

Basivertebral Nerve (BVN) RF Ablation for the Treatment of Chronic Low Back Pain

(Clinical Research Update)

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www.DenverBackPainSpecialists.com

Disclosures

- Board and Committee Positions:
 - Colorado Pain Society Board of Directors
 - Colorado Medical Society Prescription Drug Abuse Committee
- Research:
 - Mesoblast – intra-discal stem cells for low back pain
 - Relievant – Intracept RF ablation of basivertebral nerve for low back pain
 - Novartis – monoclonal antibody for ankylosing spondylitis (AS)
 - Semnur Pharmaceuticals – TFESI(depo) for lumbar disc protrusion with radicular pain
 - Seikagaku Corp. – Intra-discal Condoliase injection for lumbar disc protrusion with radicular pain
 - Grunenthal – IV naridronic acid for treatment of CRPS
- Speaking Honoraria:
 - Medical Education Resources, Inc.
 - Colorado Consortium for Prescription Drug Abuse Prevention, Provider Education Work Group
 - Spine Intervention Society Senior Instructor

Treatment of Lumbar Discogenic Pain

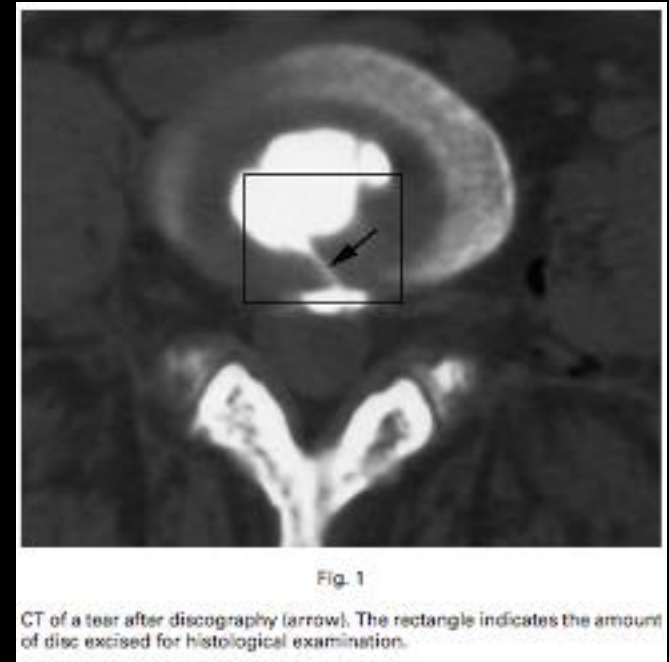
- Conservative management
- Lumbar Fusion
 - 65-85% success
- Intradiscal Stem Cells
 - Mesoblast randomized, blinded, controlled studies
 - Phase 2: 50% with both significantly decreased pain and increased function
 - Phase 3: ongoing, closed to enrollment
 - Umbilical cord vs. bone marrow aspirate concentrate (BMAC)
- Basivertebral Nerve (BVN) Ablation
 - Relievent (Intracept) study
 - SMART
 - 70% with MCSD VAS and ODI improvement to 2 years

Discogenic LBP Clinical Presentation

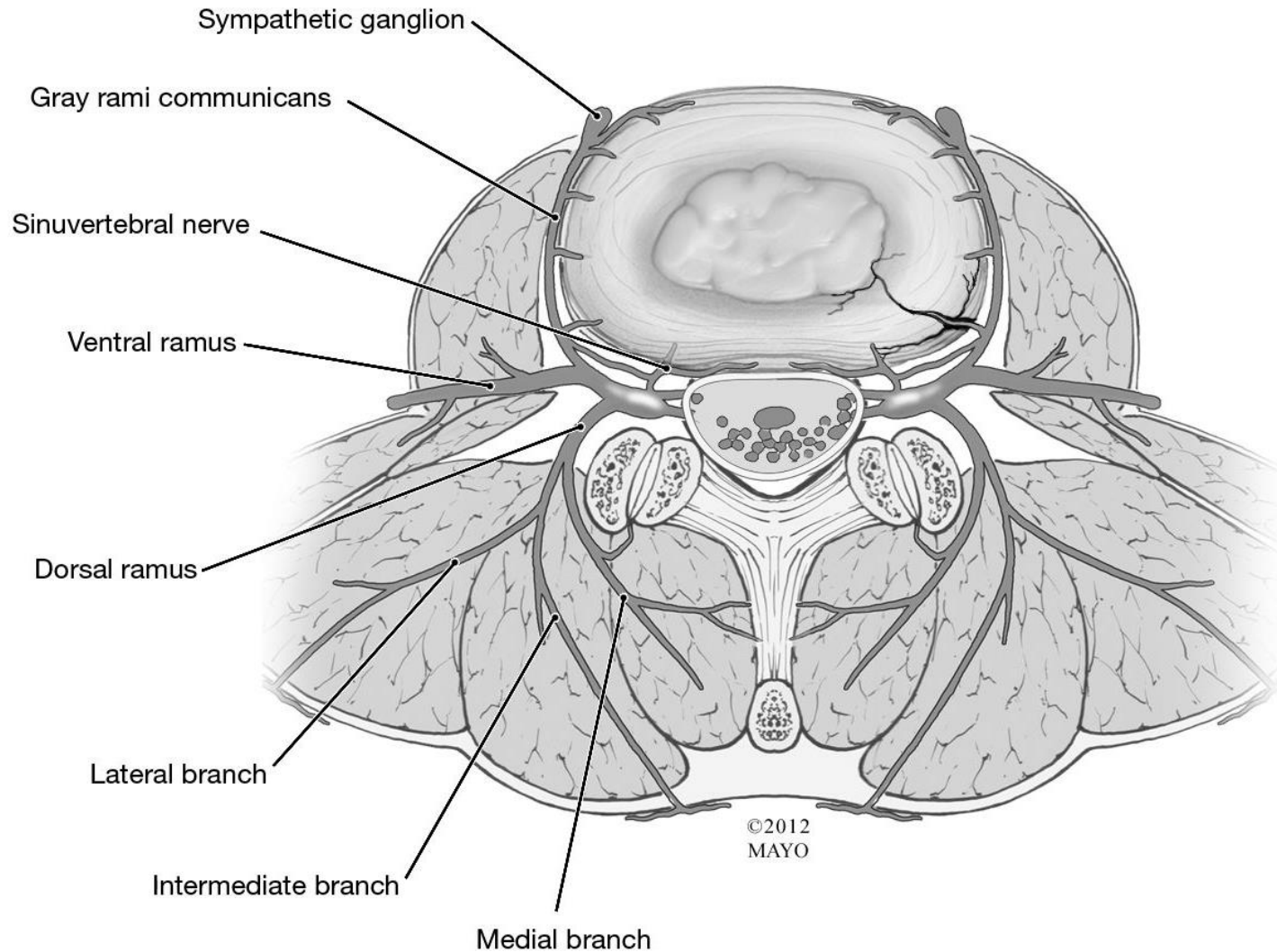
- Pain with increased intradiscal pressure
 - Sitting
 - Bend/lift
 - Valsalva (cough, sneeze)
 - Mornings (due to increased water absorption overnight)
- Midline disc may hurt with extension
- May include instability symptoms of catch/shift/crepitus, pain with arising from flexion and transitional movements
- Hx of persistent pain between acute episodes, loss of extension, “vulnerability” in neutral zone
 - Laslett, et.al., Eur Spine J. 2006 Oct; 15(10):1473-84
- Centralization of pain with McKenzie evaluation
 - Sensitivity 40%, specificity 94%, positive likelihood ratio 6.9
 - Spine J. 2005 Jul-Aug;5(4):370-80

Diagnostic Confirmation: Provocation Discography and Imaging

- Diagnose with provocative discography with manometry using [I]SIS / IASP criteria
 - Concordant >6/10 pain at <20psi above opening pressure
 - Grade III or worse annular tear on modified Dallas discogram scale (tear to outer third of annulus fibrosis)
 - Control level with non-concordant pain <6/10
- Correlation with Modic and high intensity zone (HIZ) MRI findings



Discovertebral Complex: Innervation



- Disc:** outer 1/3
annulus
- Sinuvevertebral nerve
 - Grey rami
 - Sympathetic plexus
 - Neo-innervation

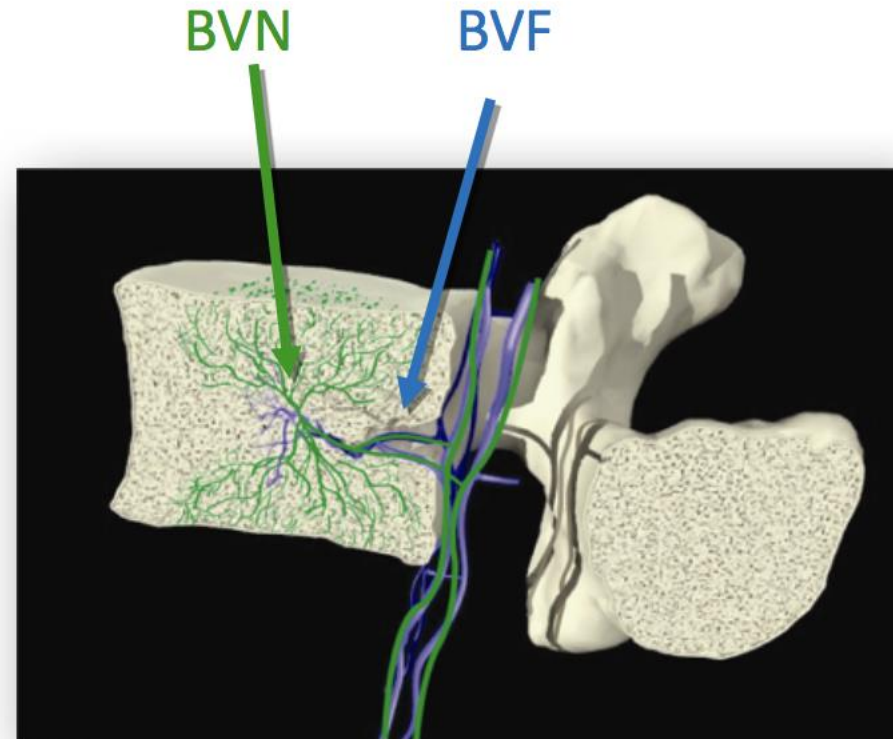
Courtesy Aaron Calodney, MD and
Spine Intervention Society

Anatomy of Innervation of Endplates

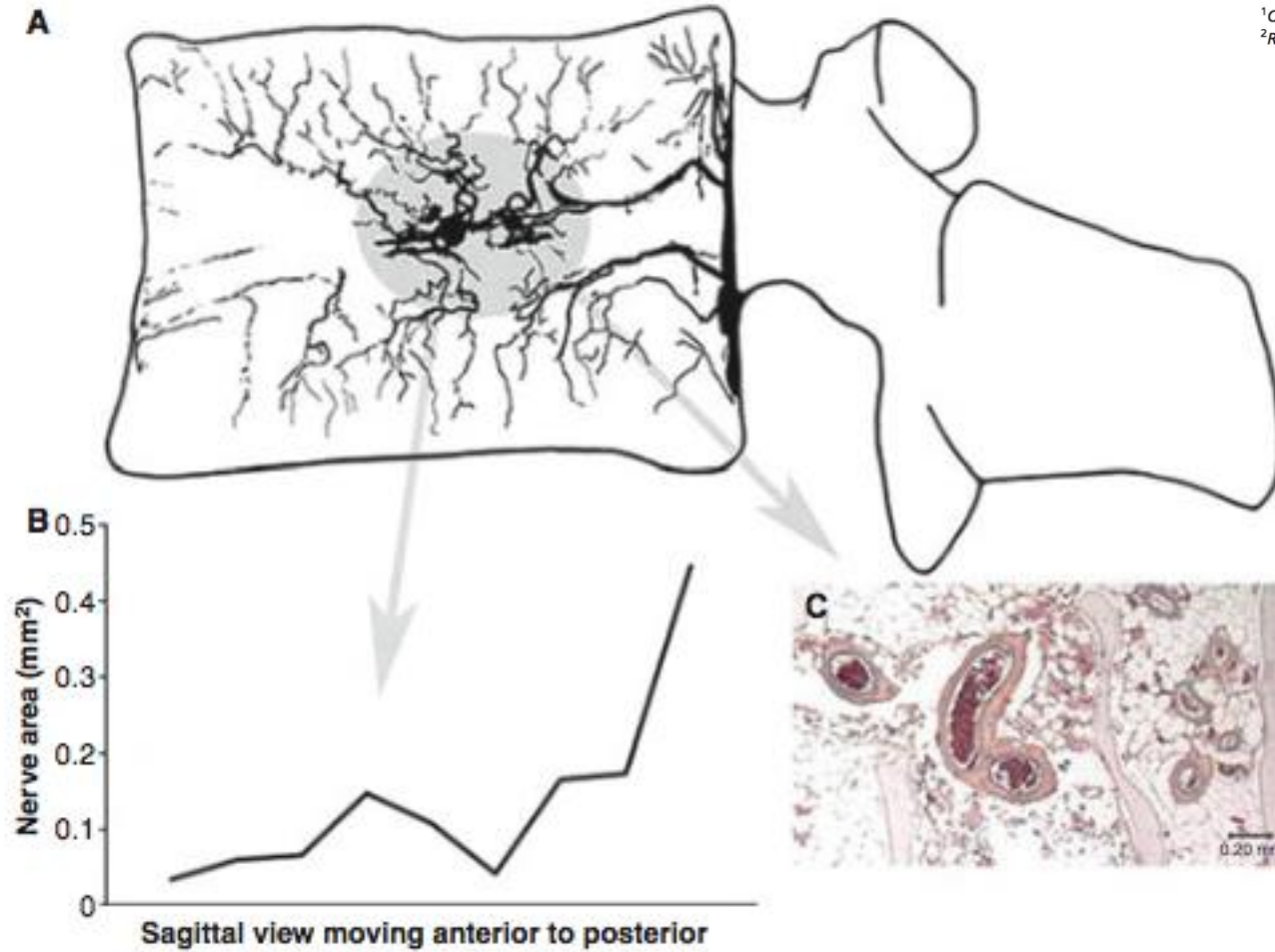
Basivertebral Nerve Anatomy

- BVN enters the vertebral body via the Basivertebral Foramen
- Bifurcates at the terminus of the BVF
- Arborizes towards the endplates.

Bailey et al.



268 PGP 9.5 fibers in the human lumbar vertebra, J. F. Bailey et al.



Innervation patterns of PGP 9.5-positive nerve fibers within the human lumbar vertebra

Jeannie F. Bailey,¹ Ellen Liebenberg,¹ Sean Degmetich^{1,2} and Jeffrey C. Lotz¹

¹Orthopaedic Bioengineering Laboratory, University of California, San Francisco, CA, USA

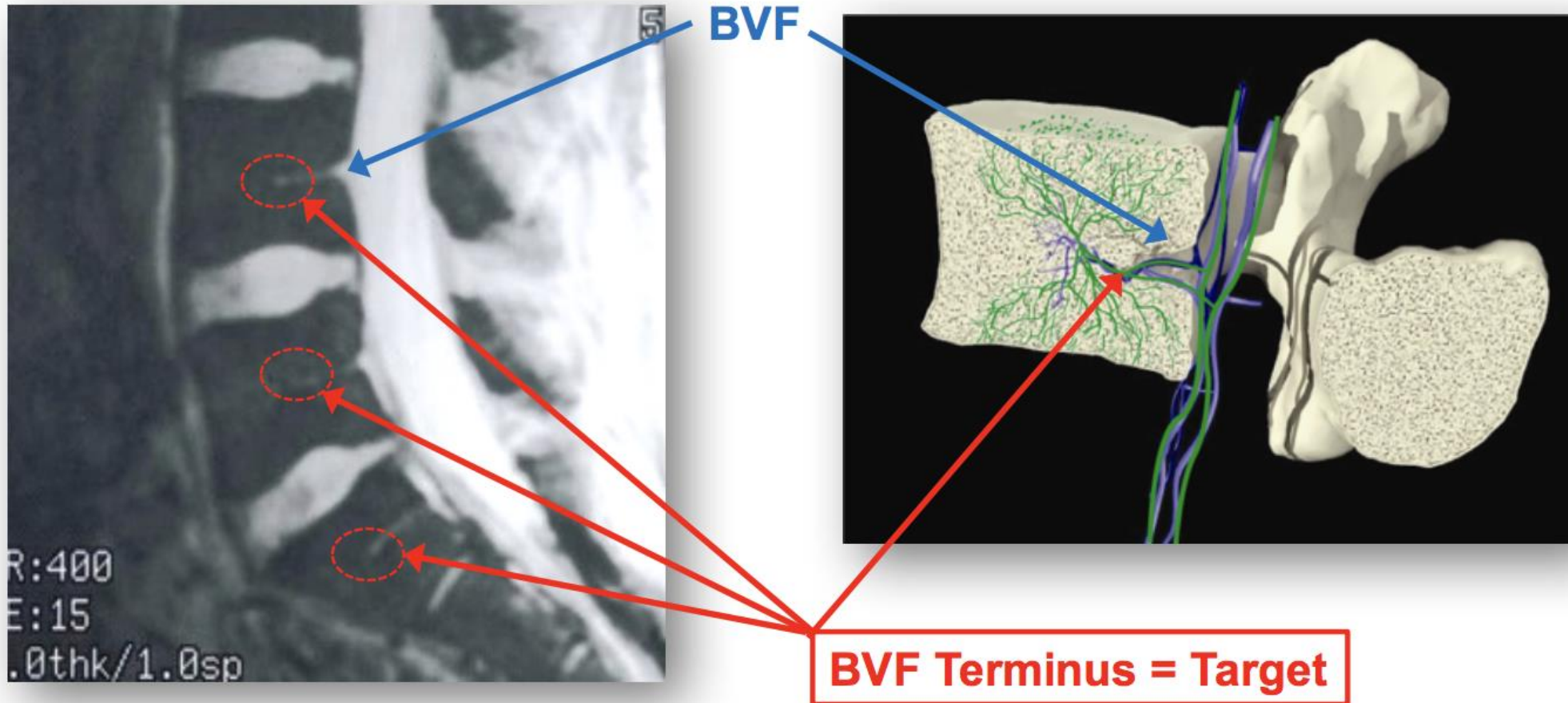
²Relivant Medsystems, Inc., Redwood City, CA, USA

Fig. 5 (A) An adaptation from Crock & Yoshizawa (1976), demonstrating the vascularity seen across a sagittal cross-section of a lumbar vertebra. (B) A nerve density graph from our L4 vertebra correlating the vascular arterial clusters from Crock & Yoshizawa (1976) to high density nerve regions in the center portion of the nerve density graph. (C) An image of a cluster of innervated vessels from a coronal section taken of the center of the vertebral body, verifying the presence of the central arterial clusters within the L4 vertebra.

Basivertebral Nerve Anatomy



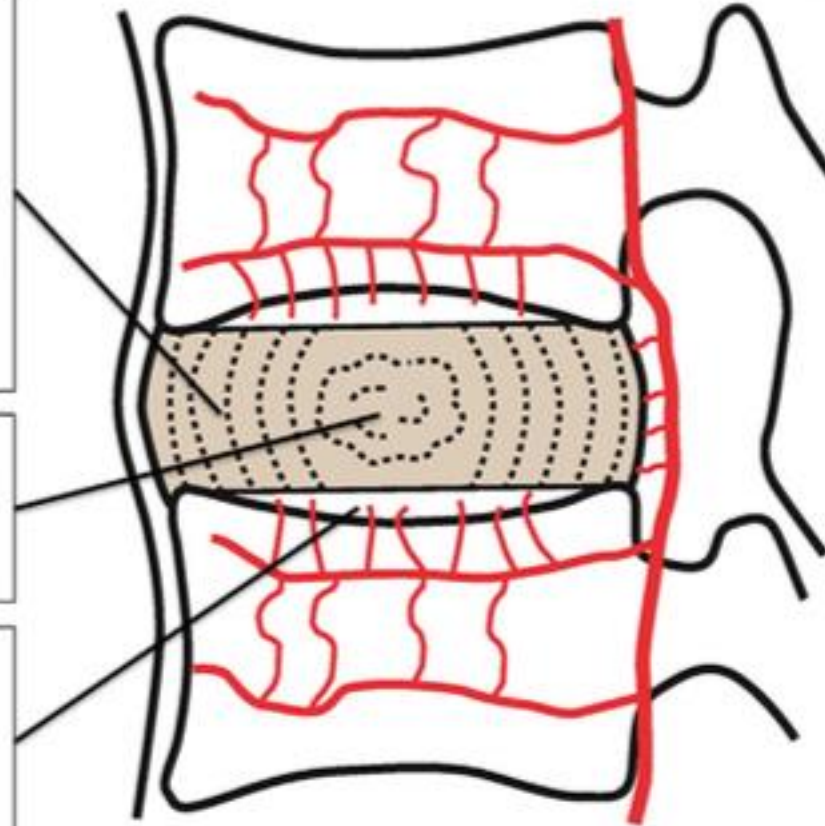
The BVF and BVF Terminus are commonly seen on Lumbar MR images.



AF: Vascularity: Slightly vascularised in the outermost layer; otherwise avascular.
Hypoxia: Becomes hypoxic in a gradient of outer to inner and distance from the end plate.
Dense lamellar structure made of type I collagen withholding biomechanical stress.

NP: Avascular, hypoxia, low pH, low nutrition, low cellularity, high GAG content (negative charge) and type II collagen

End plate: Vascularity in capillaries; avascular, hypoxia, low pH, low nutrition, low cellularity, high GAG content (negative charge)



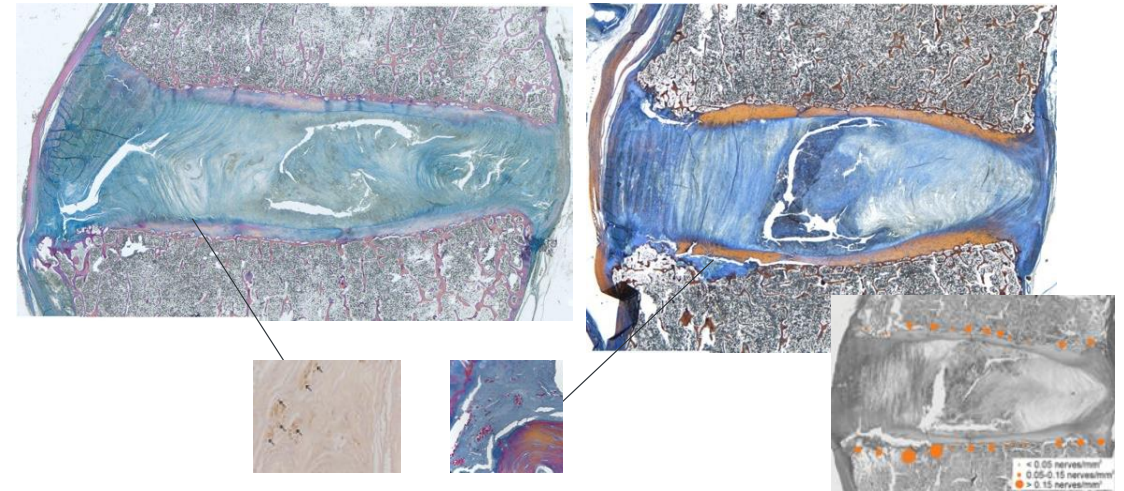
Vascularity: venous system of the vertebral body

Fig. 1. Characteristics of the IVD specific niche. The vasculature that nourishes the IVD mainly consists of the capillary network of the endplate, while a minor portion comes from a small number of capillaries that penetrate only a few millimetres into the outermost annulus fibrosus (AF). Nutrients and metabolites can reach the centre of the disc essentially by fluid flow or diffusion through the vertebral endplates and the AF. As a result, oxygen tension within the disc is significantly reduced towards the centre of the nucleus pulposus (NP) and the disc cell metabolism is partly anaerobic, leading to high concentrations of lactic acid and low pH conditions.

Vertebrogenic Pain is a **Paradigm Shift** in the Science of CLBP

While the disc has historically been the accepted source of the majority of CLBP – research confirms that the vertebral endplates are the cause of CLBP in many patients

- Nociceptors increase in damaged vertebral endplates in patients with severe low back pain¹
- Density of endplate and vertebral body innervation via the basivertebral nerve is higher than that of the disc²
- Damaged endplates with microfractures allow bone marrow and disc tissue to communicate (cross-talk)³
- ‘Frustrated Healing Response’ from persistent cross-talk leads to Modic changes³



- 2x nerves at endplate defects than radial tears⁴

¹ Brown et al. JBJS; 1996

² Fagan A et al. ISSLS Prize Winner; 2003

³ Dudli S et al. ISSLS Prize Winner; 2017

⁴ Fields A et al. The Spine Journal; 2014

End Plate Inflammatory Change

- **Modic Changes:** endplate signal change
 - **Modic I:** Vascularized granulation tissue
 - **Modic II:** Fatty infiltration
 - **Modic III:** Sclerotic change
- **Modic I > II represent an inflammatory state:** increased levels of TNF α reactive cells, & cellular products.

Endplate Inflammatory Change Modic Classification



Modic I



Modic



Modic III

Modic Changes: Association with CLBP

Research Findings:

High correlation between discography and moderate to severe Type 1 and Type 2 Modic changes¹

- 38% sensitivity
- 88% specificity with moderate Modic 1 and 2
- 100% specificity with severe Modic 1 and 2

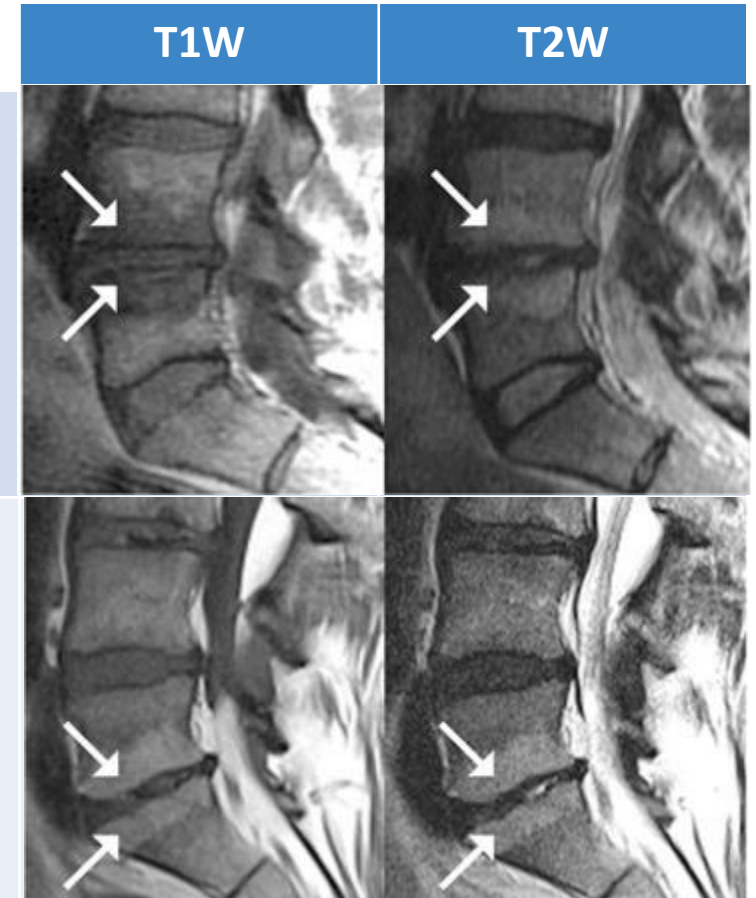
Modic Changes were associated with historical LBP, and with severity and duration of symptoms ($p < .05$)²

These patients seek care more often³, however, Modic Type 1 with CLBP associated with poor outcomes to conservative treatment^{3,4}

Modic Type 1 patients had worse outcomes after discectomy, underscoring the role of the vertebra as a possible pain generator⁵

Modic Type 1

- Hypointense T1W
- Hyperintense T2W MR images



Modic Type 2

- Hyperintense T1W and T2W MR images

¹ Weishaupt D et al. Radiology; 2001

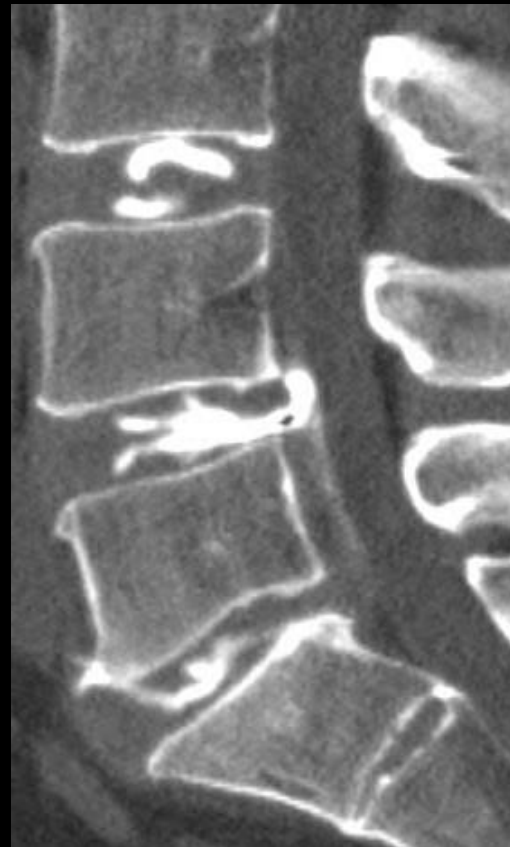
² Mok F et al. The Spine Journal; 2016

³ Jensen OK et al. The Spine Journal; 2014

⁴ Jensen RK et al. BMC Musculoskelet Disord; 2011

⁵ Lurie J et al. Spine; 2013

Modic Change



Modic Change of either Type I or II, involving $> 25\%$ of vertical height of a vertebral body very strongly correlates with positive provocation discography

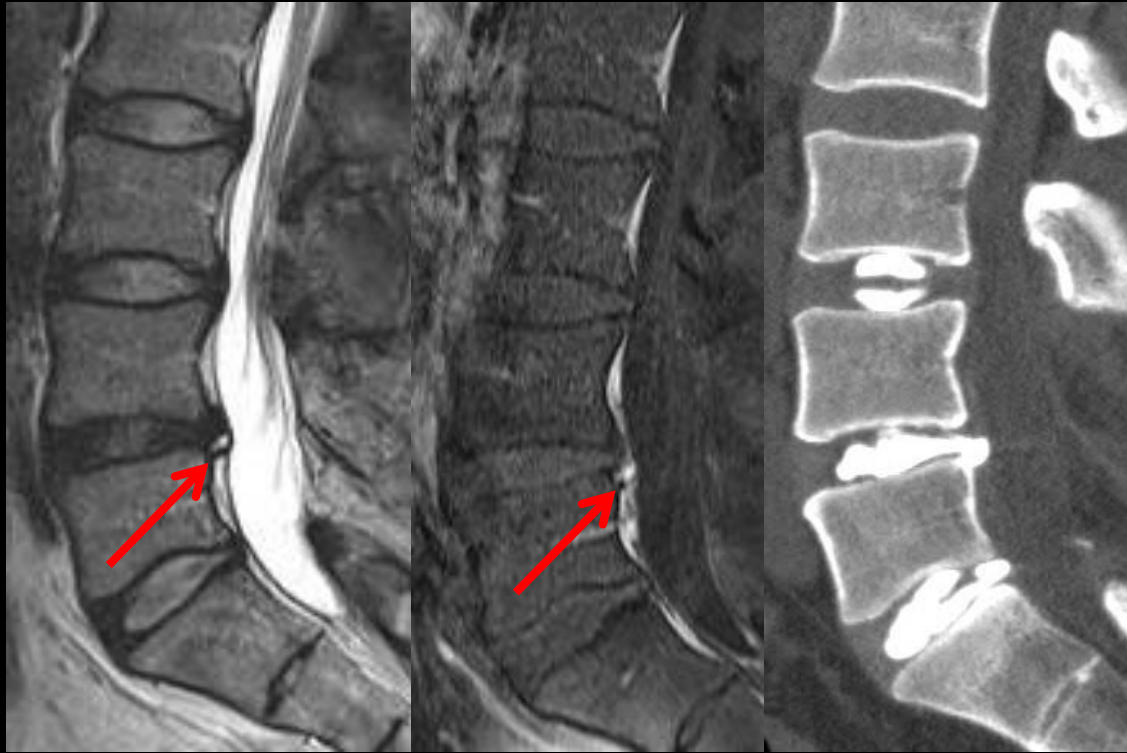
Pooled data yields a +LR of 3.4. This translates into a 69% chance of a painful disc at disc stimulation.

Courtesy SIS

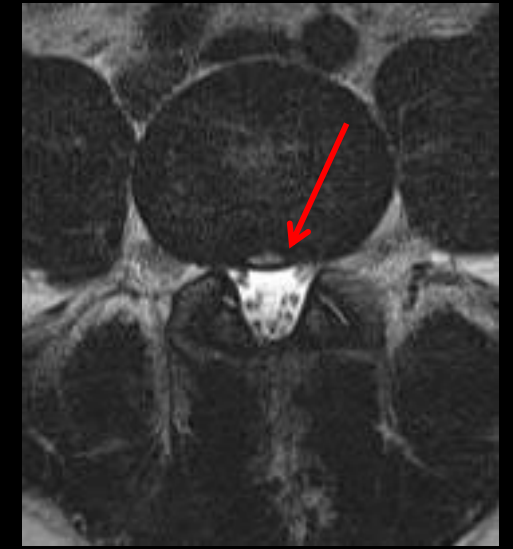
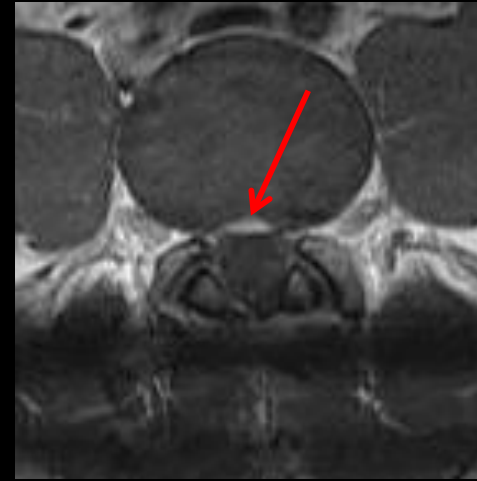
LBP with or without Modic Changes

- MC = > frequency and duration of LBP episodes and > care
 - Jensen et al, 2014
- MC 1 associated with chronic LBP refractory to conservative care
 - Jensen et al, 2011, 2014
- MC 1 = worse discectomy outcomes
 - Lurie et al, 2013

High Intensity Zone (HIZ): Strongly predicts a painful disc



Pooled data: + LR ≈ 4 If prevalence of IDD is 46%, LR of 4 provides 73% confidence of a painful disc at provocation discography



Courtesy SIS



Relievant INTRACEPT

- Transpedicular or extrapedicular approach
- Curved or straight cannula for precise placement
- Bipolar RF lesioning (85C for 15 min)
- 10mm diameter lesion

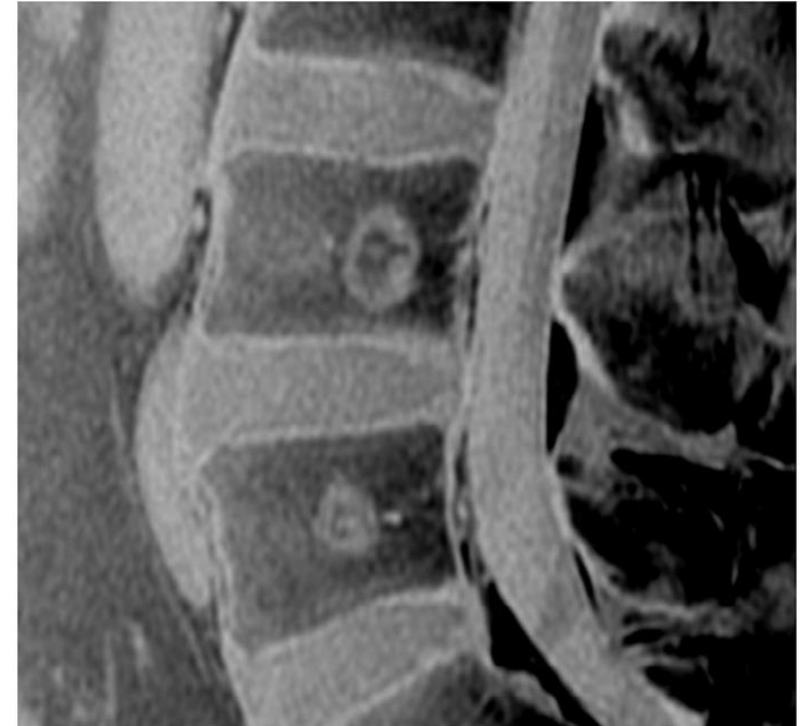
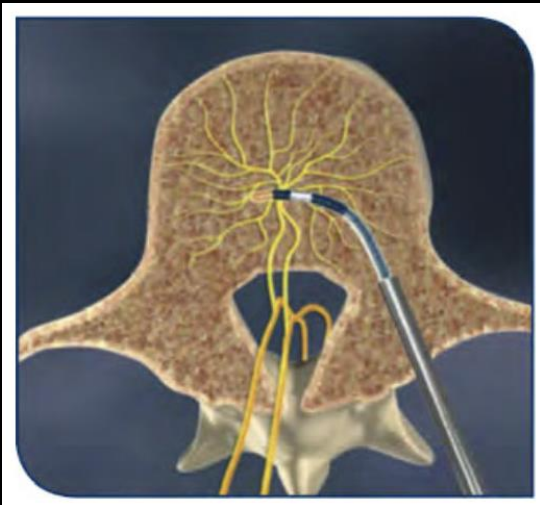


Fig. 4. Representative ablation zones at L4–L5 as seen on sagittal reconstruction at 6 weeks follow-up.

Becker 2017



- 16 treated
 - 8 male, 8 female
 - Mean age 48
 - 6+ months of LBP
 - Failed 3 months of care
 - Modic 1 or 2 changes
 - Positive discography – required only in 2 patients without Modic changes
- Outcome measures (Baseline)
 - ODI (mean 52 +/-13) = primary efficacy endpoint
 - VAS (mean 61 +/-22)

Becker et al, Results

- Outcome measures (3 month)
 - ODI (mean 52 +/-13 to 23 +/-21)
 - Durable to > 1 year
 - VAS (mean 61 +/-22 to 45 +/-35)
- Curved probe introduced late in trial (31/34, 91% proper placement)
 - 14 one level, 2 with two level (3 vertebrae)
- 13/16 treatment success at 12 months
 - Improved ODI
 - Stable neurological status
 - No adverse events

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S. Becker et al. / The Spine Journal 17 (2017) 218–223

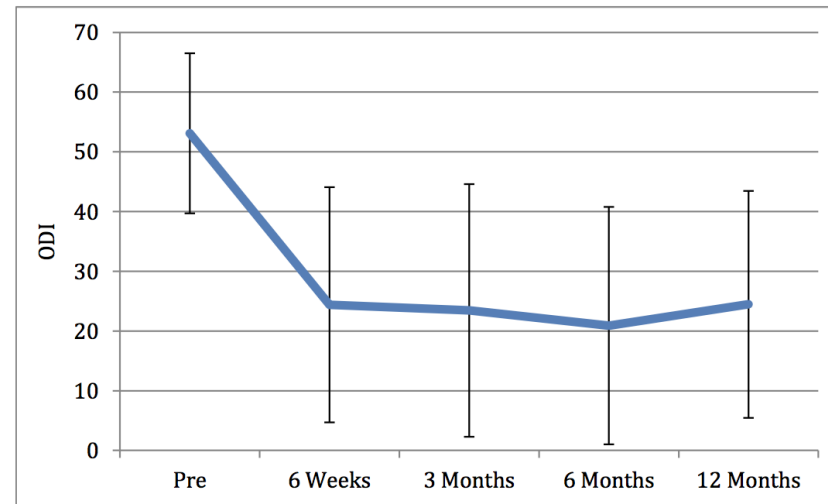


Fig. 3. Evolution of Oswestry Disability Index (ODI) over time in the 16 patients treated with basivertebral nerve (BVN) ablation, statistically significant ($p < .001$) at each time point compared with baseline. Minimum clinically significant improvement is 10 points of ODI change.

Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: a prospective randomized double-blind sham-controlled multi-center study. Fischgrund et al 2018

- **METHODS:**

- A total of 225 patients diagnosed with CLBP were randomized to either a sham (78 patients) or treatment (147 patients) intervention. The mean age within the study was 47 years (range 25-69) and the mean baseline ODI was 42. All patients had Type I or Type II Modic changes of the treated vertebral bodies. Patients were evaluated preoperatively, and at 2 weeks, 6 weeks and 3, 6 and 12 months postoperatively. The primary endpoint was the comparative change in ODI from baseline to 3 months.

- **RESULTS:**

- At 3 months, the average ODI in the treatment arm decreased 20.5 points, as compared to a 15.2 point decrease in the sham arm ($p = 0.019$, per-protocol population). A responder analysis based on ODI decrease ≥ 10 points showed that 75.6% of patients in the treatment arm as compared to 55.3% in the sham control arm exhibited a clinically meaningful improvement at 3 months.

- **CONCLUSION:**

- Patients treated with RF ablation of the BVN for CLBP exhibited significantly greater improvement in ODI at 3 months and a higher responder rate than sham treated controls. BVN ablation represents a potential minimally invasive treatment for the relief of chronic low back pain. These slides can be retrieved under Electronic Supplementary Material.

SMART – Surgical Multi-Center Assessment of RF Ablation of Vertebroprogenic Back Pain

- <https://clinicaltrials.gov/ct2/show/results/NCT01446419?sect=X870156>
- 225 patients, randomized 2:1 vs. sham
- Inclusion Criteria:
 - Skeletally mature patients age 25 - 70 years, inclusive
 - Chronic lower back pain for at least six (6) months
 - Failure to respond to at least six (6) months of non-operative conservative management. The minimum requirement is as follows:
 - Analgesic therapy (minimum of 2 weeks) and a minimum of 4 weeks of NSAID therapy
 - Supervised exercise program (minimum of 12 sessions)
 - Oswestry Disability Index (ODI) at time of evaluation of at least 30 points
 - Baseline Visual Analog Scale (VAS) of at least 4cm on a 10cm scale
 - The following test indicating that the vertebral body is the source of pain:
 1. MRI showing Type 1 or Type II Modic changes at least one vertebral endplate, at one or more levels from L3 to S1

SMART – Surgical Multi-Center Assessment of RF Ablation of Vertebroprogenic Back Pain

- Exclusion Criteria:
- Radicular pain by history or evidence of pain or neurological deficit in a dermatomal zone at or below the medial thigh.
- Previous surgery performed on the lumbar spine
- History of symptomatic spinal stenosis
- History of osteoporotic or tumor-related vertebral body compression fracture
- History of vertebral cancer or spinal metastasis
- History of spinal infection
- Metabolic bone disease (e.g. osteogenesis imperfecta)
- BMI ≥ 40
- Osteoporosis, defined as T score < -2.5
- Any radiographic evidence of other important back pathology, such as:
 - Nerve root compression or severe effacement of the thecal sac that correlates with radicular pain or muscle weakness
 - Disc extrusion or disc protrusion $> 5\text{mm}$
 - Facet arthrosis or facet effusion at any lumbar level that correlates with clinical evidence of facet mediated low back pain
 - Spondylolisthesis 2mm or greater at any level
 - Spondylolysis at any level
- MRI evidence of Modic changes, Type I or Type II at greater than 3 vertebral bodies.
- Any back pathology related to trauma, evidence of vertebral compression fracture or other spinal pathology that could affect assessment of response to back pain
- Demonstrates 3 or more Waddell's signs of Inorganic Behavior

SMART – Surgical Multi-Center Assessment of RF Ablation of Vertebrogenic Back Pain

- Secondary Outcome Measures:
- Patient Success at 3 Months [Time Frame: 3 months]Proportion of subjects with clinical success at 3 months, where clinical success was defined as:
 - 3 month ODI score represented at least a 15-point reduction from baseline
 - no device or procedure related SAE between baseline and 3 mos.
 - no increase in opioid use between procedure and 3 mos.
 - no deficit in a motor or dermatomal sensory group at the treated level at 3 mos.
 - no operative interventions or invasive procedures for lumbar back pain by a pain management or spinal specialist between procedure and 3 mos.
- Change in ODI From Baseline to 6 Months Post-treatment [Time Frame: 6 months]The improvement in ODI at 6 months compared to baseline.

SMART – Surgical Multi-Center Assessment of RF Ablation of Vertebroprogenic Back Pain

- Subjects were screened and enrolled at 15 sites in the US and 3 sites in Germany
- 2:1 Randomization (treatment: sham)

Intrasept Treatment	Intrasept Treatment: Percutaneous access and RF ablation of the basivertebral nerve within the lumbar vertebral body to treat chronic axial low back.
Sham Treatment	Sham Treatment: Percutaneous access to the lumbar vertebra, no RF ablation delivered.

SMART – Surgical Multi-Center Assessment of RF Ablation of Vertebrogenic Back Pain

	Intrasept Treatment	Sham Treatment
STARTED	147	78
3 Month Follow-up	146	77
6 Month Follow-up	144	77
12 Month Follow-up	142	77
COMPLETED	142	77
NOT COMPLETED	5	1
Death	1	0
Withdrawal by Subject	1	1
Terminated per protocol	3	0

SMART – Surgical Multi-Center Assessment of RF Ablation of Vertebrogenic Back Pain

	Intrasept Treatment	Sham Treatment
Participants Analyzed [Units: Participants]	128	77
Change in ODI From Baseline to 3 Months Post-treatment [Units: Units on a scale] Least Squares Mean (95% Confidence Interval)	-20.5 (-23.2 to -17.8)	-15.2 (-18.7 to -11.7)

SMART – Surgical Multi-Center Assessment of RF Ablation of Vertebroprogenic Back Pain

	Intrasept Treatment	Sham Treatment
Participants Analyzed [Units: Participants]	128	77
Change in ODI From Baseline to 6 Months Post-treatment [Units: Units on a scale] Least Squares Mean (95% Confidence Interval)	-20.8 (-23.4 to -18.2)	-17.0 (-20.3 to -13.7)

SMART – Surgical Multi-Center Assessment of RF Ablation of Vertebrogenic Back Pain

- Proportion of subjects with clinical success at 3 months, where clinical success was defined as:
- 3 month ODI score represented at least a 15-point reduction from baseline

	Intrasept Treatment	Sham Treatment
Participants Analyzed [Units: Participants]	128	77
Patient Success at 3 Months [Units: Percentage of patients]	55.5	45.5

SMART Study: Effectiveness and Clinical Relevance



CLINICAL OUTCOMES: Statistically Significant and Clinically Meaningful in PP Subjects treated with the Intracept device

- **Primary Efficacy Endpoints Per Protocol (PP)**

- **20 point ODI Improvement vs Baseline** ($p=0.019$)
- **~48% Improvement vs Baseline** ($p=0.012$)

- **Responder Rate**

- **75% Responder Rate** ($p=0.003$)

- **Durability**

- **Sustained Over 24 Months Follow-up**

INTRACEPT Clinical Study

- INTRACEPT: A Prospective, Randomized, Multi-Center Study of Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain. Sponsor: Relievant Medsystems, Inc.,
- Principal Investigator: J. Scott Bainbridge, MD, Bradley Duhon, MD sub-investigator
- <https://clinicaltrials.gov/ct2/show/NCT03246061>

INTRACEPT Clinical Trial

Study Design Summary

TRIAL DESIGN

Prospective, multicenter, RCT Conservative Care vs. Intracept Treatment

Blended physician model – Spine Ortho, Neuro, Interventionists and PM&R

Enrollment Criteria

150 Patients, 1:1 randomization

- Age 25 to 70 years old
- Isolated CLBP
- ≥ 6 months lumbar pain and ≥ 6 months non-responsive to conservative treatment
- Treat L3 to S1 (up to 3 VBs)
- Optional Crossover 12 months
- Modic Type 1 or 2 visible at treated FSU(s)

EFFICACY ENDPOINTS

Primary

- Improvement of function by Oswestry Disability Index (ODI) at 3 months

Additional

- ODI, VAS, SF-36 at 6,9, and 12 mo.
- Health Economics (EQ-5D and SF-6D)
- Opioid Use

A Prospective, Randomized, Multi-Center Study of Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain

Dan Nguyen, MD, Neuroradiology & Pain Solutions of Oklahoma

INTRACEPT Study Design

- Level I, prospective, parallel, multi-center, open label RCT
 - Randomized 1:1 – RF ablation of BVN compared with standard care
 - Standard care included but not limited to PT, injections, medications, manipulation
 - Follow-up at 3, 6, 9, and 12 Months
 - 24 Month follow-up (RF ablation treatment arm)
- Primary Inclusion criteria
 - LBP (> 6 months); Minimum of 6 months conservative care
 - Modic endplate changes (Type 1 or 2) at up to 4 vertebral bodies (L3-S1)
- Primary Exclusion criteria
 - Symptomatic spinal stenosis, radicular pain, instability, ODI < 30
- Outcome Measures
 - Primary Outcomes: Mean difference between arms at 3 months in ODI from baseline
 - Secondary Outcomes: VAS, SF-36, EQ-5D-5L, patient satisfaction

INTRACEPT Interim Analysis

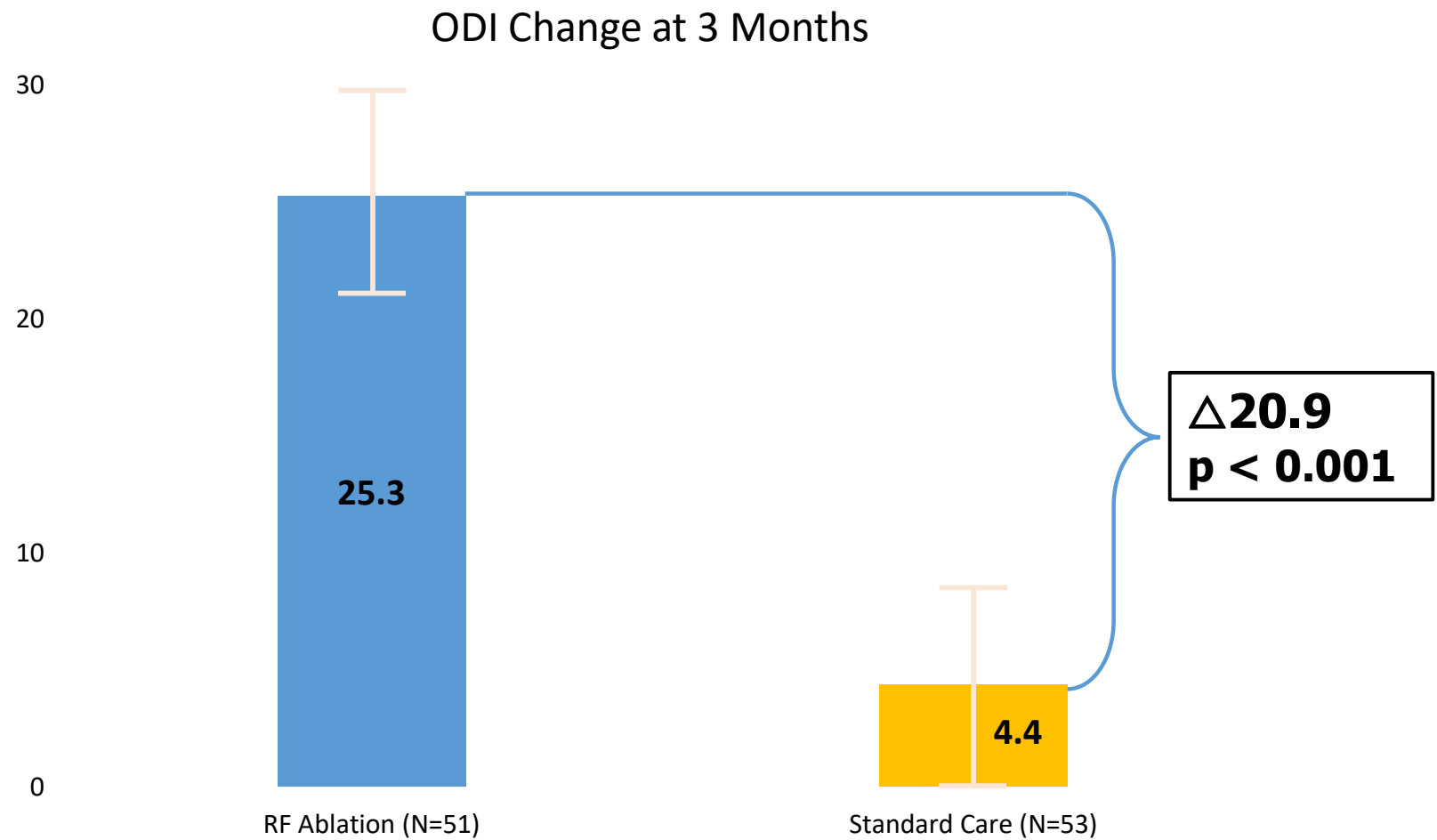
- Pre-specified Interim Analysis at $\geq 60\%$ of patients at 3 month primary endpoint
- Independent data management committee (DMC) met January 25, 2019
 - Primary endpoint and all secondary endpoints demonstrated statistical significance in favor of the RF ablation arm ($p < 0.001$)
 - DMC recommended to halt randomization and allow early cross-over of SC arm patients
- Study population at time of interim analysis:
 - 140 patients randomized
 - 104 patients at 3 month primary endpoint (51 RB ablation; 53 SC) included in ITT analysis
 - $< 1\%$ attrition at primary endpoint
- Pre-specified Interim Analysis at $\geq 60\%$ of patients at 3 month primary endpoint
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INTRACEPT Baseline Characteristics

	Interim Total (N=104)	RF Ablation (N=51)	Standard Care (N=53)	P-Value*
Mean Age (years), <i>SD (Range)</i>	50.0, 10.1 (26-70)	50.0, 9.0 (32-68)	50.0, 11.1 (26-70)	
Male, <i>n (%)</i>	51 (49.0%)	26 (51.0%)	25 (47.2%)	
Duration low back symptoms, <i>n (%)</i>				0.389
≥ 5 years	70 (67.3%)	32 (62.7%)	38 (71.7%)	
Treatment History <i>n (%)</i>				
Opioid Use at Baseline	33 (32%)	18 (35.3%)	15 (28.3%)	
Injections	73 (70.2%)	31 (60.8%)	42 (79.2%)	
Past Lower Back Surgeries	12 (11.5%)	6 (11.8%)	6 (11.3%)	
Baseline Mean ODI, <i>SD (Range)</i>	46.1, 11.30 (30-88)	44.0, 11.08 (30-70)	48.1, 11.24 (32-88)	0.064
Baseline Mean VAS, <i>SD (Range)</i>	6.67, 1.33 (4.0-10.0)	6.51, 1.31 (4.0-10.0)	6.82, 1.34 (4.0-10.0)	0.231

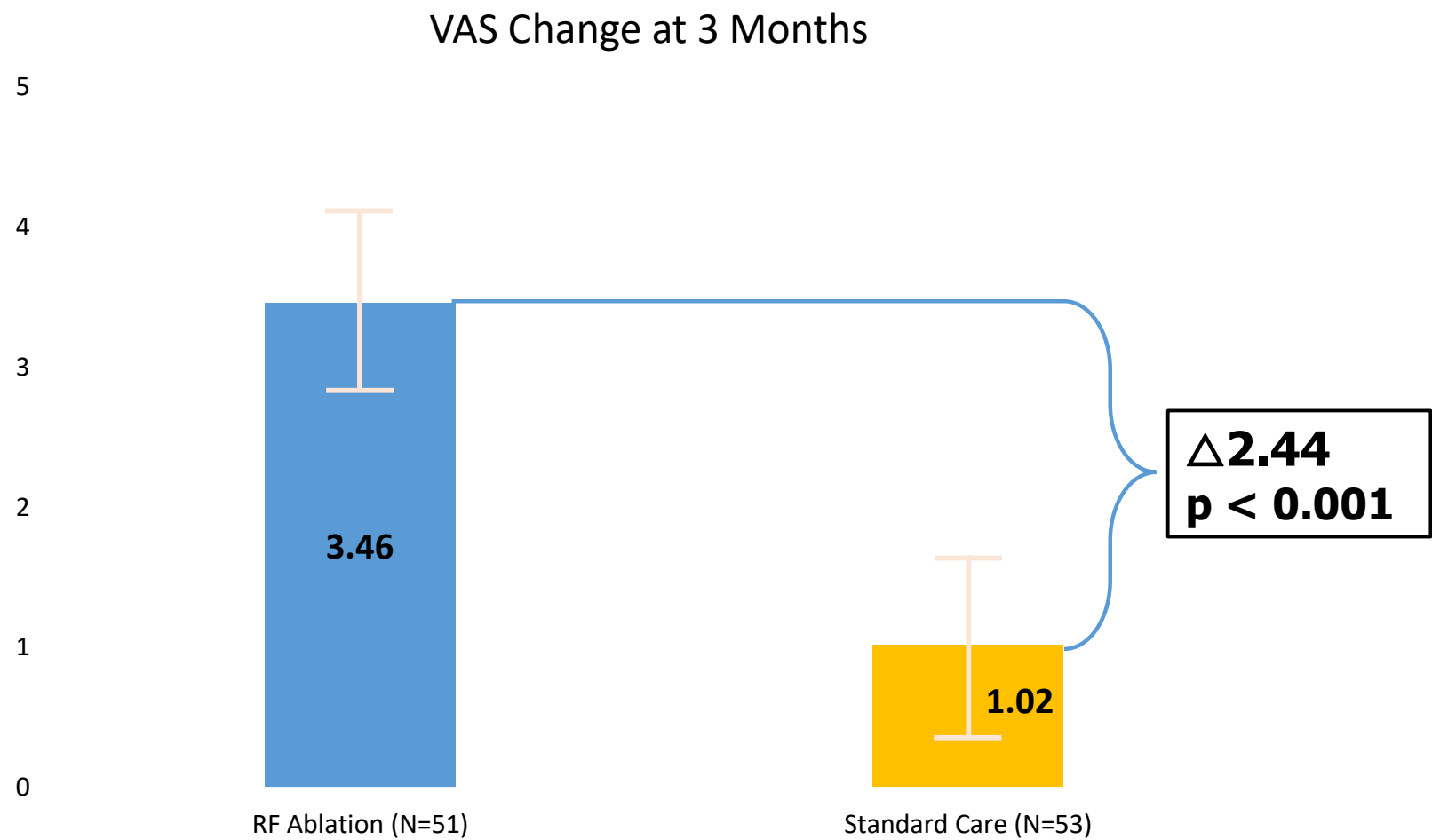
* P-value from Fischer's Exact test

Primary Endpoint: Δ ODI Difference Between Arms



- LS Mean difference (p-value per ANCOVA) in ODI between the RF ablation and SC arms, adjusted for baseline ODI

Secondary Endpoint: Δ VAS Difference Between Arms



- LS Mean difference (p-value per ANCOVA) in VAS between the RF ablation and SC arms, adjusted for baseline VAS

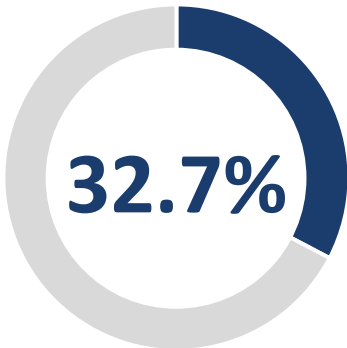
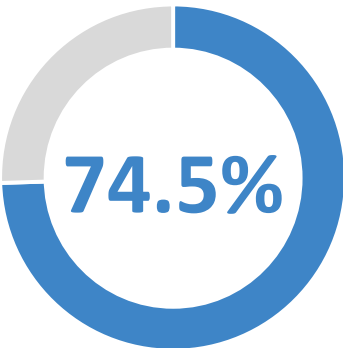
ODI Responder Rates at 3 Months

Responder Rates ODI – ITT (N=104)
(Baseline to 3 Months)

RF Ablation

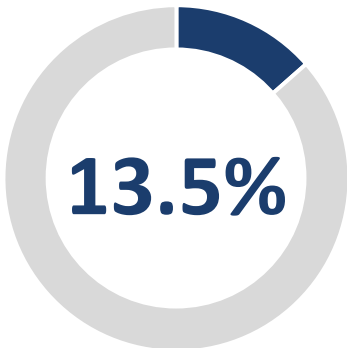
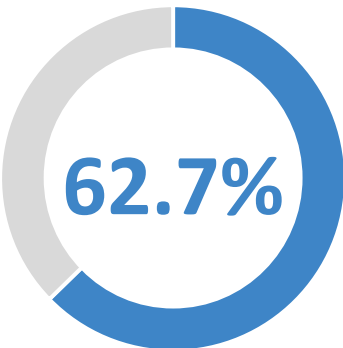
Standard Care

Patients with
≥ 10-point
reduction in ODI



p<0.001

Patients with
≥ 20-point
reduction in ODI



p<0.001

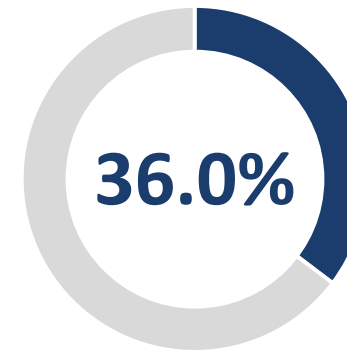
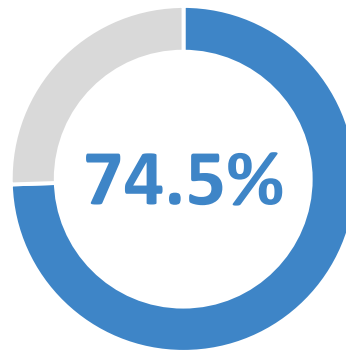
VAS Responder Rates at 3 Months

Responder Rates VAS – ITT (N=104) (Baseline to 3 Months)

RF Ablation

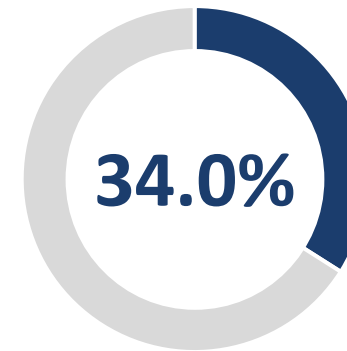
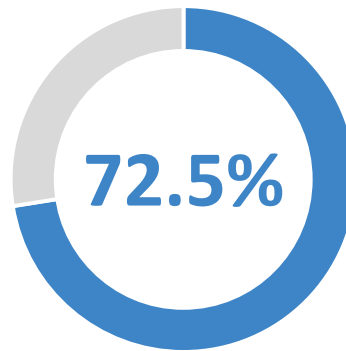
Standard Care

Patients with
 ≥ 1.5 cm
VAS decrease



p<0.001

Patients with
 ≥ 2.0 cm
VAS decrease



p<0.001

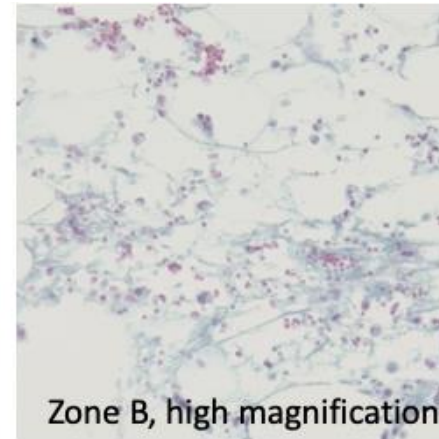
Established Safety Profile

INTRACEPT Study

- No device related AEs
- All procedure related AEs were considered mild
- Resolved with oral medications

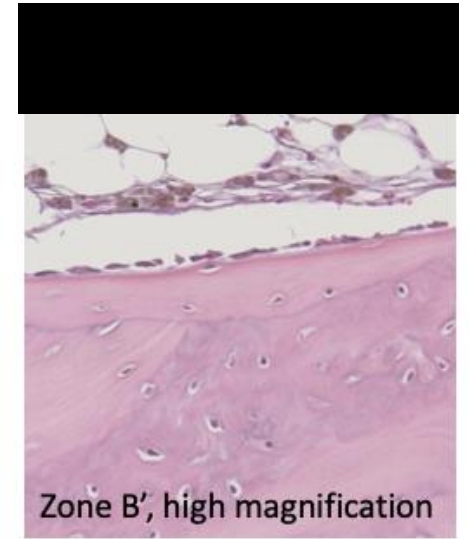
Pre-clinical (bovine) study

- No evidence of AVN
- No organized nerve regeneration
- No biomechanical instability



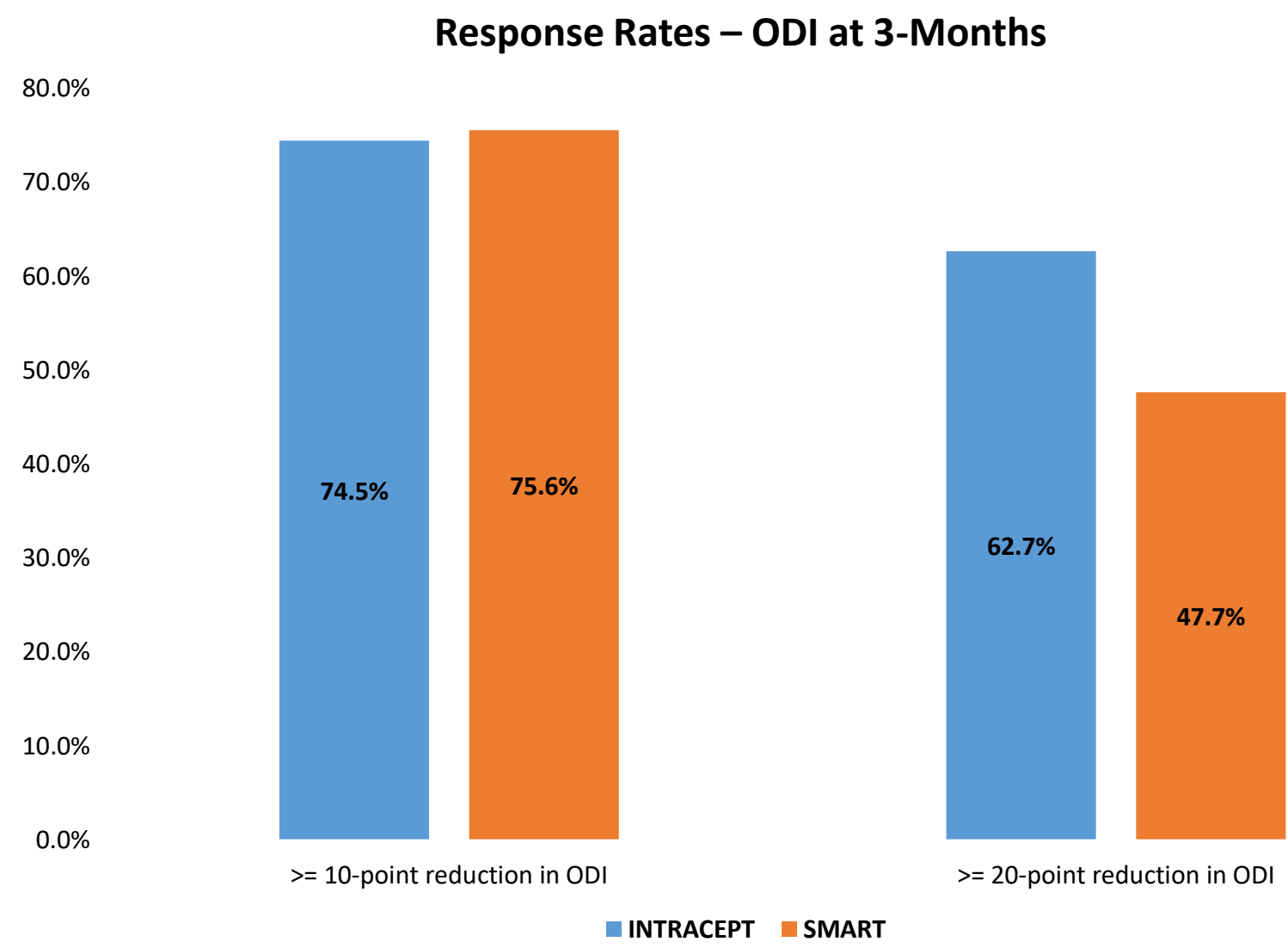
Zone B, high magnification

1 week histology

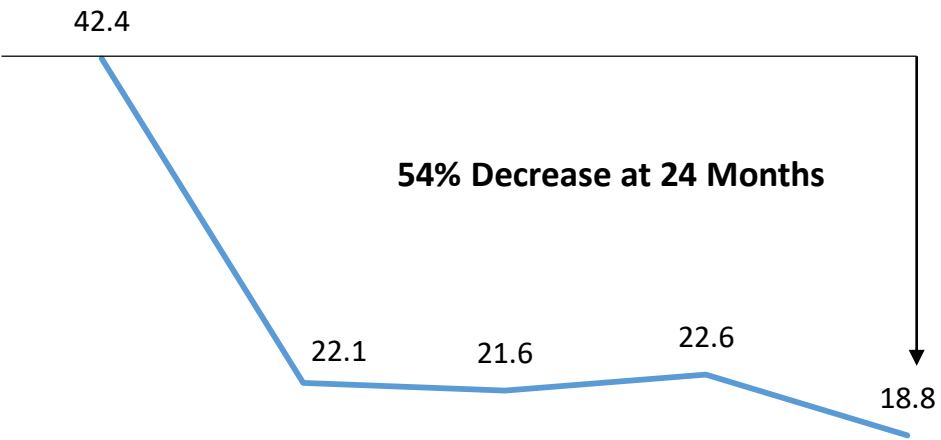
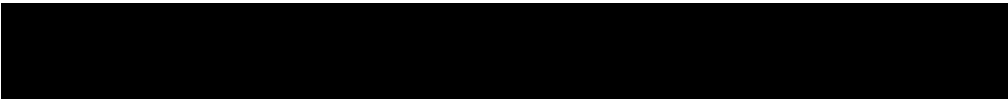


Zone B', high magnification

Consistent Outcomes in Two Level I RCTs



Level I SMART Trial Supports Durable Results



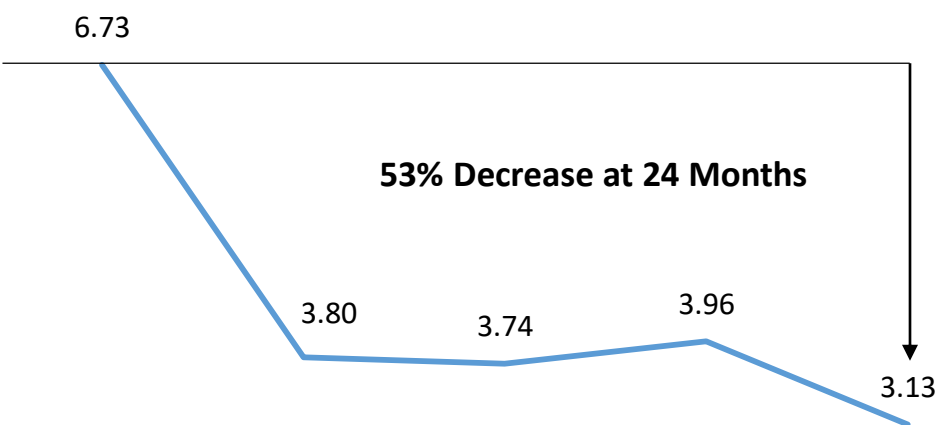
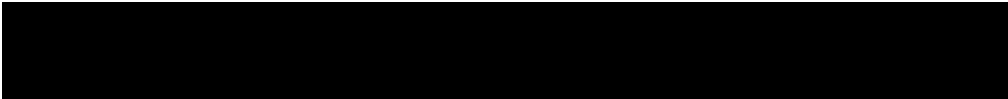
Baseline
n=128

3 Months
n=128

6 Months
n=128

12 Months
n=128

24 Months
n=106*



Baseline
n=128

3 Months
n=127

6 Months
n=126

12 Months
n=125

24 Months
n=104*

*LOCF imputation used at all time points except 24 months where all observed data without imputation used

BVN Ablation Conclusion: INTRACEPT and SMART RCTs

- Highly significant treatment effect against standard care ($p < 0.001$)
 - 4x the treatment effect of fusion over standard care from recent Meta-analysis
 - Improves function in working population (mean age of 50)
- Level I SMART Trial data support durable results at 2 years
- Two Level I RCTs validate significant improvement in function and pain from baseline
- Adverse event profile and animal studies support safety
 - No serious device related AEs; procedure AEs mild in severity
 - No regeneration of nerve, no AVN, or biomechanical instability post-RF
- Modic Changes have clinical implications



Photo by Paul Dreyfuss