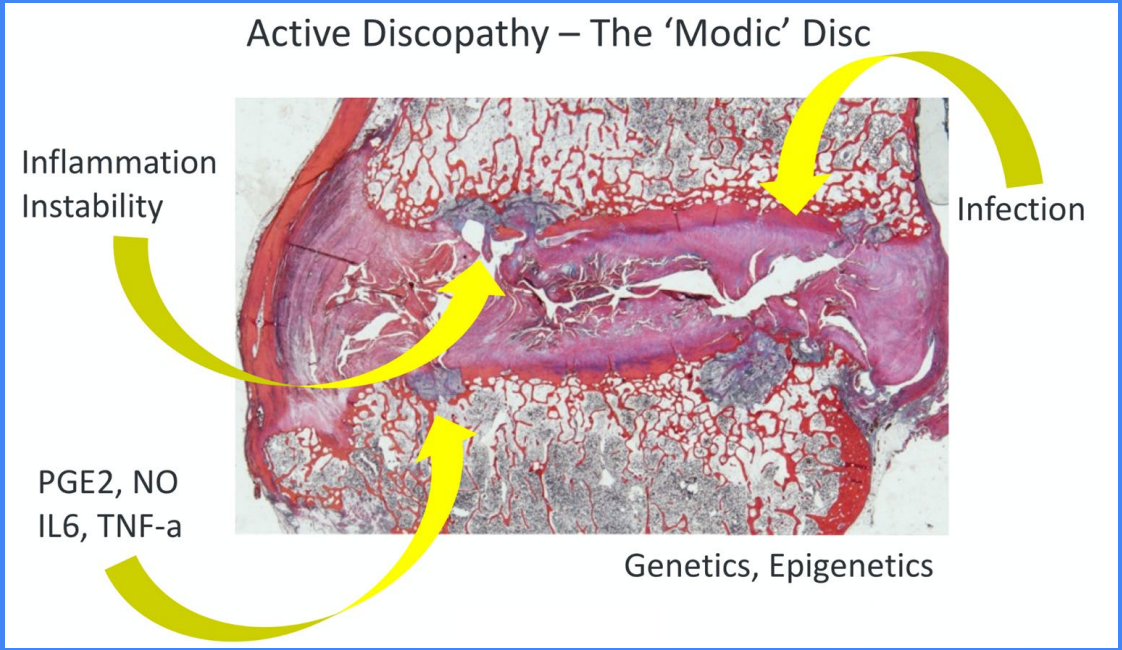
What is Vertebrogenic Low Back Pain?

- 71% have midline low back pain (anterior column pain)
- Pain that is worse with bending forward (flexion) and sitting
- DDD (Pfirrmann grade III to V) with Modic present on MRI
- Any amount of Modic on MRI (respond with even small amounts of Modic localized to the endplate or anterior corner)
  - "…the patient that is complaining of midline low back pain and is walking around in the exam room when I come in, because they can't sit in one position long"
  - Pain that is worse with bending forward (flexion) and sitting
  - "Restless spine"



Pathophysiology 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 and to increased nociceptor density
- Prevalence and density of endplate nociceptors higher in vertebral bodies with MC[1]
- Vertebrogenic Pain is a Paradigm Shift in the Science of CLBP



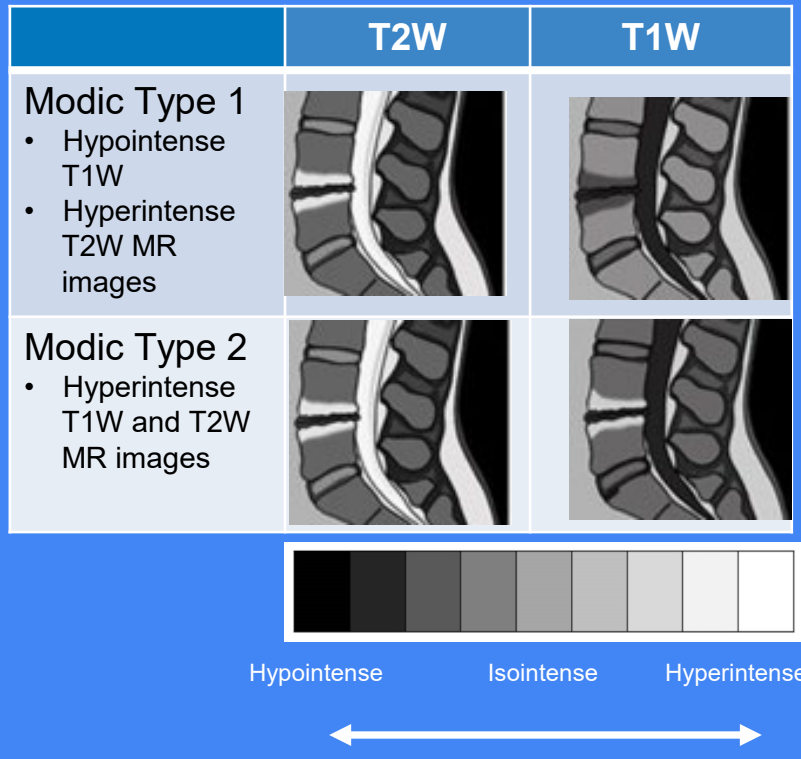
Dudli S et al. ISSLS Prize Winner; 2017

Modic Changes are Correlated with Severe CLBP

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]

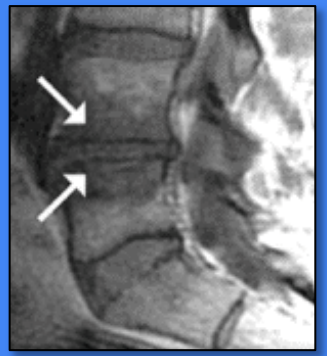
Patients with MC Type 1 seek care more often and have poor outcomes to conservative treatment [3,4]



[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

Modic Changes - Objective Biomarker & Binary Indicator of Vertebrogenic Pain

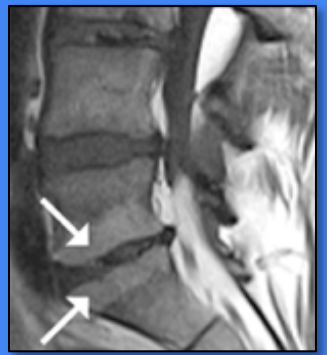
MRI T1 (fat)



MRI T2 (fat and water)

Modic Type 1 (1 tissue hyper-intense):

- Hypointense T1W
- Hyperintense T2W MR images



Modic Type 2 (2 tissues hyper-intense):

- Hyperintense T1W and T2W MR images

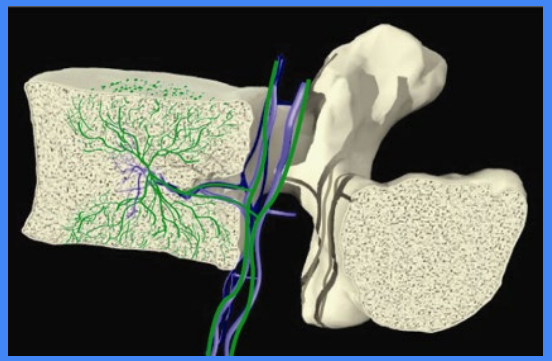
Key Messages: Chronic Vertebrogenic Low Back Pain

- Vertebral body endplates are richly innervated by nociceptors that are branches of the basivertebral nerve – with a greater prevalence and density of nociceptors than the disc
- Disc material leaking through damaged and degenerated endplates creates bone marrow inflammation, which results in vertebrogenic pain
- Chronic bone marrow inflammation leads to Modic Changes
- Modic Changes are associated with the presence and severity of CLBP, making them a good biomarker for vertebrogenic pain

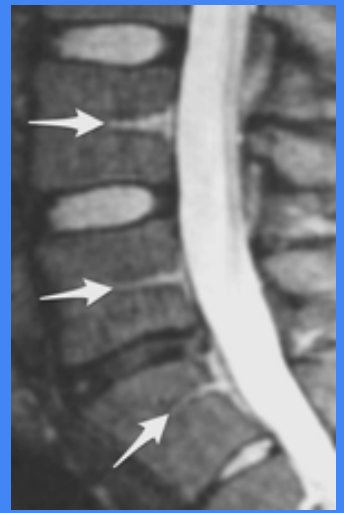
Innervation of the Vertebral Body Endplate

- The basivertebral nerve is a branch of the sinuvertebral nerve, which enters the vertebral body through the basivertebral foramen
- The basivertebral nerve was thought to be a trophic nerve, and was there to maintain bone health. In addition to its role in bone health, the BVN has been confirmed to have a nociceptive role.
- PGP 9.5 staining positive nociceptors confirmed at the vertebral endplates [1]
- Vertebral endplates are more innervated than intervertebral discs [1]
- 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



[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.

Indications/Contraindications for BVN Ablations

Indications

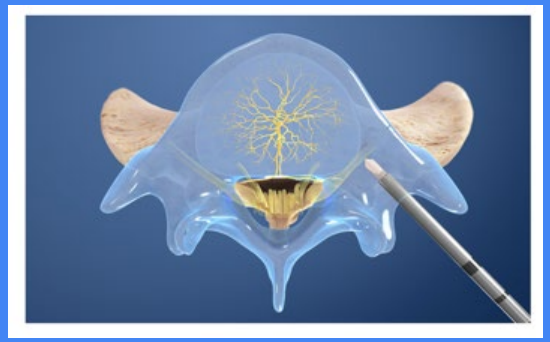
- Chronic Low Back Pain of at least 6 months duration; and
- Failure to respond to at least 6 months of conservative care; and
- MRI changes consistent with Modic Type 1 or Type 2 at one or more levels from L3 to S1

Contraindications

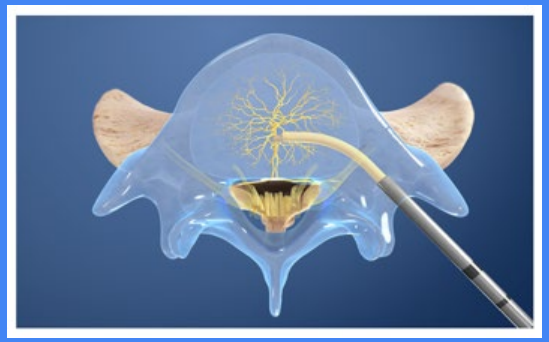
- Severe cardiac or pulmonary compromise
- Where the targeted ablation zone is <10mm away from a sensitive structure not intended to be ablated
- With active systemic infection or local infection in the treatment area
- Pregnancy
- Skeletally immature (≤18)
- With Implantable Pulse Generators (e.g. pacemakers, defibrillators)
- Where untended tissue damage may result
- With instruments not tested / specified for use with RFG

BVN (Intracept Procedure) Ablation Procedure Steps

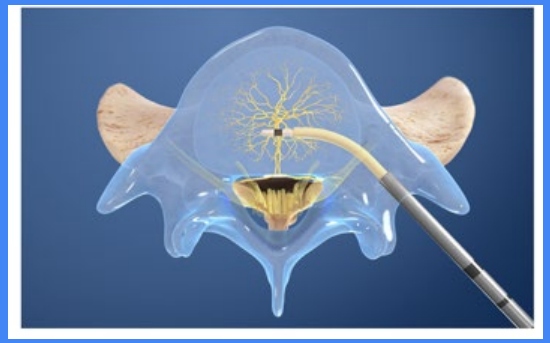
1. Access the Pedicle



2. Create the Channel



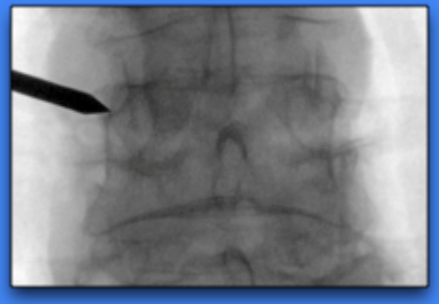
3. Place the Radiofrequency

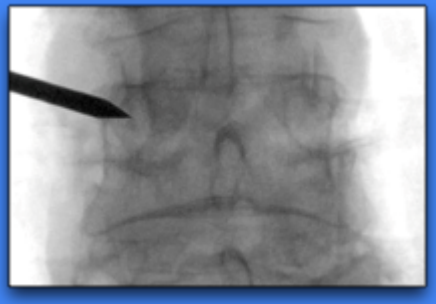


4. Ablate the BVN

Step 1 – Access the Pedicle

AP





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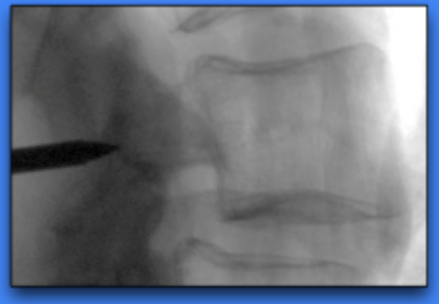
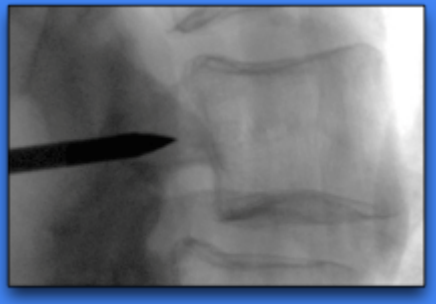
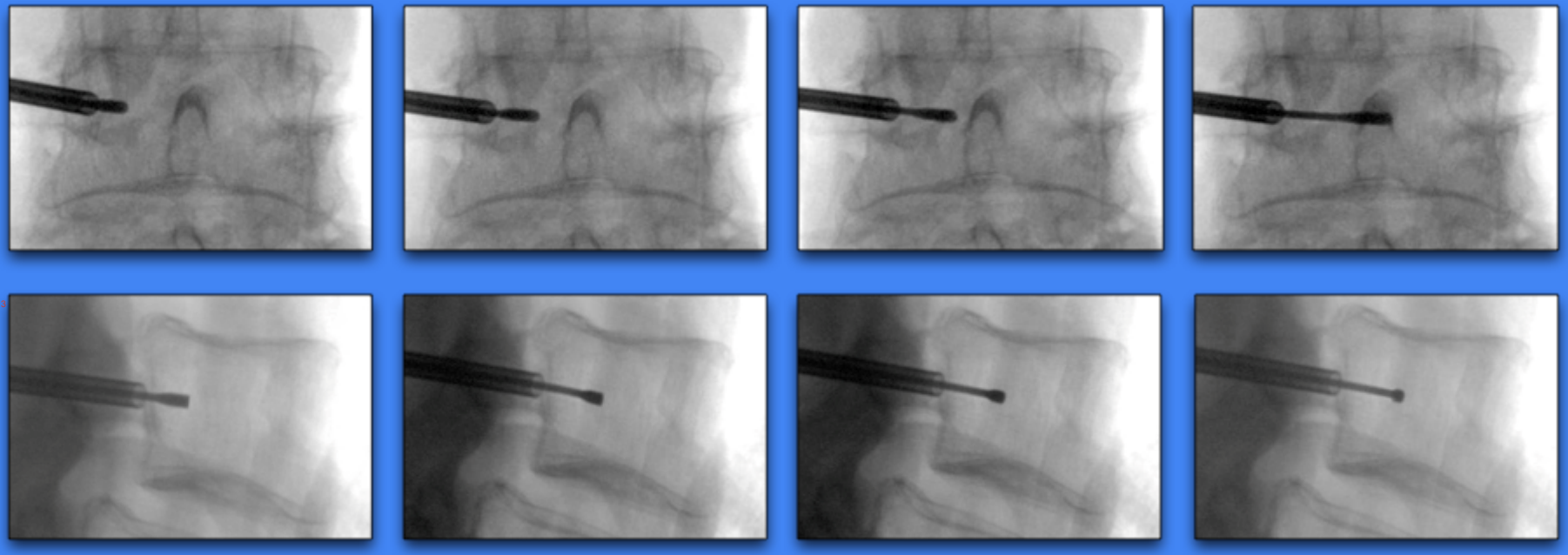
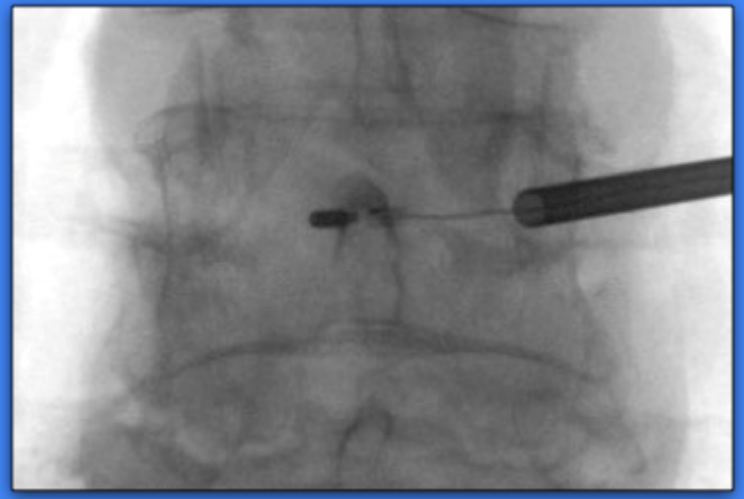




Step 2 – Create the Channel (Lumbar)



Step 3 – Place the Radiofrequency Probe (Lumbar)



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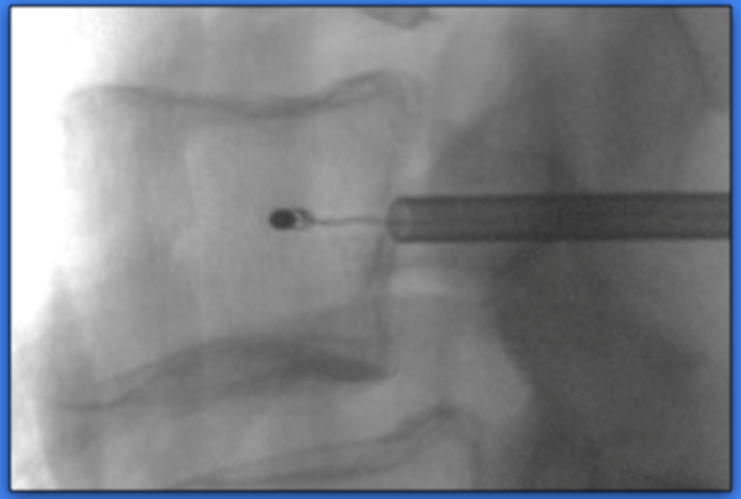

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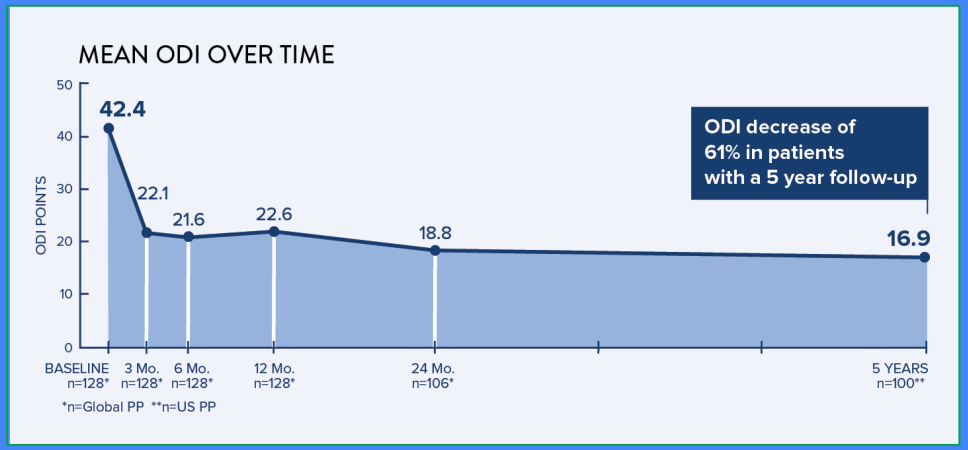
SMART 5+ Year Data: Sustained Improvements in Pain and Function Long-Term

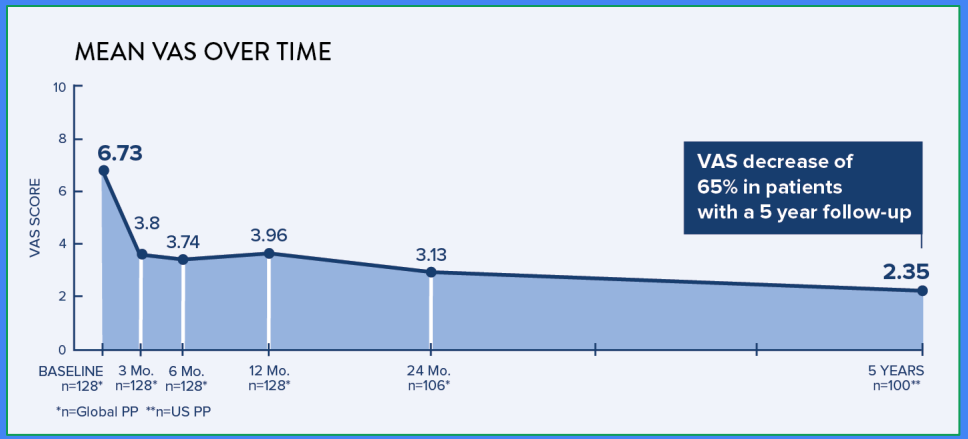
Study Design

- Five-year follow-up of the SMART US treatment arm
- US PP BVN ablated patients; 85% response rate (100/117)
- Mean follow-up 6.4 years (range 5.4 – 7.8)
- Mean age was 47 years; majority ≥5 yrs with CLBP

Key Findings

- Improvements in pain and function maintained more than 5 years post-procedure (ODI, VAS)
- 75% responder rate (defined as patients reporting both a ≥15 pt ODI and ≥2 point VAS improvement)





Fischgrund JS, Rhyne A, Macadaeg K, Moore G, Kamrava E, Yeung C, et al. Long-term outcomes following intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 5-year treatment arm results from a prospective randomized double-blind sham-controlled multi-center study. Eur Spine J. 2020 Aug;29(8):1925-1934. DOI: 10.1007/s00586-020-06448-x

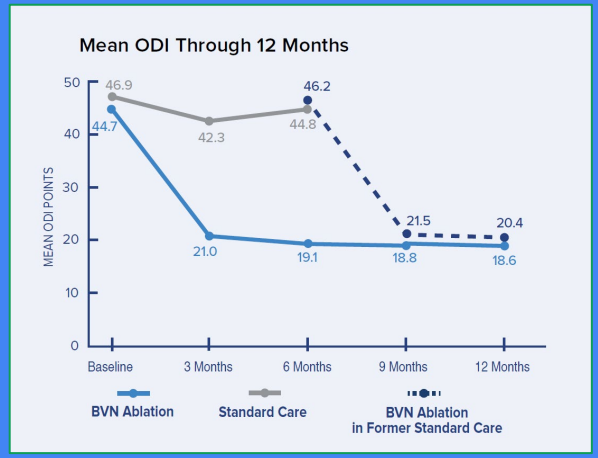
INTRACEPT 12-Month: Improvements Sustained, Replicated in Re-Baselined Group

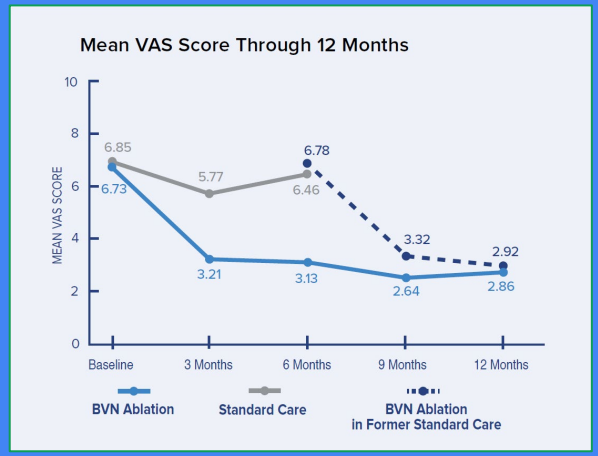
Study Design

- 2nd RCT evaluating BVN ablation; n=140 (interim analysis included 104)
- Allowed treatment of 4 VBs and also previous discectomy
- Mean age was 49 years; majority ≥5 yrs with CLBP

Key Findings

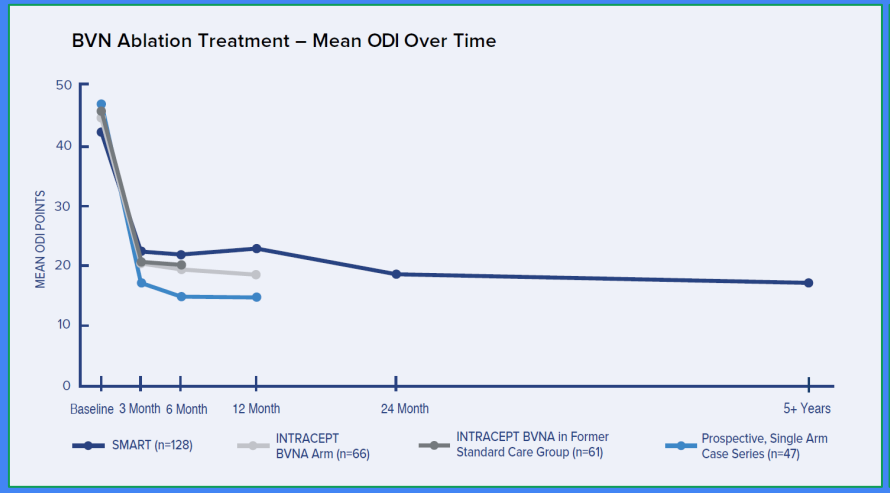
- BVN ablation arm patients maintained Improvements in pain and function 12 mo. post-procedure: 25.7 point reduction in mean ODI, 3.8cm reduction in VAS
- Patients previously in the Standard Care arm who underwent BVN ablation showed similar improvement six months post-procedure

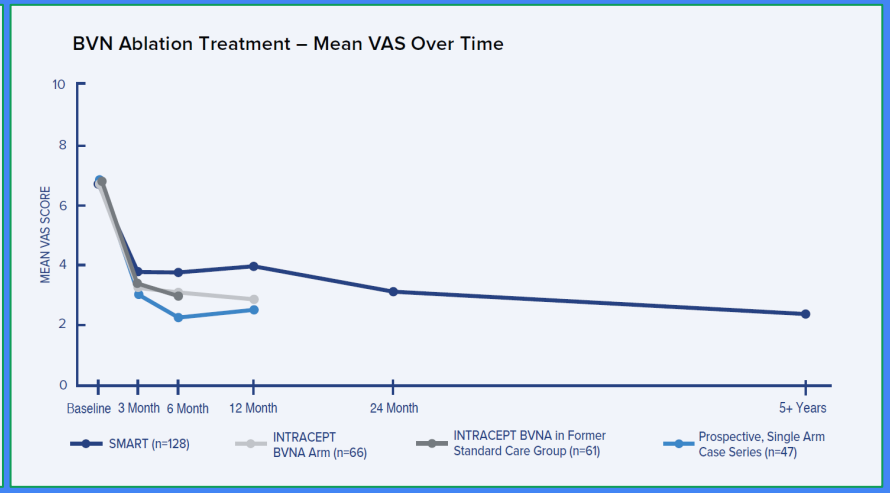




Smuck M, Khalil J, Barrette K, et al. Reg Anesth Pain Med Epub ahead of print: May 24, 2021. doi:10.1136/rapm-2020-102259

Similar Improvements in ODI and VAS Across Studies Post-Intracept Procedure





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Questions?