Intradiscal Biacuplasty for treatment of Discogenic Lower Back Pain

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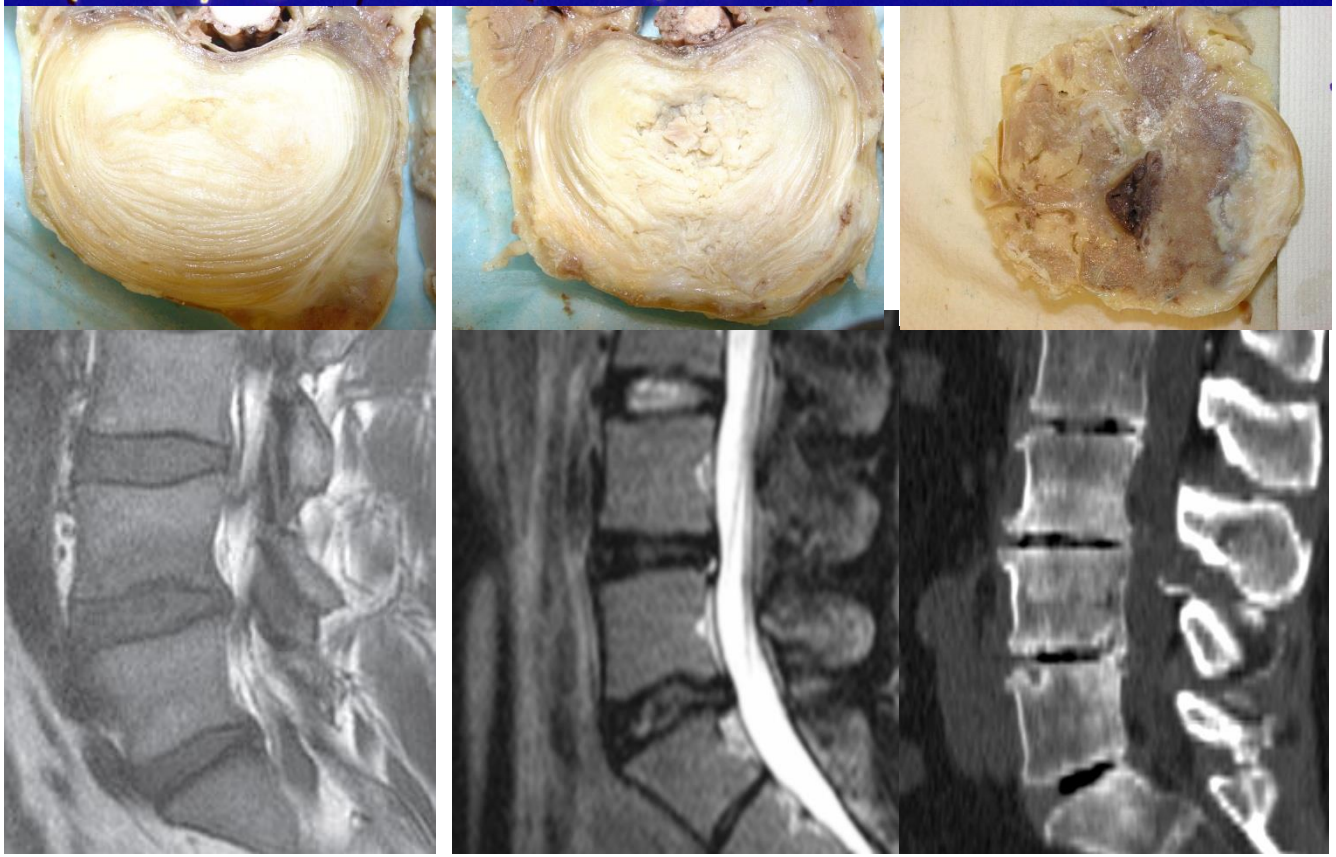
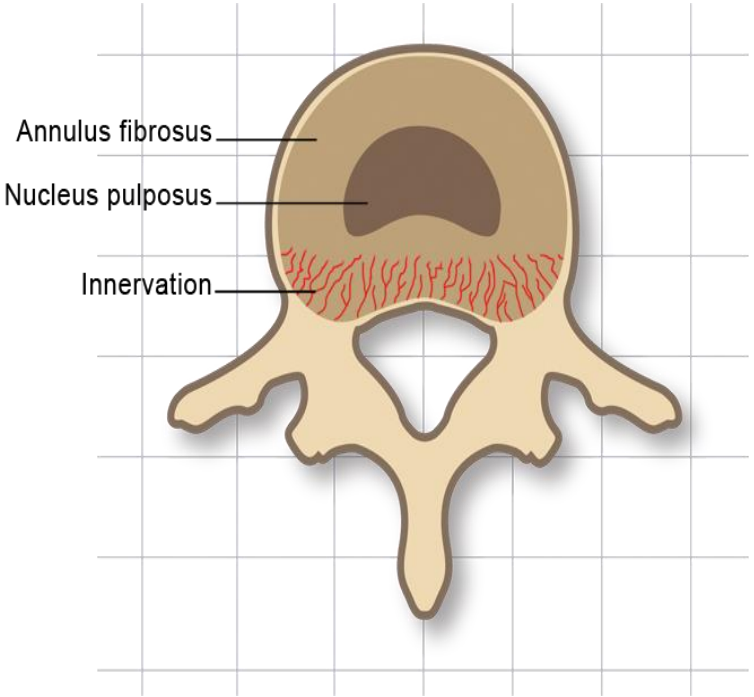
DEGENERATION AND AGING



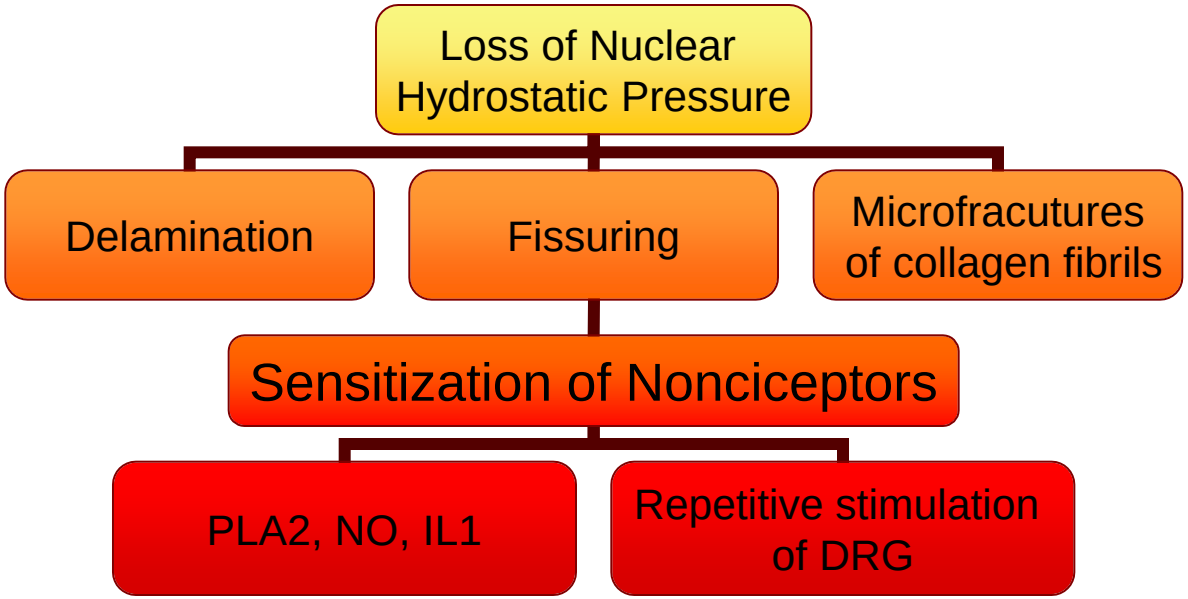
Disc Pathophysiology

- Disc degeneration and injury cause centripetal growth of nerve fibers into the disc. There is extensive disc innervation in the severely degenerated human lumbar discs compared to normal discs.
- Small unmyelinated nerve components, extensive innervation of the inner parts of the annulus.
- Nociceptive properties-substance P immunoreactivity.
- Vascular in-growth observed in peripheral tears of the annulus.
- Small, post-traumatic peripheral tears of the annulus fibrosus lead to an acceleration in dehydration of the intervertebral disc.



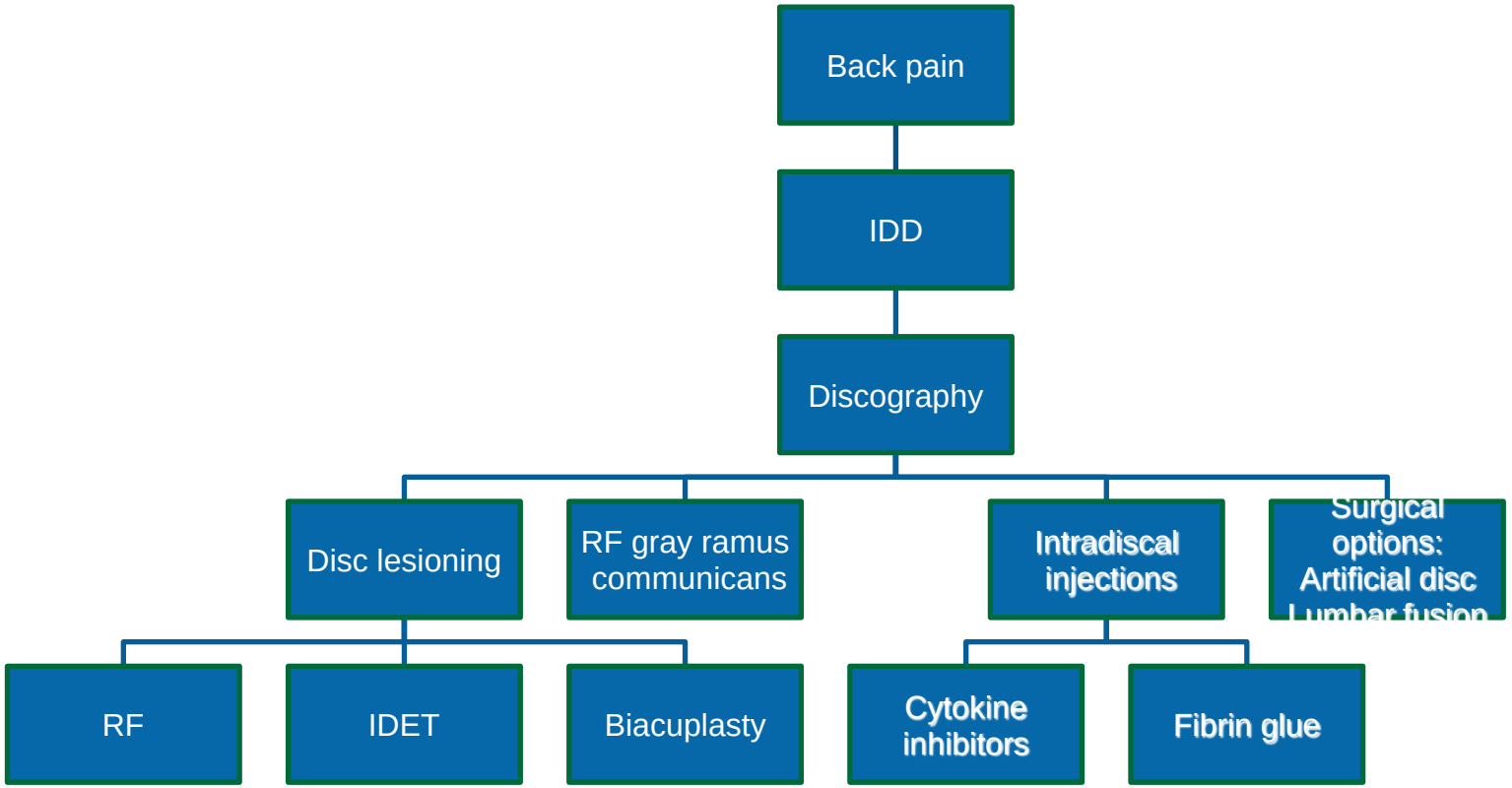
Hirsch C, Schajowicz F: Acta Orthop Scand 1953; 22:184-231
Coppes MH. Spine 1997;22:2342-2349.

Possible Scenario



Saal and Saal,2002; Ozaktay et al., 1998; Schwartzer et al., 1995

Possible algorithm (Kapural and Deer, 2011)



Kapural L, Deer T. Radiofrequency and other heat applications for the treatment of discogenic pain. Eds. Kapural L, Kim P. Diagnosis, Management and Treatment of Discogenic Pain. Interventional and Neuromodulatory Techniques for Pain Management Series Vol3. Elsevier, Philadelphia, PA 2011, pp 80-87

Mechanisms of Discogenic Pain Relief by Heating

- Unclear
- Two hypotheses:
  1. Denervation of the tissue or destruction of the overgrowth of nociceptors
  2. Change the structure of the collagen fibers in the annulus, causing an increase in annular stability
- Histological studies involving IDET did not support these two hypotheses

Shah RV, Lutz GE, Lee J, Doty SB, Rodeo S. Intradiskal electrothermal therapy: a preliminary histologic study. Arch.Phys.Med.Rehabil. 2001; 82:1230-1237.

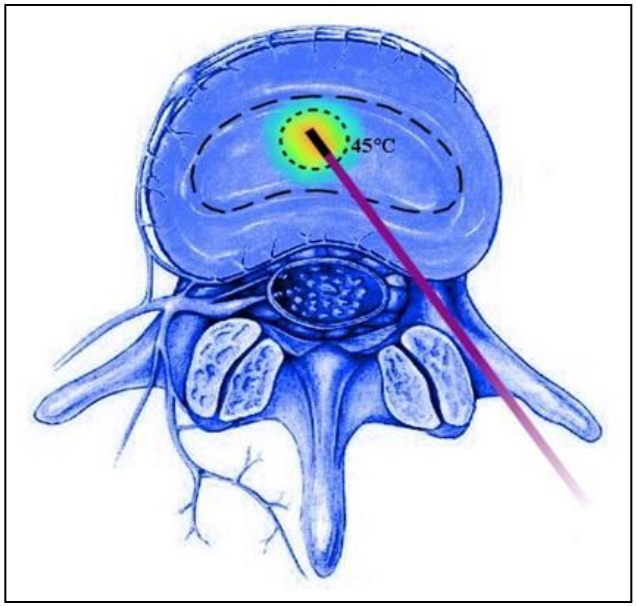
Denervation

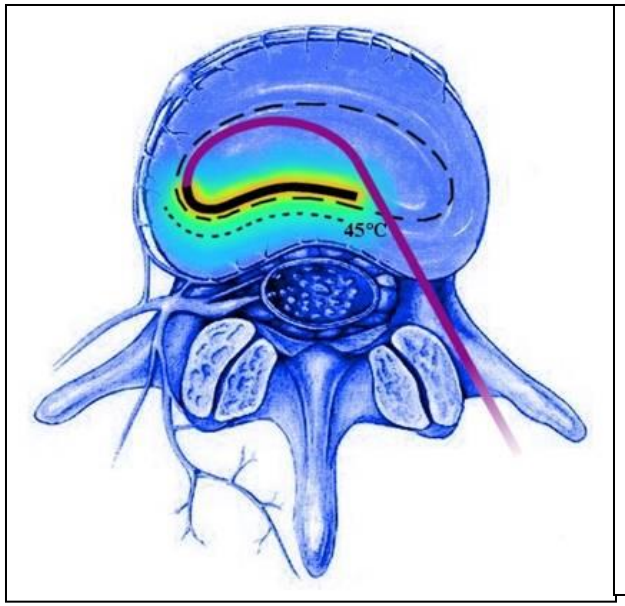
- Number of nerve endings in the experimentally induced annular tear in sheep were counted.
- 18 months after IDET, the number of nerve fibers identified in the posterior annular tear was the same for those specimens that had undergone IDET and those that did not (Freeman et al 2003)
- Irreversible nerve blocks occur at 45 degrees Centigrade in all types of nerve fibers (Smith et al 1981)

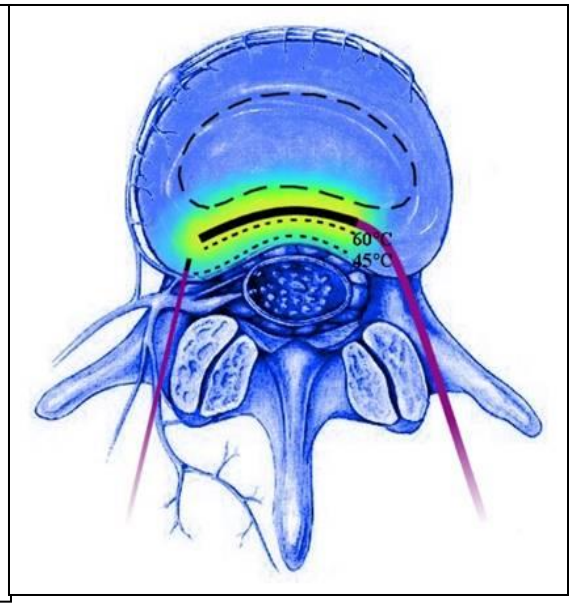
Freeman BJ, Walters RM, Moore RJ, Fraser RD. Does intradiscal electrothermal therapy denervate and repair experimentally induced posterolateral annular tears in an animal model? Spine 2003; 28:2602-2608.

Smith H.P., McWhorter J.M., Challa V.R., "Radiofrequency Neurolysis in a Clinical Model," Journal of Neurosurgery, Aug 1981, Vol. 55 pp.248-253

History of Treating The Disc with Heat







RF Cannula
Intradiscal RF
Sluijter,
1994

SpineCath®
IDET
Smith and Nephew,
1998

discTRODE ™
RF Annuloplasty
Tyco / Radionics,
2000

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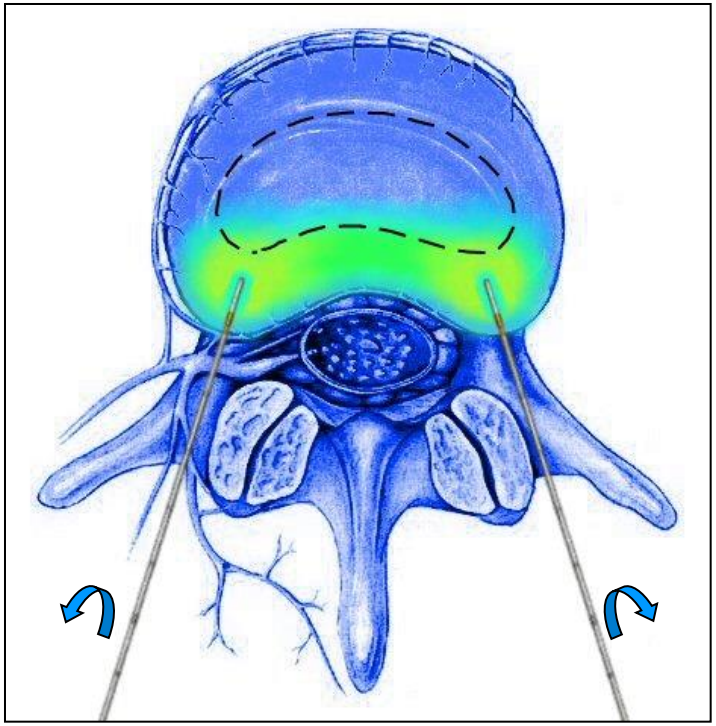
Biacuplasty

- Radiofrequency current is concentrated between electrodes on two straight probes.
- The electrodes are internally cooled allowing deep, even heating and eliminating tissue adherence.
- Temperature sensors allow monitoring at the electrode tips and disc periphery.
- The ideal temperature profile is 55-60°C in the inner posterior disc decreasing to 45°C in the peripheral edge of the posterior disc.



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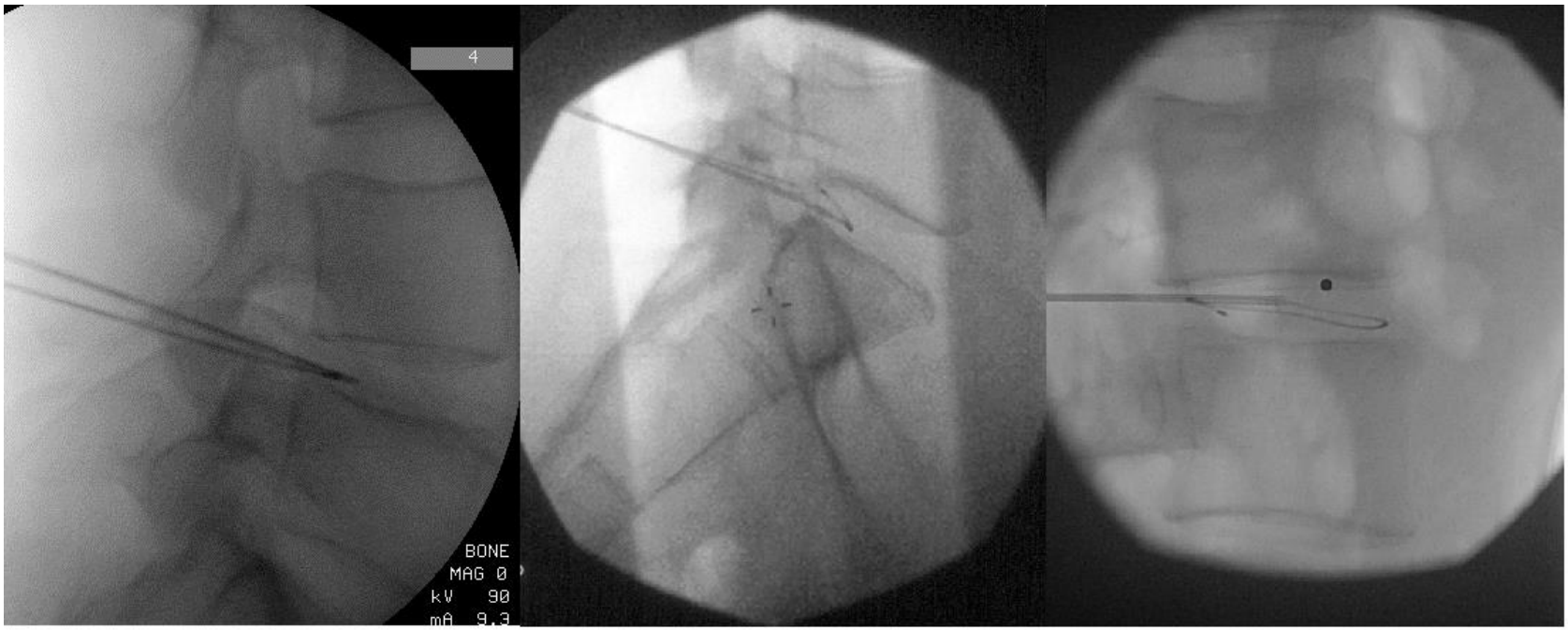

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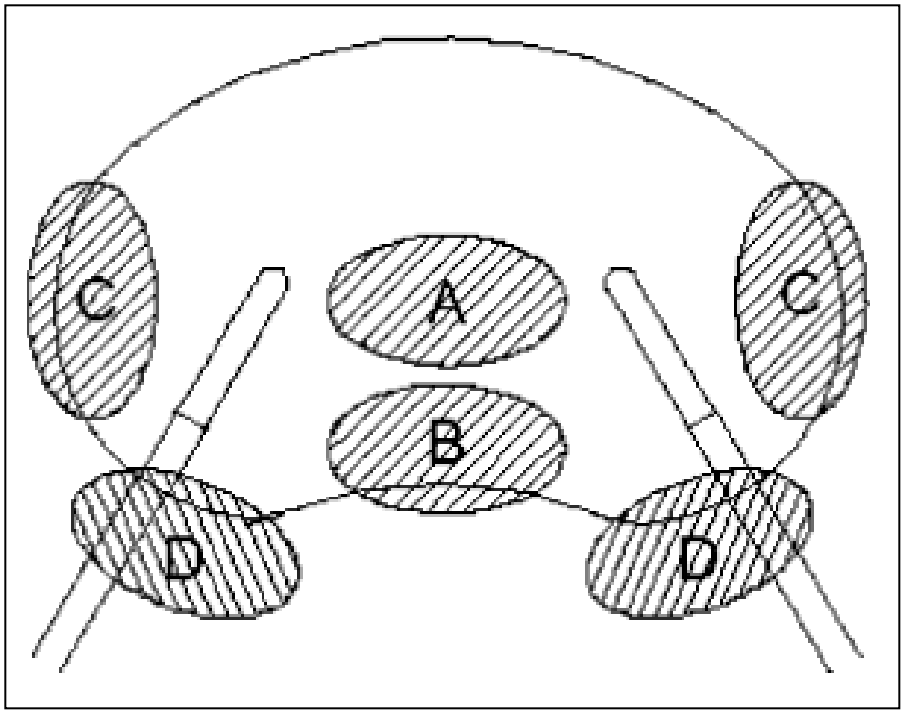
Study	Year	Type of annuloplasty	Indications	# patients	Type of study	Outcomes	Complications	Conclusions
Kapural et al.	2004	IDET	Single or two level DDD and p.disco., >50% disc height vs. multilevel DDD	34	Prospective Matched study	1,2-DDD >50% improvement in VAS and PDI	None	IDET effective, but only in one or two level DDD
Assietti et al.	2010	IDET	Single level DDD and p.disco., >60% disc height	50	Prospective	VAS 68% decrease; ODI from 59.0+/-7.6% to 20.1+/-11% at 24m	None	Effective/safe
KapuraKapural et al.	2008	Biacuplasty	Single or two level DDD and p.disco., >50% disc height	15	Prospective pilot	7 of 13>50% VAS ODI to 17.5 and SF-36-PF from 51 to 67 @12 m	None	Effective/safe
Kvarstein et al	2009	DiscTRODE™	Chronic LBP, p.disco	23	Prospective randomized, double blind	No improvement study or sham at 12m	None	Ineffective
Pauza et al.	2004	IDET	DDD and p.disco., >80% disc height	64	Randomized sham-controlled prospective	56% >2 VAS change; 50% patients >50% relief at 6 m	None	Effective/safe
Jawahar et al.	2008	IDET	DDD and p.disco., >80% disc height, WC patients	53	Prospective	VAS reduction 63%, ODI 70%	None	Useful in carefully selected WC patients
Karaman et al	2011	Biacuplasty	Axial pain>6m;one or two levels DDD	14	Prospective observational	78% of patients>10 points Oswestry improvement	None	Effective/safe
Kapural et al,	2012	Biacuplasty	Single or two level DDD and p.disco., >50% disc height	64	Randomized, sham-controlled prospective	1 level DDD: VAS -2.78, SF-36-PF +18 2 level DDD:VAS-1.3, SF36-PF+10.5(Table2)	None	Effective/safe

In vivo Testing in Porcine Model

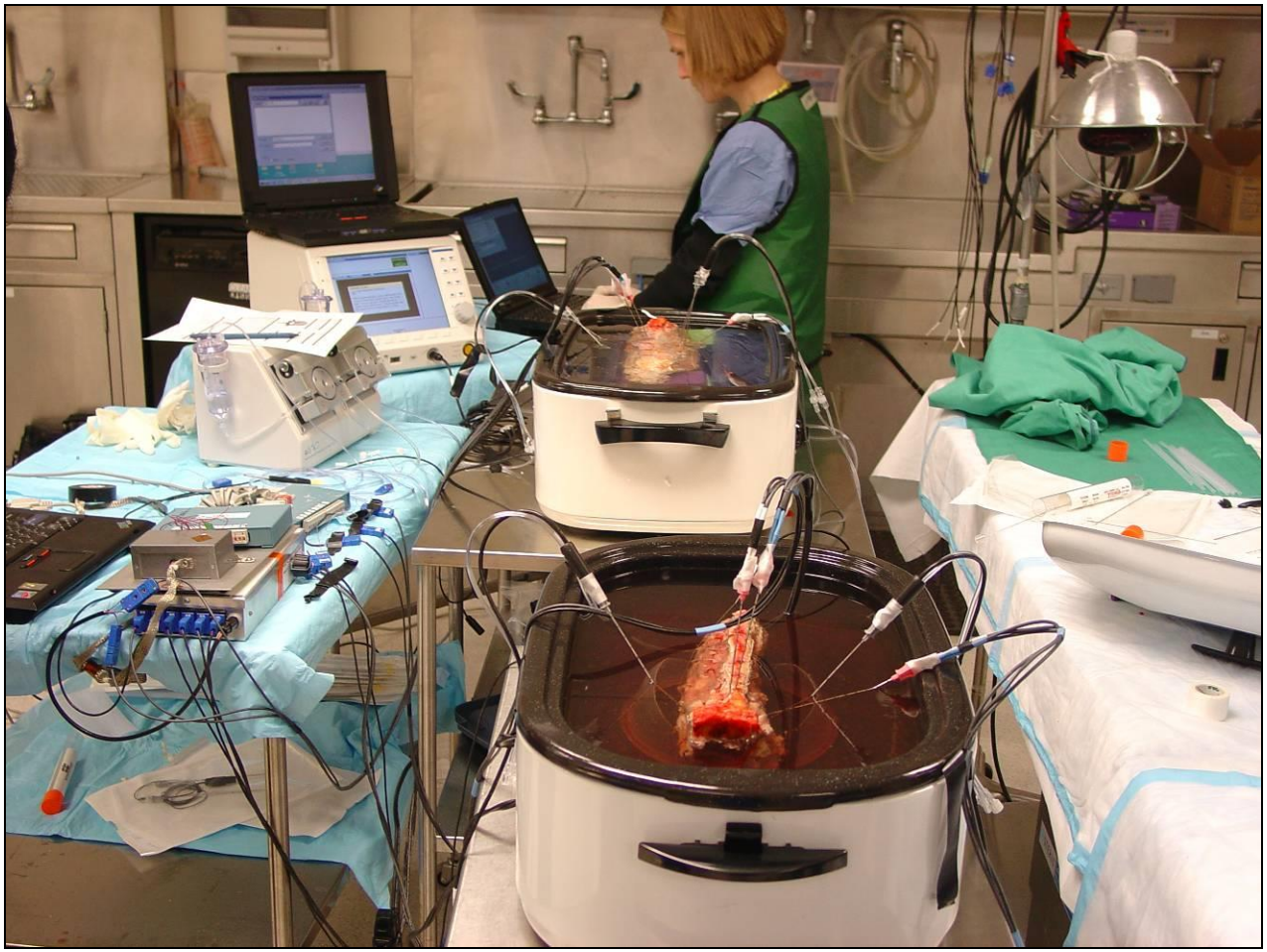


Temperatures monitoring at designated safety zones outside the disc demonstrated maintenance of near-physiologic conditions while temperature across the posterior annuls reached 65°C

Petersohn J et al. 2008 Pain Medicine (9): 26-32

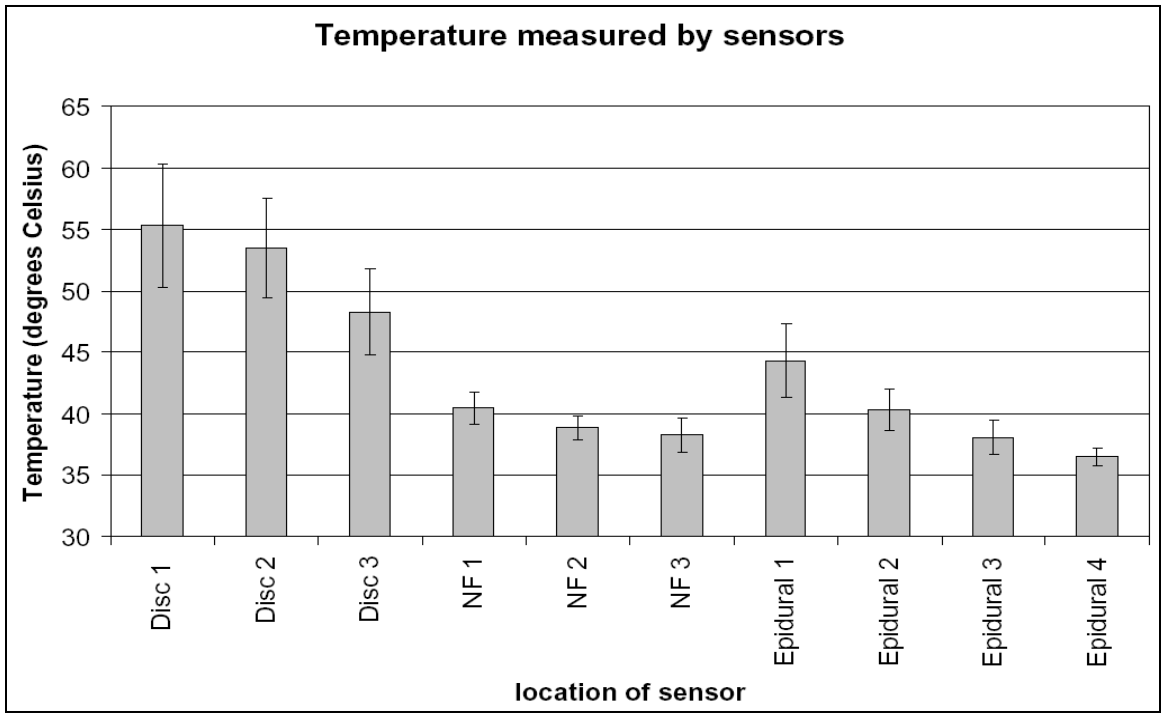
Cadaver Study

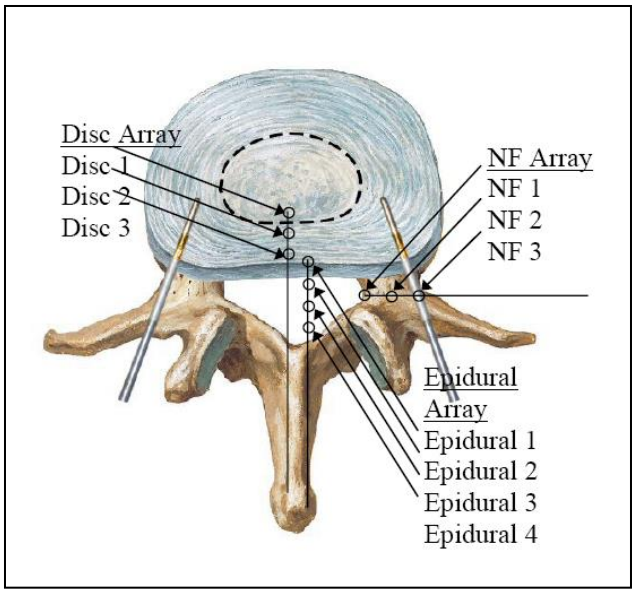
Biacuplasty study using explanted human lumbar spines.



Kapural et al. 2008 Pain Medicine (9): 68-75

Cadaver Study





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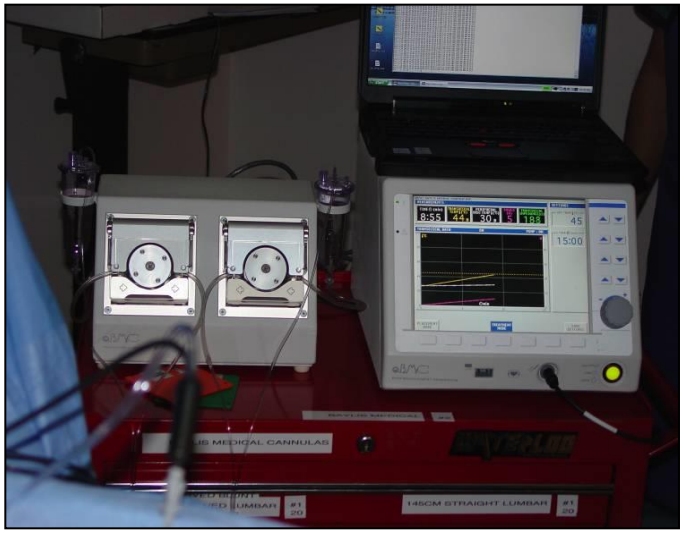
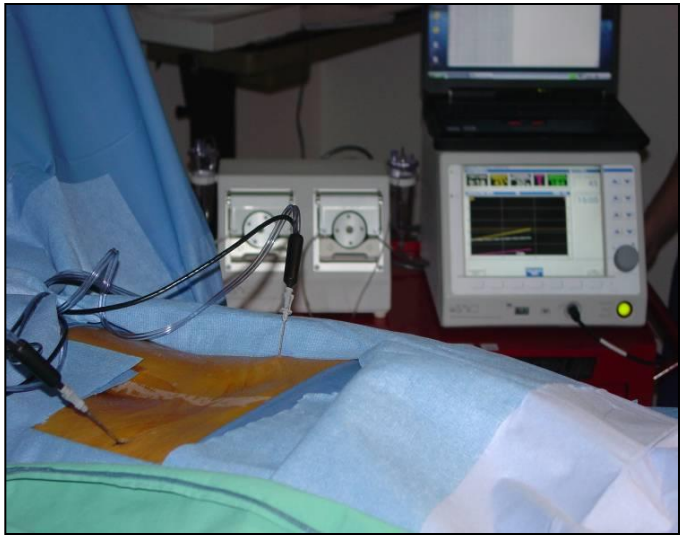
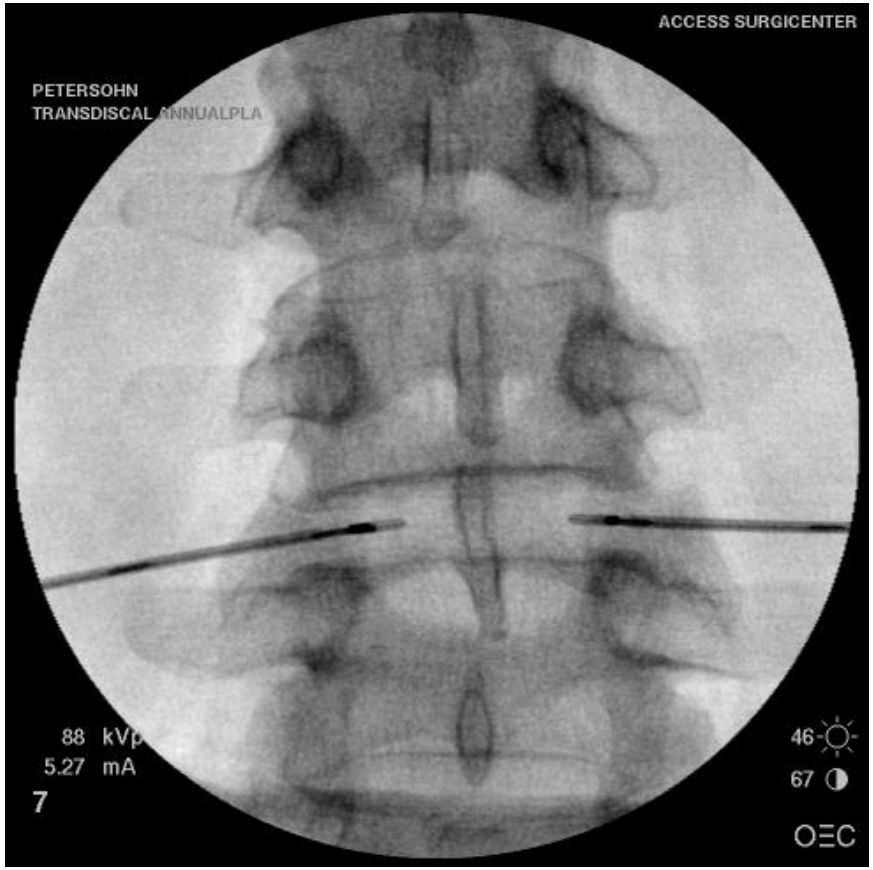
TransDiscal System During Procedure



Kapural et al. 2008 Pain Medicine (9): 60-67

Final View with Probes



Pilot Study

- Consent and approval by IRB-15 patients
- previously denied IDET
- MRI and discography within 12 months
- Two patients out of the study, 13 followed

Kapural et al. 2008 Pain Medicine (9): 60-67

Pilot Study

Inclusion criteria

- Chronic LBP unresponsive to nonoperative care >6 months
- Back>leg pain exacerbated by sitting
- Pain reproduction on discography but not in control discs (Saal and Saal, 2002)
- Disc height >50% of adjacent disc
- Single or two level degenerative disc disease without evidence of additional degenerative disc changes on MRI (Kapural et al., 2004)

Kapural et al. 2008 Pain Medicine (9): 60-67

Pilot Study

Exclusion criteria

- Compressive radiculopathy
- Nucleus pulposus herniation on MRI
- Disc bulges > 5 mm
- Prior surgery at the symptomatic level
- Symptoms or signs of LCS
- WC claim or litigation (Webster et al,2004)
- Psych issues by exam or history
- Score>13 on Becks (BDI)
- Tumor, systemic or localized infection
- Traumatic spinal fracture
- History of coagulopathy, bleeding

- Progressive neurological deficits
- Abuse or on long acting opioids
- Free disc fragments on MRI
- Manual labor
- Smoking
- BMI (body mass index)>30
- Age over 55 (Cohen et al., 2004).

Kapural et al. 2008 Pain Medicine (9): 60-67

Pilot Study

Follow Up

- Patients followed >12 months
- Follow-ups 1, 3, 6 and 12 months after procedure
- Computerized questionnaire before visit
- Oswestry, SF-36, VAS, opioid use

Kapural et al. 2008 Pain Medicine (9): 60-67

Statistics

Outcome	Median [Quartiles] Baseline	12 Month	Difference†	% Difference†	P-Value*
SF-36 Bodily Pain	35 [33, 45]	58 [45, 78]	10 [13, 35]	37 [15, 78]	0.016
SF-36 Physical Functioning	55 [40, 60]	75 [50, 95]	10 [-5, 35]	17 [-6, 73]	0.09
Oswestry Score	25 [17, 29]	17 [10, 24]	-4 [-9, 1]	-13 [-64, 6]	0.07
VAS Pain Score	7 [6, 8]	4 [1, 6]	-4 [-5, -1]	-44 [-86, -14]	0.003
Opioid Use	40 [40, 120]	0 [0, 20]	-40 [-50, -20]	-100 [-100, -62]	< 0.001

† Differences from baseline to 12 months.

* Wilcoxon signed rank test of percent difference equal to 0.

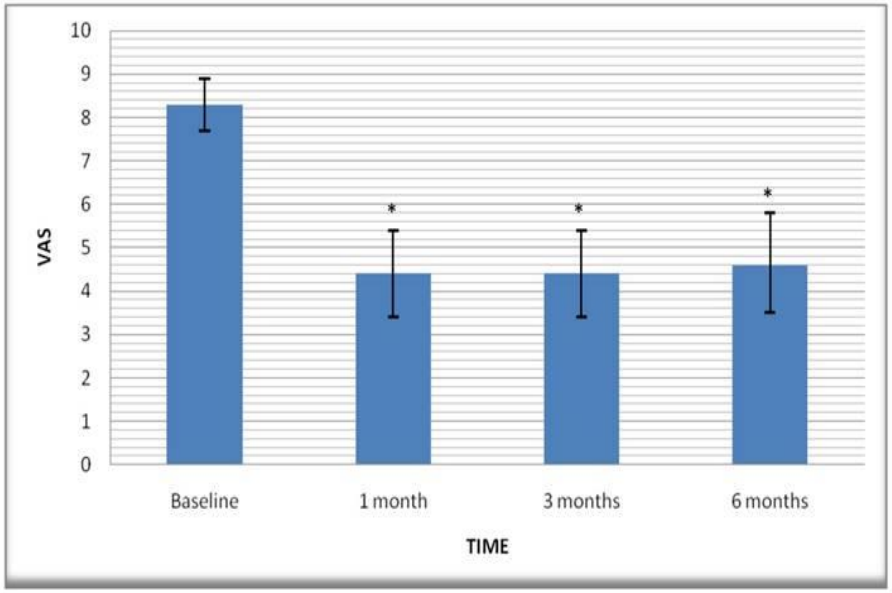
Kapural L. Intervertebral Disc Cooled Bipolar Radiofrequency (Intradiscal Biacuplasty) for the Treatment of Lumbar Discogenic Pain: a 12 month follow-up of the pilot study. **Pain Medicine 2008;8(4):464.**

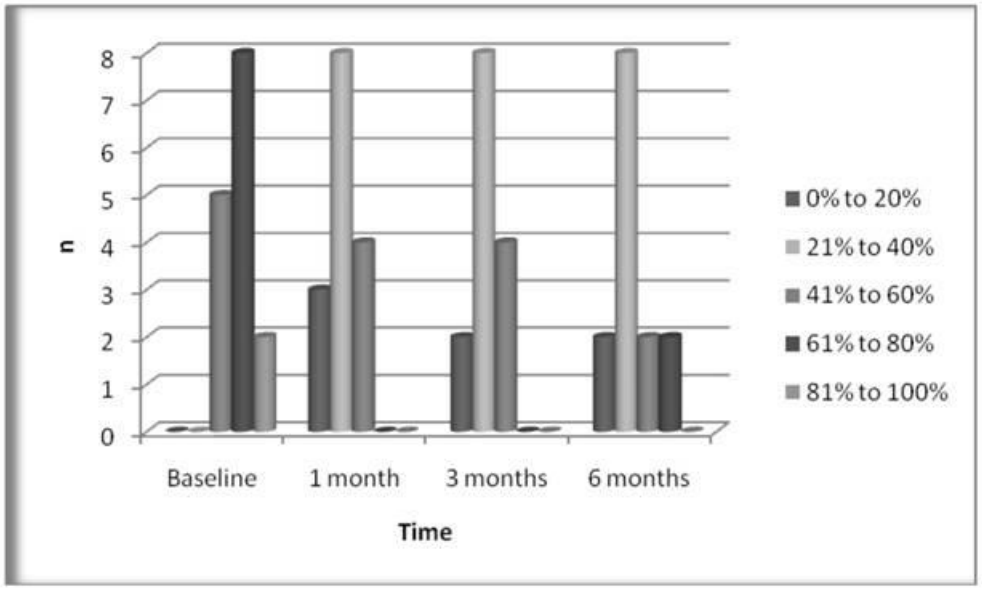
Karaman et al.,2011

- Patient selection: axial LBP>6 months; disc degeneration or internal disc disruption at 1 or 2 levels
- Oswestry; Patient satisfaction; VAS at 1, 3, and 6 months
- Age 43; 10 women; 5 men
- Average pain 40 months
- L3-4 (4 patients); L4-5 (6); L5S1 (6)
- 14 patients one level biacuplasty

Karaman H, Tufek A, Kavak GO, Kaya S, Yildirim ZB, Uysal E, Çelik F. 6-Month Results of Transdiscal Biacuplasty on Patients with Discogenic Low Back Pain: Preliminary Findings.Int J Med Sci 2011;8(1):1-8.

Karaman et al.,2011





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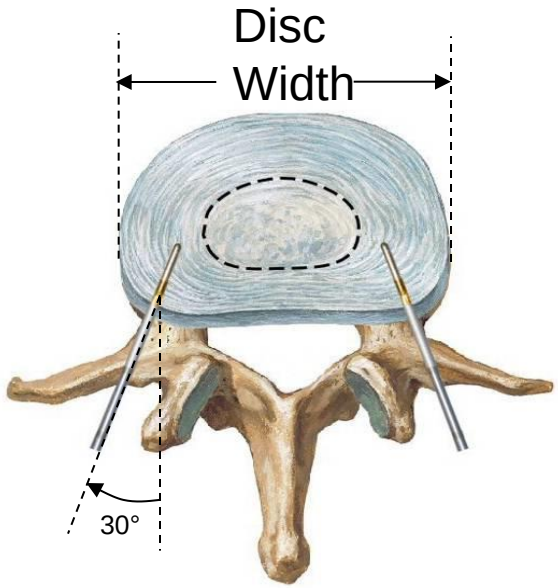
Karaman et al, 2011

- Biacuplasty was effective in improving pain scores and patient function
- Patient satisfaction after procedure was exceptionally high
- No complications were noted
- Authors concluded that biacuplasty is easily applicable, effective treatment for lumbar discogenic pain

Morphometry of Lumbar Disc

	L3	L4	L5
Disc Width	36.0 – 58.4 mm	40.2 – 63.8 mm	40.2 – 70.1 mm

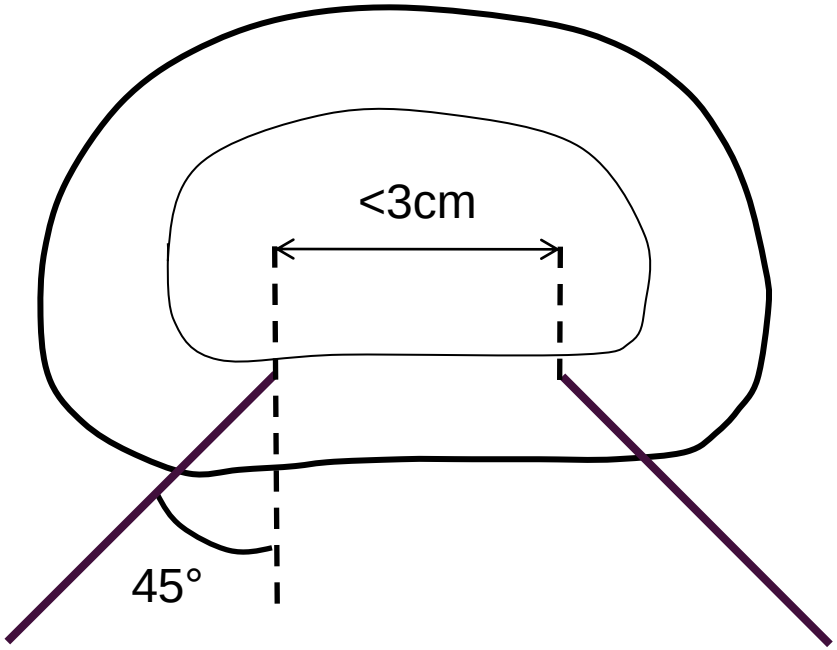


- Wider angle of insertion may be necessary for large discs to maintain maximum distance between probes to be 2.5cm – 3cm

Zhou et al., *Eur Spine J*, 9:242-248, 2000

Acceptable angle

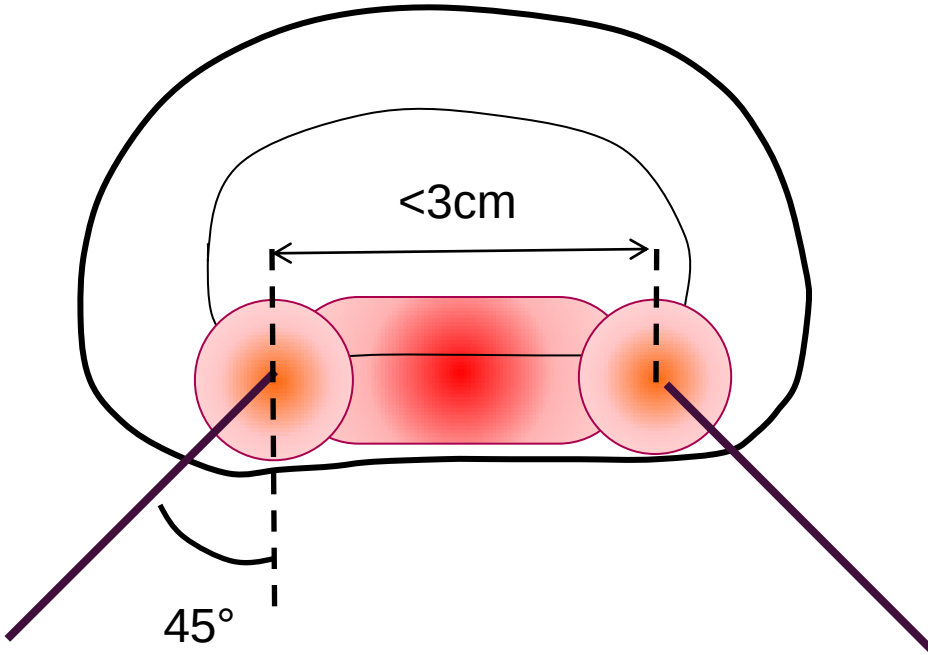
- Approach Angle is adjusted to 45° from the median
- Increased approach angle brings probes close enough to create a confluent lesion
- Set temperature is adjusted to 50 °C
- Following the bipolar lesion, monopolar lesions are created around each electrode to lesion the posterior-lateral aspect of each disc.



• 45° approach angle

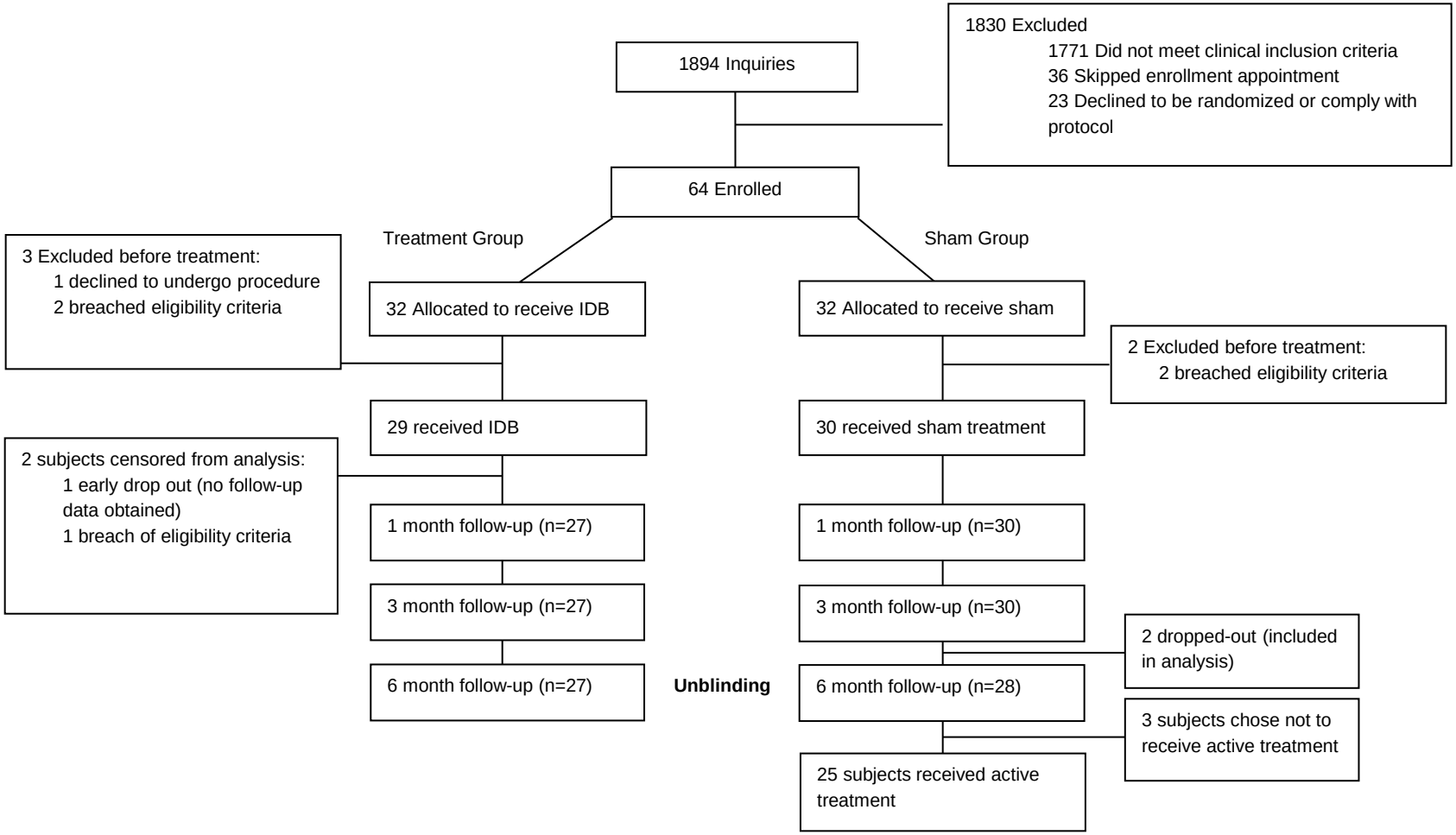
Biacuplasty

- Set temperature adjustment to 50°C increases lesion size
  - Max. tissue temperature is 75°C
- Without probe repositioning, additional monopolar lesions created around each electrode to heat posterior lateral region
- Kapural et al, 2012



- 45° approach angle
- 50°C set temperature bipolar lesion
- 60°C Monopolar lesions, 2.5min

Randomized Control Trial (Kapural et al, 2013)



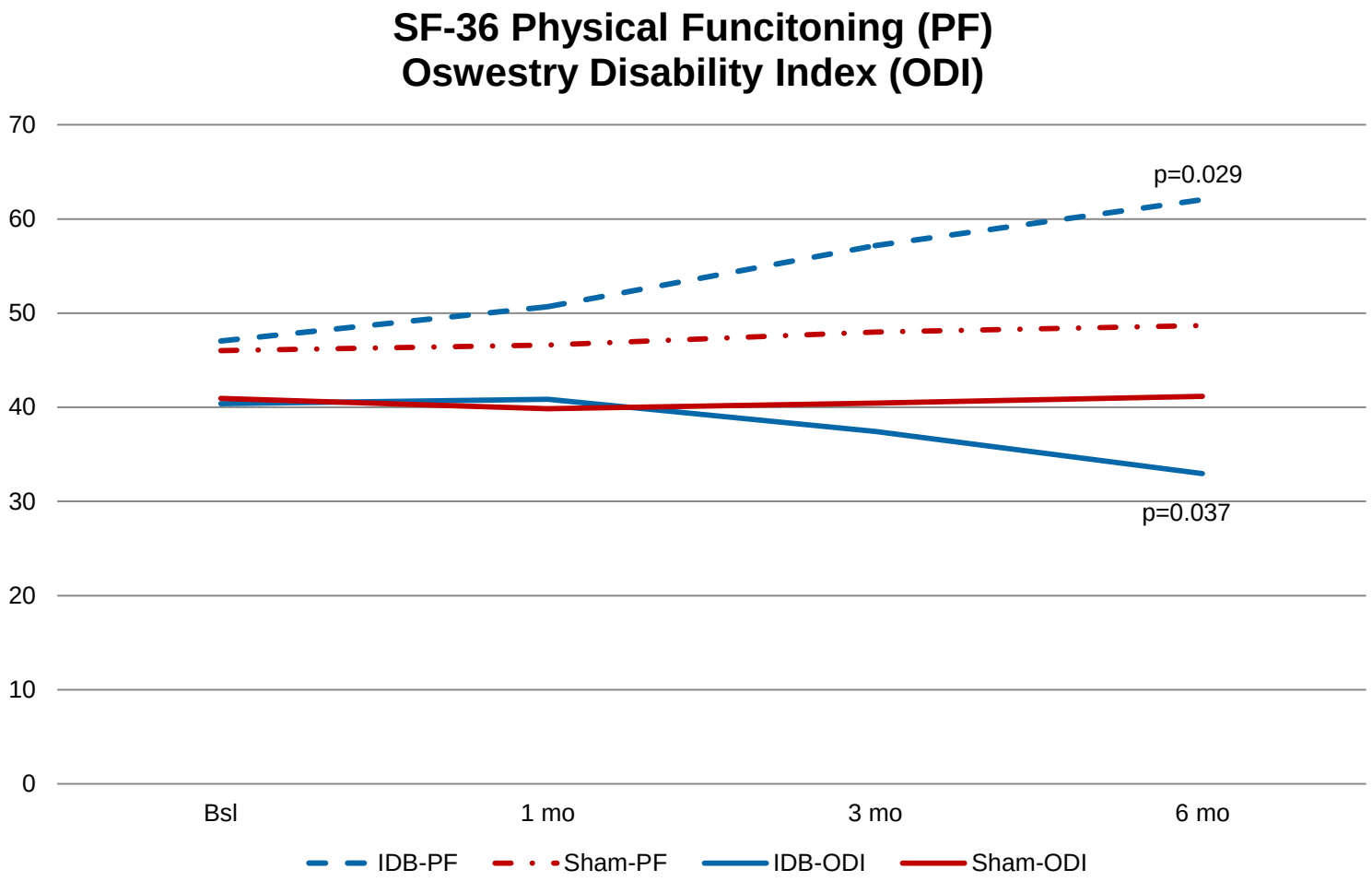
Kapural, L., Vrooman, B., Sarwar, S., Krizanac-Bengez, L., Rauck, R., Gilmore, C., North, J., Girgis, G. and Mekhail, N. (2012), A Randomized, Placebo-Controlled Trial of Transdiscal Radiofrequency, Biacuplasty for Treatment of Discogenic Lower Back Pain. Pain Medicine. doi: 10.1111/pme.12023

	IDB (n=27)		Sham (n=30)		
Feature	n	%	N	%	p Value
Male	12	44%	15	50%	.792
Female	15	56%	15	50%	
Age (mean±SD), years	40.4±10.3		38.4±10.4		.476
Work Status:					.832
Unemployed because of back pain	5	19%	5	17%	
Unemployed not because of back pain	2	7%	4	13%	
Working	20	74%	21	70%	
Work Class:					.921
Manual	3	15%	4	19%	
Sedentary	7	35%	6	29%	
Mixed	10	50%	11	52%	
Duration of pain:					1.000
6-12 months	0	0%	1	3%	
12-24 months	2	7%	3	10%	
>24 months	25	93%	26	87%	
Previous treatment					

>24 months	25	93%	26	87%	
Previous treatment					
Physiotherapy	2	7%	3	10%	.647
Bed Rest	12	44%	5	17%	.046
Anti-inflammatory drugs	17	63%	13	43%	.310
Opioids	14	52%	15	50%	1.000
Injections	8	30%	7	23%	.770
Chiropractics	2	7%	8	27%	.038
Referred Pain					
In buttock	18	67%	19	63%	.599
In thigh	9	33%	13	43%	.292
In leg	9	33%	15	50%	.118
Painful and Treated Discs					
L5-S1	7	26%	8	27%	
L4-L5	6	22%	7	23%	
L3-L4	3	11%	1	3%	
L4-L5, L5-S1	6	22%	8	27%	
L3-L4, L4-L5	3	11%	3	10%	
L3-L4, L5-S1	2	8%	3	10%	

	IDB		Sham		
Outcome Measure	Mean	SD	Mean	SD	p Value
SF-36 Physical Functioning (0-100)	n=27		n=30		
Baseline	47.04	20.30	46.03	19.30	.849
1-month	50.68	20.03	46.61	20.60	.458
3-months	57.17	20.32	48.00	22.95	.118
6-months	62.04	21.89	48.67	22.97	.029
NRS for pain (0-10)	n=27		n=29		
Baseline	7.13	1.61	7.18	1.98	.912
1-month	5.31	2.04	5.72	2.29	.486
3-months	4.94	2.05	5.98	2.36	.083
6-months	4.94	2.15	6.58	2.11	.006
Oswestry Disability Scale (0-100)	n=27		n=30		
Baseline	40.37	12.30	40.93	13.56	.871
1-month	40.85	13.36	39.85	17.03	.807
3-months	37.43	16.65	40.44	16.21	.493
6-months	32.94	16.14	41.17	13.94	.037

Primary Outcomes-Function (SF-36-PF)



	1 level (n=16)		2 levels (n=11)		
Outcome Measure	Mean	SD	Mean	SD	p Value
SF-36 Physical Functioning (0-100)					
Baseline	48.75	17.08	44.55	24.95	0.607
6-months	66.88	18.34	55.00	25.50	0.171
6-months change	18.13	15.37	10.45	18.23	0.248
NRS for pain (0-10)					
Baseline	7.47	1.45	6.64	1.76	0.191
6-months	4.69	2.38	5.32	1.81	0.465
6-months change	-2.78	2.59	-1.32	1.95	0.126
Oswestry Disability Scale (0-100)					
Baseline	38.88	8.48	42.55	16.64	0.457
6-months	28.88	13.04	38.85	18.90	0.116
6-months change	-10.00	8.91	-3.70	10.99	0.113

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Treatment patients
SF (PF) and NRS at all time points (Kapural et al, in preparation)

Per protocol	Mean PF		Δ PF	
	Mean	**SD**	**Δ**	**SD**
Baseline (n=27)	47.04	20.30		
1 month (n=26)	50.68	20.03	2.99	21.43
3 month (n=26)	58.27	19.90	11.57	15.35
6 month (n=27)	62.04	21.89	15.00	16.70
9 month (n=22)	64.55	23.45	17.27	18.43
12 month (n=22)	68.86	19.33	21.59	20.26

Per protocol	Mean NRS		Δ NRS	
	Mean	SD	Δ	SD
Baseline (n=27)	7.13	1.61		
1 month (n=26)	5.31	2.04	-1.79	2.44
3 month (n=24)	5.06	2.01	-1.98	2.16
6 month (n=25)	4.90	2.23	-2.18	2.47
9 month (n=22)	4.59	2.28	-2.70	2.49
12 month (n=22)	4.40	2.56	-2.90	2.56

Treatment patients
ODI and Opioids at all time points (Kapural et al, in preparation)

Per protocol	Mean ODI		Δ ODI	
	Mean	SD	Δ	SD
Baseline (n=27)	40.37	12.30		
1 month (n=27)	40.85	13.36	0.48	10.19
3 month (n=26)	36.41	16.10	-3.74	10.89
6 month (n=27)	32.94	16.14	-7.43	10.11
9 month (n=22)	31.81	15.66	-7.65	9.93
12 month (n=22)	32.44	16.13	-7.01	10.92

	Mean	SD	Δ	SD
Baseline (n=27)	52.47	49.58		
1 month (n=27)	47.94	46.86	-4.54	32.14
3 month (n=27)	44.65	47.21	-7.82	34.05
6 month (n=27)	36.87	40.56	-15.60	46.75
9 month (n=20)	26.80	35.28	-20.10	47.06
12 month (n=17)	34.07	47.44	-15.37	54.46

Crossover patients
SF36 (PF) and NRS at all time points

Per protocol	Mean PF		∆ PF	
	Mean	SD	∆	SD
2nd IDB (n=22)	46.36	20.60		
2nd 1 month (n=20)	47.50	23.76	3.00	15.25
3 month (n=22)	57.27	24.58	10.91	14.93
6 month (n=20)	62.50	25.83	14.75	15.34

Per protocol	Mean NRS		∆ NRS	
	Mean	SD	∆	SD
2nd IDB (n=23)	6.20	1.85		
2nd 1 month (n=20)	5.03	2.44	-1.40	1.96
3 month (n=23)	4.80	2.81	-1.39	2.52
6 month (n=20)	5.03	3.06	-1.00	2.44

Crossover patients
ODI and Opioids at all time points (Kapural et al, in preparation)

Per protocol	Mean ODI		Δ ODI	
	Mean	SD	Δ	SD
2nd IDB (n=22)	40.45	15.14		
2nd 1 month (n=20)	39.40	17.35	-1.60	9.66
3 month (n=22)	34.27	17.72	-6.18	11.58
6 month (n=20)	33.10	18.60	-7.10	10.33

	Mean	SD	Δ	SD
2nd IDB (n=22)	40.02	42.90		
2nd 1 month (n=21)	37.64	41.98	-2.14	14.88
9 month (n=21)	36.26	43.32	-5.67	17.50
12 month (n=19)	30.87	43.62	-8.37	16.02

Summary

- Biacuplasty is an effective minimally invasive alternative for treatment of lumbar discogenic back pain
- Strict selection criteria improves results of biacuplasty
- Postprocedurally an optimal rehabilitation step-by-step program is required to ascertain a good outcome
- Patients with increased body mass index, a smoking habit, and multilevel degenerative disk disease have less chance to improve long term
- Based on currently available data, such minimally invasive approach more efficacious than any surgery

Thank you
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