Vertebrogenic Pain and Basivertebral Nerve Radiofrequency Ablation

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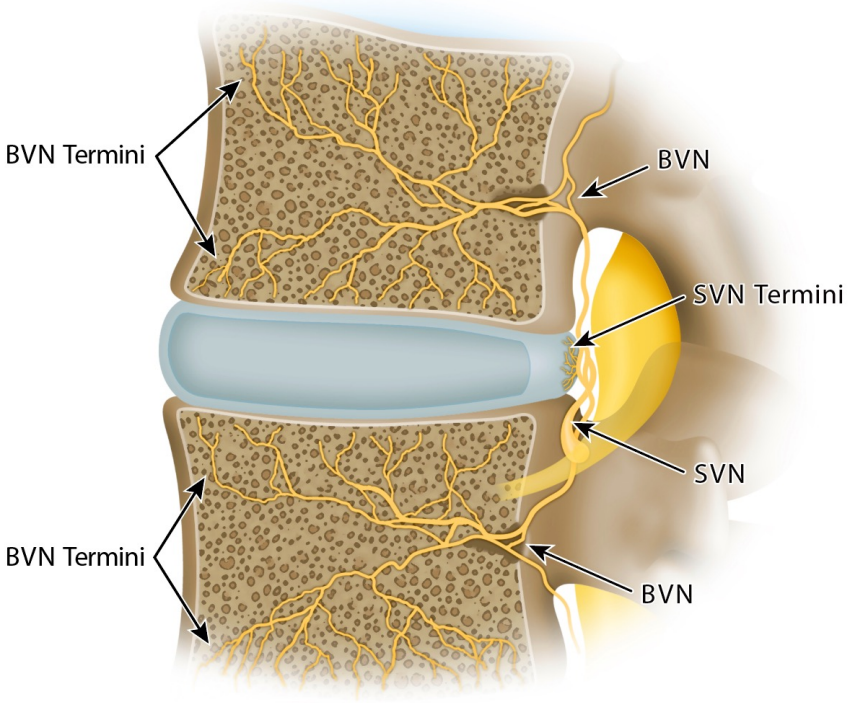
Disclosures

- **Research Grants**: Avanos Medical, Boston Scientific, Relievant Medsystems, SPR Therapeutics, US Department of Defense, Foundation of PM&R, National Institutes of Health, Skaggs Research Foundation, Spine Intervention Society, University of Utah Cell Therapy and Regenerative Medicine Program
- **Board of Directors**: Spine Intervention Society (SIS), Pacific Spine and Pain Society (PSPS), American Board of Pain Medicine (ABPM)
- **Journal Editorial Boards**: *Pain Medicine (Deputy Editor-in-Chief)*, *Physical Medicine & Rehabilitation, The Spine Journal*
- **Data Monitoring Board:** FUSmobile
- **Consulting**: Saol Therapeutics, SI Bone, Stryker

Vertebral Endplate Pain

- *Pathophysiology*
- *Clinical Phenotype*
- *Treatment*

Endplates are *vulnerable* to large forces



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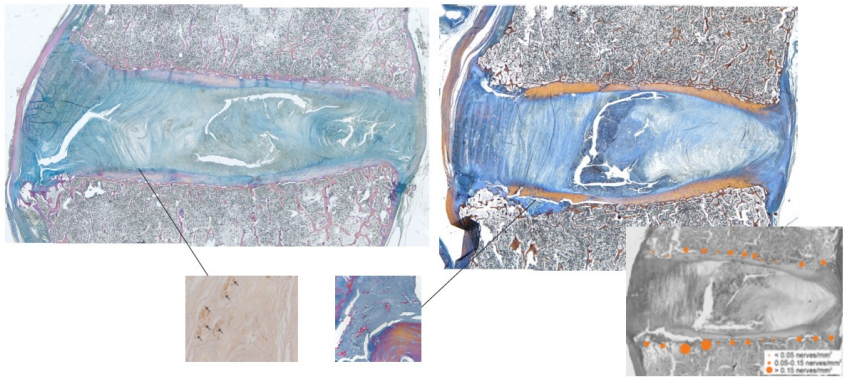
Endplates are *vulnerable* to large forces

- Damage/defects -> *leakage of proinflammatory factors* from the nucleus pulposus



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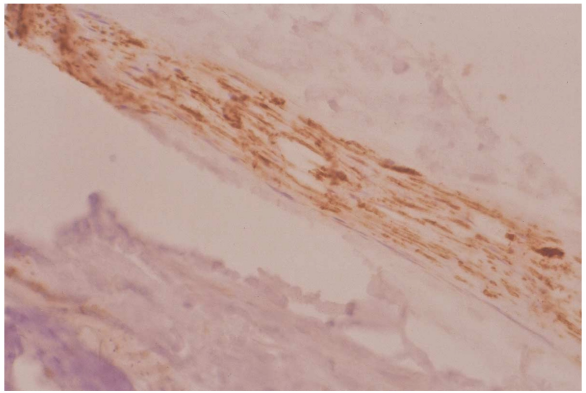
Endplates are *vulnerable* to large forces

- Damage/defects -> *leakage of proinflammatory factors* from the nucleus pulposus
  - Chemical *sensitization*
  - *Increased nerve fiber density*
  - Nociceptor *proliferation* at basivertebral nerve termini



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Bailey JF, Liebenberg E, Degmetich S, Lotz JC. Innervation patterns of PGP 9.5-positive nerve fibers within the human lumbar vertebra. J Anat. 2011 Mar;218(3):263–70.

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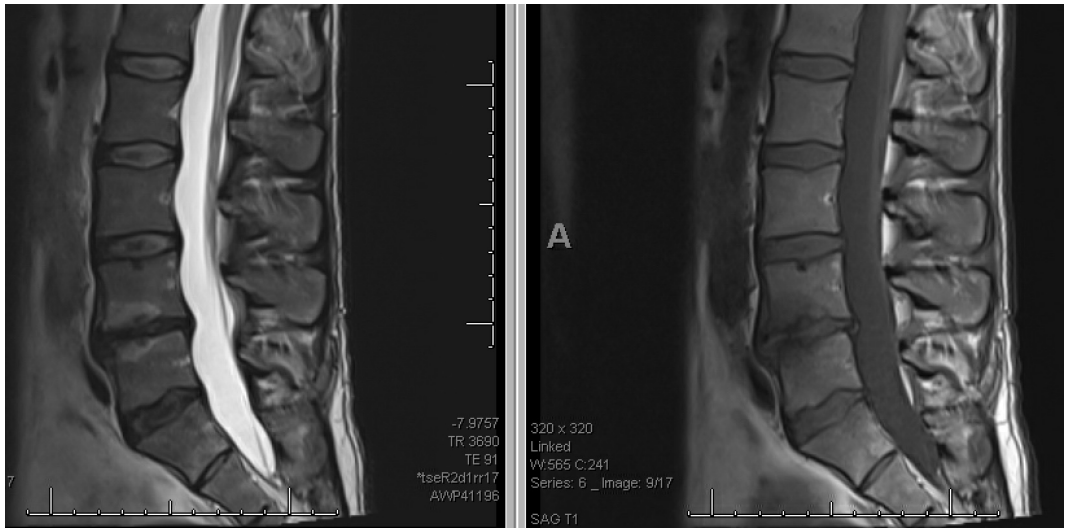
Patients with Chronic LBP:

- *Basivertebral nerve termini*: Immunoreactive to substance P at levels with Modic 1 or 2 changes

- *Increase* in CGRP containing sensory nerves compared with normal levels.



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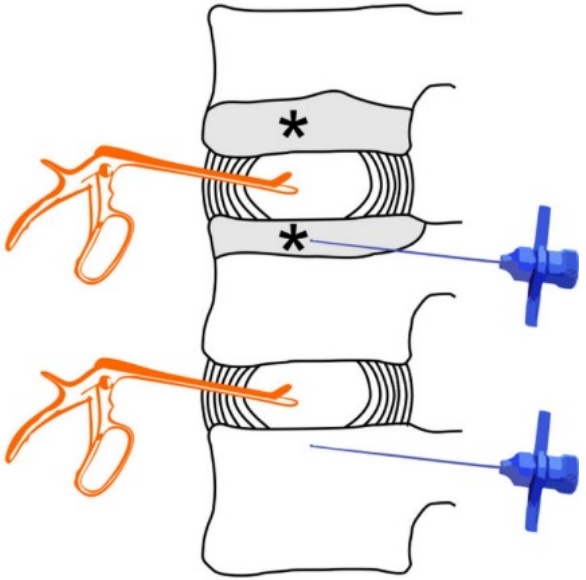
Eur Spine J. 2017 May;26(5):1362-1373. doi: 10.1007/s00586-017-4955-4. Epub 2017 Jan 31.

ISSLS PRIZE IN BASIC SCIENCE 2017: Intervertebral disc/bone marrow cross-talk with Modic changes.

Dudli S[1], Sing DC[2], Hu SS[3], Berven SH[2], Burch S[2], Deviren V[2], Cheng I[3], Tay BKB[2], Alamin TF[2], Ith MAM[3], Pietras EM[4], Lotz JC[2].

- *N=22: undergoing 2 level fusion*
- *Modic changes at one level and one without (control)*
- Gene expression profiles of the marrow and disc assessed *by comparing disc/bone marrow features at levels with Modic relative to those without.*



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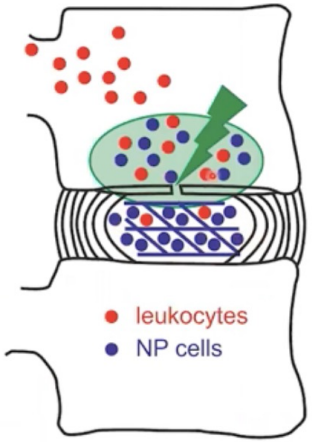
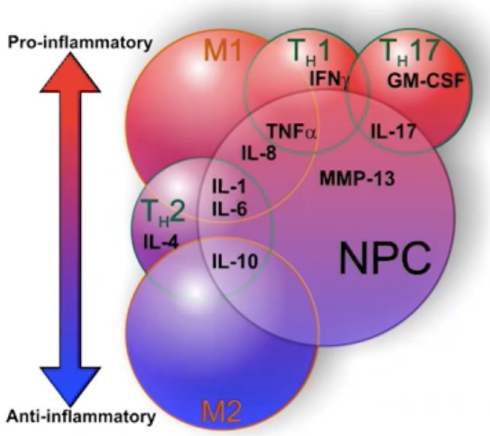
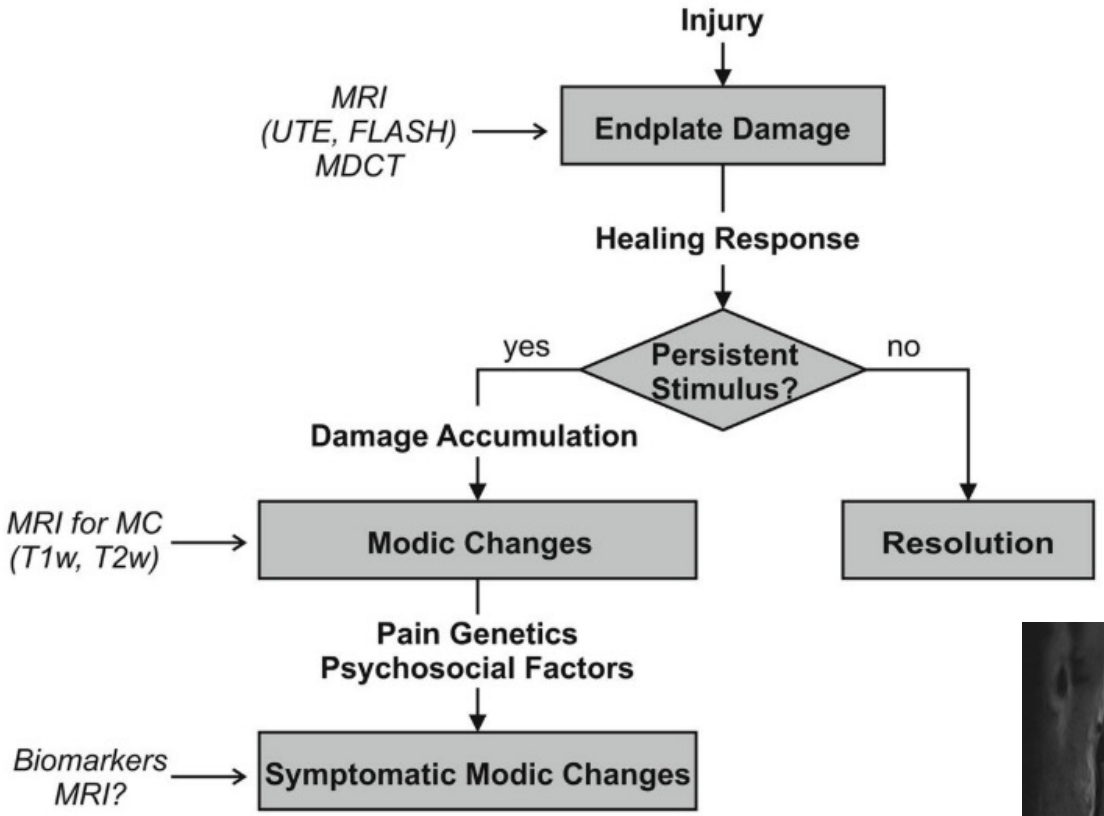
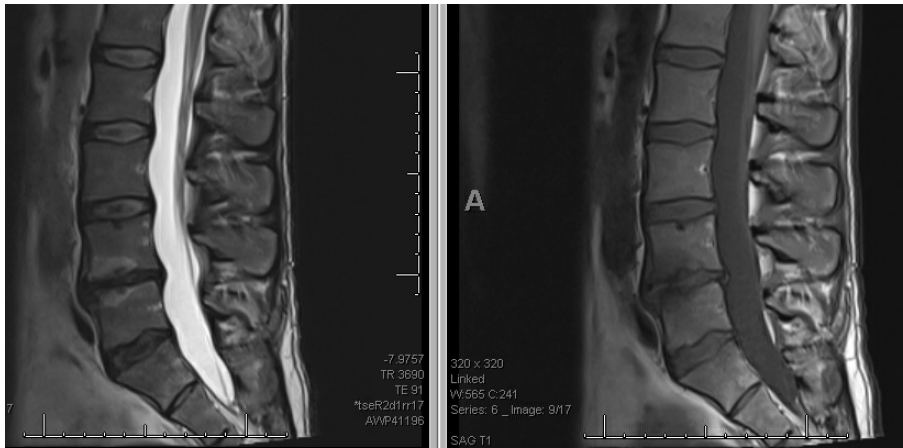
- *Pro-osteoclastic changes in MC2 levels, an inflammatory dysmyelopoiesis with fibrogenic changes in MC1 and MC2 marrow*

- *Upregulation of neurotrophic receptors in MC1 and MC2 bone marrow and discs.*






Injury
MRI
(UTE, FLASH)
MDCT
Endplate Damage
Healing Response
yes
Persistent
Stimulus?
no
Damage Accumulation
MRI for MC
(T1w, T2w)
Modic Changes
Resolution
Pain Genetics
Psychosocial Factors
Biomarkers
MRI?
Symptomatic Modic Changes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TE 91
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Clinical Phenotype of Vertebrogenic Pain?

- How do we *recognize* patients with Vertebrogenic pain?
- How do we *best select* patients for the BVNA procedure?

Pain Medicine, 23(S2), 2022, S2–S13
doi: 10.1093/pm/pnac050
Original Research Article

OXFORD

The Relationship Between Patient Demographic and Clinical Characteristics and Successful Treatment Outcomes After Basivertebral Nerve Radiofrequency Ablation: A Pooled Cohort Study of Three Prospective Clinical Trials

Barrett S. Boody, MD,* Beau P. Sperry, BA,† Katrina Harper, MS,‡ Kevin Macadaeg, MD,* and Zachary L. McCormick, MD§

Pain Medicine, 23(S2), 2022, S14–S33
https://doi.org/10.1093/pm/pnac069
Original Research Article

OXFORD

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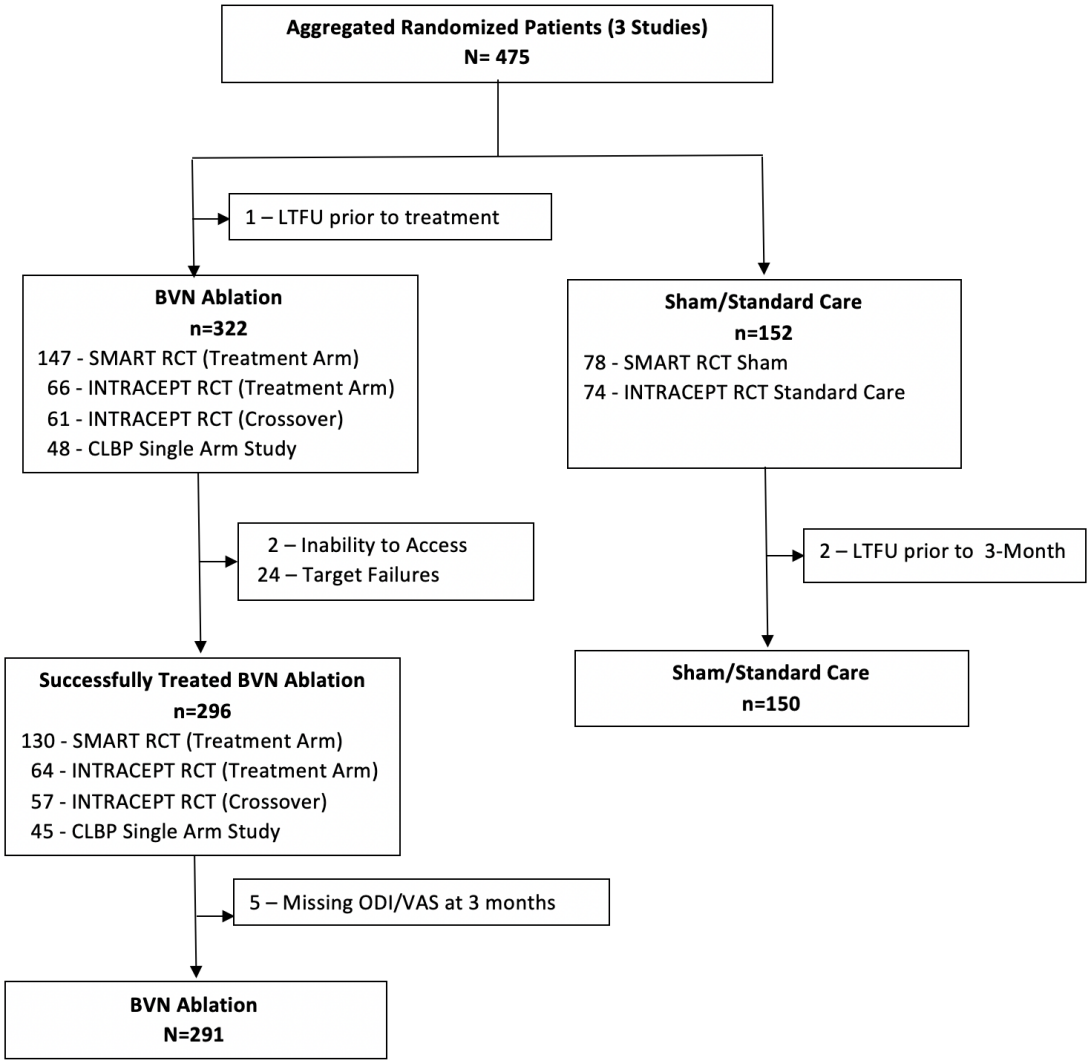
Pain Medicine, 23(S2), 2022, S34–S49
https://doi.org/10.1093/pm/pnac093
Original Research Article

OXFORD

Magnetic Resonance Imaging Characteristics Associated with Treatment Success from Basivertebral Nerve Ablation: An Aggregated Cohort Study of Multicenter Prospective Clinical Trials Data

Zachary L. McCormick, MD,* Aaron Conger, DO,* Matthew Smuck, MD,† Jeffrey C. Lotz, PhD,‡ Joshua A. Hirsch, MD,§ Colton Hickman, DO,* Katrina Harper, MS,¶ and Taylor R. Burnham, DO, MS*

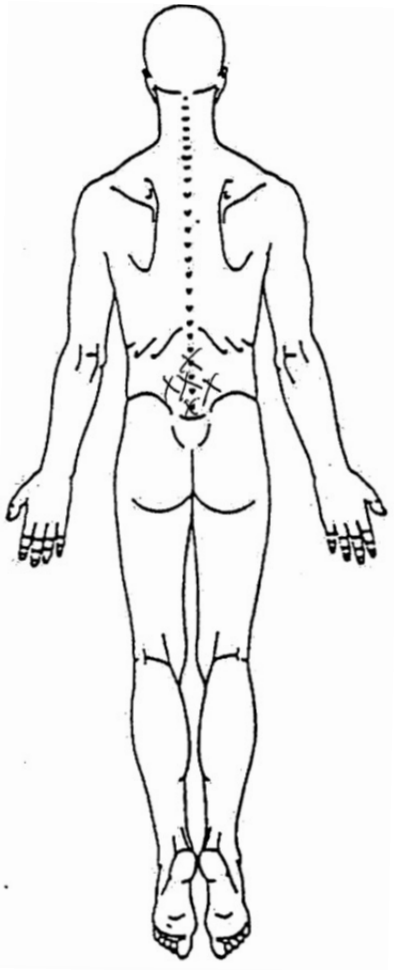


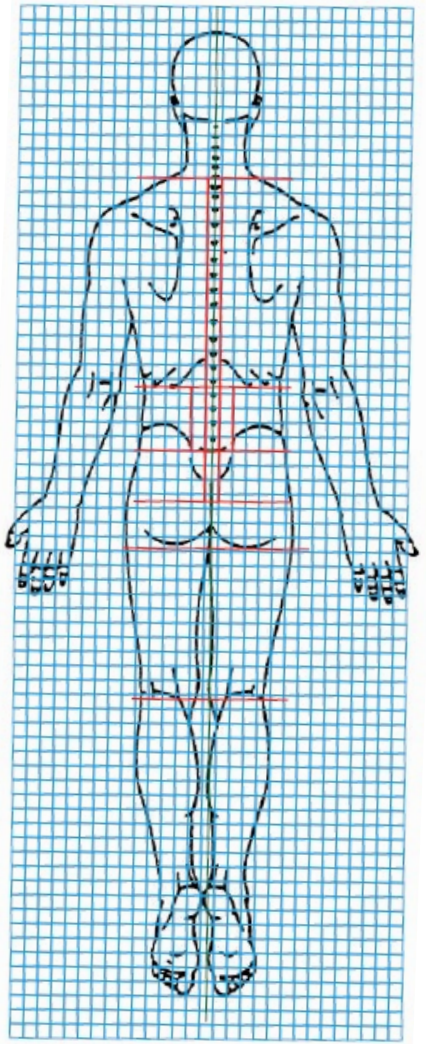
Inclusion Criteria	Exclusion Criteria
1. Skeletally mature patients with chronic (≥6 months) isolated lumbar back pain, who had not responded to at least 6 months of nonoperative management	1. MRI evidence of Modic at levels other than L3–S1
2. Type 1 or Type 2 Modic changes at one or more vertebral body for levels L3–S1	2. Radicular pain (defined as nerve pain following a dermatomal distribution that correlates with nerve compression in imaging)
3. Minimum ODI of 30 points (100-point scale)	3. Previous lumbar spine surgery (discectomy/laminectomy allowed if >6 months before baseline and radicular pain resolved)
4. Minimum VAS of 4 cm (10-cm scale) (average low back pain in past 7 days)	4. Symptomatic spinal stenosis (defined as the presence of neurogenic claudication and confirmed by imaging)
5. Ability to provide informed consent, read, and complete questionnaires	5. Metabolic bone disease, spine fragility fracture history, or trauma/compression fracture, or spinal cancer
	6. Spine infection, active systemic infection, bleeding diathesis
	7. Radiographic evidence of other pain etiology
	8. Disc extrusion or protrusion >5 mm
	9. Spondylolisthesis >2 mm at any level
	10. Spondylolysis at any level
	11. Facet arthrosis/effusion correlated with facet-mediated LBP
	12. BDI >24 or ≥3 Waddell's signs
	13. Compensated injury or litigation
	14. Currently taking extended-release narcotics with addiction behaviors
	15. BMI >40
	16. Bedbound or neurological condition that prevents early mobility or any medical condition that impairs follow-up
	17. Contraindication to MRI, allergies to components of the device, or active implantable devices, pregnant, or lactating

Included Based on *Presumed* Vertebral Endplate Pain

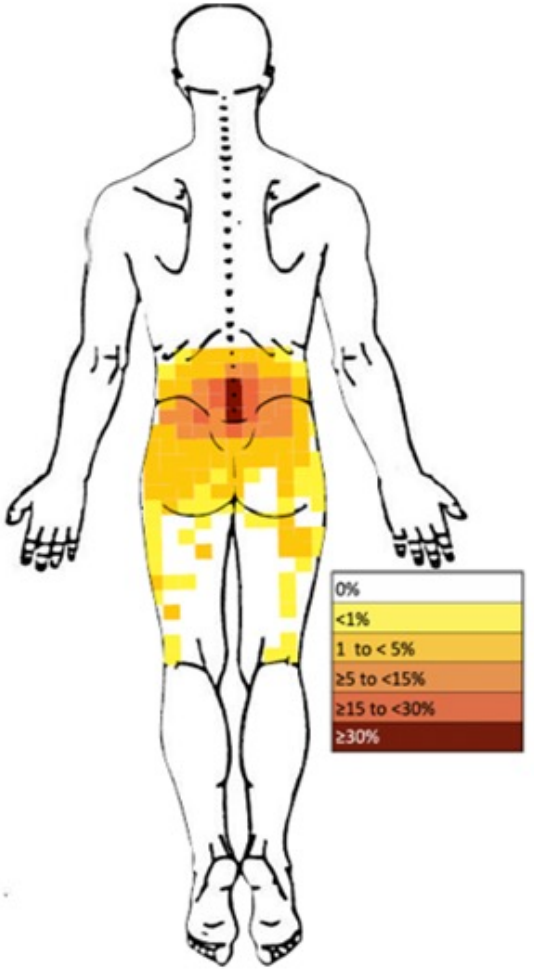
- *Lacked* significant stenosis and/or radicular pathology
- *Lacked* significant spinal instability
- *Lacked* scoliosis
- *Lacked* high depression scores
- *Lacked* morbid obesity

- Grid created in Adobe Illustrator
- *Overlaid* on patient-completed body diagram
- Blinded research assistant:
  - Location of patient markings *translated to binary "1 or 0"* within each grid box

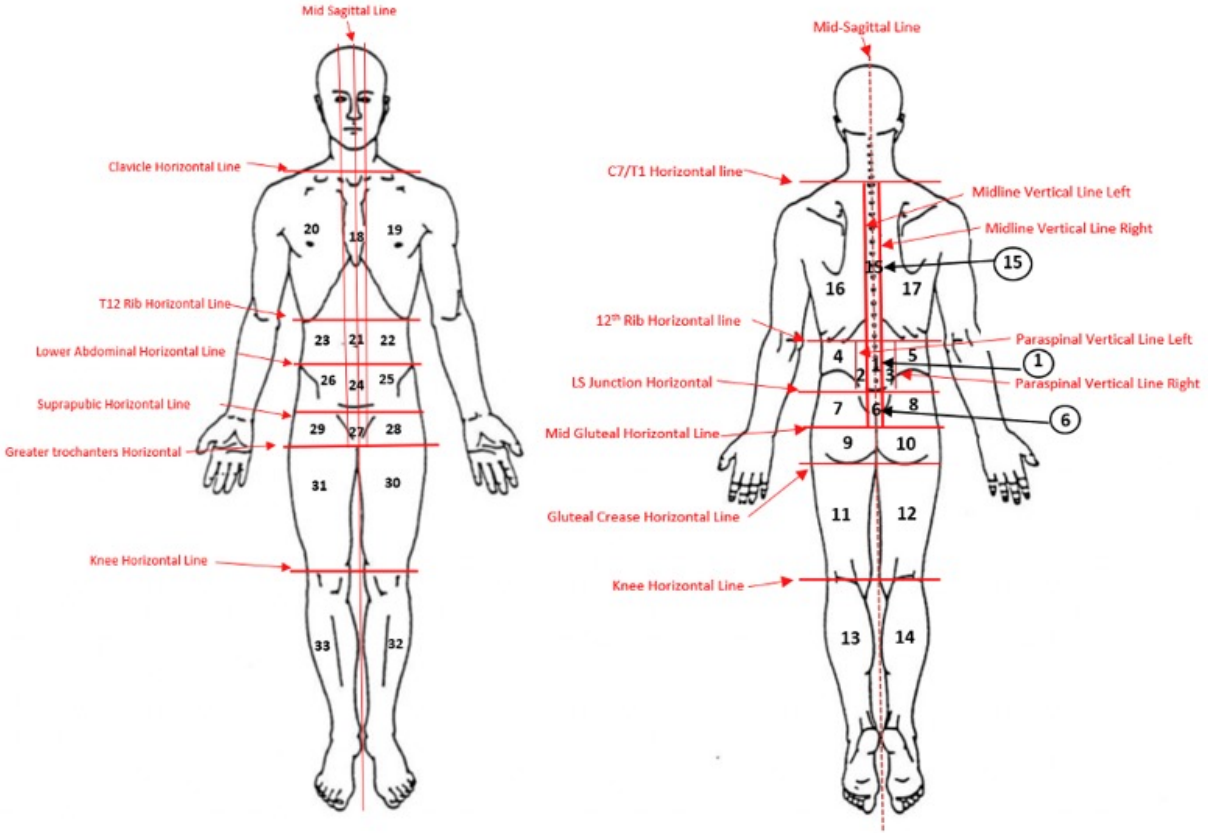


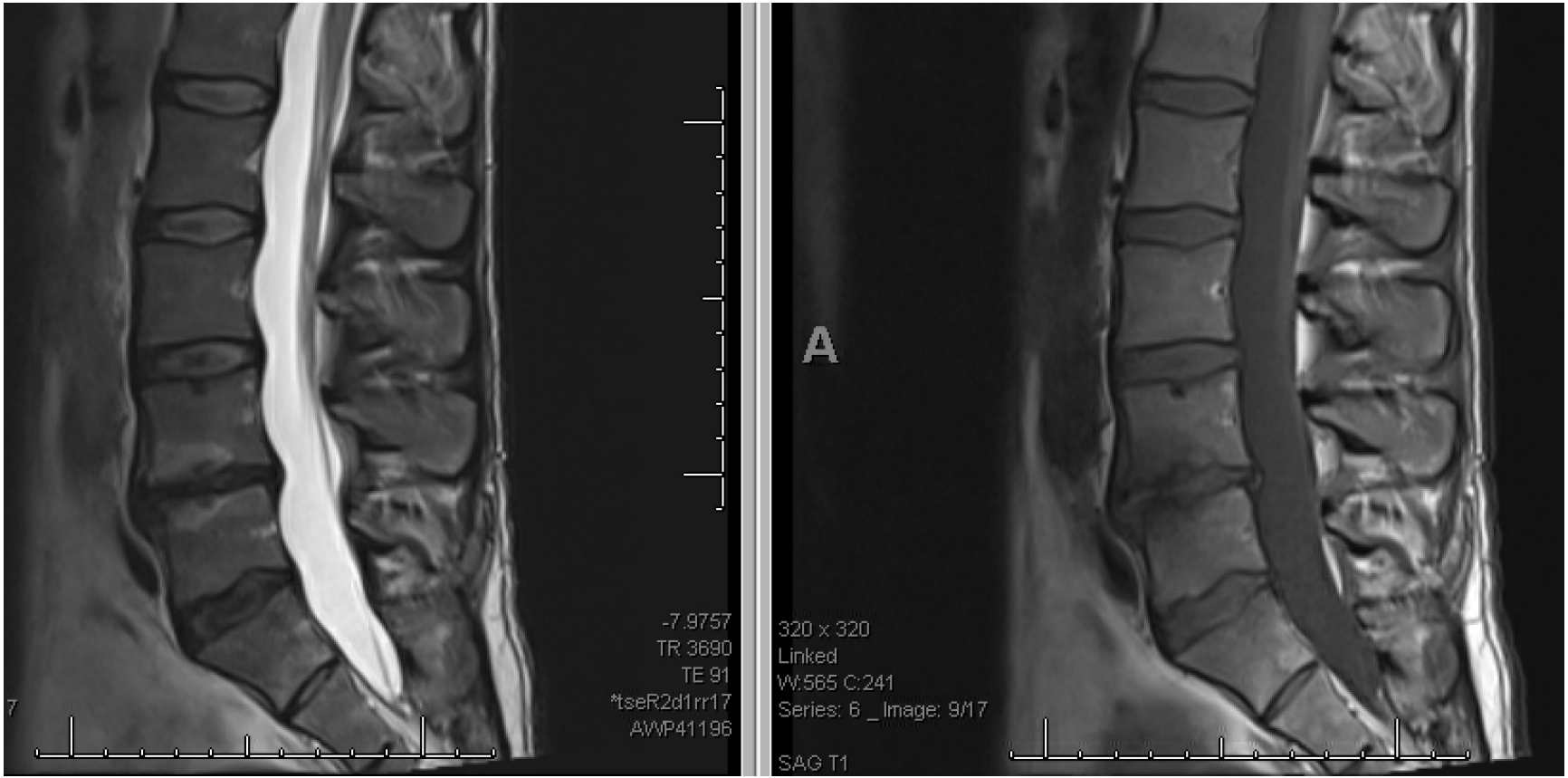


- *Binary "1 or 0"* within each grid box *summed across all study participants* who underwent BVN to create a "heat map"



Also coded for regions of *clinical* interest

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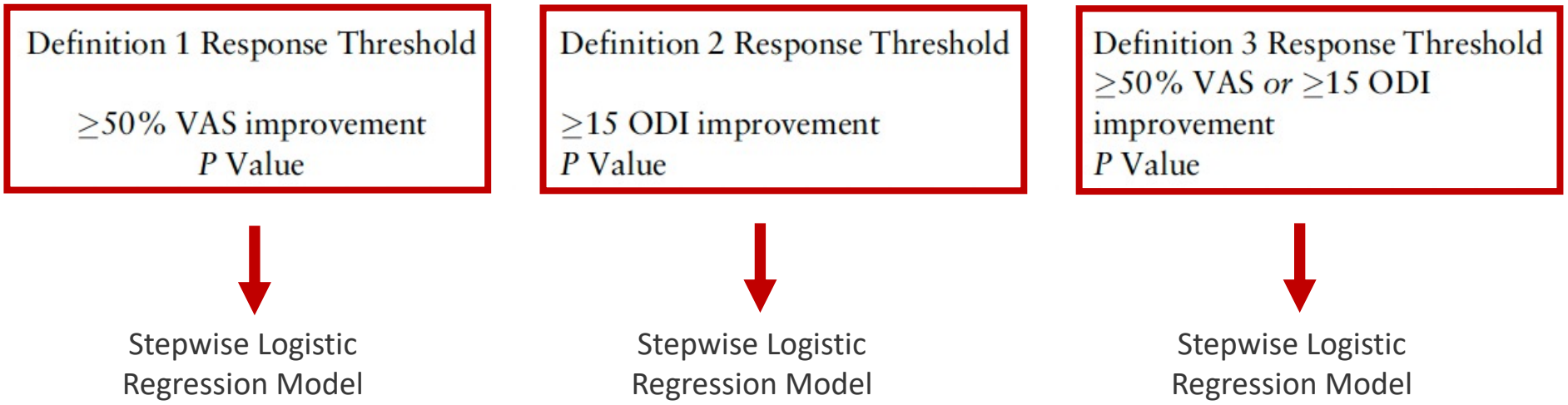
Definition 1 Response Threshold
≥50% VAS improvement
P Value
Definition 2 Response Threshold
≥15 ODI improvement
P Value
Definition 3 Response Threshold
≥50% VAS or ≥15 ODI
improvement
P Value
Stepwise Logistic
Regression Model
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Regression Model
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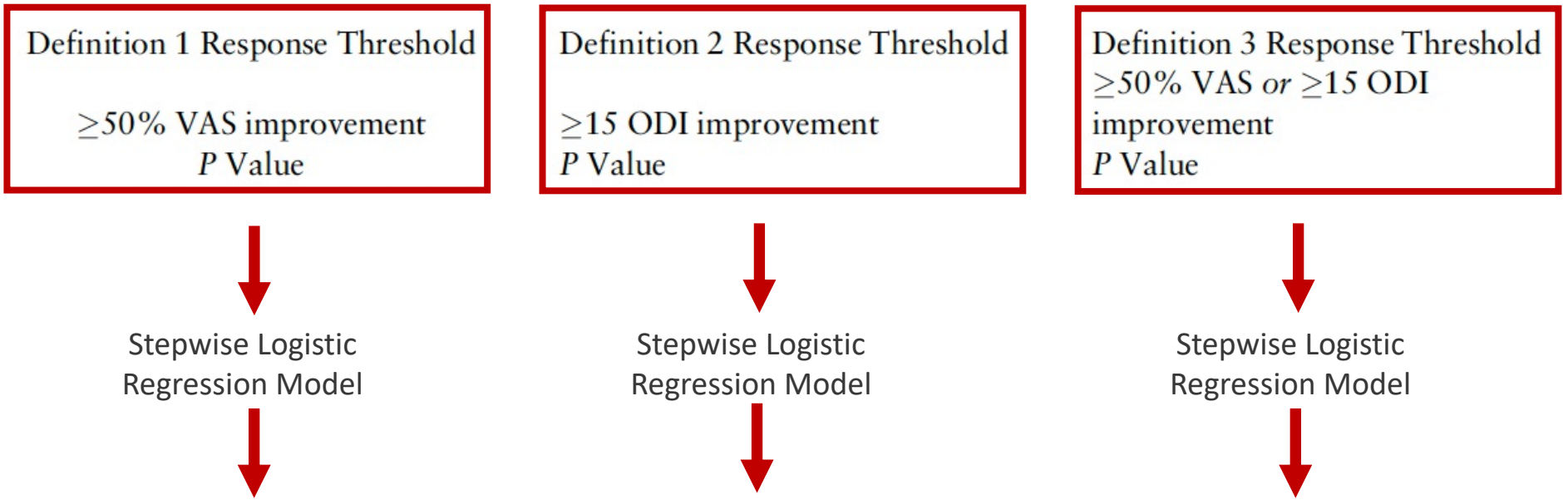
Regression Model



AUC (Area under the receiver-operating characteristics (ROC) curve)

0.5 = no discrimination between treatment success/failure in the model
0.5 - 0.7 = some predictive ability
0.7 - 0.8 = acceptable predictive ability
0.8 - 0.9 = excellent predictive ability
>0.9 = outstanding predictive ability

Results – *Demographic and Historical Factors*

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Table 3. Nonpredictive variables removed from the final regression model

Variable	Definition 1 Response Threshold ≥50% VAS improvement *P* Value (n=292)	Definition 2 Response Threshold ≥15 ODI improvement *P* Value (n=291)	Definition 3 Response Threshold ≥50% VAS *or* ≥15 ODI improvement *P* Value (n=292)
Age	0.1933	0.5762	0.5024
Sex	0.6798	0.0927	0.2686
Married	0.5416	0.7837	0.8384
Pain duration ≥5 years	*Included in the final model*	0.5994	0.2003
History of depression	0.2102	0.3024	0.166
History of anxiety	0.9015	0.2146	0.2214
History of opioid use	0.886	*Included in the final model*	0.239
Employed	0.1874	0.5707	0.6254
Facet arthropathy	0.3546	0.7962	0.8707
Radicular pain/weakness	0.7015	0.4162	0.4715
Baseline BMI	0.2058	0.5708	0.6929
Baseline BDI	*Included in the final model*	*Included in the final model*	*Included in the final model*
Baseline VAS score	0.3585	0.1853	0.2089
Baseline ODI score	0.8449	*Included in the final model*	*Included in the final model*
Baseline SF-36 PCS score	0.4977	0.3379	0.7675
Baseline SF-36 MCS score	0.2175	0.795	0.6659
Modic Type 1	0.5802	0.6332	0.7288
Modic Type 2	0.6146	0.49	0.5947
Number of treated levels	0.8768	0.5385	0.3919

SF-36= Short-Form-36; PCS= Physical Component Score; MCS= Mental Component Score.

Variables that were not selected for the final model based on the stepwise logistic regression approach with each definition of response are shown. Except as noted, these predictors were not considered statistically significant predictors when fitting the regression model with an entry *P* value of 0.05 and a stay *P* value of 0.10.

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Table 6. Predictive model from the final selected model following stepwise logistic regression (Response Definition 2)

Model	Variable Included	Odds Ratio	*P* Value	Pseudo R^2	Area Under ROC Curve
Treated subjects n = 296	History of opioid use (yes vs no)	0.544	0.0424		
n = 289 used for selection	Baseline BDI	0.943	0.0203	0.10	0.70
n = 291 for final selected model	Baseline ODI	1.062	<0.0001		

Final candidate predictors for the final model are shown: Opioid use, baseline BDI score, and baseline ODI demonstrated a *P* value <0.05 with Response Definition 2 (≥15-point ODI improvement). Of the variables examined, higher baseline ODI score (greater functional impairment related to LBP) increased the odds of treatment success, whereas history of opioid use and higher baseline BDI score (greater depression symptoms) decreased the odds of treatment success. The AUC for this model is 0.70, for borderline acceptable predictive ability.

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Border of "*acceptable*"

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Results – *Pain Location and Exacerbating Activities*

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Table 3. Variables not selected for the final model

Variables that were not selected for the final model based on the stepwise logistic regression approach using each definition of response are shown. Except as noted, these predictors were not considered statistically significant predictors when fitting the regression model using an entry *P* values of 0.05 and a stay *P* values of 0.10.

Variable	VAS ≥50% Reduction *P*-value	ODI ≥15-point Reduction *P*-value	ODI ≥15-point OR VAS ≥50% Reduction *P*-value
Age	.1745	.2647	.3977
Gender	.6381	*Included in model*	.0722
History of epidural use	*Included in model*	.5077	.4269
History of opioid use	.5934	*Included in model*	.2036
Lateral pain	.1871	.2752	.4195
Lower gluteal pain	.9627	.4403	.5232
Lower leg pain	.1165	.8708	.2352
Mid upper gluteal pain	.4257	.2148	.3304
Midline pain	.307	.185	.1594
Pain duration ≥ 5 years	*Included in model*	.241	.1016
Paraspinal pain	.4927	.8534	.8507
Upper gluteal lateral pain	.9169	.8154	.9209
Upper leg pain	.9956	.5291	.8885
Worse pain bending backward	.3244	.0502	*Included in model*
Worse pain bending forward	.9212	.4392	.5419
Worse pain bending to the left	.401	.3061	*Included in model*
Worse pain bending to the right	.8135	.7047	.1098
Worse pain with laying down	.5628	.3767	.69
Worse pain with physical activity	.1191	*Included in model*	.0675
Worse pain with sitting	.2137	.565	.3134
Worse pain with standing	.522	.2508	.7271
Worse pain with walking	.7596	.9351	.6287
Worse pain with work activity	.4596	.9111	.9304

VAS = Visual Analog Scale; ODI = Oswestry* Disability Index.

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Worse pain bending to the left	.401	.3061	*Included in model*
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Worse pain with laying down	.5628	.3767	.69
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Worse pain with sitting	.2137	.565	.3134
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Worse pain with walking	.7596	.9351	.6287
Worse pain with work activity	.4596	.9111	.9304

VAS = Visual Analog Scale; ODI = Oswestry* Disability Index.

Table 4. Predictive model results by response definition

Final candidate predictors for the three models are shown: pain duration and baseline Beck Depression Inventory (BDI) score demonstrated a *P* values <.05 using the Response Definition 1 (≥50% VAS improvement). Of the variables examined, pain duration ≥5 years increased the odds of treatment success while higher baseline BDI scores (greater depression symptoms) decreased the odds of treatment success. The AUC for this model is 0.62 for limited predictive ability.

Model	Variable Included	OR	*P*-value	Pseudo R^2	Area Under ROC Curve
Definition no. 1: ≥ 50% VAS Improvement from Baseline					
Treated subjects N = 296, N = 283 used for selection, N = 292 for final selected model	Pain duration ≥ 5 years (Yes vs No)	2.366	.001	0.05	0.63
	History of Epidural use (Yes vs No)	0.556	.0162		
Definition no. 2: ≥ 15-point ODI Improvement from Baseline					
Treated subjects N = 296, N = 282 used for selection, N = 291 for final selected model	Gender (Female vs Male)	1.925	.0119	0.05	0.64
	History of opioid use (Yes vs No)	0.509	.017		
	Worse pain with physical activity (Yes vs No)	2.099	.0253		
Definition no. 3: ≥ 15-point ODI Improvement *or* ≥ 50% VAS Improvement from Baseline					
Treated subjects N = 296, N = 283 used for selection, N = 290 for final selected model	Worse pain bending to the left (Yes vs No)	2.184	.0049	0.04	0.61
	Worse pain bending backward (Yes vs No)	0.542	.038		

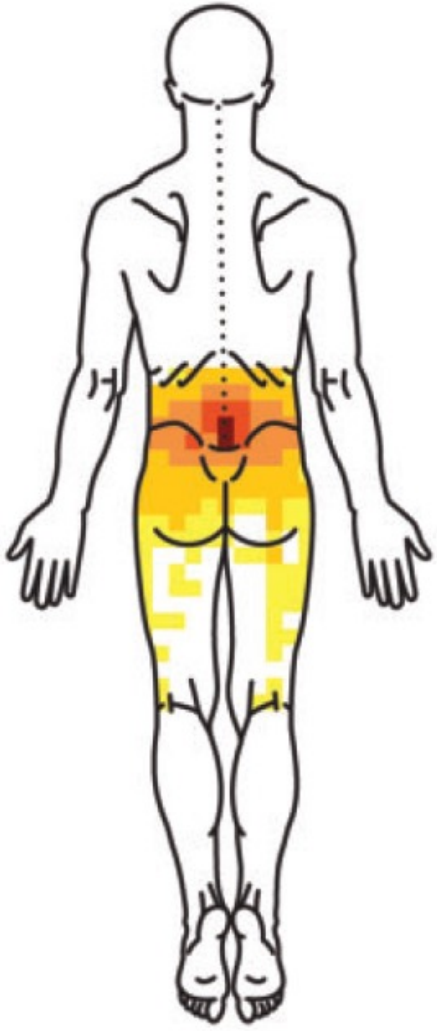
Table 4. Predictive model results by response definition

Final candidate predictors for the three models are shown: pain duration and baseline Beck Depression Inventory (BDI) score demonstrated a *P* values <.05 using the Response Definition 1 (≥50% VAS improvement). Of the variables examined, pain duration ≥5 years increased the odds of treatment success while higher baseline BDI scores (greater depression symptoms) decreased the odds of treatment success. The AUC for this model is 0.62 for limited predictive ability.

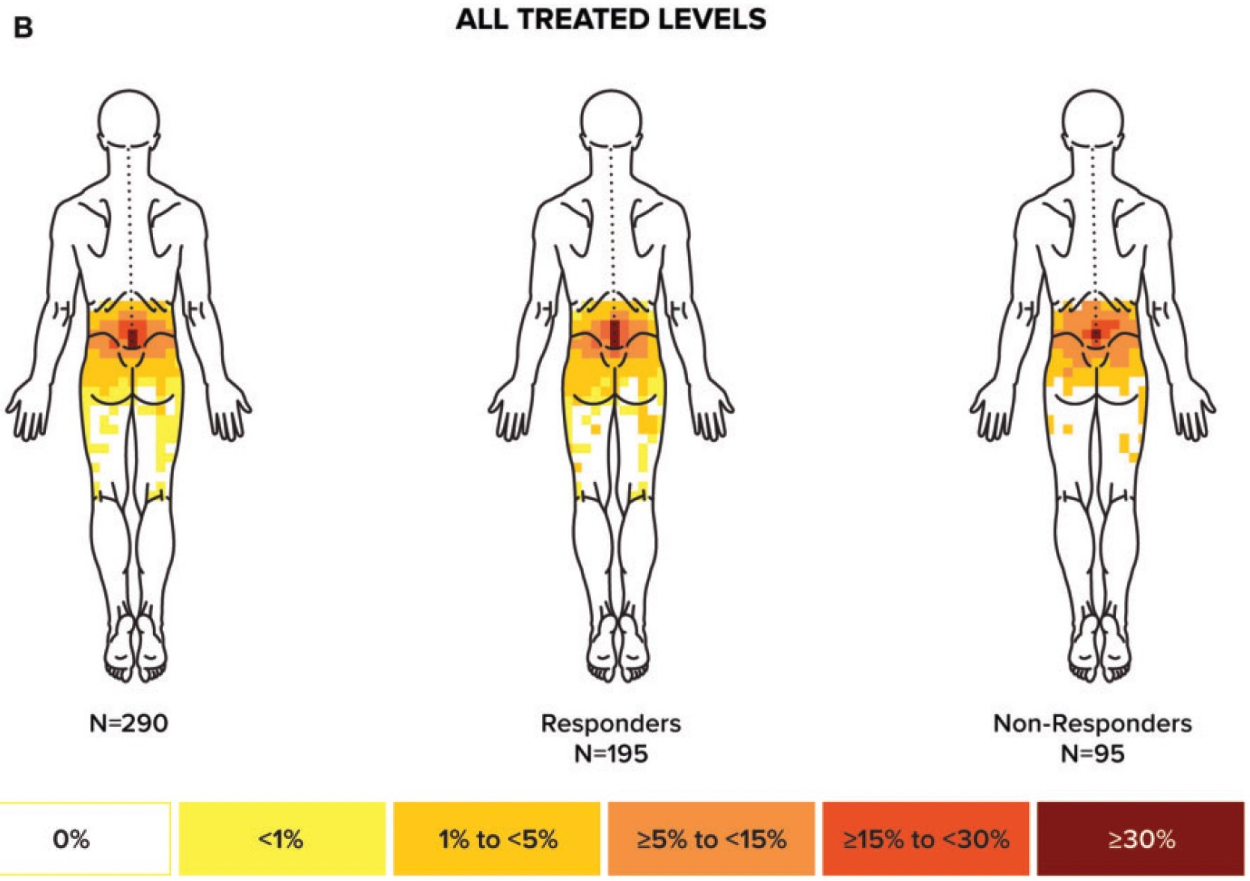
Model	Variable Included	OR	*P*-value	Pseudo R^2	Area Under ROC Curve
Definition no. 1: ≥ 50% VAS Improvement from Baseline					
Treated subjects N = 296, N = 283 used for selection, N = 292 for final selected model	Pain duration ≥ 5 years (Yes vs No)	2.366	.001	0.05	0.63
	History of Epidural use (Yes vs No)	0.556	.0162		
Definition no. 2: ≥ 15-point ODI Improvement from Baseline					
Treated subjects N = 296, N = 282 used for selection, N = 291 for final selected model	Gender (Female vs Male)	1.925	.0119	0.05	0.64
	History of opioid use (Yes vs No)	0.509	.017		
	Worse pain with physical activity (Yes vs No)	2.099	.0253		
Definition no. 3: ≥ 15-point ODI Improvement *or* ≥ 50% VAS Improvement from Baseline					
Treated subjects N = 296, N = 283 used for selection, N = 290 for final selected model	Worse pain bending to the left (Yes vs No)	2.184	.0049	0.04	0.61
	Worse pain bending backward (Yes vs No)	0.542	.038		

"*Some* predictive ability"

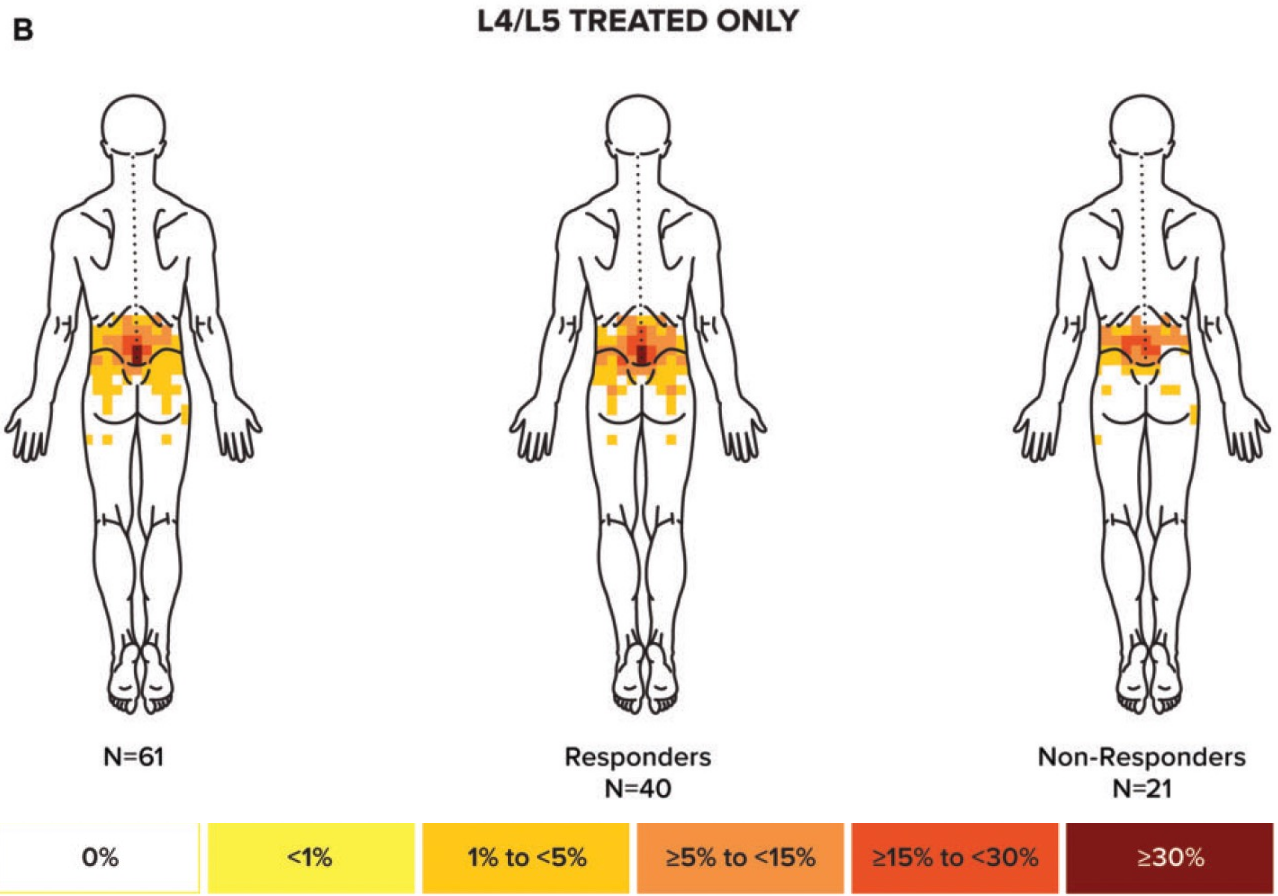
Pain Location Heat Maps



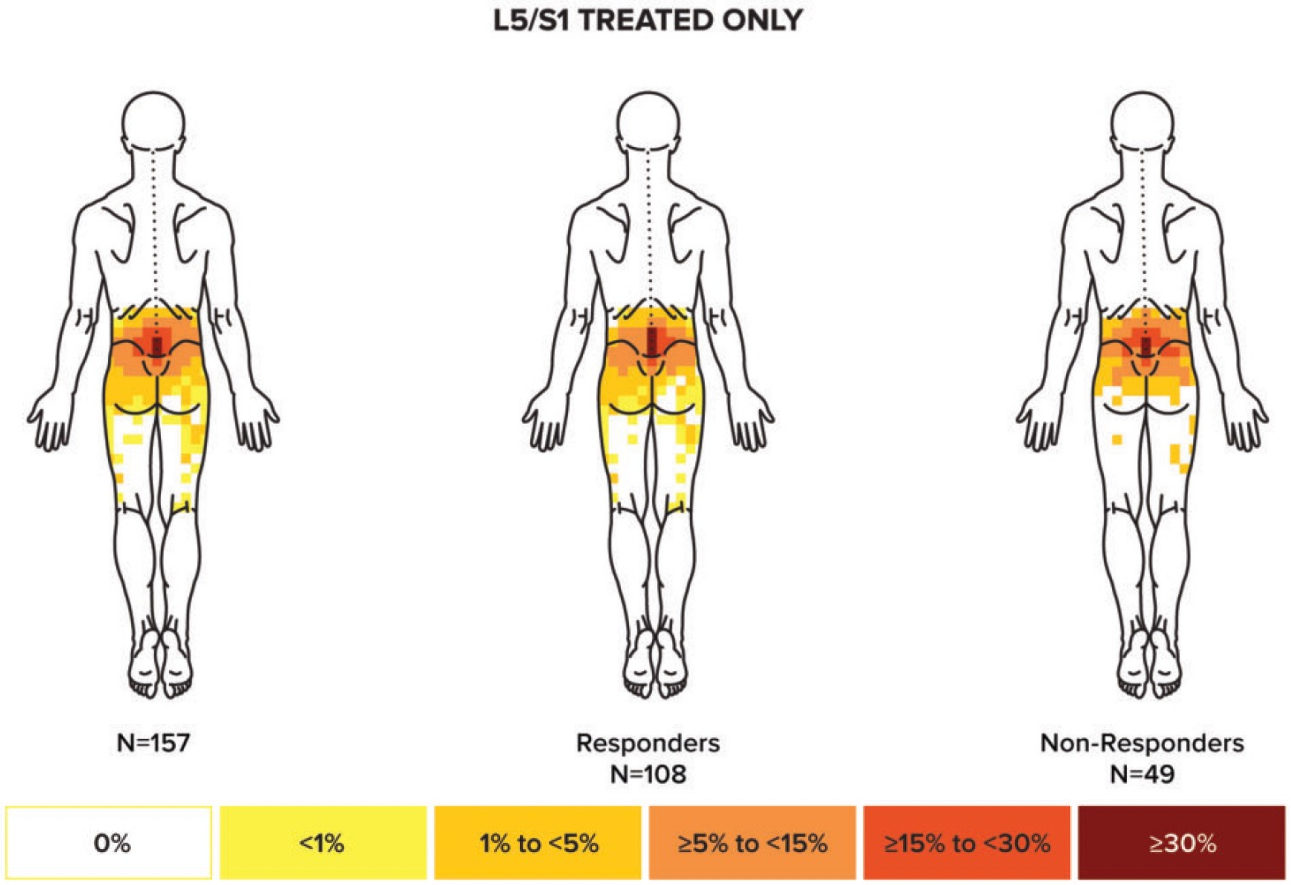
Participants with Improvement in ODI of ≥15



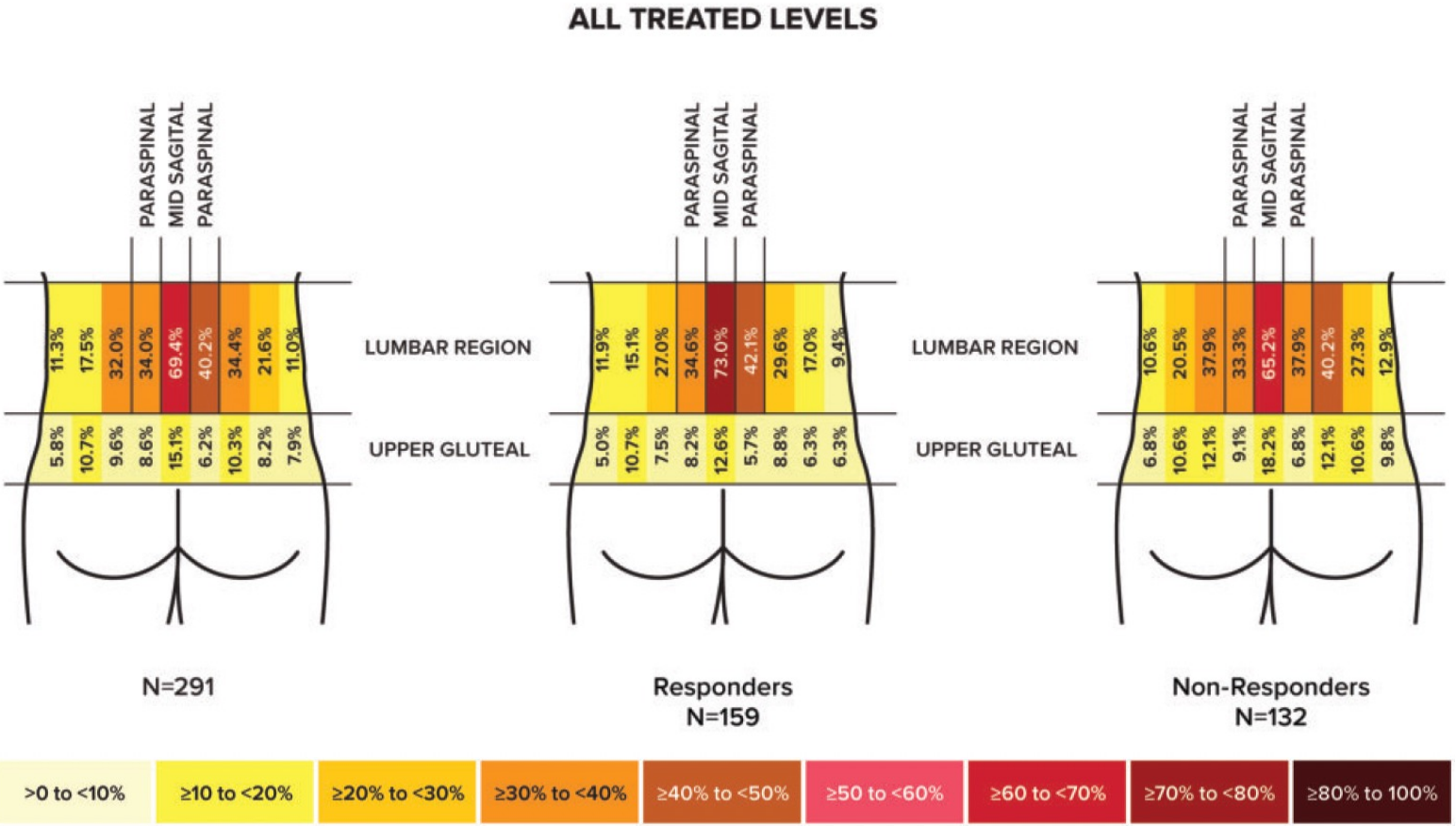
Participants with Improvement in ODI of ≥15



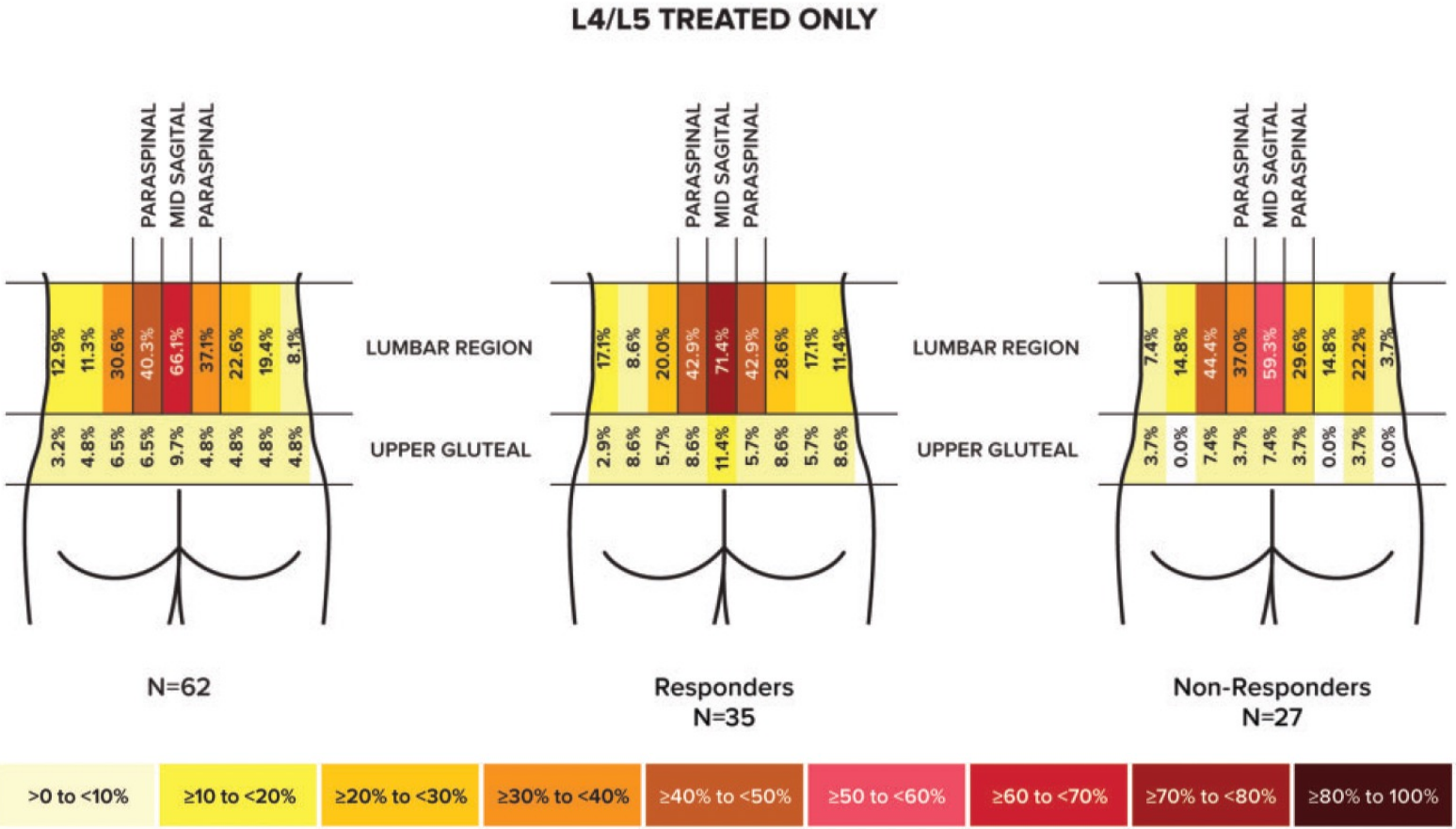
Participants with Improvement in ODI of ≥15



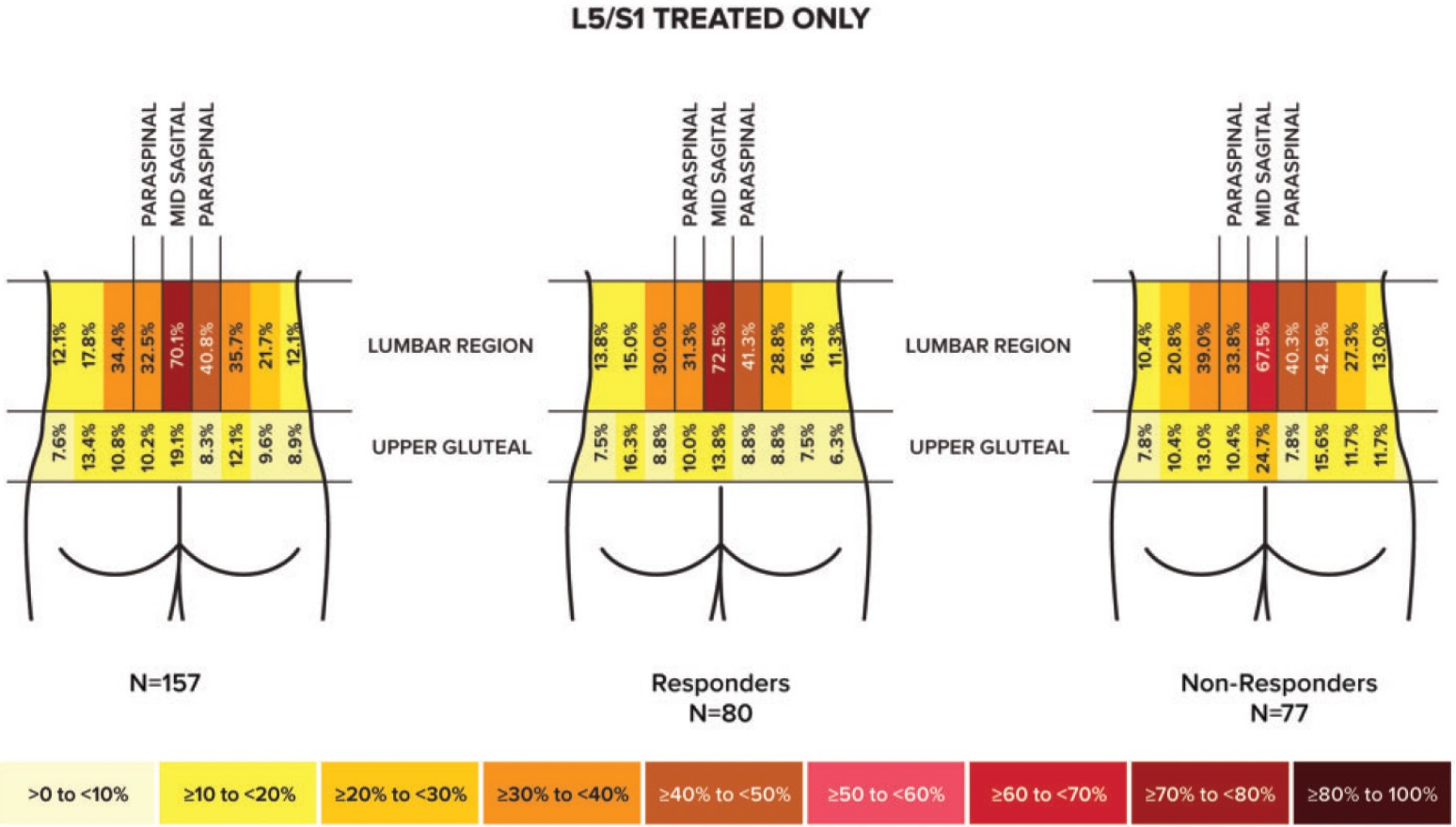
Participants with Improvement in NRS of ≥50%



Participants with Improvement in NRS of ≥50%



Participants with Improvement in NRS of ≥50%



Results – *MRI Characteristics*

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Table 2. Descriptive summaries by patient and endplate with greatest bone marrow intensity changes (BMIC) height

Characteristics	Successfully Treated Patients (n = 292)	VAS ≥50% Improvement			ODI ≥15 Point Improvement		
		Responders	Non Responder	*P* value*	Responders	Non Responders	*P* value*
BMIC							
Yes	100.0% (292)	54.2% (156/288)	45.8% (132/288)		67.2% (193/287)	32.8% (94/287)	
BMIC type				.42			.58
Type 1	54.8% (160)	56.1% (88/157)	43.9% (69/157)		69.4% (109/157)	30.6% (48/157)	
Type 2	44.5% (130)	51.2% (66/129)	48.8% (63/129)		64.3% (83/129)	35.7% (46/129)	
Type 3	0.7% (2)	100.0% (2/2)	0.0% (0/2)		100.0% (1/1)	0.0% (0/1)	
BMIC height				.24			.78
Localized to endplate only	27.7% (81)	60.5% (49/81)	39.5% (32/81)		71.6% (58/81)	28.4% (23/81)	
Less than 25% of vertebral body height	35.3% (103)	49.5% (50/101)	50.5% (51/101)		65.3% (66/101)	34.7% (35/101)	
25 to 50% of vertebral body height	31.5% (92)	56.7% (51/90)	43.3% (39/90)		66.3% (59/89)	33.7% (30/89)	
More than 50% vertebral body height	5.5% (16)	37.5% (6/16)	62.5% (10/16)		62.5% (10/16)	37.5% (6/16)	
BMIC area				.54			.68
Less than 25% of endplate area	28.1% (82)	55.6% (45/81)	44.4% (36/81)		65.4% (53/81)	34.6% (28/81)	
25 to 50% of endplate area	26.7% (78)	58.4% (45/77)	41.6% (32/77)		71.4% (55/77)	28.6% (22/77)	
More than 50% of endplate area	45.2% (132)	50.8% (66/130)	49.2% (64/130)		65.9% (85/129)	34.1% (44/129)	

Table 2. Descriptive summaries by patient and endplate with greatest bone marrow intensity changes (BMIC) height

Characteristics	Successfully Treated Patients (n = 292)	VAS ≥50% Improvement			ODI ≥15 Point Improvement		
		Responders	Non Responder	*P* value*	Responders	Non Responders	*P* value*
Endplate defect				.25			.13
No	22.3% (65)	47.6% (30/63)	52.4% (33/63)		58.7% (37/63)	41.3% (26/63)	
Yes	77.7% (227)	56.0% (126/225)	44.0% (99/225)		69.6% (156/224)	30.4% (68/224)	
Endplate defect shape				.50			.63
Sharp, angular	1.8% (4)	25.0% (1/4)	75.0% (3/4)		50.0% (2/4)	50.0% (2/4)	
Schmorl's node	4.4% (10)	60.0% (6/10)	40.0% (4/10)		80.0% (8/10)	20.0% (2/10)	
Irregular	93.8% (213)	56.4% (119/211)	43.6% (92/211)		69.5% (146/210)	30.5% (64/210)	
Endplate defect size				.41			.15
Less than 1/3 endplate area	22.9% (52)	59.6% (31/52)	40.4% (21/52)		71.2% (37/52)	28.8% (15/52)	
Between 1/3 and 2/3 endplate area	22.5% (51)	62.0% (31/50)	38.0% (19/50)		80.0% (40/50)	20.0% (10/50)	
More than 2/3 endplate area	54.6% (124)	52.0% (64/123)	48.0% (59/123)		64.8% (79/122)	35.2% (43/122)	

Table 2. Descriptive summaries by patient and endplate with greatest bone marrow intensity changes (BMIC) height

Characteristics	Successfully Treated Patients (n = 292)	VAS ≥50% Improvement			ODI ≥15 Point Improvement		
		Responders	Non Responder	*P* value*	Responders	Non Responders	*P* value*
Degenerative disc disease				.60			.12
Homogeneous disc structure with bright white disc (Pfirrmann Grade 1)	0.0% (0)	0.0% (0/0)	0.0% (0/0)		0.0% (0/0)	0.0% (0/0)	
Inhomogeneous structure with or without horizontal bands (Grade 2)	1.4% (4)	75.0% (3/4)	25.0% (1/4)		75.0% (3/4)	25.0% (1/4)	
Inhomogeneous structure with gray disc (Grade 3)	21.6% (63)	47.5% (29/61)	52.5% (32/61)		55.7% (34/61)	44.3% (27/61)	
Inhomogeneous structure with gray to black disc (Grade 4)	39.7% (116)	55.7% (64/115)	44.3% (51/115)		73.0% (84/115)	27.0% (31/115)	
Inhomogeneous structure with black disc (Grade 5)	37.3% (109)	55.6% (60/108)	44.4% (48/108)		67.3% (72/107)	32.7% (35/107)	
Nuclear signal				.27			.44
Normal, pure white signal on T2-weighted images	1.4% (4)	50.0% (2/4)	50.0% (2/4)		75.0% (3/4)	25.0% (1/4)	
Moderate loss, intermediate between normal and severe	20.2% (59)	44.8% (26/58)	55.2% (32/58)		60.3% (35/58)	39.7% (23/58)	
Severe loss, homogenous black signal	78.4% (229)	56.6% (128/226)	43.4% (98/226)		68.9% (155/225)	31.1% (70/225)	
Disc height				.61			.22
Normal, less than 10% loss of expected height	12.7% (37)	47.2% (17/36)	52.8% (19/36)		58.3% (21/36)	41.7% (15/36)	
Moderate narrowing, 10–50% loss	33.9% (99)	56.7% (55/97)	43.3% (42/97)		63.9% (62/97)	36.1% (35/97)	
Severe narrowing, 50% loss	53.4% (156)	54.2% (84/155)	45.8% (71/155)		71.4% (110/154)	28.6% (44/154)	

Table 2. Descriptive summaries by patient and endplate with greatest bone marrow intensity changes (BMIC) height

		VAS ≥50% Improvement			ODI ≥15 Point Improvement		
Characteristics	Successfully Treated Patients (n = 292)	Responders	Non Responder	*P* value*	Responders	Non Responders	*P* value*
High intensity zone				.74			.49
No	84.2% (246)	53.7% (131/244)	46.3% (113/244)		66.3% (161/243)	33.7% (82/243)	
Yes	15.8% (46)	56.8% (25/44)	43.2% (19/44)		72.7% (32/44)	27.3% (12/44)	

Table 2. Descriptive summaries by patient and endplate with greatest bone marrow intensity changes (BMIC) height

Characteristics	Successfully Treated Patients (n = 292)	VAS ≥50% Improvement		*P* value*	ODI ≥15 Point Improvement		*P* value*
		Responders	Non Responder		Responders	Non Responders	
Disc contour				.89			.63
Normal, no extension beyond the interspace	3.4% (10)	60.0% (6/10)	40.0% (4/10)		50.0% (5/10)	50.0% (5/10)	
Bulge, circumferential, symmetrical disc extension	81.2% (237)	54.5% (127/233)	45.5% (106/233)		67.4% (157/233)	32.6% (76/233)	
Protrusion, focal or asymmetrical disc extension	15.1% (44)	50.0% (22/44)	50.0% (22/44)		69.8% (30/43)	30.2% (13/43)	
Extrusion, focal disc extension beyond the interspace	0.3% (1)	100.0% (1/1)	0.0% (0/1)		100.0% (1/1)	0.0% (0/1)	

Table 2. Descriptive summaries by patient and endplate with greatest bone marrow intensity changes (BMIC) height

Characteristics	Successfully Treated Patients (n = 292)	VAS ≥50% Improvement		*P* value*	ODI ≥15 Point Improvement		*P* value*
		Responders	Non Responder		Responders	Non Responders	
Nerve root compromise				.15			.30
No nerve root contact	94.5% (276)	53.3% (145/272)	46.7% (127/272)		67.2% (182/271)	32.8% (89/271)	
Nerve root contact without deviation	3.8% (11)	63.6% (7/11)	36.4% (4/11)		63.6% (7/11)	36.4% (4/11)	
Nerve root deviation	1.4% (4)	100.0% (4/4)	0.0% (0/4)		100.0% (4/4)	0.0% (0/4)	
Nerve root compression/deformation	0.3% (1)	0.0% (0/1)	100.0% (1/1)		0.0% (0/1)	100.0% (1/1)	

Table 2. Descriptive summaries by patient and endplate with greatest bone marrow intensity changes (BMIC) height

Characteristics	Successfully Treated Patients (n = 292)	VAS ≥50% Improvement			ODI ≥15 Point Improvement		
		Responders	Non Responder	*P* value*	Responders	Non Responders	*P* value*
Facet joint arthropathy				.47			.62
Normal facet joint space (2–4 mm width)	8.9% (26)	44.0% (11/25)	56.0% (14/25)		60.0% (15/25)	40.0% (10/25)	
Narrowing of the FJ space (<2 mm) and/or small osteophytes	60.6% (177)	57.4% (101/176)	42.6% (75/176)		69.3% (122/176)	30.7% (54/176)	
Narrowing of the FJ space and/or moderate osteophytes	28.8% (84)	51.2% (42/82)	48.8% (40/82)		65.9% (54/82)	34.1% (28/82)	
Narrowing of the FJ space and/or large osteophytes	1.7% (5)	40.0% (2/5)	60.0% (3/5)		50.0% (2/4)	50.0% (2/4)	
Facet joint fluid				.03			.42
No	66.4% (194)	58.6% (112/191)	41.4% (79/191)		68.9% (131/190)	31.1% (59/190)	
Yes	33.6% (98)	45.4% (44/97)	54.6% (53/97)		63.9% (62/97)	36.1% (35/97)	

Table 2. Descriptive summaries by patient and endplate with greatest bone marrow intensity changes (BMIC) height

		VAS ≥50% Improvement			ODI ≥15 Point Improvement		
Characteristics	Successfully Treated Patients (n = 292)	Responders	Non Responder	*P* value*	Responders	Non Responders	*P* value*
Olisthesis				.80			.78
No	94.5% (276)	54.4% (148/272)	45.6% (124/272)		67.5% (183/271)	32.5% (88/271)	
Yes	5.5% (16)	50.0% (8/16)	50.0% (8/16)		62.5% (10/16)	37.5% (6/16)	

Table 2. Descriptive summaries by patient and endplate with greatest bone marrow intensity changes (BMIC) height

Characteristics	Successfully Treated Patients (n = 292)	VAS ≥50% Improvement		*P* value*	ODI ≥15 Point Improvement		*P* value*
		Responders	Non Responder		Responders	Non Responders	
Congenital stenosis				.34			.10
No	98.6% (288)	54.6% (155/284)	45.4% (129/284)		67.8% (192/283)	32.2% (91/283)	
Yes	1.4% (4)	25.0% (1/4)	75.0% (3/4)		25.0% (1/4)	75.0% (3/4)	
Foraminal stenosis				.11			.46
Normal foramina with normal dorsolateral border	33.6% (98)	49.5% (47/95)	50.5% (48/95)		62.1% (59/95)	37.9% (36/95)	
Slight foraminal stenosis and deformity of the epidural fat	53.1% (155)	52.6% (81/154)	47.4% (73/154)		68.2% (105/154)	31.8% (49/154)	
Marked foraminal stenosis and deformity of the epidural fat	12.0% (35)	71.4% (25/35)	28.6% (10/35)		76.5% (26/34)	23.5% (8/34)	
Advanced stenosis with obliteration of the epidural fat	1.4% (4)	75.0% (3/4)	25.0% (1/4)		75.0% (3/4)	25.0% (1/4)	
Central spinal stenosis				.65			.59
No constriction of thecal sac	95.5% (279)	53.8% (148/275)	46.2% (127/275)		67.3% (185/275)	32.7% (90/275)	
Mild constriction of thecal sac with minimal loss of CSF	2.7% (8)	62.5% (5/8)	37.5% (3/8)		71.4% (5/7)	28.6% (2/7)	
CSF diminished but still present	1.4% (4)	75.0% (3/4)	25.0% (1/4)		75.0% (3/4)	25.0% (1/4)	
Complete loss of CSF in the thecal sac	0.3% (1)	0.0% (0/1)	100.0% (1/1)		0.0% (0/1)	100.0% (1/1)	
Lateral regions spinal stenosis				.25			.55
No nerve root contact	99.0% (289)	53.7% (153/285)	46.3% (132/285)		66.9% (190/284)	33.1% (94/284)	
Nerve root contact without deviation	1.0% (3)	100.0% (3/3)	0.0% (0/3)		100.0% (3/3)	0.0% (0/3)	
Nerve root deviation	0.0% (0)	0.0% (0/292)	0.0% (0/292)		0.0% (0/0)	0.0% (0/0)	

Table 4. Regression model 1 - motion segment predictors of BVN RFA treatment success according to the treated vertebral endplate with the greatest height of bone marrow intensity change

Model	Variable Included	OR	*P* value*	Pseudo R^2	Area Under ROC Curve
Treated subjects N = 296, N = 288 used for selection, N = 288 used for final model	Facet Joint Fluid (Yes vs No)	0.586	.0333	0.0157	0.5567

The table shows the results for the stepwise logistic regression model for motion segment characteristics using the motion segment that is adjacent to the endplate with the *greatest* BMIC height treated as the patient-level predictor set. One predictor, the presence of facet joint fluid, had a *P* value of .03 for the response definition no. 1—VAS $\geq$ 50% improvement, and was included in the final fitted models across all response definitions. While the presence of facet joint fluid reduced the odds of treatment success (OR 0.586) with the response definition no. 1—VAS $\geq$ 50% improvement, the AUC was 0.5567 for weak predictability. VAS = Visual Analogue Score (average low back pain in past 7 days); OR = Odds Ratio; ROC = Receiver-Operating Characteristics.

* *P* values calculated used Wald χ^2 test.

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"*Some* predictive ability"

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* *P* values calculated used Wald χ^2 test.

Clinical Phenotype

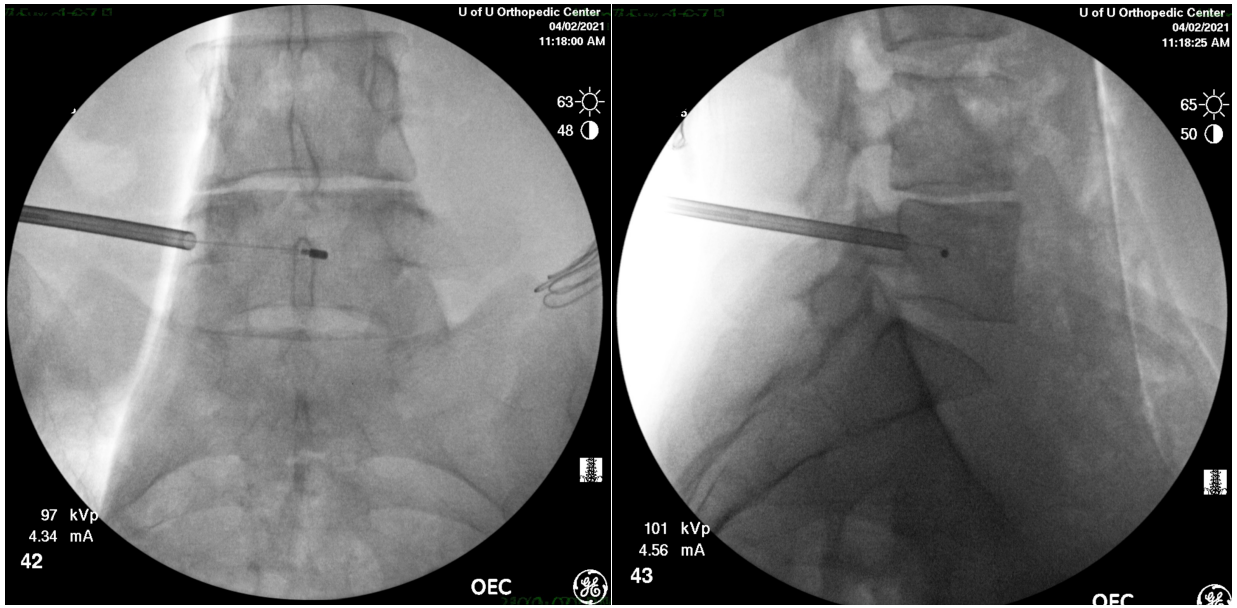
1. Chronic axial LBP
2. *Mid-line predominant*, possible gluteal referral
3. *Worse* with activity, *not worse* with lumbar extension
4. Type 1 or 2 Modic Changes
   - DDD grade and Endplate defect characteristics *may not be related*

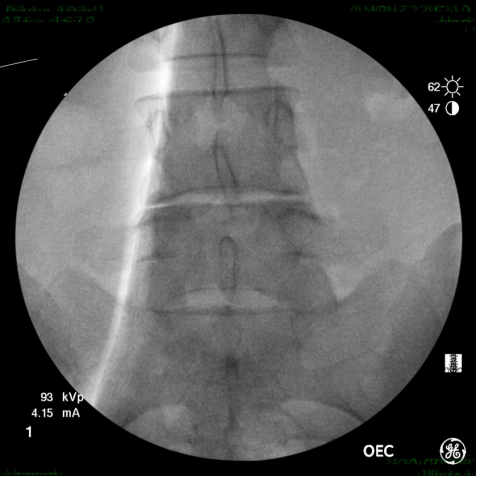
Treatment

Treatment

1. Intradiscal injectables?
2. Basivertebral Nerve Radiofrequency
3. Neuromodulation?
4. Fusion surgery?

Basivertebral Nerve Radiofrequency Ablation

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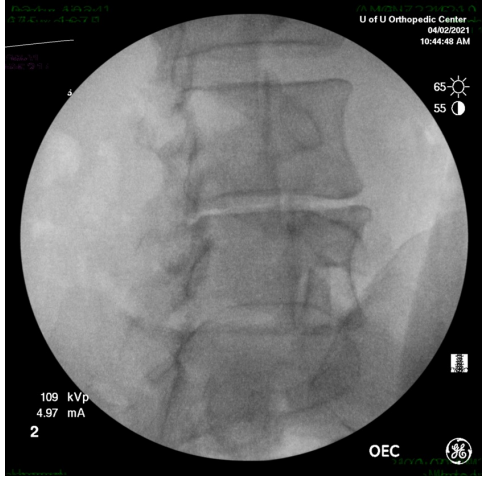
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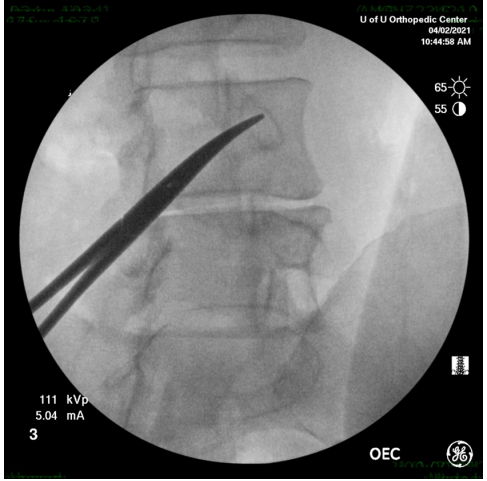
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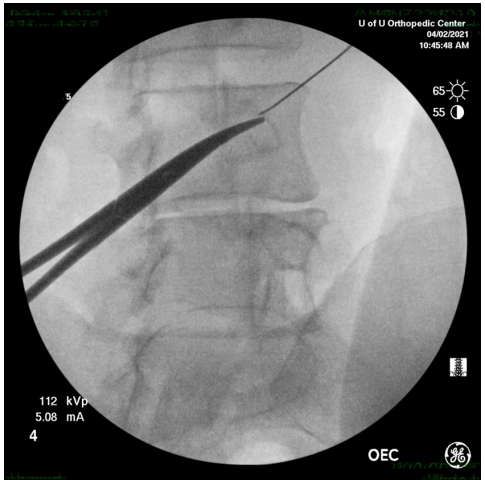
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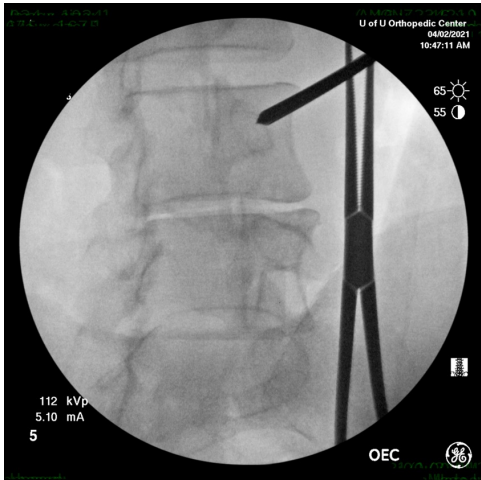
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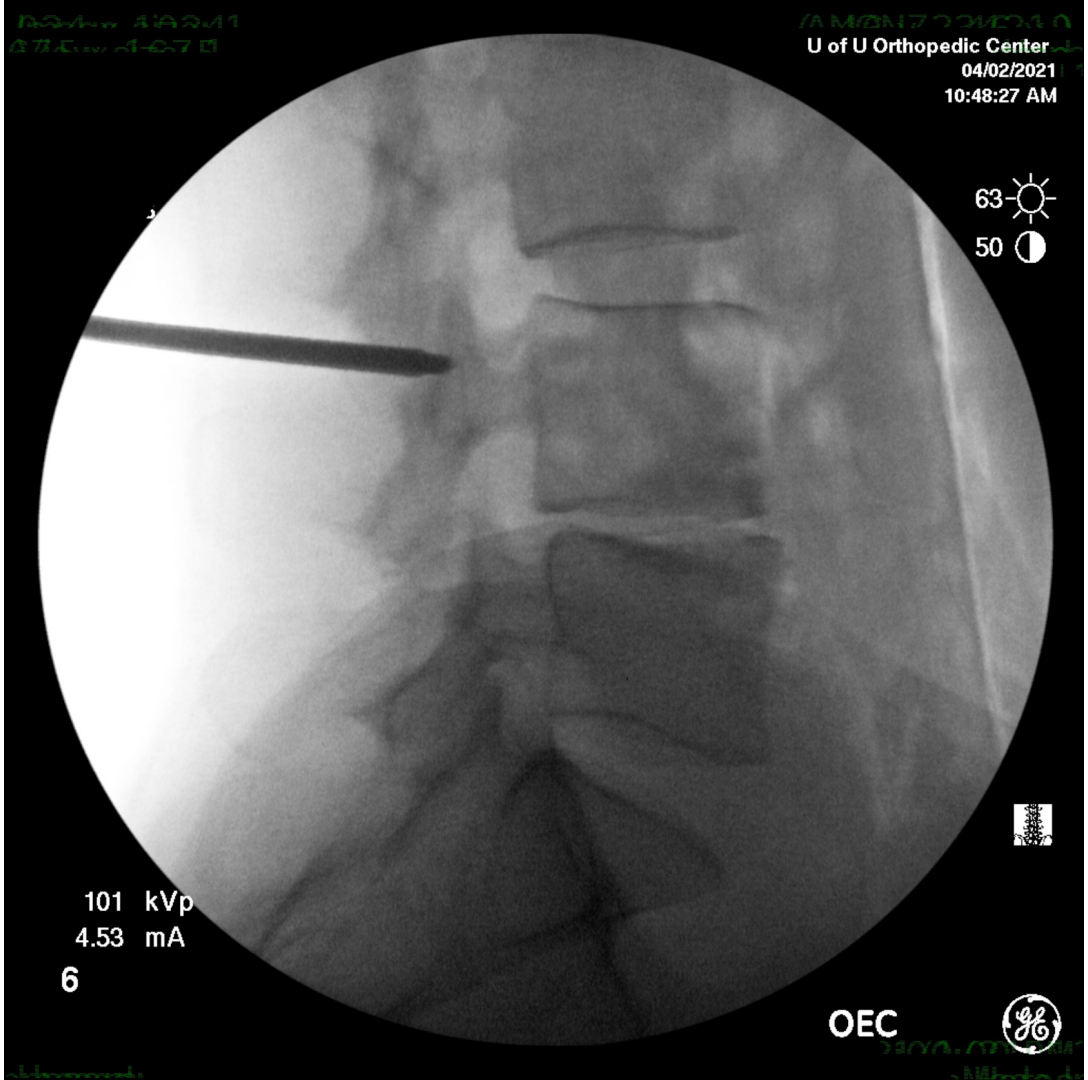
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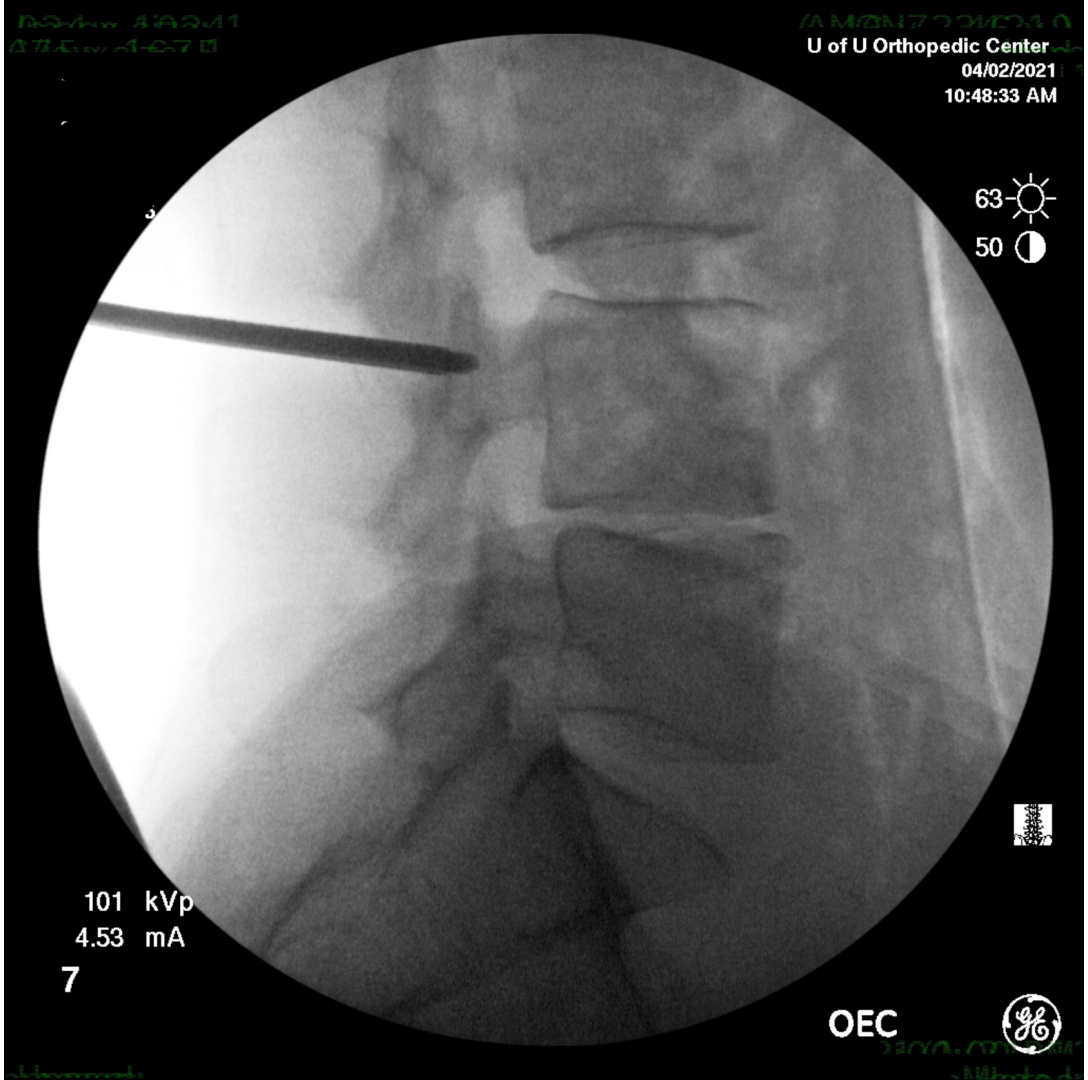
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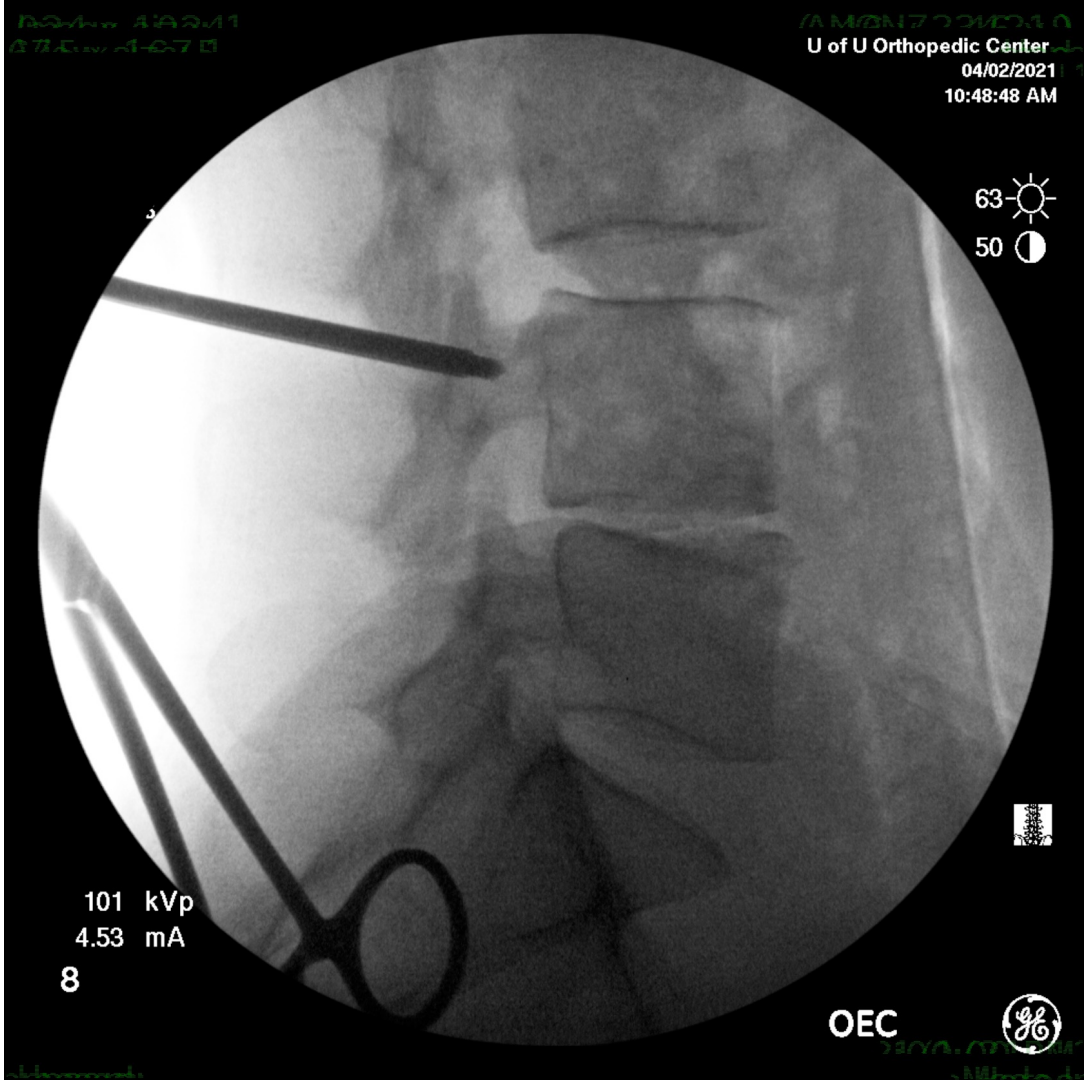
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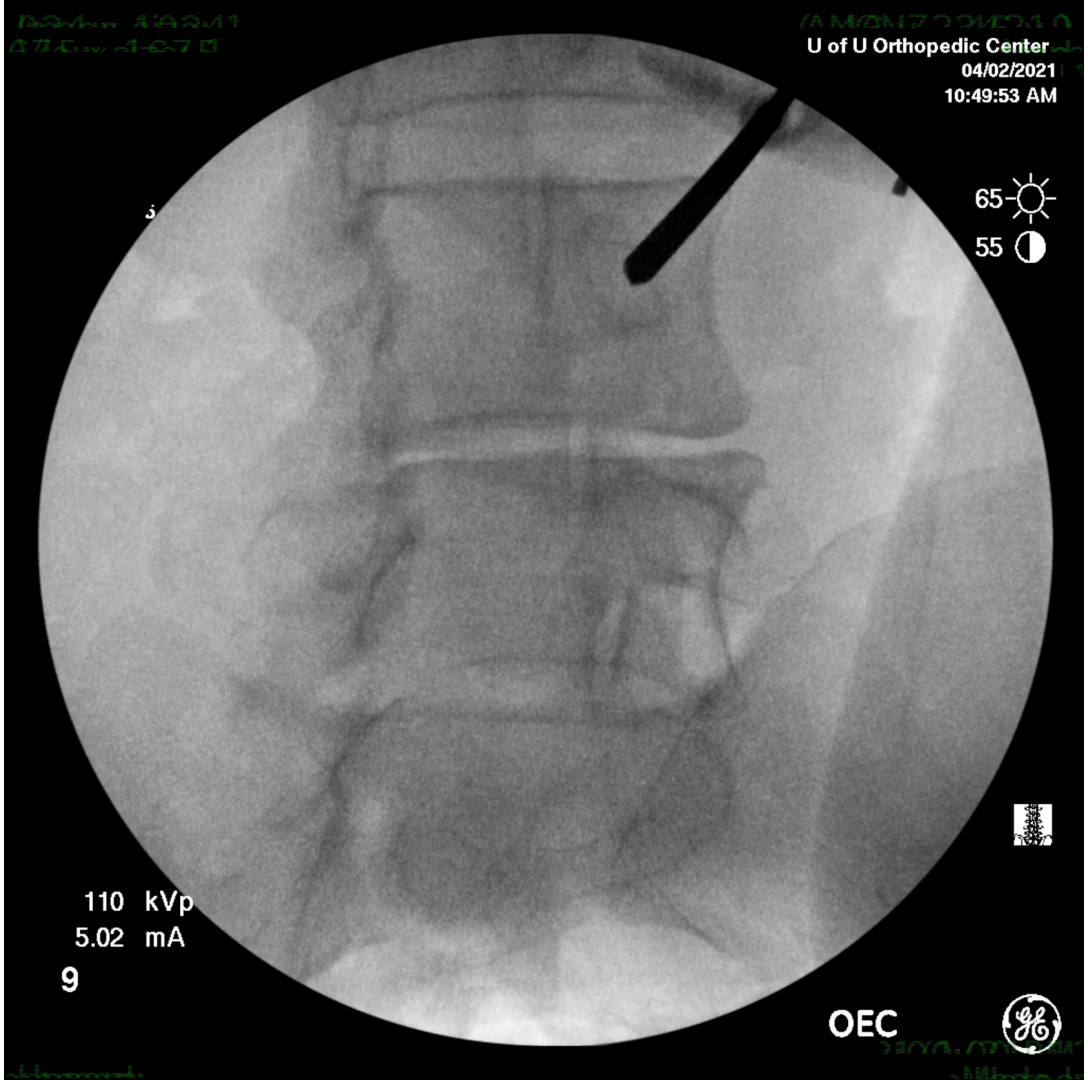
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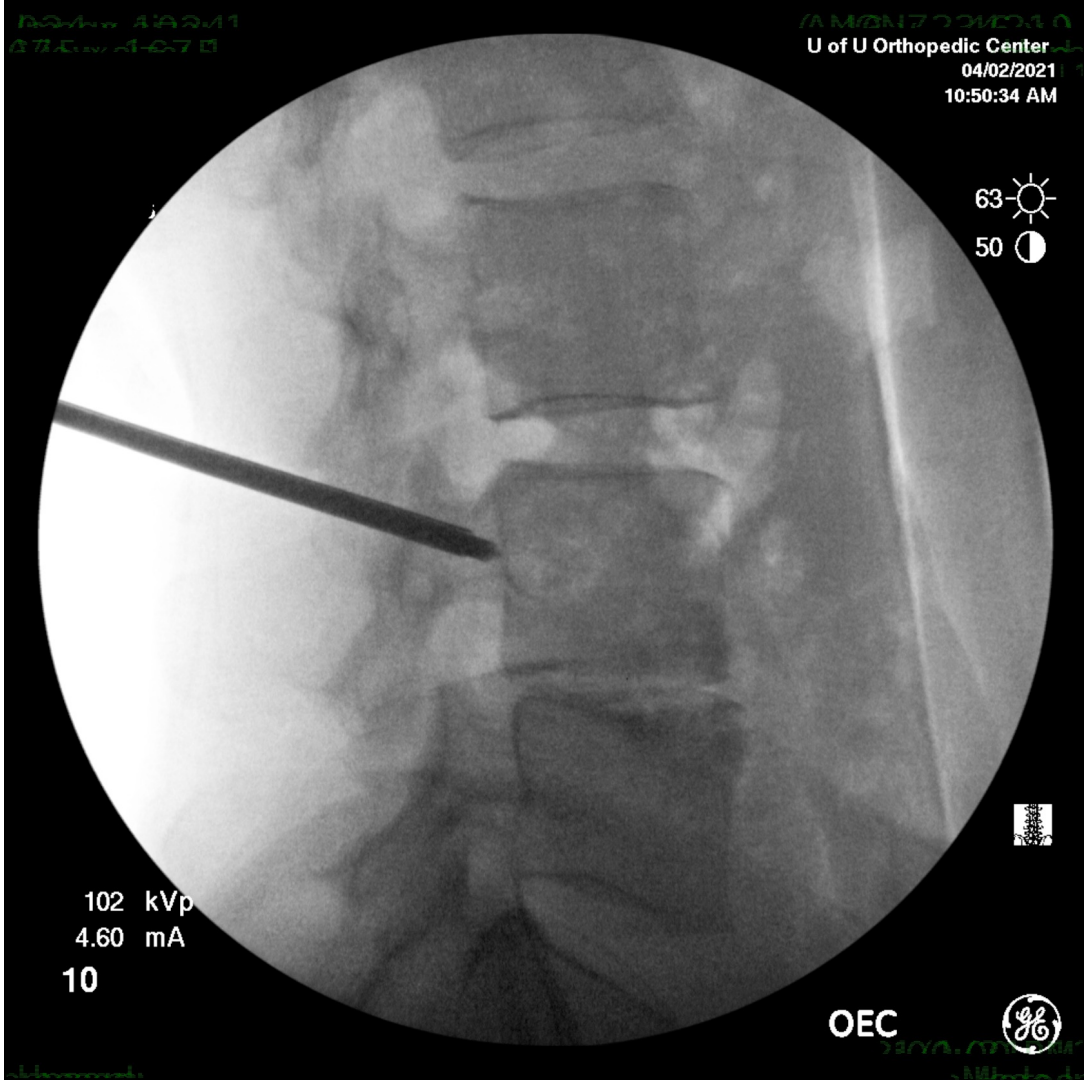
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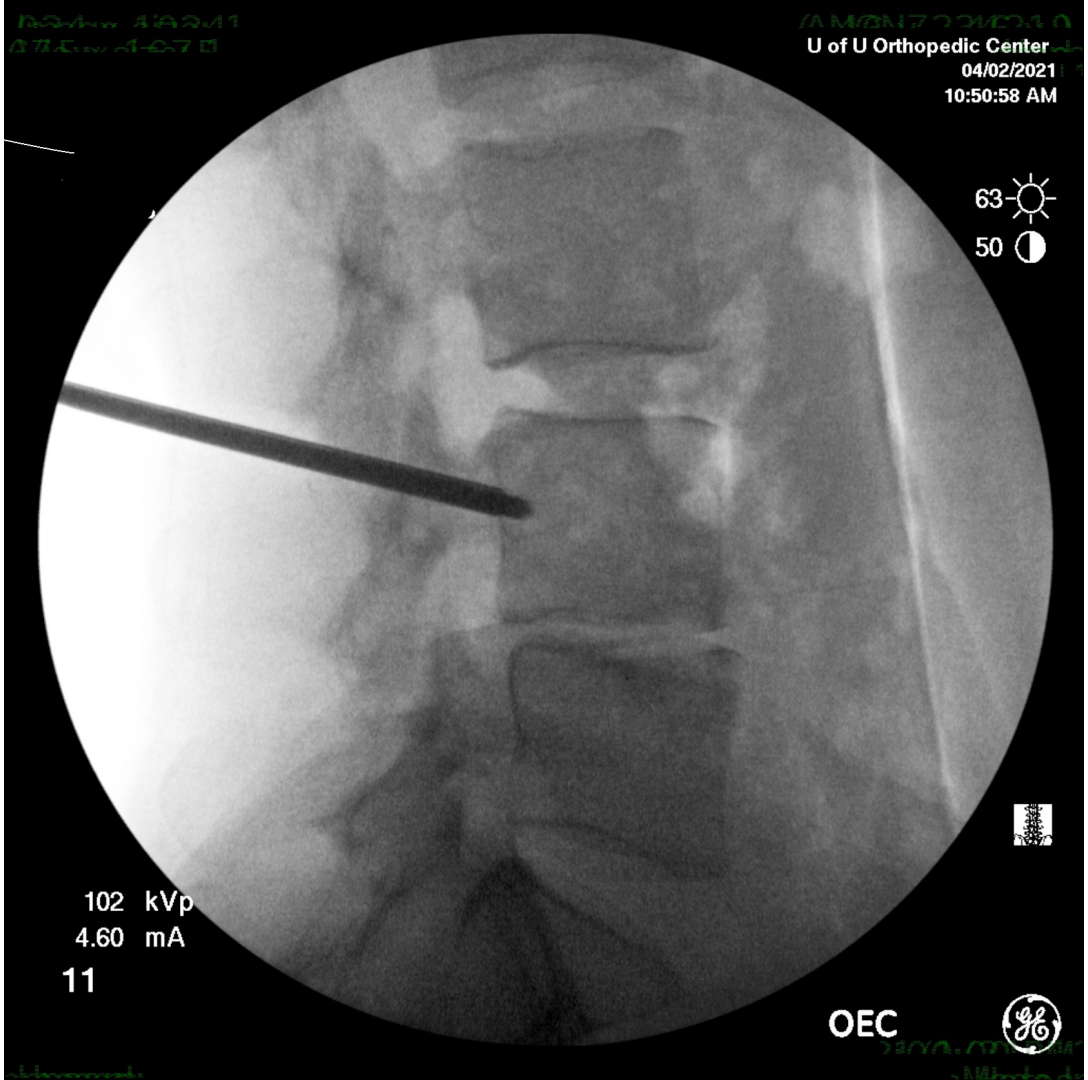
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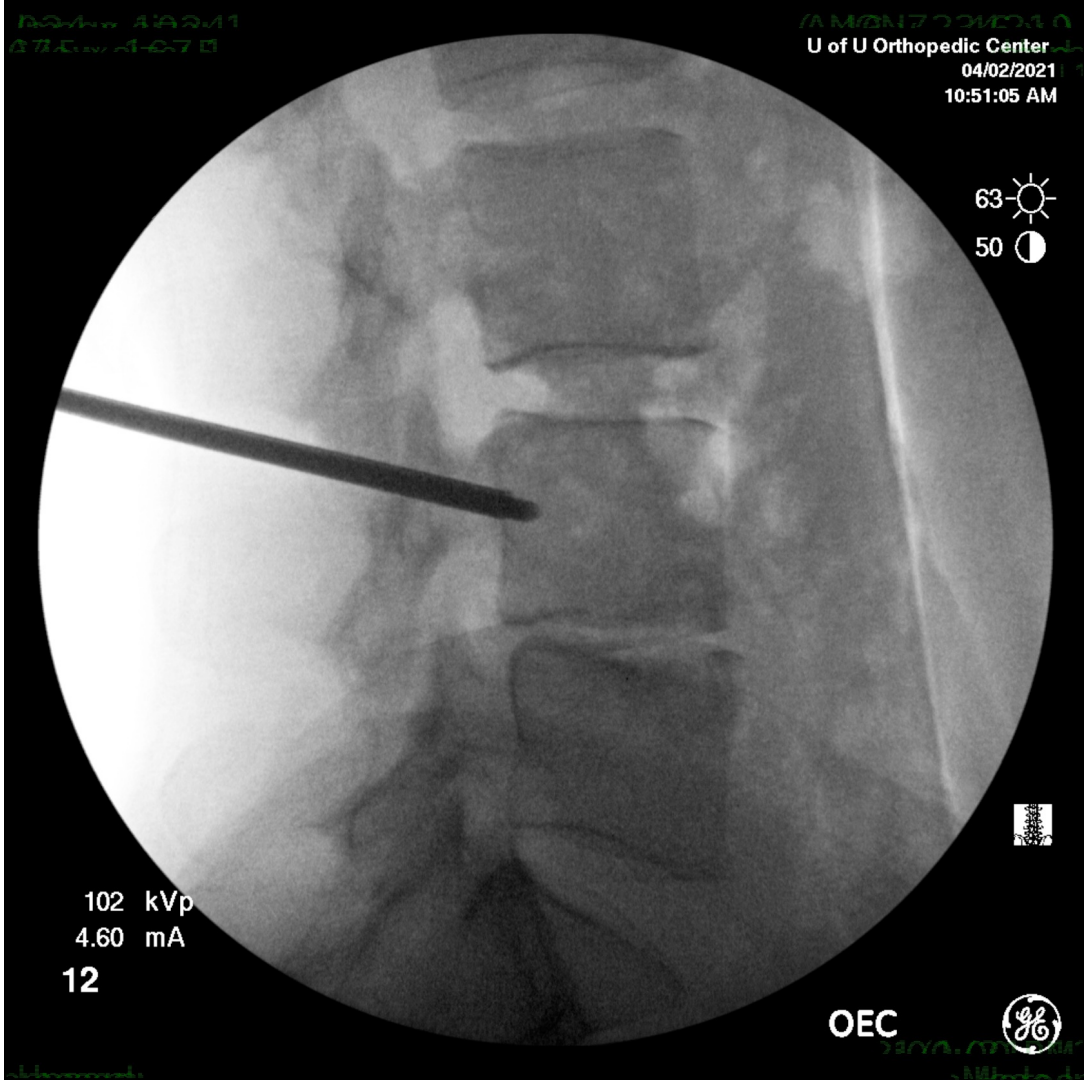
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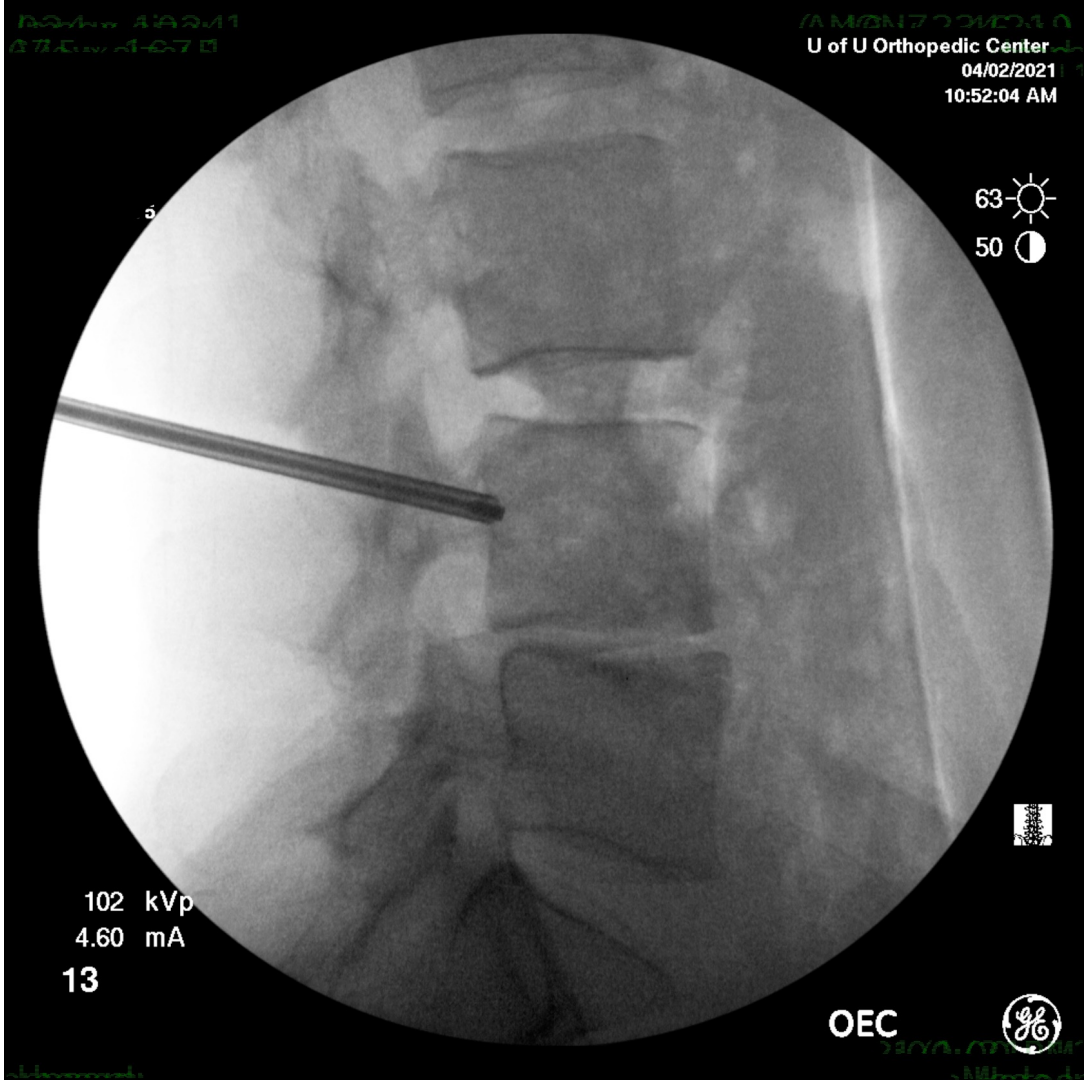
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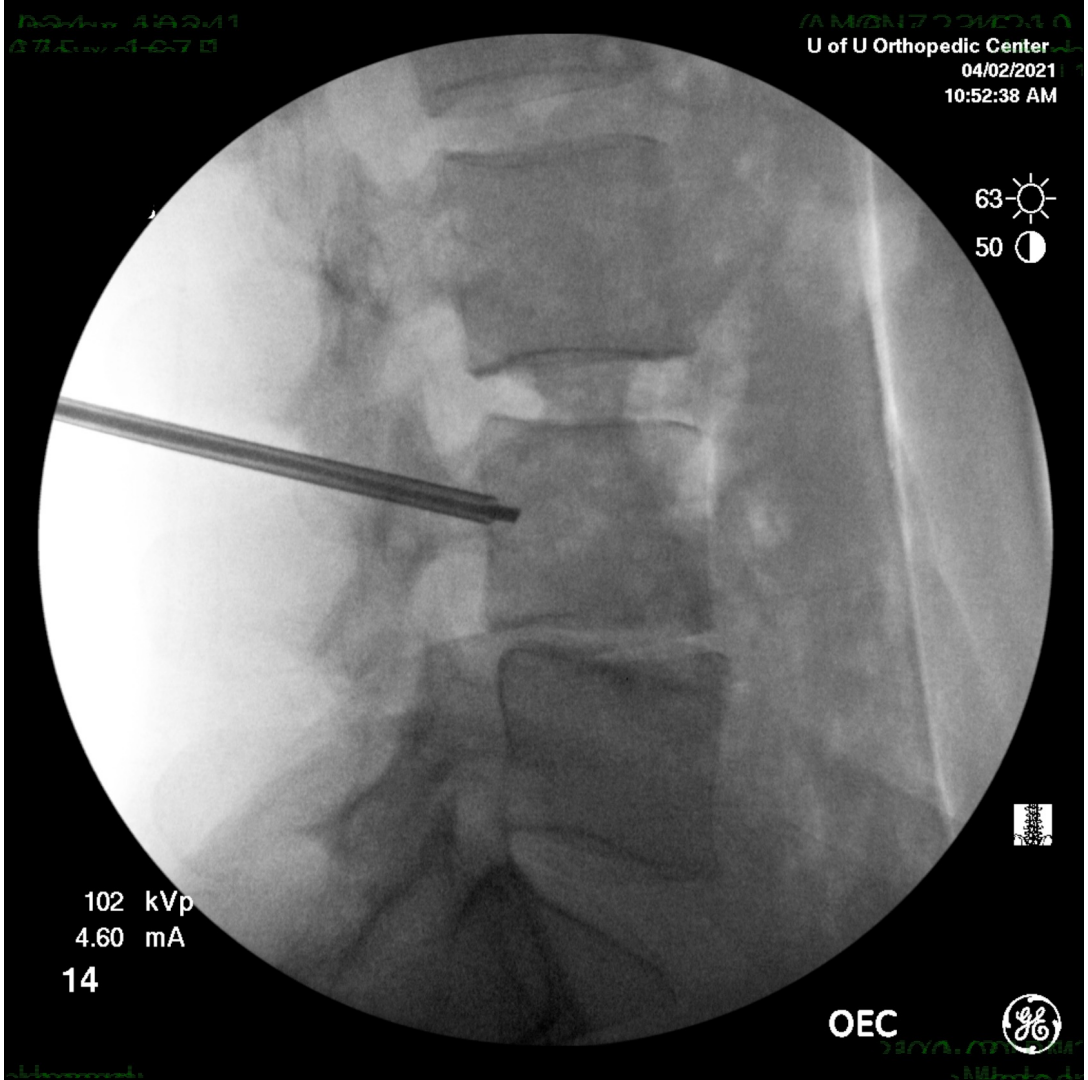
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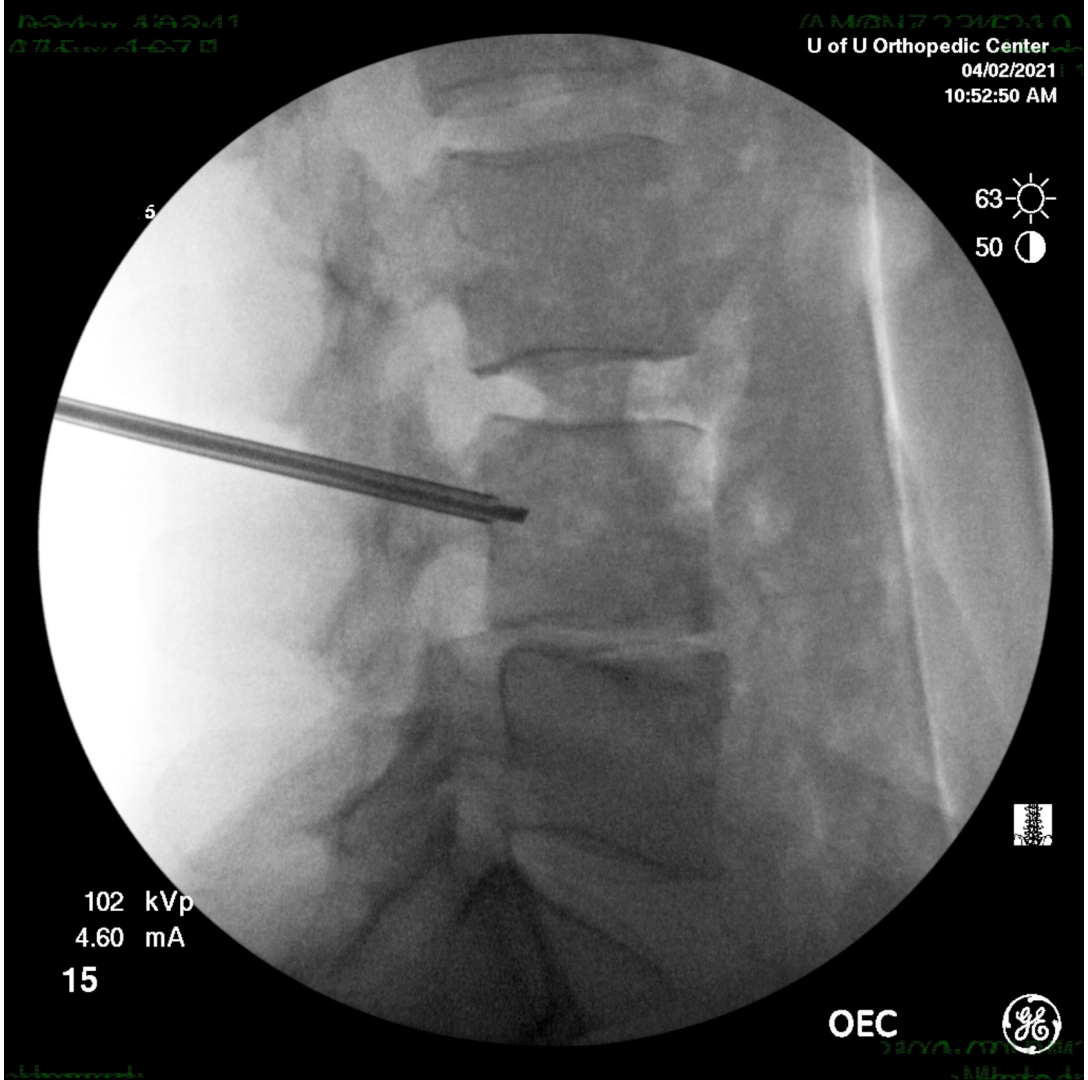
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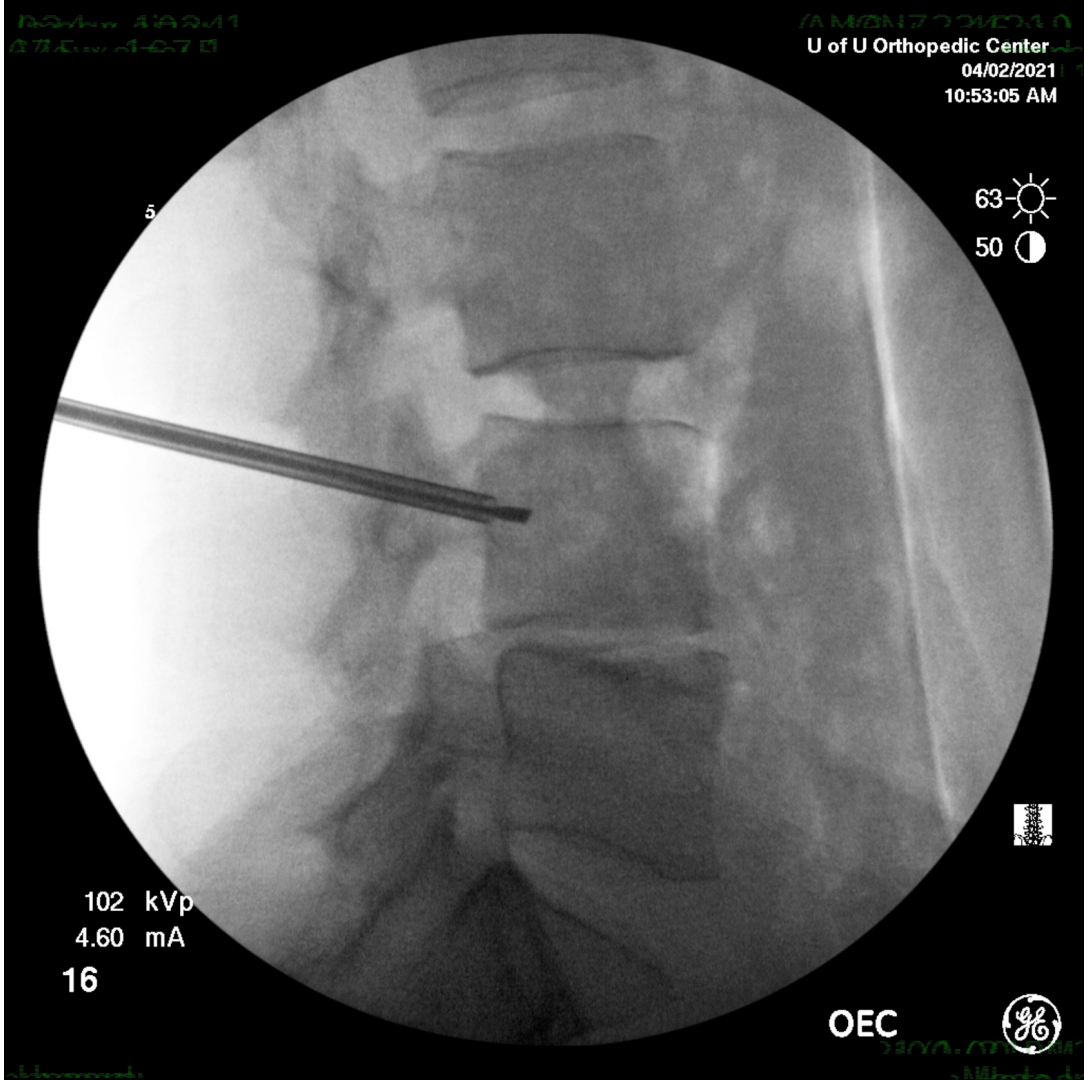
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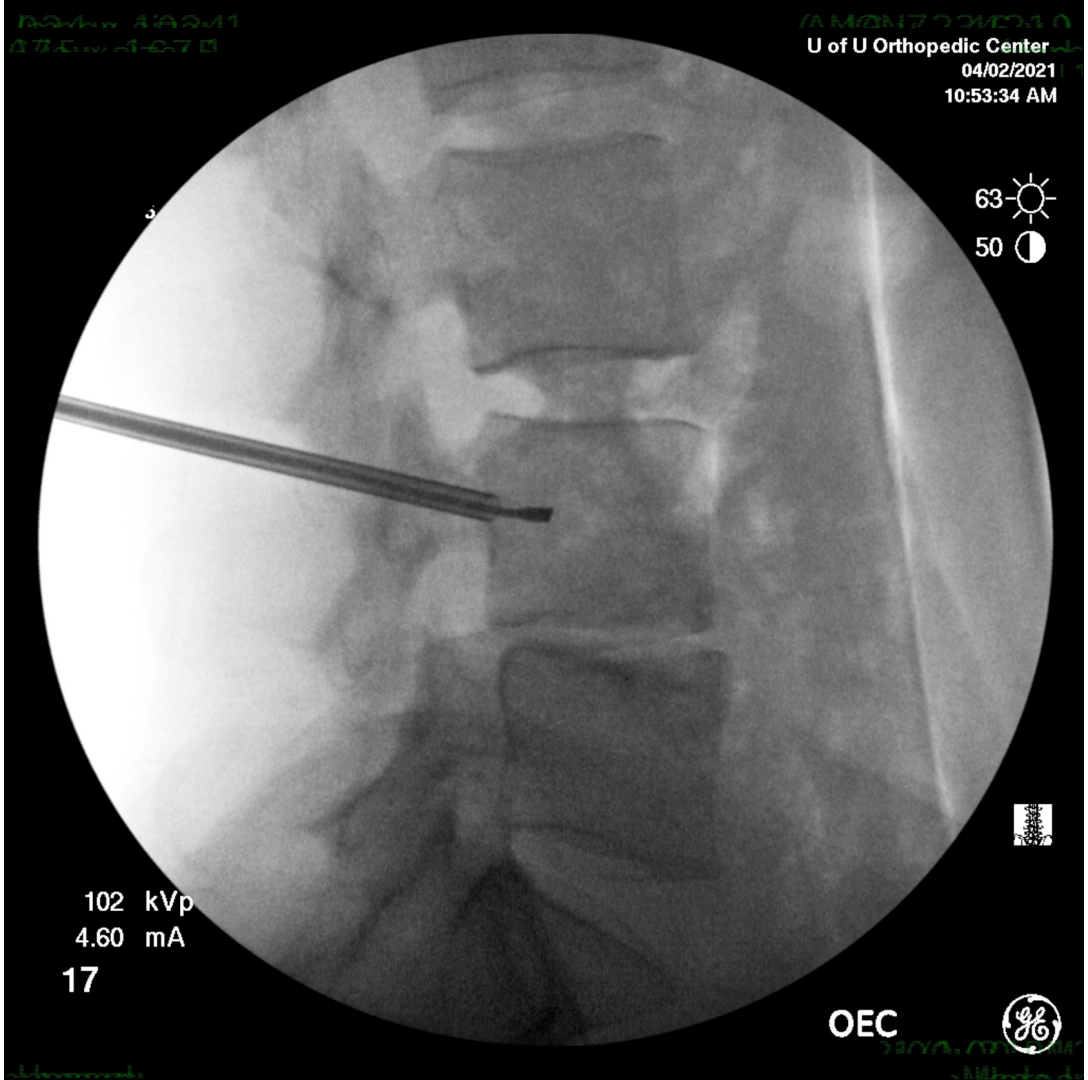
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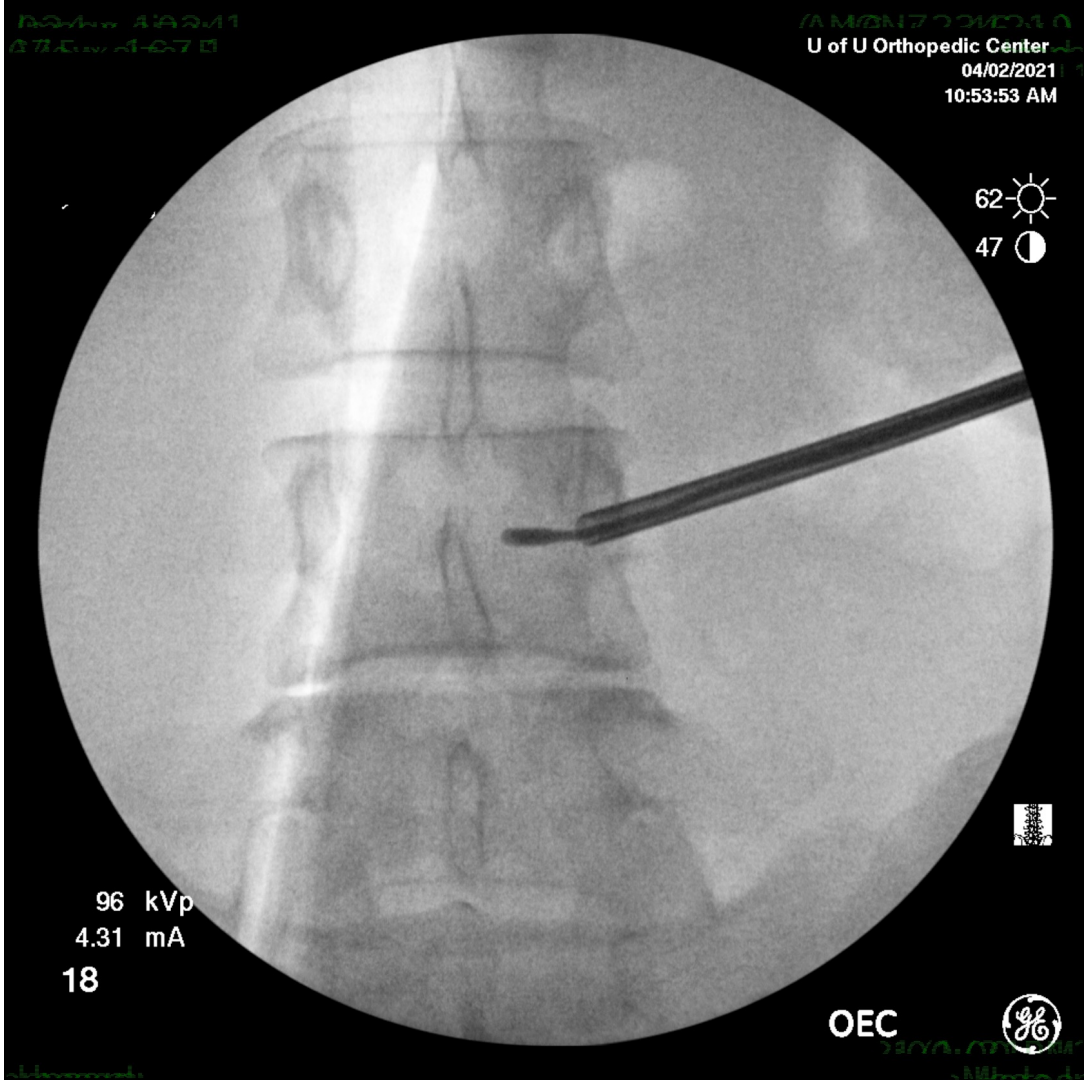
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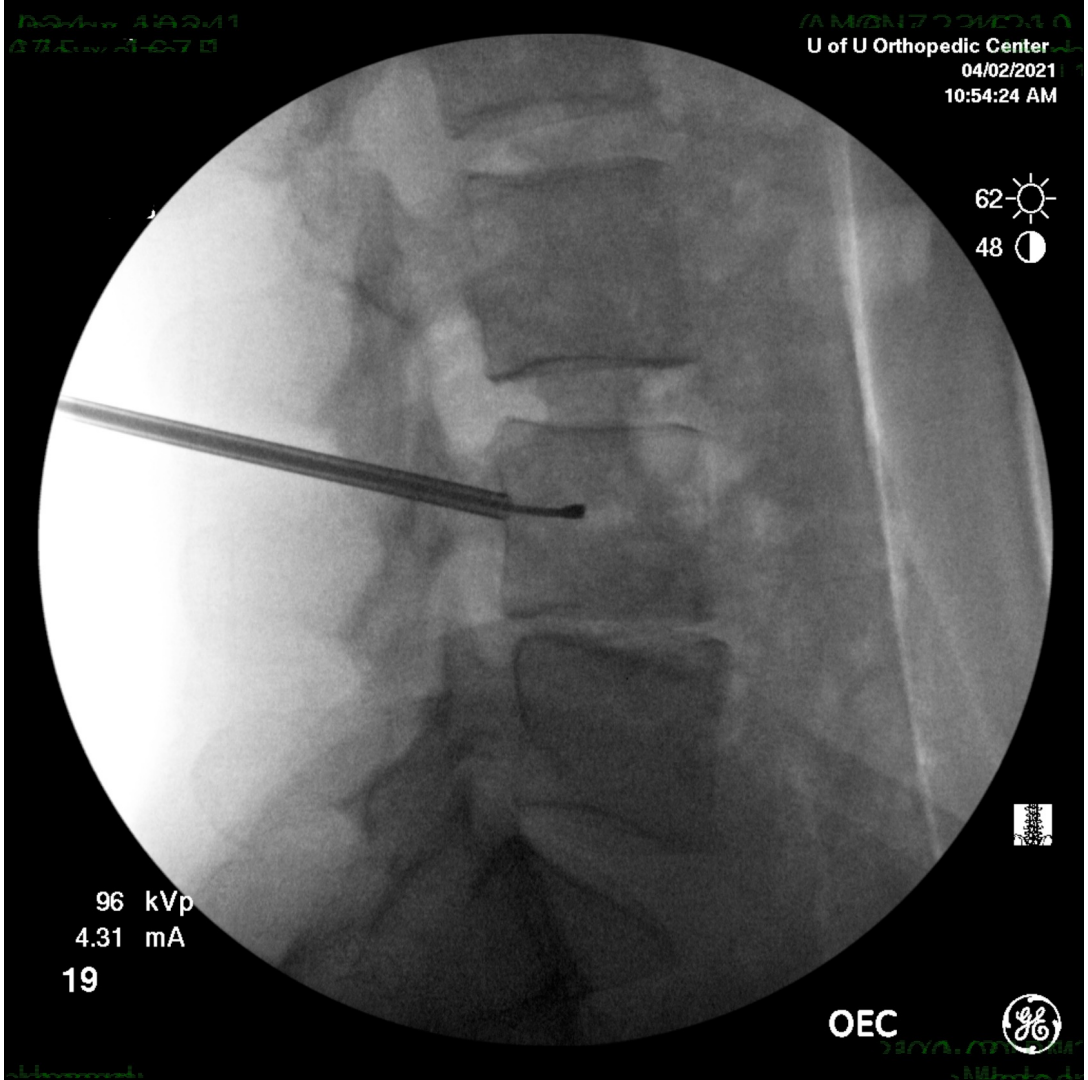
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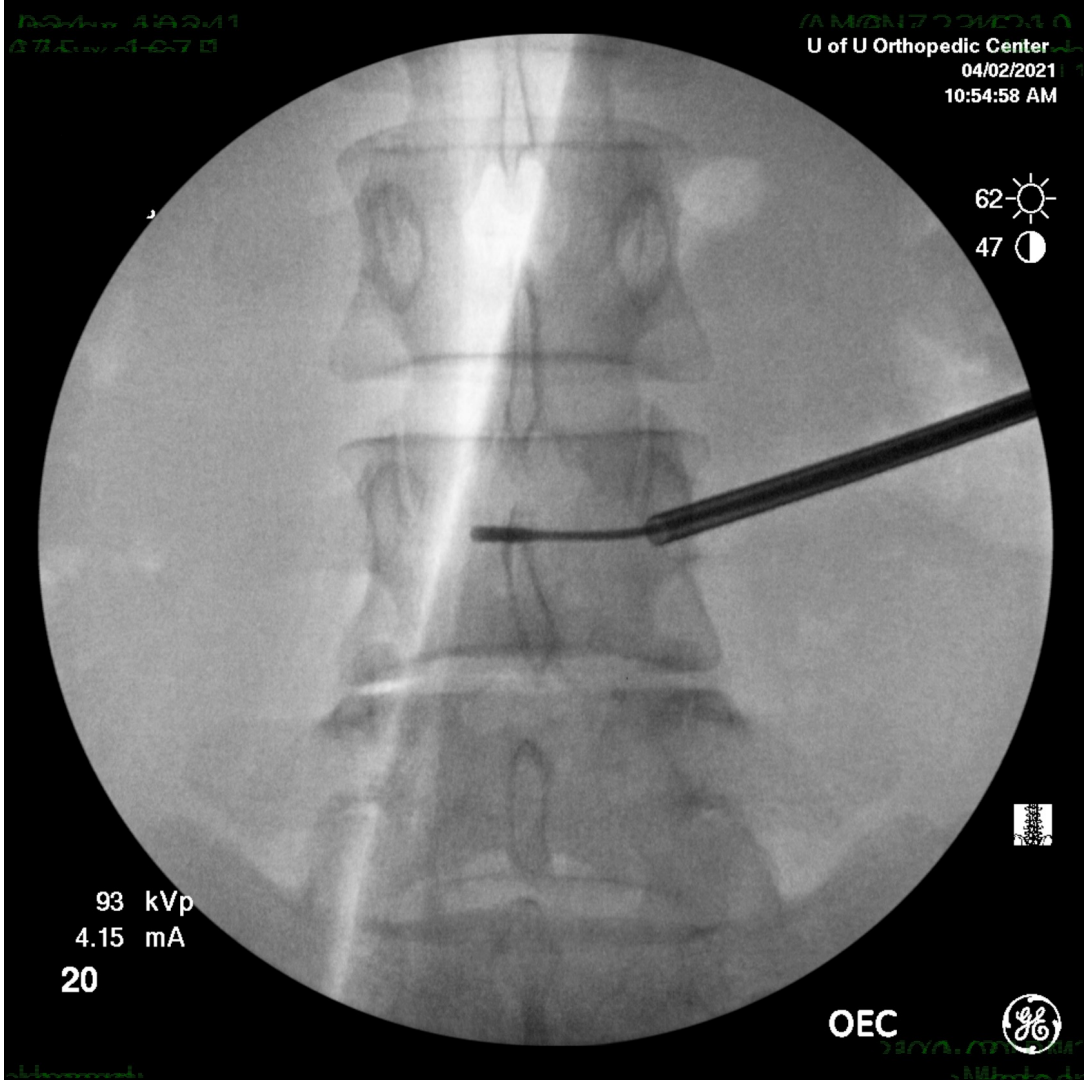
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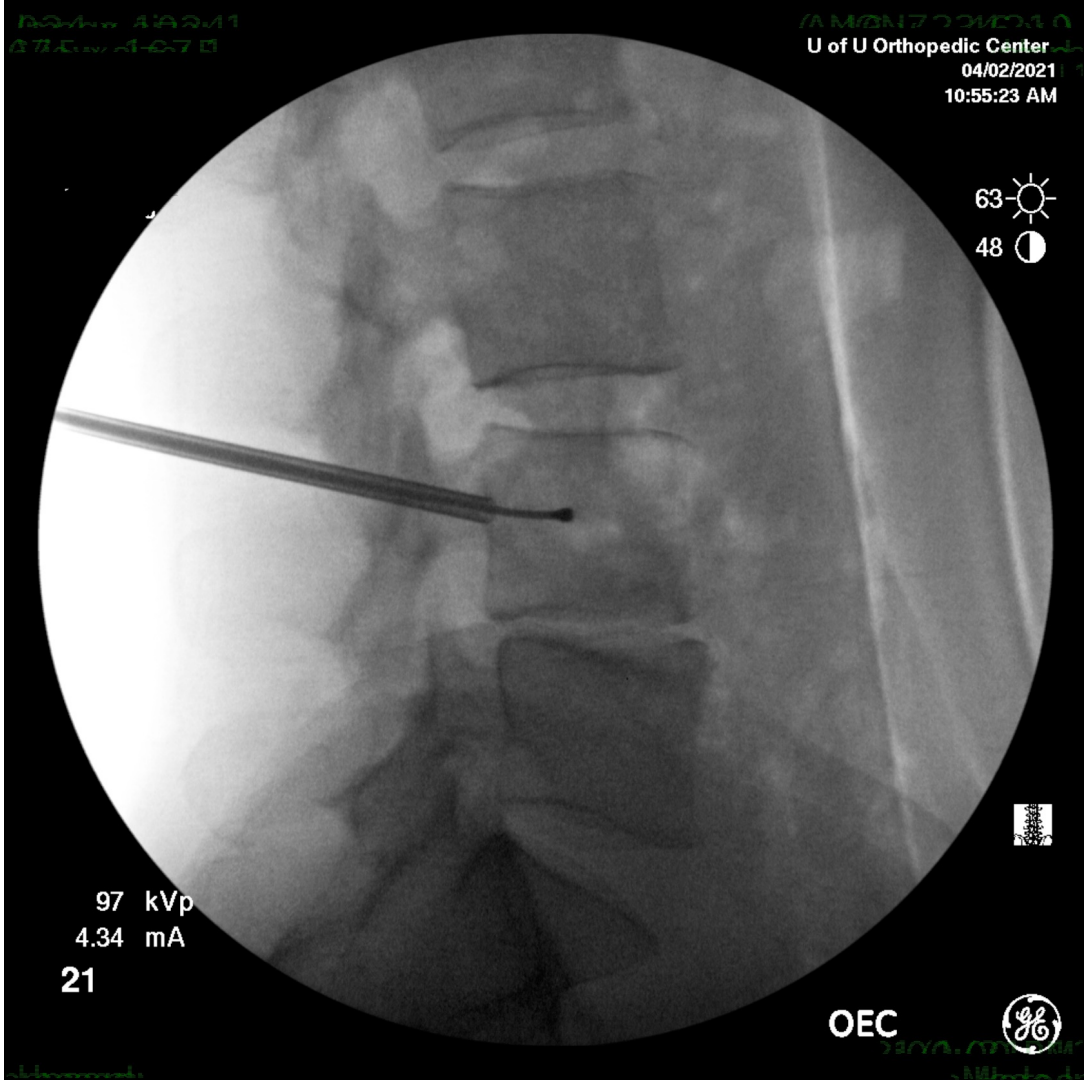
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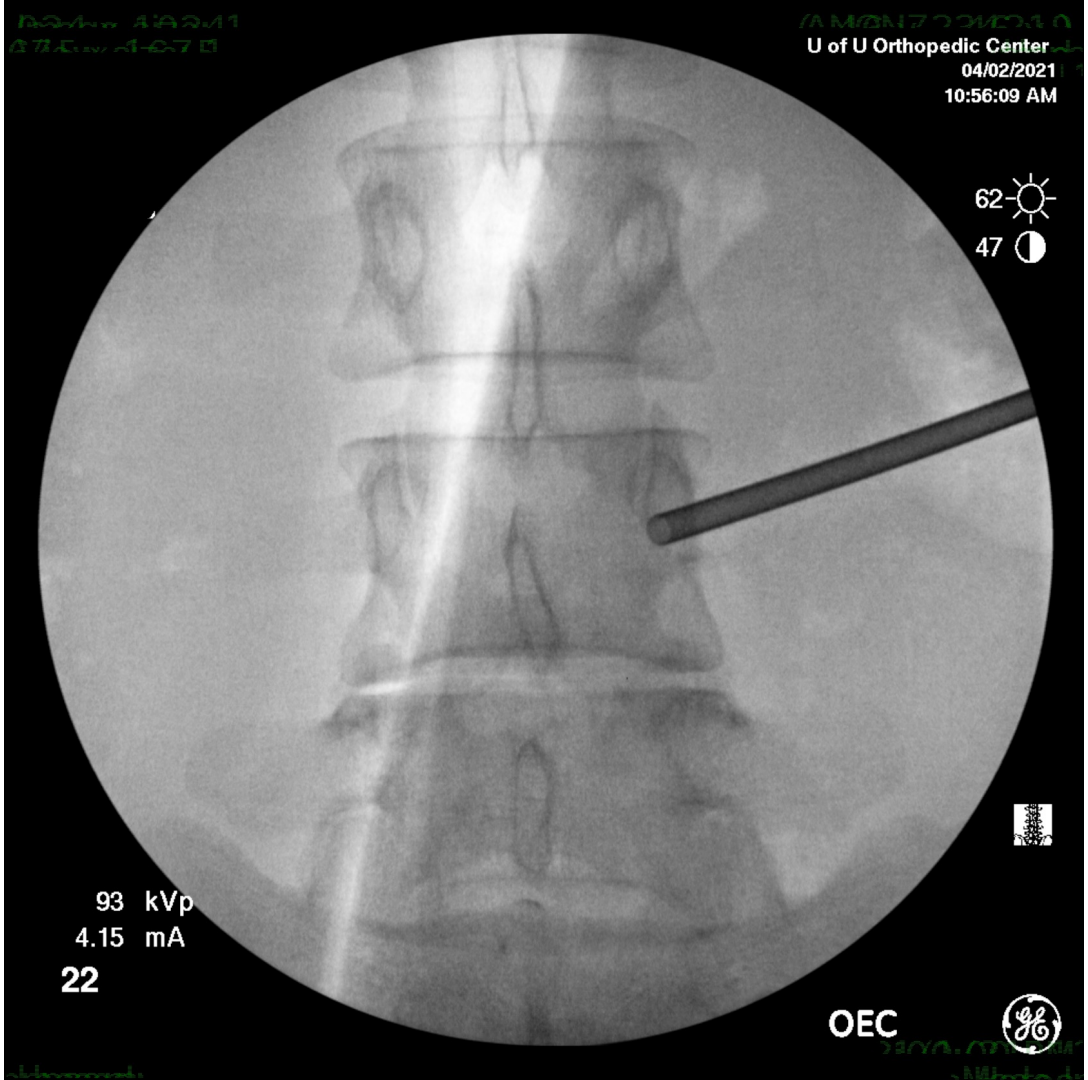
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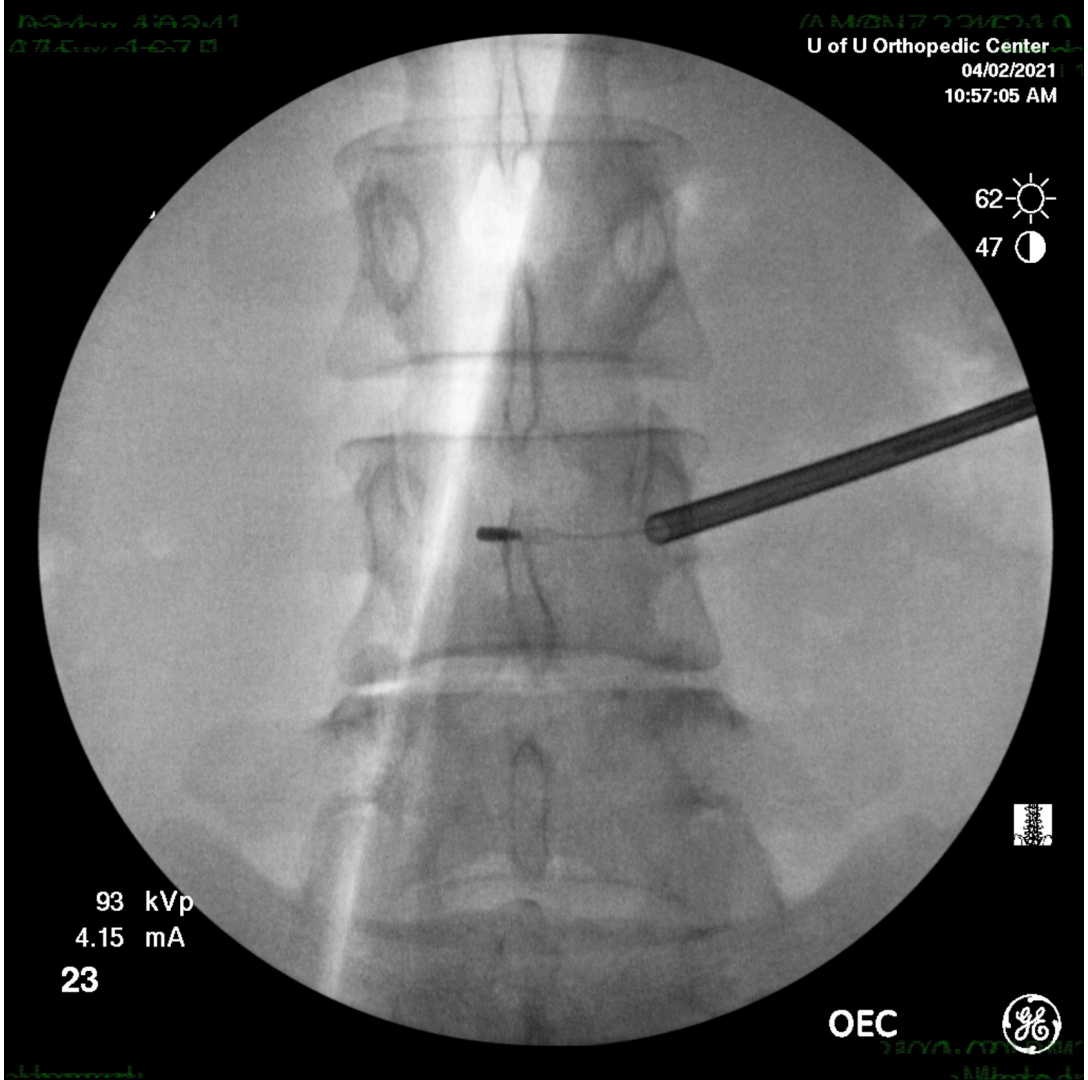
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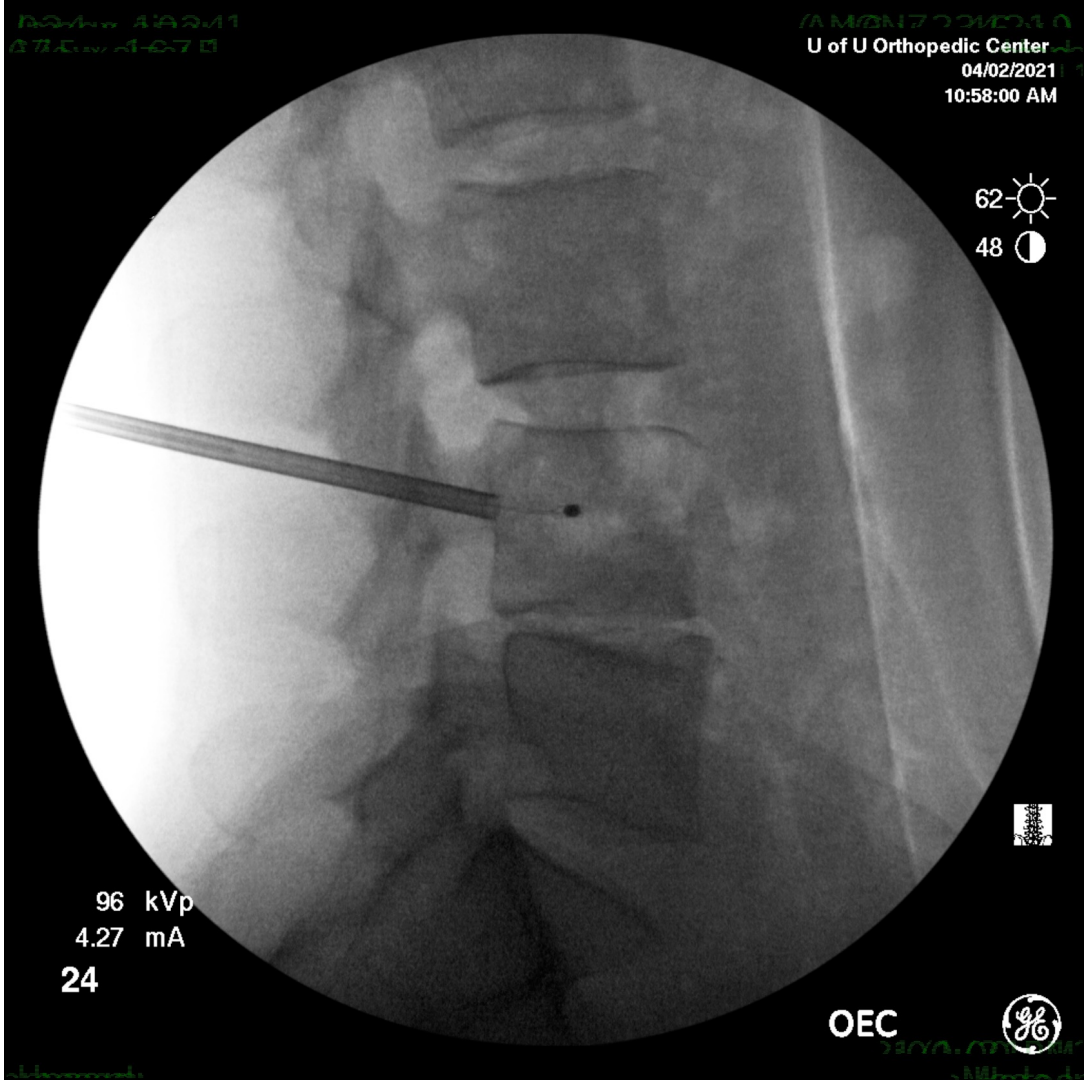
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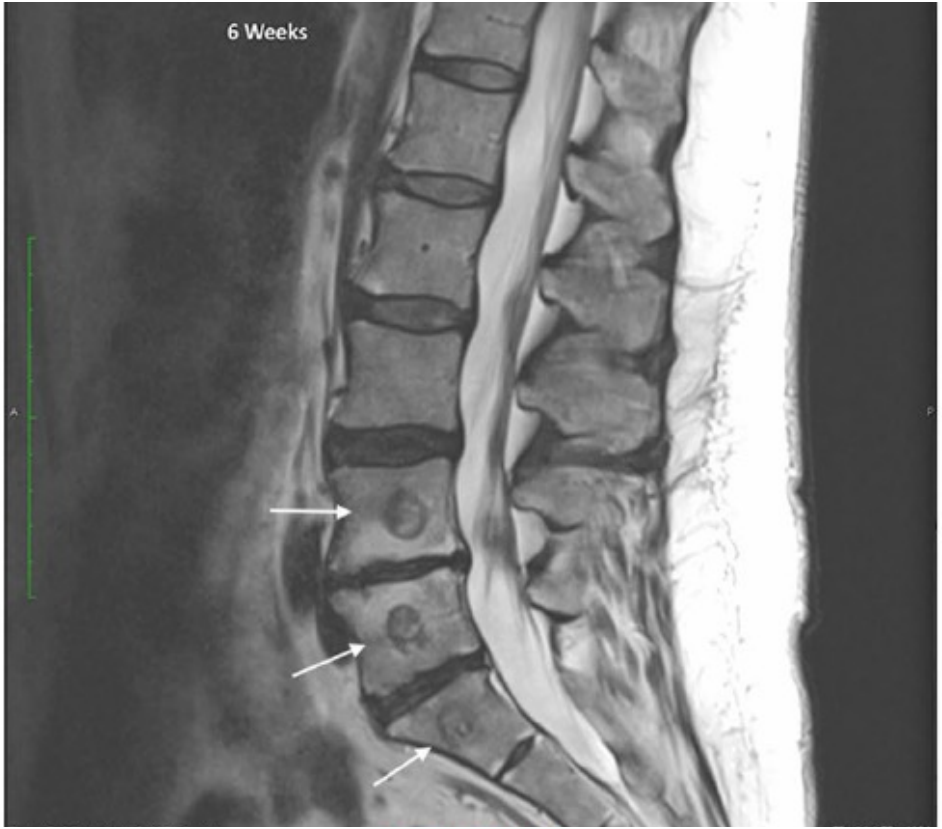
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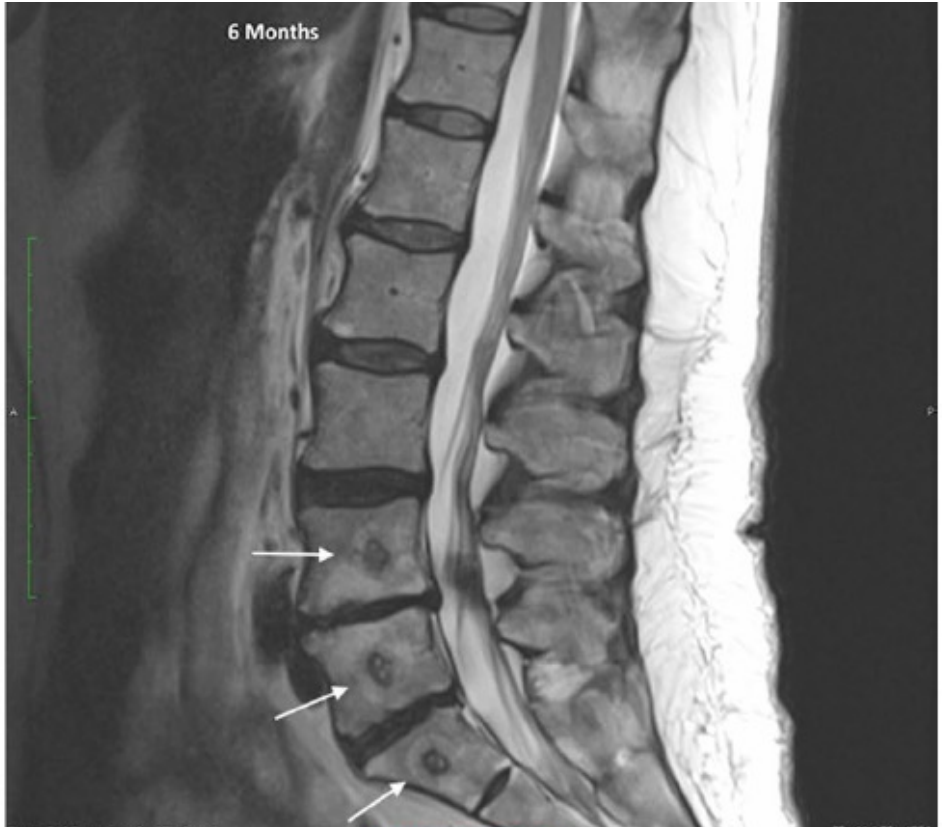

6 Months

ELSEVIER

The Spine Journal 000 (2019) 1–13

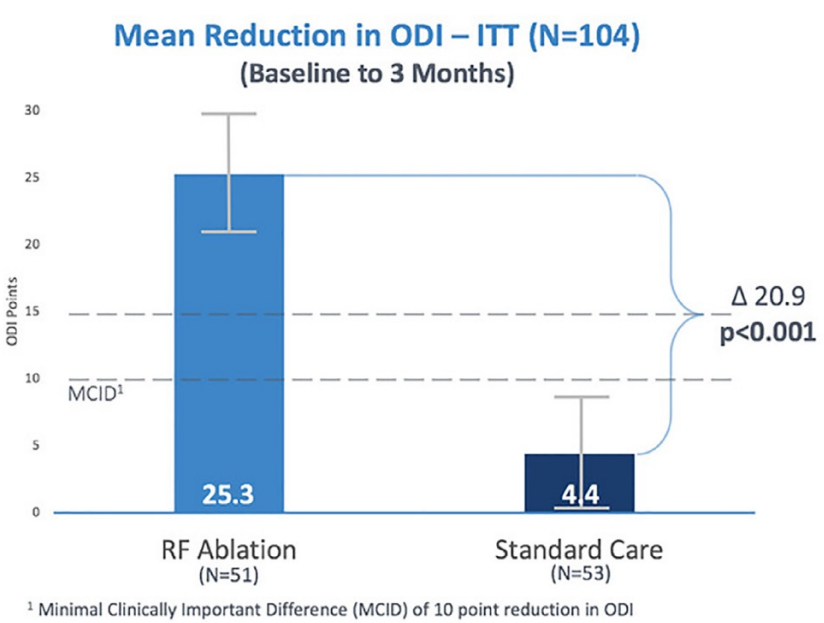
THE SPINE JOURNAL

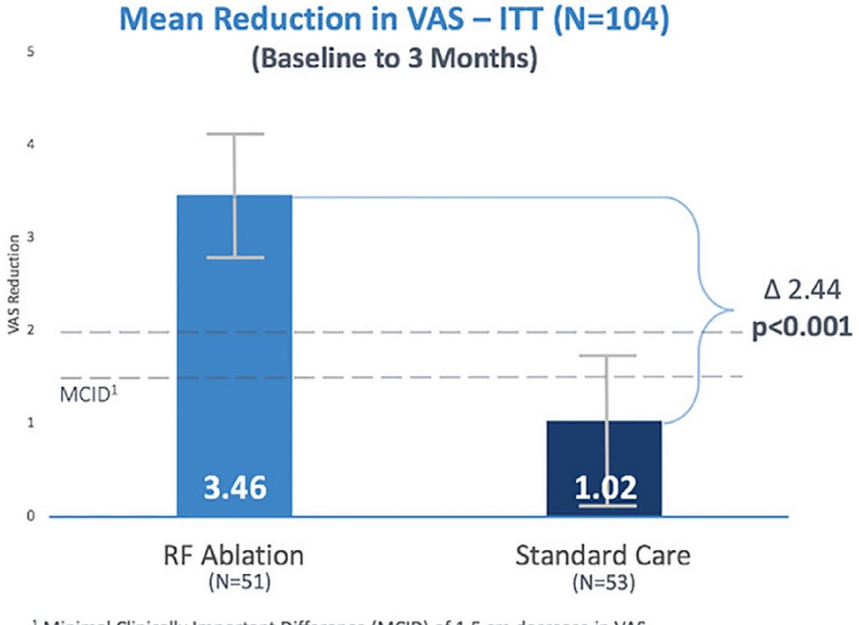
Clinical Study

A prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain

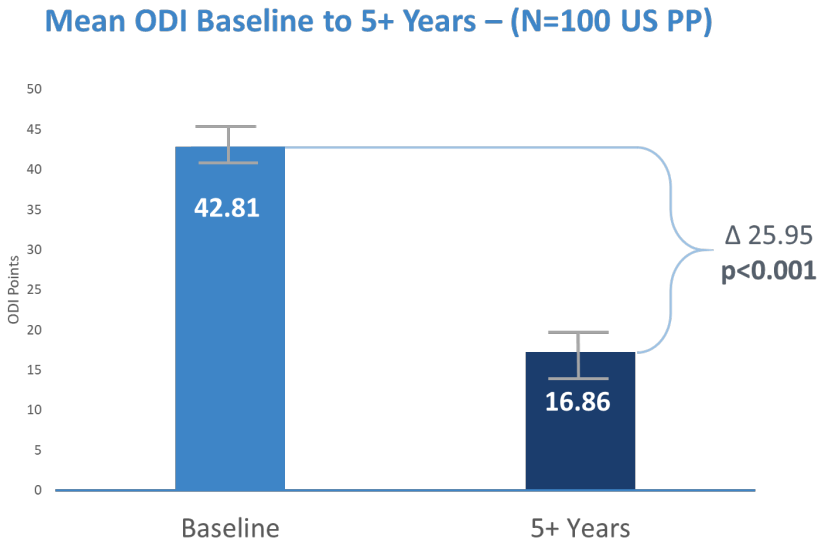
Jad G. Khalil, MD[a,*], Matthew Smuck, MD[b], Theodore Koreckij, MD[c], John Keel, MD[d], Douglas Beall, MD[e], Bradly Goodman, MD[f], Paul Kalapos, MD[g], Dan Nguyen, MD[h], Steven Garfin, MD[i], on behalf of the INTRACEPT Trial Investigators[1]

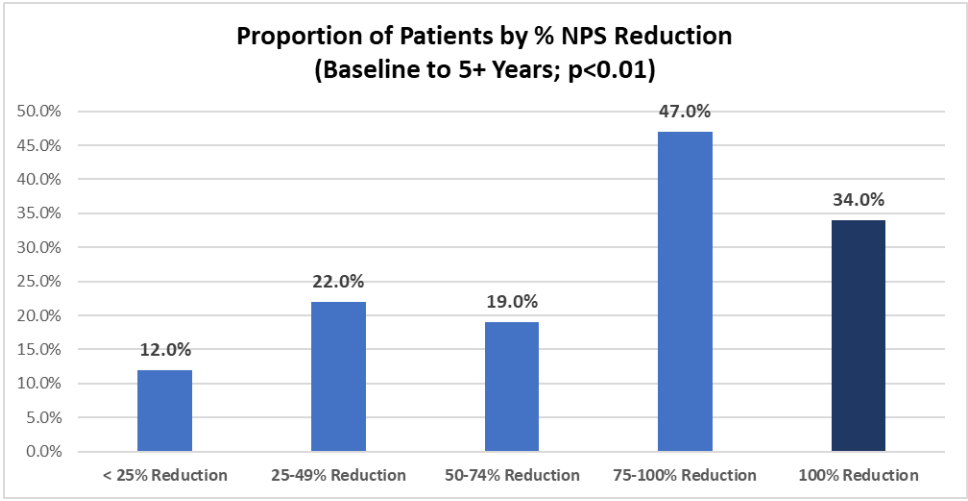
- BVN RFA vs. Conventional medical management (PT, medications, injections, etc.)
- 20-sites, n=104
- **Interim analysis when 60% of participants reached 3-month follow-up**
- Data Management Committee decision to stop enrollment
- *-> statistical superiority for all PROs favoring BVN RFA.*





5 year outcomes





Opioids: 60% *reduction in opioid use* at 5 years

Injections: 93% *reduction in injection use* for LBP at 5 years

Post Ablation Procedures: 8% of patients progressed to a fusion (*5/8 at a single study site)*

Pain Medicine, 23(S2), 2022, S50–S62
https://doi.org/10.1093/pm/pnac070
Review Article

OXFORD

The Effectiveness of Intraosseous Basivertebral Nerve Radiofrequency Ablation for the Treatment of Vertebrogenic Low Back Pain: An Updated Systematic Review with Single-Arm Meta-analysis

Aaron Conger, DO, Taylor R. Burnham DO, MS, Tyler Clark, MD, Masaru Teramoto, PhD, MPH, PStat®, and Zachary L. McCormick, MD

Pain Medicine

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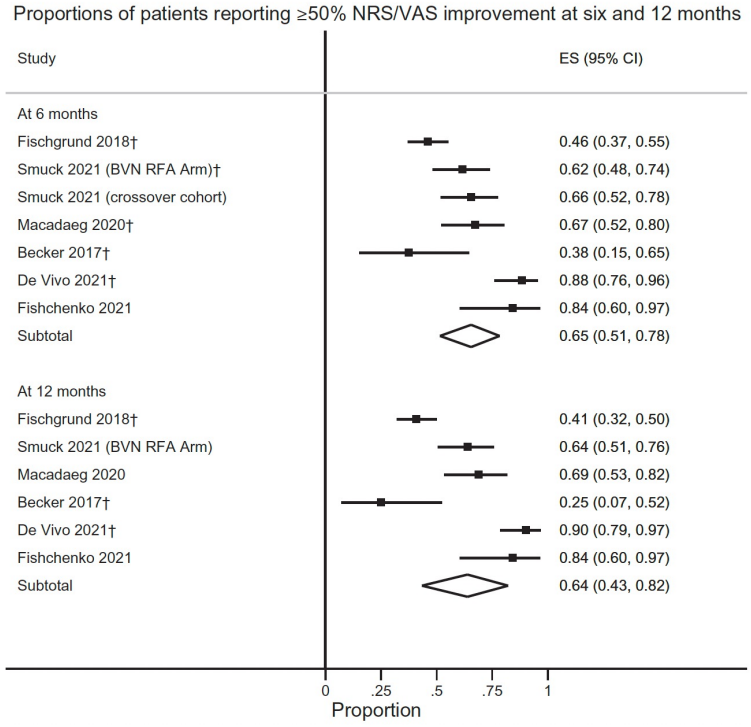
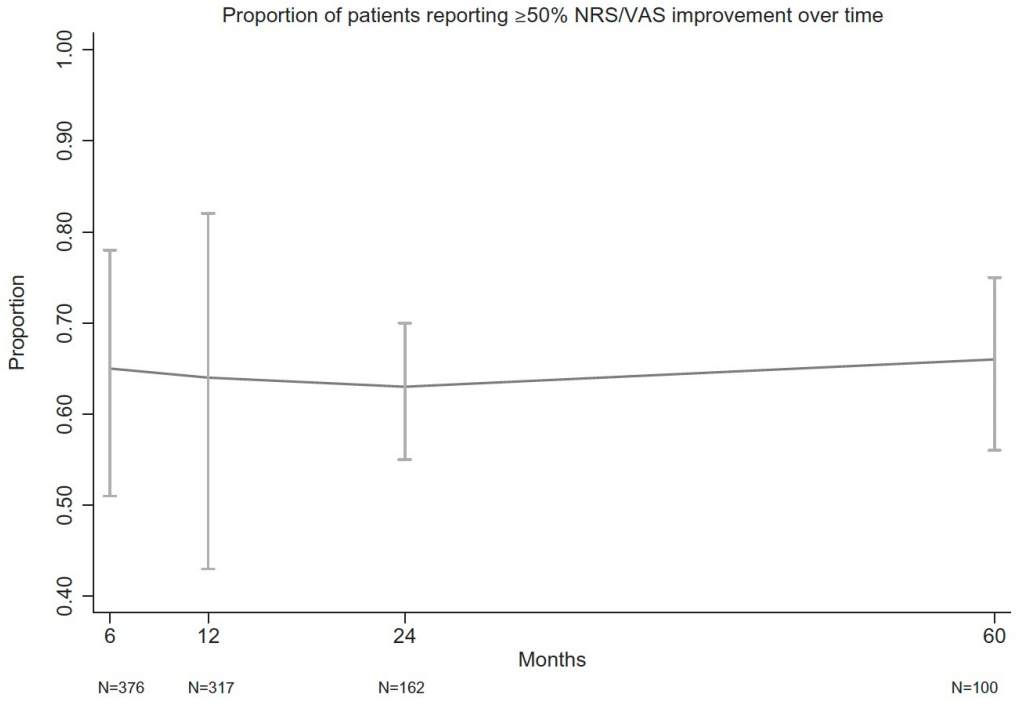
Participants with *Improvement* in NRS of ≥50%





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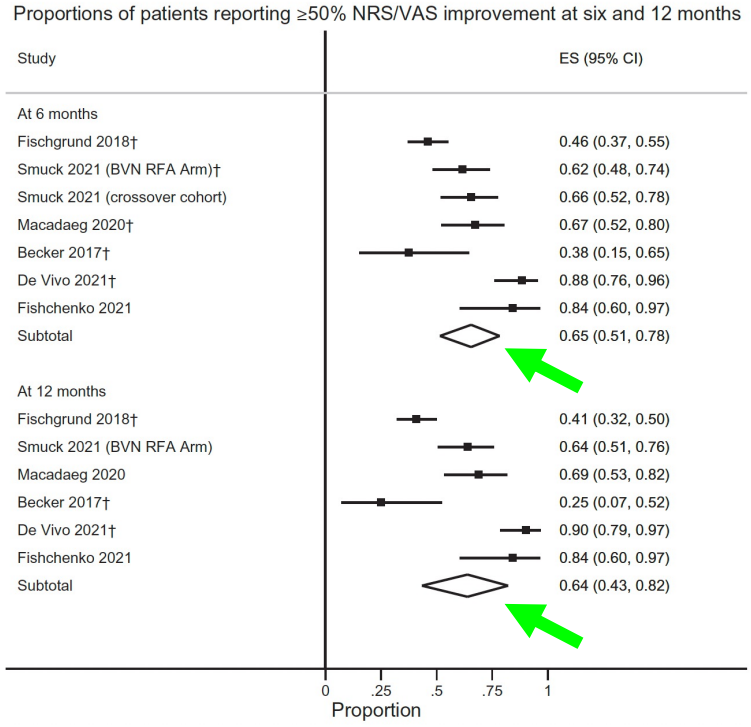

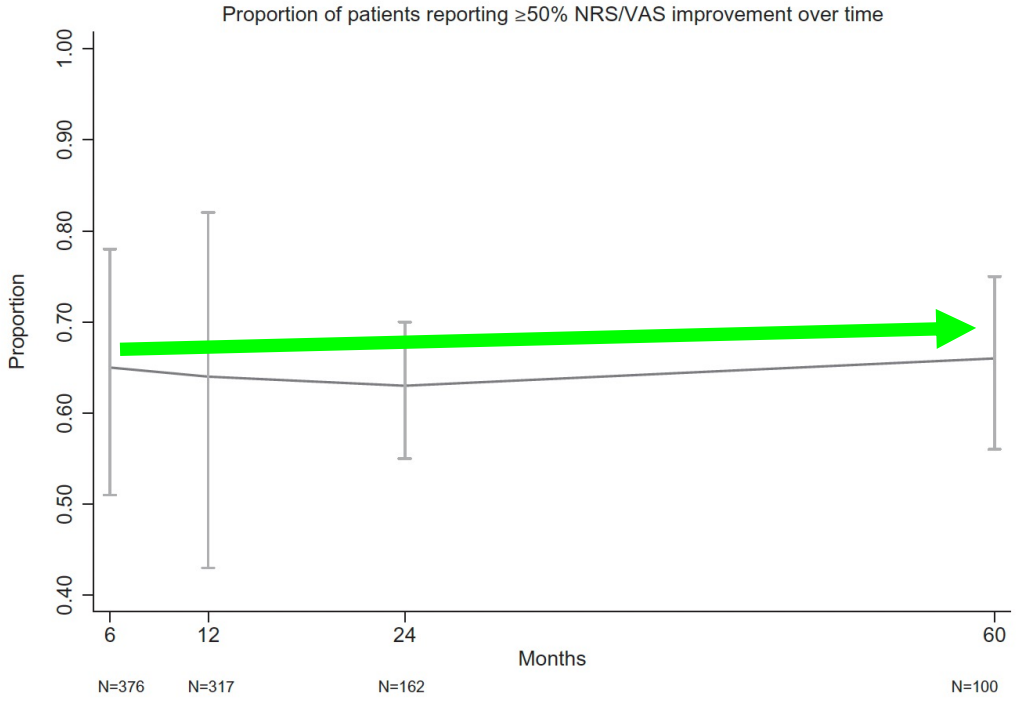

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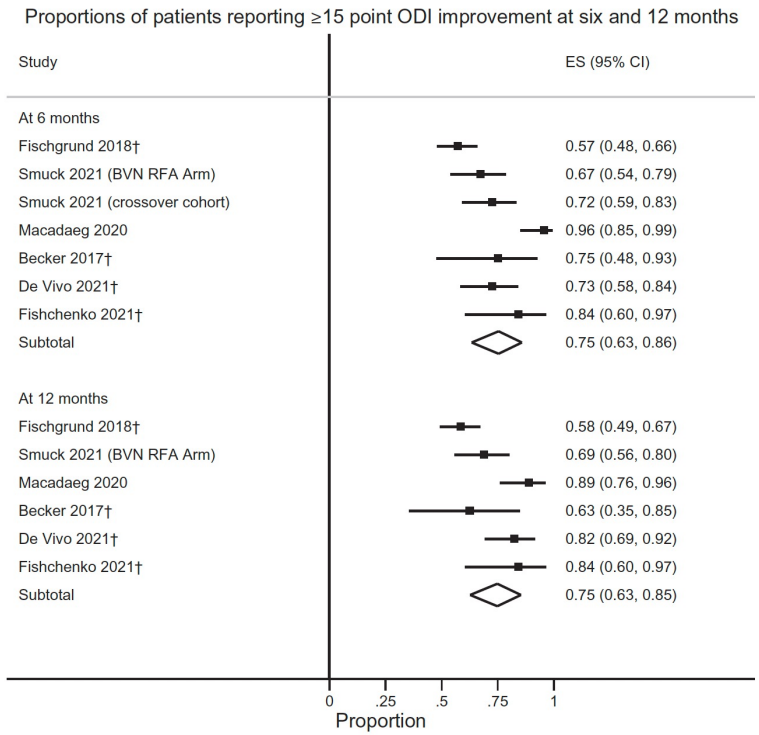
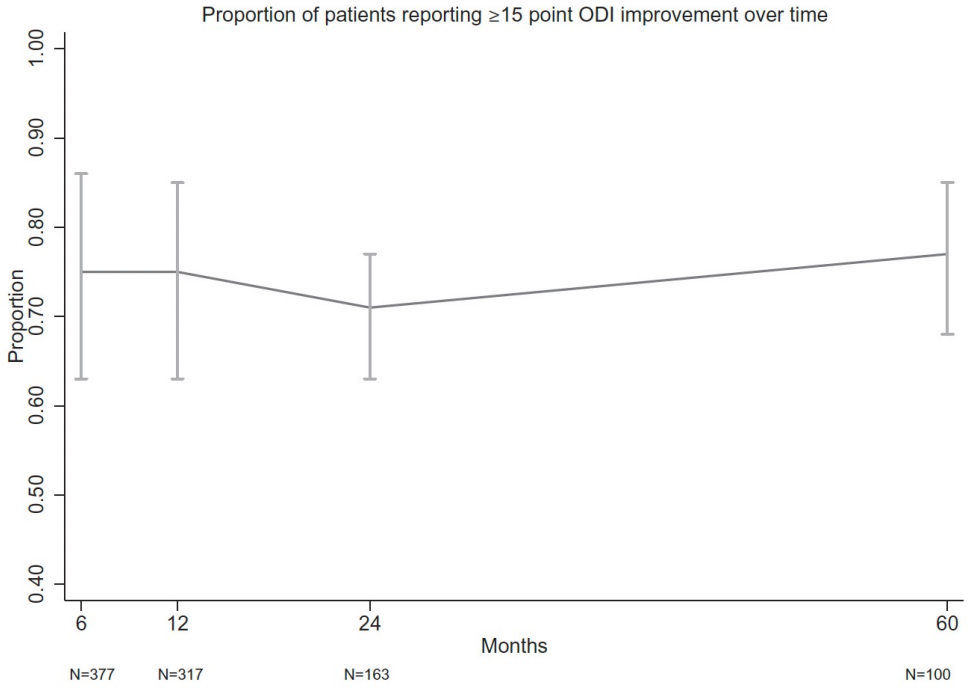


Participants with *Improvement* in ODI of ≥15



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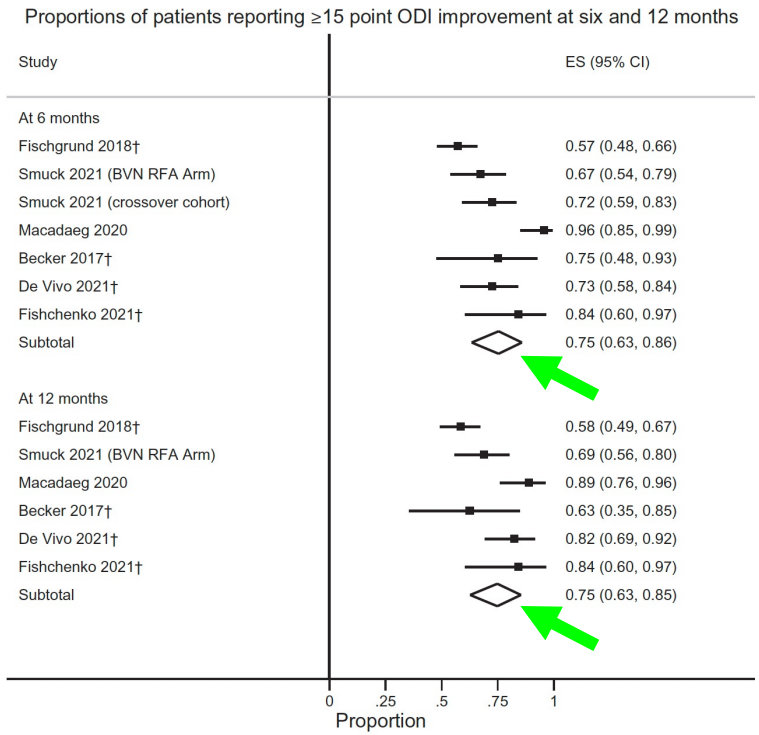
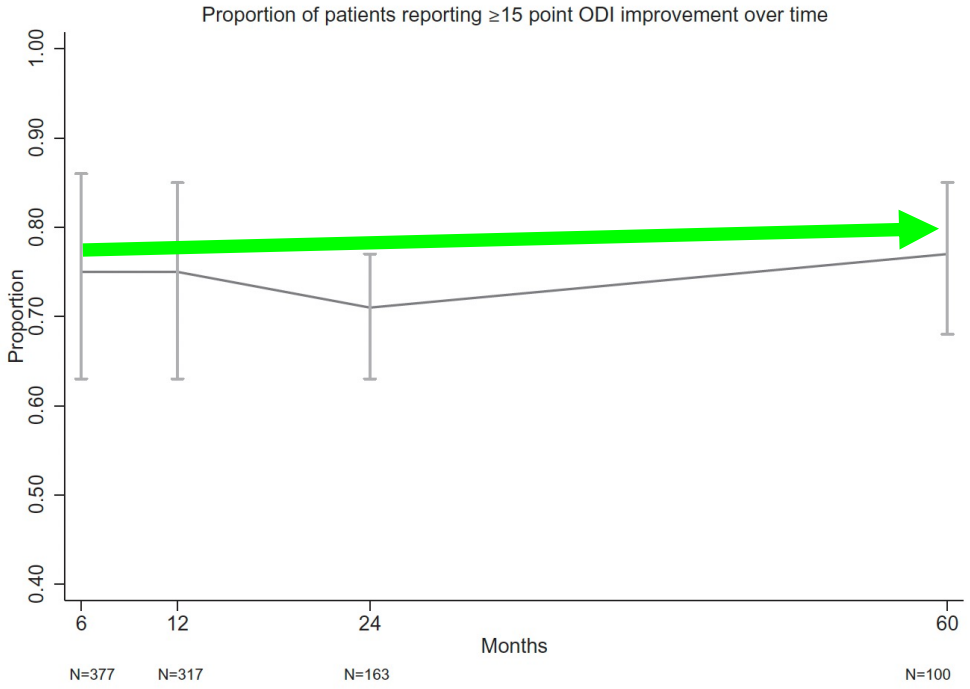


Participants with *Improvement* in ODI of ≥15



University of Utah: The Intercept Global Registry Pilot Study

Candidates: refractory axial Low Back Pain without evidence of nerve root impingement

***Outcomes**: NRS, ODI, Opioid use*
- 3 and 12 months

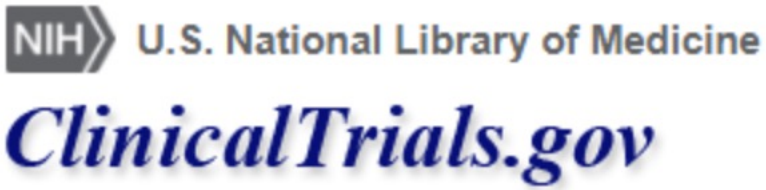
***Complications data** (immediate, short-term, long-term)*

Subject ID	Baseline ODI	3 Mo ODI	Change in ODI	% Change	Baseline NRS	3 Mo NRS	Change in NRS	% Change	Treatment Location	Baseline Opioid Use	3 Mo Opioid Use	Complications
001-0001	24	32	-8	-33%	7	7	0	0%	L5, S1	Yes	Yes	Procedure aborted due to pedicle access challenge
001-0002	40	34	6	15%	8	7	1	13%	L5, S1	No	No	none
001-0003	34	18	16	**47%**	6	3	3	**50%**	L5, S1	No	No	none
001-0004	54	22	32	**59%**	7	3	4	**57%**	L5, S1	Yes	Yes	none
001-0005	54	69	-15	-28%	9	10	-1	-11%	L3, L4	Yes	Yes	none
001-0006	76	56	20	26%	6	4	2	33%	L3, L4, L5	Yes	**No**	none
001-0007	28	6	22	**79%**	7	2	5	**71%**	L3, L4, L5, S1	No	No	none
001-0008	30	4	26	**87%**	5	0	5	**100%**	L5, S1	No	No	none
001-0009	18	20	-2	-11%	7	8	-1	-14%	L3, L4, L5, S1	Yes	**No**	none
001-0010	49	33	16	**33%**	10	5	5	**50%**	L5, S1	Yes	**No**	none

- **5/10 patients with >50% pain improvement and >30% ODI improvement**
- **7/10 patient with >50% pain improvement and >30% ODI improvement OR Opioid Cessation**

The Intercept Global Registry

https://clinicaltrials.gov/ct2/show/NCT04449835



Information from the National Library of Medicine

NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04449835***

The Intercept Global Registry

Candidates: refractory axial low back pain without evidence of nerve root impingement, Type 1 or Type 2 Modic Changes

***Outcomes**: NRS, ODI, PROMIS-29, EQ-5D, Opioid and non-opioid analgesic use, additional healthcare utilization*

- *1, 3, 12 months, 2 and 5 year data*

***Complications data** (immediate, short-term, long-term)*

Future Directions

- **Selection in patients with additional spinal pathology?** *i.e stable spondy, mild to moderate scoliosis, adjacent fusion level, mixed pain*
- **Interventional selection methods?** *i.e. discography, discoblock, other?*
- **Novel imaging biomarker(s)?**

Thank you!

Zachary L. McCormick, MD

Vice Chair and Associate Professor, PM&R

Chief, Division of Spine and Musculoskeletal Medicine

Founding Director, Clinical Spine Research Program

Founding Director, Interventional Spine Fellowship

University of Utah School of Medicine

HEALTH
UNIVERSITY OF UTAH

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