

Health Technology Assessment

Facet Neurotomy

Final Evidence Report - Appendices

February 21, 2014

Health Technology Assessment Program (HTA) Washington State Health Care Authority PO Box 42712 Olympia, WA 98504-2712 (360) 725-5126 www.hca.wa.gov/hta/Pages/ shtap@hca.wa.gov

Facet Neurotomy

Provided by:



Spectrum Research, Inc.

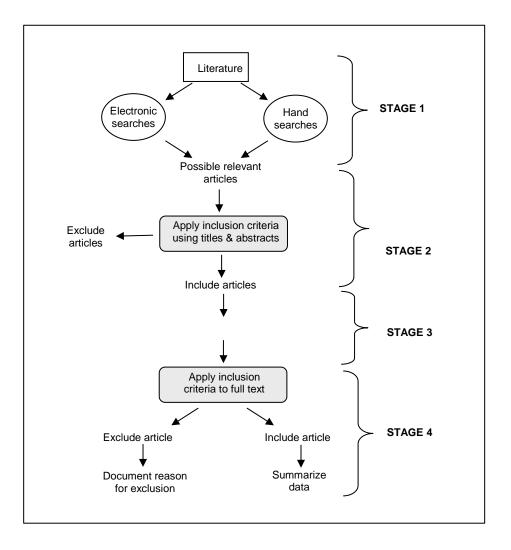
Final Report - Appendices

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APPENDIX A. Algorithm for Article Selection

APPENDIX B. Search Strategies

Below is the search strategy for PubMed. Parallel strategies were used to search other electronic databases listed below. Keyword searches were conducted in the other listed resources.

Search strategy (PubMed)

Search date: 10/04/13

Filters: Abstract available, English

	Search code	Number of articles
1	Facet OR Zygapophyseal OR "Zygapophyseal Joint"[Mesh] OR "medial branch"	7,864
2	Neurotomy OR "Rhizotomy"[Mesh] OR Rhizotomy OR "Articular rhizolysis" OR rhizolysis OR "Radiofrequency neurotomy" OR "Radiofrequency denervation" OR (radiofrequency AND "denervation"[MeSH Terms]) OR Denervation OR "Radiofrequency neurolysis" OR "Radiofrequency facet denervation" OR "Pulsed Radiofrequency Treatment"[Mesh] OR "Cooled radiofrequency ablation" OR "cooled ablation" OR ablat* OR chemodenervation OR "Chemical facet neurolysis" OR "cryosurgery"[MeSH Terms] OR Cryoablation OR radiofrequency	115,820
3	#1 AND #2	438
4	(In Vitro[Publication Type] OR Cadaver*[TIAB] OR Case Reports[Publication Type] OR rat[TI] OR rats[TI] OR mouse[TI] OR mice[TI] OR dog[TI] OR dogs[TI] OR sheep[TI] OR rabbit[TI] OR "experimental model"[TI])	
5	#3 NOT #4	369
	Additional references identified from hand searching	60
	Total	429

Parallel strategies were used to search the Cochrane Library and others listed below. Keyword searches were conducted in the other listed resources.

Electronic Database Searches

The following databases have been searched for relevant information:

Agency for Healthcare Research and Quality (AHRQ) Cumulative Index to Nursing and Allied Health (CINAHL) Cochrane Database of Systematic Reviews Cochrane Registry of Clinical Trials (CENTRAL) Cochrane Review Methodology Database Database of Reviews of Effectiveness (Cochrane Library) EMBASE PubMed Informational Network of Agencies for Health Technology Assessment (INAHTA) NHS Economic Evaluation Database HSTAT (Health Services/Technology Assessment Text) EconLIT

Additional Economics, Clinical Guideline and Gray Literature Databases

AHRQ - Healthcare Cost and Utilization Project Canadian Agency for Drugs and Technologies in Health Centers for Medicare and Medicaid Services (CMS) Food and Drug Administration (FDA) Google Institute for Clinical Systems Improvement (ICSI) National Guideline Clearinghouse

APPENDIX C. Excluded Articles

Note. As shown in Figure 1 of the Evidence Report, 27 studies were completely excluded from the report.

Articles excluded as primary studies <u>after full text review</u>, with reason for exclusion.

	Citation	Reason for Exclusion	Included in different KQ of report?
	Studies considered and excluded for Key Question 1a (n=5)		
1.	Cohen, S. P., T. M. Larkin, et al. (2004). The causes of false- positive medial branch (facet joint) blocks in soldiers and retirees. Mil Med 169(10): 781-786.	Included patients did not undergo facet neurotomy.	-
2.	Derby, R., I. Melnik, et al. (2013). Cost comparisons of various diagnostic medial branch block protocols and medial branch neurotomy in a private practice setting. Pain Med 14(3): 378-391.	No patients received zero blocks.	KQ1d
3.	Jung, J. H., H. I. Kim, et al. (2007). Usefulness of pain distribution pattern assessment in decision-making for the patients with lumbar zygapophyseal and sacroiliac joint arthropathy. J Korean Med Sci 22(6): 1048-1054.	No patients received zero blocks.	-
4.	Park, J., J. Y. Park, et al. (2006). Long term results from percutaneous radiofrequency neurotomy on posterior primary ramus in patients with chronic low back pain. Acta Neurochir Suppl 99: 81-83.	Compared patients with symptoms and signs of facet joint pain to those without symptoms and signs.	-
5.	Stojanovic, M. P., J. Sethee, et al. (2010). MRI analysis of the lumbar spine: can it predict response to diagnostic and therapeutic facet procedures? Clin J Pain 26(2): 110-115.	All patients selected for FN by diagnostic block.	-
	Studies considered and excluded for Key Question 1b (n=0)		
	Studies considered and excluded for Key Question 1c: (n=6)		
1.	Derby, R., I. Melnik, et al. (2013). Cost comparisons of various diagnostic medial branch block protocols and medial branch neurotomy in a private practice setting. Pain Med 14(3): 378-391	Controlled diagnostic blocks were not performed.	KQ1d
2.	Derby, R., I. Melnik, et al. (2013). Indications for repeat diagnostic medial branch nerve blocks following a failed first medial branch nerve block. Pain Physician 16(5): 479-488.	Controlled diagnostic blocks were not performed.	-

	Citation	Reason for Exclusion	Included in different KQ of report?
3.	Derby, R., I. Melnik, et al. (2012). Correlation of lumbar medial branch neurotomy results with diagnostic medial branch block cutoff values to optimize therapeutic outcome. Pain Med 13(12): 1533-1546.	Controlled diagnostic blocks were not performed.	KQ1d
4.	Jung, J. H., H. I. Kim, et al. (2007). Usefulness of pain distribution pattern assessment in decision-making for the patients with lumbar zygapophyseal and sacroiliac joint arthropathy. J Korean Med Sci 22(6): 1048-1054.	Controlled diagnostic blocks were not performed.	-
5.	Manchikanti, L., S. Pampati, et al. (2010). Making sense of the accuracy of diagnostic lumbar facet joint nerve blocks: an assessment of the implications of 50% relief, 80% relief, single block, or controlled diagnostic blocks. Pain Physician 13(2): 133-143.	Patients were treated with either medial branch blocks or radiofrequency neurotomy; no details were provided regarding the percentage of patients undergoing each procedure and results were not provided only for those patients undergoing radiofrequency neurotomy.	-
6.	McDonald, G. J., S. M. Lord, et al. (1999). "Long-term follow- up of patients treated with cervical radiofrequency neurotomy for chronic neck pain." Neurosurgery 45(1): 61-67; discussion 67-68.	Single diagnostic blocks were not performed.	-
	Studies considered and excluded for Key Question 1d: (n=7)		
1.	Cohen, S. P., S. A. Strassels, et al. (2011). Does sensory stimulation threshold affect lumbar facet radiofrequency denervation outcomes? A prospective clinical correlational study. Anesth Analg 113(5): 1233-1241.	Differential definition of successful block not assessed in terms of outcome following facet neurotomy.	-
2.	Cohen, S. P., R. W. Hurley, et al. (2007). Clinical predictors of success and failure for lumbar facet radiofrequency denervation. Clin J Pain 23(1): 45-52.	Differential definition of successful block not assessed in terms of outcome following facet neurotomy.	-
3.	Cohen, S. P., Z. H. Bajwa, et al. (2007). Factors predicting success and failure for cervical facet radiofrequency denervation: a multi-center analysis. Reg Anesth Pain Med 32(6): 495-503.	65% of pts (those from JHMI and WRAMC hospitals) were included in the larger Cohen 2008 study which reports on the same outcomes.	-
4.	Derby, R., I. Melnik, et al. (2013). Indications for repeat diagnostic medial branch nerve blocks following a failed first medial branch nerve block. Pain Physician 16(5): 479-488.	There were less than 5 patients in two of the three treatment groups.	-
5.	Gallagher, J., P. L. Petriccion Di Vadi, et al. (1994). Radiofrequency facet joint denervation in the treatment	The definitions of pain relief criteria following diagnostic	KQ2

	Citation	Reason for Exclusion	Included in different KC of report?
	of low back pain: a prospective controlled double-blind study to assess its efficacy. The Pain Clinic 7(3): 193-198.	block were not clear- they authors only used descriptions of "equivocal" and "good".	
6.	Manchikanti, L., S. Pampati, et al. (2010). Making sense of the accuracy of diagnostic lumbar facet joint nerve blocks: an assessment of the implications of 50% relief, 80% relief, single block, or controlled diagnostic blocks." Pain Physician 13(2): 133-143.	Patients were treated with either medial branch blocks or radiofrequency neurotomy; no details were provided regarding the percentage of patients undergoing each procedure and results were not provided only for those patients undergoing radiofrequency neurotomy.	-
7.	Shin, W. R., H. I. Kim, et al. (2006). Radiofrequency neurotomy of cervical medial branches for chronic cervicobrachialgia. J Korean Med Sci 21(1): 119-125.	Less than 10 patients per group of patients with <75% pain relief in one or more blocks (n = 8).	-
	Studies considered and excluded for Key Question 1e: (n=6)		
1.	Cohen, S. P., S. A. Strassels, et al. (2013). Establishing an optimal "cutoff" threshold for diagnostic lumbar facet blocks: a prospective correlational study. Clin J Pain 29(5): 382-391.	Unilateral vs bilateral blocks not clearly evaluated.	KQ1d
2.	Cohen, S. P., M. P. Stojanovic, et al. (2008). Lumbar zygapophysial (facet) joint radiofrequency denervation success as a function of pain relief during diagnostic medial branch blocks: a multicenter analysis. Spine J 8(3): 498-504.	Unilateral vs bilateral blocks not clearly evaluated.	KQ1d
3.	Cohen, S. P., R. W. Hurley, et al. (2007). Clinical predictors of success and failure for lumbar facet radiofrequency denervation. Clin J Pain 23(1): 45-52.	Unilateral vs bilateral blocks not clearly evaluated.	-
4.	Cohen, S. P., Z. H. Bajwa, et al. (2007). Factors predicting success and failure for cervical facet radiofrequency denervation: a multi-center analysis. Reg Anesth Pain Med 32(6): 495-503.	Unilateral vs bilateral blocks not clearly evaluated.	-
5.	North, R. B., M. Han, et al. (1994). Radiofrequency lumbar facet denervation: analysis of prognostic factors. Pain 57(1): 77-83.	Unilateral vs bilateral blocks not evaluated in terms of FN outcome.	-
6.	Shin, W. R., H. I. Kim, et al. (2006). Radiofrequency neurotomy of cervical medial branches for chronic cervicobrachialgia. J Korean Med Sci 21(1): 119-125.	Less than 10 patients per group (patients with bilateral blocks: n = 8).	-

	Citation	Reason for Exclusion	Included in different K(of report?
	Studies considered and excluded for Key Question 1f: (n=4)		
1.	Cohen, S. P., S. A. Strassels, et al. (2013). Establishing an optimal "cutoff" threshold for diagnostic lumbar facet blocks: a prospective correlational study. Clin J Pain 29(5): 382-391.	Single- vs. multi-level blocks not clearly evaluated.	KQ1d
2.	Cohen, S. P., M. P. Stojanovic, et al. (2008). Lumbar zygapophysial (facet) joint radiofrequency denervation success as a function of pain relief during diagnostic medial branch blocks: a multicenter analysis. Spine J 8(3): 498-504.	Single- vs. multi-level blocks not clearly evaluated.	KQ1d
3.	Cohen, S. P., R. W. Hurley, et al. (2007). Clinical predictors of success and failure for lumbar facet radiofrequency denervation. Clin J Pain 23(1): 45-52.	Single- vs. multi-level blocks not clearly evaluated.	-
4.	Shin, W. R., H. I. Kim, et al. (2006). Radiofrequency neurotomy of cervical medial branches for chronic cervicobrachialgia. J Korean Med Sci 21(1): 119-125.	Less than 10 patients per group (patients with single level blocks: n = 1).	-
	Studies considered and excluded for Key Question 2: (n=4)		
1.	Dobrogowski, J., A. Wrzosek, et al. (2005). Radiofrequency denervation with or without addition of pentoxifylline or methylprednisolone for chronic lumbar zygapophysial joint pain. Pharmacol Rep 57(4): 475-480.	All patients treated with neurotomy; compares injections of different drugs with neurotomy.	-
2.	Stovner, L. J., F. Kolstad, et al. (2004). Radiofrequency denervation of facet joints C2-C6 in cervicogenic headache: a randomized, double-blind, sham-controlled study. Cephalalgia 24(10): 821-830.	Less than 10 patients per treatment group.	-
3.	van Kleef, M., L. Liem, et al. (1996). Radiofrequency lesion adjacent to the dorsal root ganglion for cervicobrachial pain: a prospective double blind randomized study. Neurosurgery 38(6): 1127-1131; discussion 1131-1122.	Unrelated to facet joint ablation.	-
4.	Wallis, B. J., S. M. Lord, et al. (1997). Resolution of psychological distress of whiplash patients following treatment by radiofrequency neurotomy: a randomised, double-blind, placebo-controlled trial. Pain 73(1): 15-22.	Data not reported separately for each treatment group.	-
	Studies considered and excluded for Key Question 2a: (n=2)		
1.	Andres, R. H., T. Graupner, et al. (2010). Laser-guided lumbar medial branch kryorhizotomy. J Neurosurg Spine 13(3): 341-345.	Compares different types of guidance, not neurotomy (laser vs conventional guidance).	-
2.	Lindner, R., M. E. Sluijter, et al. (2006). Pulsed radiofrequency treatment of the lumbar medial branch for facet pain: a retrospective analysis. Pain Med 7(5):	Pulsed RF given to all patients and then conventional RF used only in	-

	Citation	Reason for Exclusion	Included in different KC of report?
	435-439.	those patients who had failed pulsed RF.	orreport
	Studies considered and excluded for Key Question 2b: (n=6)		
1.	Cabraja, M., A. Abbushi, et al. (2009). The short- and mid- term effect of dynamic interspinous distraction in the treatment of recurrent lumbar facet joint pain. Eur Spine J 18(11): 1686-1694.	<10 patients (n = 5) underwent repeat neurotomy.	-
2.	McDonald, G. J., S. M. Lord, et al. (1999). Long-term follow- up of patients treated with cervical radiofrequency neurotomy for chronic neck pain. Neurosurgery 45(1): 61-67; discussion 67-68.	The calculated outcome data on repeat neurotomies were not reported and that we are unable to accurately calculate the only data reported (mean length of complete pain relief.	-
3.	Mikeladze, G., R. Espinal, et al. (2003). Pulsed radiofrequency application in treatment of chronic zygapophyseal joint pain. Spine J 3(5): 360-362.	Data not reported for repeat neurotomy.	-
4.	Staender, M., U. Maerz, et al. (2005). Computerized tomography-guided kryorhizotomy in 76 patients with lumbar facet joint syndrome. J Neurosurg Spine 3(6): 444-449.	The only outcome that is clearly reported for the primary (n = 76) AND the repeat neurotomy(ies) (n = 18 for the second neurotomy) is the median duration of pain relief. However, even though we know that the median duration of pain relief for those patients who had a repeat neurotomy was 14 months, we don't know what the median duration of pain relief was for those same patients following the primary neurotomy (of those 18 pts). We only know what the median duration of pain relief was after the primary neurotomy for all 76 patients enrolled, and this number includes all those patients who didn't undergo a successful or repeat neurotomy.	-
5.	Tzaan, W. C. and R. R. Tasker (2000). Percutaeous radiofrequency facet rhizotomyexperience with 118 procedures and reappraisal of its value. Can J Neurol Sci	Data not reported for repeat neurotomy.	KQ2c

	Citation	Reason for Exclusion	Included i different I of report?
	27(2): 125-130.		
	Studies considered and excluded for Key Question 2c: (n=4)		
1.	Mikeladze, G., R. Espinal, et al. (2003). Pulsed radiofrequency application in treatment of chronic zygapophyseal joint pain. Spine J 3(5): 360-362.	Data not reported for unilateral vs. bilateral neurotomy.	-
2.	North, R. B., M. Han, et al. (1994). Radiofrequency lumbar facet denervation: analysis of prognostic factors. Pain 57(1): 77-83.	No data reported.	-
3.	Shin, W. R., H. I. Kim, et al. (2006). Radiofrequency neurotomy of cervical medial branches for chronic cervicobrachialgia. J Korean Med Sci 21(1): 119-125.	<10 patients underwent bilateral neurotomy.	-
4.	Son, J. H., S. D. Kim, et al. (2010). The efficacy of repeated radiofrequency medial branch neurotomy for lumbar facet syndrome. J Korean Neurosurg Soc 48(3): 240-243.	Data not reported for unilateral vs. bilateral neurotomy.	KQ2t
	Studies considered and excluded for Key Question 2d: (n=6)		
1.	Cohen, S. P., R. W. Hurley, et al. (2007). Clinical predictors of success and failure for lumbar facet radiofrequency denervation. Clin J Pain 23(1): 45-52.	Data not reported for single vs. mulitlevel neurotomy.	-
2.	Cohen, S. P., Z. H. Bajwa, et al. (2007). Factors predicting success and failure for cervical facet radiofrequency denervation: a multi-center analysis. Reg Anesth Pain Med 32(6): 495-503.	Data not reported for single vs. mulitlevel neurotomy.	-
3.	Klessinger, S. (2010). Radiofrequency neurotomy for the treatment of therapy-resistant neck pain after ventral cervical operations. Pain Med 11(10): 1504-1510.	Percent of pain relief not clearly defined for all outcome data.	-
4.	Shin, W. R., H. I. Kim, et al. (2006). Radiofrequency neurotomy of cervical medial branches for chronic cervicobrachialgia. J Korean Med Sci 21(1): 119-125.	<10 patients underwent neurotomy at a single level.	-
5.	Tzaan, W. C. and R. R. Tasker (2000). Percutaeous radiofrequency facet rhizotomyexperience with 118 procedures and reappraisal of its value. Can J Neurol Sci 27(2): 125-130.	Data not reported for single vs. mulitlevel neurotomy.	KQ2d
6.	Yilmaz, C., S. Kabatas, et al. (2010). Radiofrequency facet joint neurotomy in treatment of facet syndrome. J Spinal Disord Tech 23(7): 480-485.	Data not reported for single vs. mulitlevel neurotomy.	-
	Studies considered and excluded for Key Question 3: (n=0)		
	(all studies considered were excluded at title/abstract review)		

	Citation	Reason for Exclusion	Included in different KQ of report?
	Studies considered and excluded for Key Question 5: (n=6)		
1.	Bogduk, N. and S. Holmes (2000). Controlled zygapophysial joint blocks: the travesty of cost-effectiveness. Pain medicine 1(1): 24-34.	Not a true cost-effectiveness study: appears to provide costs for different scenarios but no formal comparison of them. (poorly describes wrt to cost basis and influence on diagnosis; data for 'best epidemiologic basis" not provided).	-
2.	Burnham, R. S., S. Holitski, et al. (2009). A prospective outcome study on the effects of facet joint radiofrequency denervation on pain, analgesic intake, disability, satisfaction, cost, and employment. Arch Phys Med Rehabil 90(2): 201-205.	Not a full economic study; No ICER or comparable measure of C-E. Further, this is a pre- /post- study, and as such is effectively a case series.	-
3.	Cohen, S. P., K. A. Williams, et al. (2010). Multicenter, randomized, comparative cost-effectiveness study comparing 0, 1, and 2 diagnostic medial branch (facet joint nerve) block treatment paradigms before lumbar facet radiofrequency denervation. Anesthesiology 113(2): 395-405.	Reports cost of treatment following three different diagnostic block scenarios. Study designed to evaluate cost effectiveness of diagnostic block, not of neurotomy compared to other treatments.	KQ1a,c
4.	Derby, R., I. Melnik, et al. (2013). Cost comparisons of various diagnostic medial branch block protocols and medial branch neurotomy in a private practice setting. Pain Med 14(3): 378-391.	Reports cost for three different diagnostic block scenarios, per successful treatment in a real and hypothesized cohort in different cutoffs for pain relief following diagnostic blocks but not in comparison to any other treatment.	KQ2b
5.	Manchikanti, L., V. Pampati, et al. (2010). Explosive growth of facet joint interventions in the Medicare population in the United States: a comparative evaluation of 1997, 2002, and 2006 data. BMC Health Serv Res 10: 84.	Not a costing study.	-
6.	van Wijk, R. M., J. W. Geurts, et al. (2005). Radiofrequency denervation of lumbar facet joints in the treatment of chronic low back pain: a randomized, double-blind, sham lesion-controlled trial. Clin J Pain 21(4): 335-344.	Per point of VAS following neurotomy vs sham is used as "effectiveness"; they provided no real information on any modeling parameters; they do not formally evaluate difference in cost with respect to differences in effectiveness. Further,	KQ2

Citation	Reason for Exclusion	Included in different KQ of report?
	evaluation is versus sham treatment, which is not a real-world alternative treatment in terms of evaluating cost.	

Complete list of studies excluded from the entire evidence report (excluded at full-text review)

- 1. Andres, R. H., T. Graupner, et al. (2010). Laser-guided lumbar medial branch kryorhizotomy. J Neurosurg Spine 13(3): 341-345.
- 2. Bogduk, N. and S. Holmes (2000). Controlled zygapophysial joint blocks: the travesty of cost-effectiveness. Pain medicine 1(1): 24-34.
- 3. Burnham, R. S., S. Holitski, et al. (2009). A prospective outcome study on the effects of facet joint radiofrequency denervation on pain, analgesic intake, disability, satisfaction, cost, and employment. Arch Phys Med Rehabil 90(2): 201-205.
- 4. Cabraja, M., A. Abbushi, et al. (2009). The short- and mid-term effect of dynamic interspinous distraction in the treatment of recurrent lumbar facet joint pain. Eur Spine J 18(11): 1686-1694.
- 5. Cohen, S. P., T. M. Larkin, et al. (2004). The causes of false-positive medial branch (facet joint) blocks in soldiers and retirees. Mil Med 169(10): 781-786.
- 6. Cohen, S. P., R. W. Hurley, et al. (2007). Clinical predictors of success and failure for lumbar facet radiofrequency denervation. Clin J Pain 23(1): 45-52.
- 7. Cohen, S. P., Z. H. Bajwa, et al. (2007). Factors predicting success and failure for cervical facet radiofrequency denervation: a multi-center analysis. Reg Anesth Pain Med 32(6): 495-503.
- Cohen, S. P., S. A. Strassels, et al. (2011). Does sensory stimulation threshold affect lumbar facet radiofrequency denervation outcomes? A prospective clinical correlational study. Anesth Analg 113(5): 1233-1241.
- 9. Derby, R., I. Melnik, et al. (2013). Indications for repeat diagnostic medial branch nerve blocks following a failed first medial branch nerve block. Pain Physician 16(5): 479-488.
- Dobrogowski, J., A. Wrzosek, et al. (2005). Radiofrequency denervation with or without addition of pentoxifylline or methylprednisolone for chronic lumbar zygapophysial joint pain. Pharmacol Rep 57(4): 475-480.
- 11. Jung, J. H., H. I. Kim, et al. (2007). Usefulness of pain distribution pattern assessment in decision-making for the patients with lumbar zygapophyseal and sacroiliac joint arthropathy. J Korean Med Sci 22(6): 1048-1054.
- 12. Lindner, R., M. E. Sluijter, et al. (2006). Pulsed radiofrequency treatment of the lumbar medial branch for facet pain: a retrospective analysis. Pain Med 7(5): 435-439.
- 13. Manchikanti, L., V. Pampati, et al. (2010). Explosive growth of facet joint interventions in the Medicare population in the United States: a comparative evaluation of 1997, 2002, and 2006 data. BMC Health Serv Res 10: 84.
- 14. Manchikanti, L., S. Pampati, et al. (2010). Making sense of the accuracy of diagnostic lumbar facet joint nerve blocks: an assessment of the implications of 50% relief, 80% relief, single block, or controlled diagnostic blocks. Pain Physician 13(2): 133-143.
- 15. McDonald, G. J., S. M. Lord, et al. (1999). "Long-term follow-up of patients treated with cervical radiofrequency neurotomy for chronic neck pain." Neurosurgery 45(1): 61-67; discussion 67-68.

- 16. Mikeladze, G., R. Espinal, et al. (2003). Pulsed radiofrequency application in treatment of chronic zygapophyseal joint pain. Spine J 3(5): 360-362.
- 17. North, R. B., M. Han, et al. (1994). Radiofrequency lumbar facet denervation: analysis of prognostic factors. Pain 57(1): 77-83.
- 18. Park, J., J. Y. Park, et al. (2006). Long term results from percutaneous radiofrequency neurotomy on posterior primary ramus in patients with chronic low back pain. Acta Neurochir Suppl 99: 81-83.
- 19. Shin, W. R., H. I. Kim, et al. (2006). Radiofrequency neurotomy of cervical medial branches for chronic cervicobrachialgia. J Korean Med Sci 21(1): 119-125.
- 20. Staender, M., U. Maerz, et al. (2005). Computerized tomography-guided kryorhizotomy in 76 patients with lumbar facet joint syndrome. J Neurosurg Spine 3(6): 444-449.
- 21. Stojanovic, M. P., J. Sethee, et al. (2010). MRI analysis of the lumbar spine: can it predict response to diagnostic and therapeutic facet procedures? Clin J Pain 26(2): 110-115.
- 22. Stovner, L. J., F. Kolstad, et al. (2004). Radiofrequency denervation of facet joints C2-C6 in cervicogenic headache: a randomized, double-blind, sham-controlled study. Cephalalgia 24(10): 821-830.
- van Kleef, M., L. Liem, et al. (1996). Radiofrequency lesion adjacent to the dorsal root ganglion for cervicobrachial pain: a prospective double blind randomized study. Neurosurgery 38(6): 1127-1131; discussion 1131-1122.
- Wallis, B. J., S. M. Lord, et al. (1997). Resolution of psychological distress of whiplash patients following treatment by radiofrequency neurotomy: a randomised, double-blind, placebo-controlled trial. Pain 73(1): 15-22.
- 25. Yilmaz, C., S. Kabatas, et al. (2010). Radiofrequency facet joint neurotomy in treatment of facet syndrome. J Spinal Disord Tech 23(7): 480-485.

APPENDIX D. Class of Evidence and QHES Determination

Each study is rated against pre-set criteria that resulted in an evidence rating (Class of Evidence I, II, III, or IV) and presented in a table. The criteria are listed in the Tables below.

Definition of the class of evidence and risk of bias for studies on therapy

		Studies of Therapy		
Class	Bias Risk	Study design	Criteria	
I	Low risk: Study adheres to commonly held tenets of high quality design, execution and avoidance of bias	Good quality RCT	 Random sequence generation Allocation concealment Intent-to-treat analysis Blind or independent assessment for important outcomes Co-interventions applied equally F/U rate of 80%+ Adequate sample size 	
II	Moderately low risk: Study has potential for some	Moderate or poor quality RCT	 Violation of one of the criteria for good quality RCT Blind or independent assessment in a 	
	bias; study does not meet all criteria for class I, but deficiencies not likely to invalidate results or introduce significant bias	Good quality cohort	 prospective study, or use of reliable data* in a retrospective study Co-interventions applied equally F/U rate of 80%+ Adequate sample size Controlling for possible confounding[†] 	
ш	Moderately High risk:	Moderate or poor quality cohort	 Violation of any of the criteria for good quality cohort 	
	Study has significant flaws in design and/or execution that increase potential for bias that may invalidate study results	Case-control	Any case-control design	
IV	High risk:	Case series	Any case series design	
	Study has significant potential for bias; lack of comparison group precludes direct assessment of important outcomes			

* Outcome assessment is independent of healthcare personnel judgment. Reliable data are data such as mortality or re-operation.

⁺ Authors must provide a description of robust baseline characteristics, and control for those that are unequally distributed between treatment groups.

		Studies of Prognosis			
Class	Risk of Bias	Study Design	Criteria		
1	Low risk; Study adheres to commonly held tenets of high quality design, execution and avoidance of bias	Good quality cohort*	 Prospective design Patients at similar point in the course of their disease or treatment F/U rate of ≥ 80%[†] Patients followed long enough for outcomes to occur Accounting for other prognostic factors[‡] 		
II	Moderately low risk: Study has potential for some bias; does not meet all criteria for class I but deficiencies not likely to invalidate results or introduce significant bias	Moderate quality cohort	 Prospective design, with violation of one of the other criteria for good quality cohort study Retrospective design, meeting all the rest of the criteria in class I 		
	Moderately high risk: Study has flaws in design and/or execution that increase potential for bias that may invalidate study results	Poor quality cohort Good quality case- control or cross- sectional study	 Prospective design with violation of 2 or more criteria for good quality cohort, or Retrospective design with violation of 1 or more criteria for good quality cohort A good case-control study§ A good cross-sectional study** 		
IV	High risk: Study has significant potential for bias; does not include design features geared toward minimizing bias and/or does not have a comparison group	Poor quality case-contro or cross-sectional Case series§	 Other than a good case-control study Other than a good cross-sectional study Any case series^{††} design 		

Table D2. Definition of the class of evidence and risk of bias for studies on prognosis

*Cohort studies follow individuals with the exposure of interest over time and monitor for occurrence of the outcome of interest.

⁺Applies to cohort studies only.

‡Authors must consider other factors that might influence patient outcomes and should control for them if appropriate.

§A good case-control study must have the all of the following: all incident cases from the defined population over a specified time period, controls that represent the population from which the cases come, exposure that precedes an outcome of interest, and accounting for other prognostic factors.

**A good cross-sectional study must have all of the following: a representative sample of the population of interest, an exposure that precedes an outcome of interest (e.g., sex, genetic factor), an accounting for other prognostic factors, and for surveys, at least a 80% return rate.

⁺⁺A case-series design for prognosis is one where all the patients in the study have the exposure of interest. Since all the patients have the exposure, risks of an outcome can be calculated only for those with the exposure, but cannot be compared with those who do not have the exposure. For example, a case-series evaluating the effect of smoking on spine fusion that only recruits patients who smoke can simply provide the risk of patients who smoke that result in pseudarthrosis but cannot compare this risk to those that do not smoke.

Determination of Overall Strength of Evidence

Following the assessment of the quality of each individual study included in the report, an overall "strength of evidence" for the relevant question or topic is determined. Methods for determining the overall strength of evidence are variable across the literature and are most applicable to evaluation of therapeutic studies.

SRI's method incorporates the primary domains of quality (LoE), quantity of studies and consistency of results across studies as described by AHRQ.

The following four possible levels and their definition will be reported:

- **High** High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
- **Moderate** Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- Low Low confidence that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and likely to change the estimate.
- **Insufficient** Evidence either is unavailable or does not permit a conclusion.

Table D3. Methodology outline for determining overall strength of evidence (SoE):

All AHRQ "required" and "additional" domains* are assessed. Only those that influence the baseline grade are listed in table.

<u>Baseline strength</u>: Risk of bias (including control of confounding) is accounted for in the individual article evaluations. HIGH = majority of articles Level I/II. LOW = majority of articles Level III/IV.

<u>DOWNGRADE</u>: Inconsistency^{**} of results (1 or 2); Indirectness of evidence (1 or 2); Imprecision of effect estimates (1 or 2); Sub-group analyses not stated *a priori* and no test for interaction (2)

Outcome	Strength of Evidence	Conclusions & Comments	Baseline	DOWNGRADE	UPGRADE
Outcome	HIGH	Summary of findings	HIGH Level I/II studies	NO consistent, direct, and precise estimates	NO
Outcome	MODERATE	Summary of findings	LOW Level III studies	NO consistent, direct, and precise estimates	YES Large effect
Outcome	LOW	Summary of findings	HIGH Level I/II studies	YES (2) Inconsistent Indirect	NO

UPGRADE: Large magnitude of effect (1 or 2); Dose response gradient (1)

*<u>Required domains</u>: risk of bias, consistency, directness, precision. Plausible confounding that would decrease observed effect is accounted for in our baseline risk of bias assessment through individual article evaluation. <u>Additional domains</u>: dose-response, strength of association, publication bias.

**Single study = "consistency unknown

Assessment of Economic Studies

Full formal economic analyses evaluate both costs and clinical outcomes of two or more alternative interventions. The four primary types are cost minimization analysis (CMA), cost-utility analysis (CUA), cost-effectiveness analysis (CEA), and cost-benefit analyses (CBA). Each employs different methodologies, potentially complicating critical appraisal, but some common criteria can be assessed across studies.

No standard, universally accepted method of critical appraisal of economic analyses is currently in use. A number of checklists [Canadian, BMJ, AMA] are available to facilitate critique of such studies. The Quality of Health Economic Studies (QHES) instrument developed by Ofman, et al¹. QHES embodies the primary components relevant for critical appraisal of economic studies^{1, 2}. It also incorporates a weighted scoring process and which was used as one factor to assess included economic studies. This tool has not yet undergone extensive evaluation for broader use but provides a valuable starting point for critique.

In addition to assessment of criteria in the QHES, other factors are important in critical appraisal of studies from an epidemiologic perspective to assist in evaluation of generalizability and potential sources of study bias.

Such factors include:

- Are the interventions applied to similar populations (eg, with respect to age, gender, medical conditions, etc)? To what extent are the populations for each intervention comparable and are differences considered or accounted for? To what extent are population characteristics consistent with "real world" applications of the comparators?
- Are the sample sizes adequate so as to provide a reasonable representation of individuals to whom the technology would be applied?
- What types of studies form the basis for the data used in the analyses? Data (eg, complication rates) from randomized controlled trials or well-conducted, methodologically rigorous cohort studies for data collection are generally of highest quality compared with case series or studies with historical cohorts.
- Were the interventions applied in a comparable manner (eg, similar protocols, follow-up procedures, evaluation of outcomes, etc)?
- How were the data and/or patients selected or sampled (eg, a random selection of claims for the intervention from a given year/source or all claims)? What specific inclusion/exclusion criteria or processes were used?
- Were the outcomes and consequences of the interventions being compared comparable for each? (eg, were all of the relevant consequences/complications for each intervention considered or do they primarily reflect those for one intervention?)

Assessment of the overall strength of evidence for formal economic analyses does not appear to be documented in the literature. For the purposes of this HTA, overall strength was determined by:

- Quality of the individual studies: Where the majority of quality indicators described in the QHES met and were the methods related to patient/claim selection, patient population considerations and other factors listed above consistent with a high quality design?
- Number of formal analyses (3 or more)

• Consistency of findings and conclusions from analyses across studies.

QHES evaluation of economic studies

No economic studies met our inclusion criteria.

APPENDIX E. Class of Evidence (CoE) Evaluation

KQ 1a – Diagnostic block versus alternative diagnostic test (e.g., physical examination, radiological examination)

Methodological Principle	Cohen 2010
Study design	
Randomized controlled trial	-
Prospective cohort study	
Retrospective cohort study	
Case-control	
Case-series	
Random sequence generation*	
Statement of concealed allocation*	
Intention to treat*	
Independent or blind assessment	
Co-interventions applied equally	
Complete follow-up of <u>></u> 80%	
Adequate sample size	
Controlling for possible confounding ⁺	
Evidence Level	II

*Applies only to randomized controlled trials

⁺Groups must be comparable on baseline characteristics or evidence of control for confounding presented Blank cells indicate that the criterion was either not met or that it could not be determined

Cohen (2010):

- Adequate sequence generation? No, no information provided aside from "sealed envelopes".
- Allocation concealment? No, no information provided aside from "sealed envelopes" which is an inadequate method of concealment.
- Intention to treat analysis? Credit. While there was no explicit statement that ITT analysis was used, it appeared that patients underwent no diagnostic blocks or diagnostic blocks as randomized prior to facet neurotomy. Details of patient randomization, treatment, follow-up, and analysis provided in Figure 1.
- Independent or blind assessment of primary outcome assessment? No credit, the primary outcomes were patient-reported outcomes but patients could not have been blinded to their diagnostic block status (i.e., 0, 1, or 2 diagnostic blocks).
- Co-interventions applied equally? Credit; aside from the different diagnostic blocks being assessed, all patients received radiofrequency facet neurotomy.
- Complete follow-up of \ge 80% for each main outcome? Credit, 99% follow-up.
- Adequate sample size? Credit, there were statistically meaningful differences b/w treatment groups in the primary outcome at 1 month.
- Controlled for possible confounding variables? Credit, a robust table of demographic information and baseline characteristics was provided with no major differences between treatment groups.

KQ 1b – Diagnostic MBB versus Diagnostic Intraarticular Injection

Methodological Principle	Birkenmaier 2007
Study design	
Randomized controlled trial	
Prospective cohort study	
Retrospective cohort study	
Case-control	
Case-series	
Random sequence generation*	
Statement of concealed allocation*	
Intention to treat*	
Independent or blind assessment	
Co-interventions applied equally	
Complete follow-up of <u>></u> 80%	
Adequate sample size	
Controlling for possible confounding ⁺	
Evidence Level	II

*Applies only to randomized controlled trials

⁺Groups must be comparable on baseline characteristics or evidence of control for confounding presented Blank cells indicate that the criterion was either not met or that it could not be determined

Birkenmaier (2007):

- Adequate sequence generation? Credit, "patients were assigned to receive either pericapsular blocks or medial branch blocks according to a computer-generated randomization list."
- Allocation concealment? No, no information provided.
- Intention to treat analysis? Credit. While there was no explicit statement that ITT analysis was used, patients were treated as randomized and it does not appear that cross-over was an option.
- Independent or blind assessment of primary outcome assessment? No credit, patient-reported outcomes were used however there was no indication that patients (or data collectors) were blinded to the treatment received.
- Co-interventions applied equally? Credit; aside from the different diagnostic blocks being assessed, all patients received radiofrequency facet neurotomy.
- Complete follow-up of \ge 80% for each main outcome? No credit, % follow-up not reported.
- Adequate sample size? Credit, there were statistically meaningful differences b/w treatment groups in the pain ratings at 6 weeks and 3 months.
- Controlled for possible confounding variables? No credit, almost no demographic information was provided.

KQ 1c – Single versus controlled diagnostic blocks

Methodological Principle	Cohen 2010
Study design	
Randomized controlled trial	
Prospective cohort study	
Retrospective cohort study	
Case-control	
Case-series	
Random sequence generation*	
Statement of concealed allocation*	
Intention to treat*	
Independent or blind assessment	
Co-interventions applied equally	
Complete follow-up of <u>></u> 80%	
Adequate sample size	
Controlling for possible confounding ⁺	
Evidence Level	11

*Applies only to randomized controlled trials

⁺Groups must be comparable on baseline characteristics or evidence of control for confounding presented Blank cells indicate that the criterion was either not met or that it could not be determined

Cohen (2010):

- Adequate sequence generation? No, no information provided aside from "sealed envelopes".
- Allocation concealment? No, no information provided aside from "sealed envelopes" which is an inadequate method of concealment.
- Intention to treat analysis? Credit. While there was no explicit statement that ITT analysis was used, it appeared that patients underwent no diagnostic blocks or diagnostic blocks as randomized prior to facet neurotomy. Details of patient randomization, treatment, follow-up, and analysis provided in Figure 1.
- Independent or blind assessment of primary outcome assessment? No credit, the primary outcomes were patient-reported outcomes but patients could not have been blinded to their diagnostic block status (i.e., 0, 1, or 2 diagnostic blocks).
- Co-interventions applied equally? Credit; aside from the different diagnostic blocks being assessed, all patients received radiofrequency facet neurotomy.
- Complete follow-up of \ge 80% for each main outcome? Credit, 99% follow-up.
- Adequate sample size? Credit, there were statistically meaningful differences b/w treatment groups in the primary outcome at 1 month.
- Controlled for possible confounding variables? Credit, a robust table of demographic information and baseline characteristics was provided with no major differences between treatment groups.

Methodological Principle	Cohen 2008	Cohen 2013	Derby 2012	Derby 2013 ("Cost")
Study design				
Randomized controlled trial				
Prospective cohort study				
Retrospective cohort study	•		•	-
Case-control				
Case-series				
Random sequence generation*	n/a	n/a	n/a	n/a
Statement of concealed allocation*	n/a	n/a	n/a	n/a
Intention to treat*	n/a	n/a	n/a	n/a
Independent or blind assessment				
Co-interventions applied equally				
Complete follow-up of <u>></u> 80%	•			
Adequate sample size				
Controlling for possible confounding ⁺				
Evidence Level	Ш	Ш	Ш	Ш

KQ 1d – Differential requirements of pain relief following diagnostic block

*Applies only to randomized controlled trials

⁺Groups must be comparable on baseline characteristics or evidence of control for confounding presented Blank cells indicate that the criterion was either not met or that it could not be determined

<u> Cohen (2008):</u>

- Independent or blind assessment of primary outcome assessment? No credit, the primary outcomes were patient-reported outcomes but there was no statement indicating that patients were blinded to the level of pain relief following diagnostic block.
- Co-interventions applied equally? No credit as there was no statement regarding any posttreatment care and whether there were differences in this between groups.
- Complete follow-up of \ge 80% for each main outcome? Credit, 90% follow-up.
- Adequate sample size? Credit, there were statistically meaningful differences b/w treatment groups in some outcomes.
- Controlled for possible confounding variables? Credit, a robust table of demographic information and baseline characteristics was provided with no major differences between treatment groups.

Cohen (2013):

- Independent or blind assessment of primary outcome assessment? No credit, the primary outcomes were patient-reported outcomes but there was no statement indicating that patients were blinded to the level of pain relief following diagnostic block.
- Co-interventions applied equally? No credit as there was no statement regarding any posttreatment care and whether there were differences in this between groups.

- Complete follow-up of ≥ 80% for each main outcome? No credit; percent follow-up not reported, as the authors did not provide information on the percentage of patients who did not return their pain diaries following diagnostic block.
- Adequate sample size? No credit, there were not statistically meaningful differences b/w treatment groups in any outcomes.
- Controlled for possible confounding variables? No credit. Although robust table of demographic information and baseline characteristics was provided with no major differences between those patients who had no pain relief from diagnostic block and those who had adequate relief from diagnostic block, no demographic information was available for the different pain relief groups for which outcomes were reported (ie., <50% versus 50-66% versus 67-83% versus >84% pain relief from diagnostic block).

Derby (2012):

- Independent or blind assessment of primary outcome assessment? No credit, the primary outcomes were patient-reported outcomes but there was no statement indicating that patients were blinded to the level of pain relief following diagnostic block.
- Co-interventions applied equally? No credit as there was no statement regarding any posttreatment care and whether there were differences in this between groups.
- Complete follow-up of ≥ 80% for each main outcome? No credit, 61% (57/94) follow-up of patients with a diagnostic block.
- Adequate sample size? No credit, statistical significance not evaluated for the primary outcome.
- Controlled for possible confounding variables? No credit. Although robust table of demographic information and baseline characteristics was provided with no major differences between those patients who had one versus two diagnostic blocks, no demographic information was available for the different pain relief groups for which outcomes were reported (ie., 50% versus 60% versus 70% versus 80% versus 90% versus 100% pain relief from diagnostic block).

<u>Derby (2013):</u>

- Independent or blind assessment of primary outcome assessment? No credit, the primary outcomes were patient-reported outcomes but there was no statement indicating that patients were blinded to the level of pain relief following diagnostic block.
- Co-interventions applied equally? No credit as there was no statement regarding any posttreatment care and whether there were differences in this between groups.
- Complete follow-up of ≥ 80% for each main outcome? No credit, 57% (48/84) follow-up of patients with a positive diagnostic block.
- Adequate sample size? No credit, statistical significance not evaluated for the primary outcome.
- Controlled for possible confounding variables? No credit. Although robust table of demographic information and baseline characteristics was provided with no major differences between those patients who had one versus two diagnostic blocks, no demographic information was available for the different pain relief groups for which outcomes were reported (ie., 50% versus 60% versus 70% versus 80% versus 90% versus 100% pain relief from diagnostic block).

KQ2 – Efficacy and Effectiveness, Lumbar spine

Methodological Principle	Chakraverty 2004	Civelek 2012	Gallagher 1994	Lakemeier 2013	Leclaire 2001
Study design					
Randomized controlled trial		-	-	■	
Prospective cohort study					
Retrospective cohort study					
Case-control					
Case-series					
Random sequence generation*	n/a				
Statement of concealed allocation*	n/a				
Intention to treat*	n/a				
Independent or blind assessment					
Co-interventions applied equally					
Complete follow-up of <u>></u> 80%					
Adequate sample size					
Controlling for possible confounding ⁺					
Evidence Level	Ш	II	II	II	Ш

Nath 2008	Tekin 2007	Van Kleef 1999	Van Wijk 2005
-	-	•	-
•	-	•	•
			•
			•
			•
Ш	Ш	Ш	Ш
	2008	2008 2007 • •	2008 2007 1999 • • •

*Applies only to randomized controlled trials

⁺Groups must be comparable on baseline characteristics or evidence of control for confounding presented

Blank cells indicate that the criterion was either not met or that it could not be determined

Chakraverty (2004)

- Independent or blind assessment of primary outcome assessment? No; retrospective study performed by hospital audit, so data collectors would not have been blinded when assessing outcomes.
- Co-interventions applied equally? No, insufficient information to fully evaluate interventions; also the facet joint injections (2000-2001) were not performed during the same time period as facet neurotomies (2002-2004).
- Complete follow-up of ≥ 80% for each main outcome? No; the number of eligible patients from which the data were taken was not reported so the complete f/u cannot be calculated.
- Adequate sample size? No, testing for statistical significance not done, clinically important differences not defined and the absolute differences b/w groups doesn't seem large, and there is less than 100 patients per treatment group.
- Controlled for possible confounding variables? No, inadequate list of baseline characteristics provided, no statements discussing evaluation of possible confounding variables.

<u>Civelek</u>

- Adequate sequence generation? Yes, "random number generation, balancing after every ten patients".
- Allocation concealment? No, no information provided.
- Intention to treat analysis? No credit, as there was no statement indicating that the authors analyzed the data according to the intention to treat principle or any way to tell that this was done (no patient numbers reported for each treatment group for follow-up data).
- Independent or blind assessment of primary outcome assessment? No; the primary outcome was pain (NASS) (function NR) and patient satisfaction was also reported; both of which were based on patient reports of outcomes, and the patients were not blinded to treatment received. (Although data collectors were blinded).
- Co-interventions applied equally? Yes
- Complete follow-up of \geq 80% for each main outcome? Yes (100%).
- Adequate sample size? Yes; there were statistically significant differences b/w the groups in terms of pain.
- Controlled for possible confounding variables? No; although the authors state there were no differences b/w groups w/ respect to age, gender, level number, symptom duration, VNS-pre, and EQ-5D pre, no data were reported to adequately assess the actual data in both treatment groups.

Gallagher (1994)

- Adequate sequence generation? No credit, no information provided beyond that patients were "randomly allocated".
- Allocation concealment? No credit, no information provided beyond that patients were "randomly allocated".
- Intention to treat analysis? No credit, no explicit statement and we are unable to determine whether patients were treated as randomly allocated.
- Independent or blind assessment of primary outcome assessment? Partial credit: Credit for McGill Pain Questionnaire (clinician-reported outcome) but no credit for VAS pain, which is a patient-reported outcome as it was not clear that patients were blinded to treatment received.

(Note data collectors were blinded; "patients were assessed before any treatment, before denervation and at 1 and 6 months by "blind observers".)

- Co-interventions applied equally? No credit as there was no statement regarding any post-treatment care.
- Complete follow-up of \geq 80% for each main outcome? Yes (100%).
- Adequate sample size? Yes, statistically significant difference in pain outcomes between gp A and gp C at 1 month.
- Controlled for possible confounding variables? No credit, inadequate demographic data provided.

Lakemeier (1994)

- Adequate sequence generation? Yes, computer-generated random allocation sequence with permuted blocks of 4 and 6.
- Allocation concealment? Credit, the study says randomization was concealed and was performed by an independent institution.
- Intention to treat analysis? Yes, explicit statement that this was used.
- Independent or blind assessment of primary outcome assessment? Yes- everyone was blinded (except surgeon and nurse during the procedure and they weren't involved after that point).
- Co-interventions applied equally? Credit; no obvious differences b/w treatment groups.
- Complete follow-up of \ge 80% for each main outcome? Yes (93%).
- Adequate sample size? No, the differences b/w groups in the improvement in the primary outcomes (pain (VNS), function (Roland-Morris, ODI)) were not statistically significant.
- Controlled for possible confounding variables? No, inadequate list of baseline characteristics provided. (only age, sex, and baseline Roland-Morris, ODI, and VAS scores). Length of symptoms not reported.

LeClaire (2001)

- Adequate sequence generation? No credit; no information on how random sequence generation was performed besides that "randomization was performed in blocks of four."
- Allocation concealment? Credit, "an opaque prenumbered envelope containing the assignement of the patient was given to the physician."
- Intention to treat analysis? Yes, explicit statement that this was used.
- Independent or blind assessment of primary outcome assessment? Credit, "the patients, the research assistant, and the physicians responsible for the patients' return to work were kept blind to the treatment group."
- Co-interventions applied equally? Credit; no obvious differences b/w treatment groups.
- Complete follow-up of \ge 80% for each main outcome? Yes (94%).
- Adequate sample size? Credit, no statistically significant differences in primary outcomes b/w groups, but an adequate sample size was calculated to find a significant difference in the clinically important difference.
- Controlled for possible confounding variables? Credit, no obvious differences in demographics or baseline scores.

<u>Nath (2008)</u>

- Adequate sequence generation? Yes, "randomized... using a computer-generated randomization schedule."
- Allocation concealment? No, no information provided.
- Independent or blind assessment of primary outcome assessment? Yes, patient-reported pain was the primary outcome, and patients were blinded.
- Co-interventions applied equally? No credit as there was no statement regarding any post-treatment care.
- Complete follow-up of \geq 80% for each main outcome? Yes (100%).
- Adequate sample size? Credit; statistically significant differences in pain improvement b/w treatment groups.
- Controlled for possible confounding variables? No credit, sufficient demographic information provided (age, sex, duration of pain reported in methods section), but there were considerable differences in baseline generalized pain, back pain, and leg pain between treatment groups that weren't controlled for.

<u>Tekin (2007)</u>

- Adequate sequence generation? Credit, "randomization into 3 groups was performed by random number generation, balancing after every 8 patients."
- Allocation concealment? No credit, no information provided.
- Intention to treat: No credit, no explicit statement and no information was provided regarding whether the number of patients treated in each group were the same number randomized to each treatment group.
- Independent or blind assessment of primary outcome assessment? Credit, patients blinded and data collectors independent.
- Co-interventions applied equally? Credit; both groups appear to have been treated equally regarding ablation, and "no other interventional therapy beside NSAIDs if the pain was greater than a 4 (on VAS 0-10 scale) was applied to the patients during the follow-up period."
- Complete follow-up of \geq 80% for each main outcome? Yes (100%).
- Adequate sample size? Credit; statistically significant differences in pain improvement and ODI scores b/w treatment groups.
- Controlled for possible confounding variables? Credit given because no significant differences were found at baseline between groups for age, sex, duration of pain, VAS and ODI scores (Table 1).

<u>van Kleef (1999)</u>

- Adequate sequence generation? Credit, were randomized "with the help of a computer program... in blocks of two into two treatment groups".
- Allocation concealment? No credit, no information provided.
- Intention to treat: No credit, no explicit statement and one patient was excluded from analysis after randomization (did not want to return to the hospital after the procedure).
- Independent or blind assessment of primary outcome assessment? Credit, both patients and data collectors blinded.

- Co-interventions applied equally? No; no obvious differences b/w treatment groups but no information was reported regarding post-treatment interventions.
- Complete follow-up of \ge 80% for each main outcome? No credit, f/u NR.
- Adequate sample size? Credit, significant difference b/w groups in VAS pain improvement.
- Controlled for possible confounding variables? Credit, although patients in the RF group had considerably shorter median duration of pain (26 months, range 12 to 120 months) than did those in the sham group (median, 48 months, range of 12 to 192 months), baseline differences in gender, age, duration of pain, pretreatment pain intensity, and Likert scores after diagnostic block were controlled for using adjusted analysis.

<u>van Wijk (2005)</u>

- Adequate sequence generation? Credit: "randomization was performed independently and in a separate setting by the Center for Biostatistics at the University. Patients were stratified according to sex and history of low back surgery as previous studies suggested these factors might be related to outcome. Four sets of closed envelopes (M+, M-, F+, F-) were produced. Just before treatment, an envelope was drawn at random from the appropriate set of envelopes and opened by an independent physician, who read the contents and accordingly instructed the RF generator setup by a tech. These contents... were then placed into another enveloped, which was sealed and returned to the randomization center.
- Allocation concealment? Credit, as randomization was performed at a separate location.
- Intention to treat: Credit, no explicit statement but information in Figure 1 indicates that data were analyzed in accordance with this principle.
- Independent or blind assessment of primary outcome assessment? Credit, primary outcomes were patient-reported and patients were blinded..
- Co-interventions applied equally? No credit as there was no statement regarding any post-treatment care.
- Complete follow-up of ≥ 80% for each main outcome? ? No credit, although f/u at 3 months is 100%, it wasn't reported for the other f/u periods.
- Adequate sample size? Credit, significant difference between groups for global perceived effect of low back pain (*P* = .044).
- Controlled for possible confounding variables? Credit, similar baseline data between treatment groups.

KQ 2 – Efficacy and Effectiveness: Cervical

Methodological Principle	Haspeslagh 2006	Lord 1996
Study design		
Randomized controlled trial	•	•
Prospective cohort study		
Retrospective cohort study		
Case-control		
Case-series		
Random sequence generation*		
Statement of concealed allocation*		
Intention to treat*		
Independent or blind assessment		
Co-interventions applied equally		
Complete follow-up of <u>></u> 80%		
Adequate sample size		
Controlling for possible confounding ⁺		
Evidence Level	II	II

*Applies only to randomized controlled trials

⁺Groups must be comparable on baseline characteristics or evidence of control for confounding presented Blank cells indicate that the criterion was either not met or that it could not be determined

Haspeslagh (2006):

- Adequate sequence generation? No, no information provided.
- Allocation concealment? No, no information provided.
- Intention to treat analysis? Credit; no explicit statement but data up to 8 weeks appears to have been handled this way.
- Independent or blind assessment of primary outcome assessment? No, although patients evaluated by blinded investigator, there was no statement that the patients themselves were blinded to treatment received, and the primary outcomes were patient-reported.
- Co-interventions applied equally? No credit, as patients in the injection group did not receive steroid injection, only injection of local anesthetic. Therapeutic injections typically include steroids for longer term pain relief.
- Complete follow-up of \geq 80% for each main outcome? Yes, 93%.
- Adequate sample size? No. Statistical analysis showed no significant differences between treatment groups.
- Controlled for possible confounding variables? No, the neurotomy group had considerably longer mean duration of pain than the injection group (9.7 versus 6.6 years, respectively); this was not controlled for.

Lord (1996):

- Adequate sequence generation? Credit, "patients were assigned on the basis of a computergenerated schedule of random numbers".
- Allocation concealment? No, no information provided.
- Intention to treat analysis? Credit, no explicit statement but the data appear to have been handled this way.
- Independent or blind assessment of primary outcome assessment? Credit, "neither the patient nor the surgeon knew the patient's treatment assignment until the completion of the trial." Outcomes were assessed by the surgeon and/or the patient.
- Co-interventions applied equally? Yes, no obvious differences b/w treatment groups.
- Complete follow-up of \geq 80% for each main outcome? Yes; 100%.
- Adequate sample size? No, no statistically significant differences b/w the groups in terms of primary outcomes plus there were only 12 patients in each treatment group.
- Controlled for possible confounding variables? Credit given "no significant differences between groups with respect to age, sex, employment status, duration of pain, joints treated, or baseline scores on VAS, McGill Pain Questionnaire, and SCL-90R." (Table 1)

Methodological Principle	Joo 2013	Kroll 2008	Tekin 2007
Study design			
Randomized controlled trial		-	-
Prospective cohort study			
Retrospective cohort study			
Case-control			
Case-series			
Random sequence generation*		•	•
Statement of concealed allocation*			
Intention to treat*			
Independent or blind assessment			
Co-interventions applied equally			
Complete follow-up of <u>></u> 80%			
Adequate sample size			
Controlling for possible confounding ⁺			
Evidence Level	II	Ш	II
*Applies only to randomized controlled trials			

KQ 2a – Efficacy and Effectiveness of different types of neurotomy

*Applies only to randomized controlled trials

[†]Groups must be comparable on baseline characteristics or evidence of control for confounding presented Blank cells indicate that the criterion was either not met or that it could not be determined

<u>Joo (2013):</u>

- Adequate sequence generation? No, no information provided.
- Allocation concealment? No, no information provided.
- Intention to treat analysis? Credit. While there was no explicit statement that ITT analysis was used, patients were treated as randomized and it does not appear that cross-over was an option.
- Independent or blind assessment of primary outcome assessment? No credit, the patientreported outcomes of VAS and ODI were used however there was no indication that patients were blinded to the treatment received.
- Co-interventions applied equally? No credit; while both groups appear to have been treated equally regarding ablation, there was no mention as to what additional post-ablation treatments (i.e., meds, physical therapy) patients may have received.
- Complete follow-up of \ge 80% for each main outcome? No credit, follow-up not reported.
- Adequate sample size? Credit, there were statistically meaningful differences b/w treatment groups in the primary outcome of recurrence.
- Controlled for possible confounding variables? No credit, no baseline pain levels (or ODI scores) or time since last successful ablation were reported.

<u>Kroll (2008)</u>

- Adequate sequence generation? Credit, "subjects were randomly assigned via a random numbers generator."
- Allocation concealment? No, no information provided.
- Intention to treat analysis? No credit, although 50 patients were randomized, only the 13 patients with complete f/u in each treatment group were reported on. Nothing about the remaining patients (including the number of patients randomized to each treatment group) was reported.
- Independent or blind assessment of primary outcome assessment? Credit, patients were blinded and primary outcomes were patient-reported.
- Co-interventions applied equally? No credit; while both groups appear to have been treated equally regarding ablation, there was no mention as to what additional post-ablation treatments (i.e., meds, physical therapy) patients may have received
- Complete follow-up of \ge 80% for each main outcome? No credit, complete f/u was 52% (26/50).
- Adequate sample size? No credit, there were not statistically significant differences b/w treatment groups in any of the primary outcomes.
- Controlled for possible confounding variables? No credit, although 50 patients were randomized, only the 13 patients with complete f/u in each treatment group were reported on (including for baseline characteristics). Very little baseline data were reported.

<u> Tekin (2007)</u>

- Adequate sequence generation? Credit, "randomization into 3 groups was performed by random number generation, balancing after every 8 patients."
- Allocation concealment? No credit, no information provided.
- Intention to treat: No credit, no explicit statement and no information was provide regarding the number of patients randomized to each treatment group.
- Independent or blind assessment of primary outcome assessment? Credit, patients blinded and data collectors independent.

- Co-interventions applied equally? No credit; while both groups appear to have been treated equally regarding ablation, there was no mention as to what additional post-ablation treatments (i.e., meds, physical therapy) patients may have received.
- Complete follow-up of \geq 80% for each main outcome? Yes (100%).
- Adequate sample size? Credit; statistically significant differences in pain improvement (but not ODI scores) b/w treatment groups.
- Controlled for possible confounding variables? No credit, insufficient demographic information provided.

KQ 2b – Repeat Neurotomy: Lumbar spine

Methodological Principle	Joo 2013	Rambaransingh 2010	Schofferman 2004	Son 2010	Speldewinde 2011	Zotti 2010
Study design						
Randomized controlled trial						
Prospective cohort study						
Retrospective cohort study						
Case-control						
Case-series	-			-		•
Random sequence generation*	n/a	n/a	n/a	n/a	n/a	n/a
Statement of concealed allocation*	n/a	n/a	n/a	n/a	n/a	n/a
Intention to treat*	n/a	n/a	n/a	n/a	n/a	n/a
Independent or blind assessment						
Co-interventions applied equally						
Complete follow-up of <u>></u> 80%						
Adequate sample size						
Controlling for possible confounding ⁺	n/a	n/a	n/a	n/a		n/a
Evidence Level	IV	IV	IV	IV	IV	IV

*Applies only to randomized controlled trials

⁺Groups must be comparable on baseline characteristics or evidence of control for confounding presented Blank cells indicate that the criterion was either not met or that it could not be determined

KQ 2b – Repeat Neurotomy: Cervical spine

Methodological Principle	Husted 2008	Rambaransingh 2010	Speldewinde 2011	
Study design				
Randomized controlled trial				
Prospective cohort study				
Retrospective cohort study				
Case-control				
Case-series				
Random sequence generation*	n/a	n/a	n/a	
Statement of concealed allocation*	n/a	n/a	n/a	
Intention to treat*	n/a	n/a	n/a	
Independent or blind assessment				
Co-interventions applied equally				
Complete follow-up of <u>></u> 80%			•	
Adequate sample size				
Controlling for possible confounding ⁺	n/a	n/a	n/a	
Evidence Level	IV	IV	IV	

*Applies only to randomized controlled trials

⁺Groups must be comparable on baseline characteristics or evidence of control for confounding presented Blank cells indicate that the criterion was either not met or that it could not be determined

<u>Joo (2013):</u>

- Independent or blind assessment of primary outcome assessment? No credit: all patients received facet neurotomy and of course were aware of whether they were undergoing the first or second treatment; outcomes reported were patient-reported.
- Co-interventions applied equally? No credit; while both groups appear to have been treated equally regarding ablation, there was no mention as to what additional post-ablation treatments (i.e., meds, physical therapy) patients may have received. No information regarding primary treatment.
- Complete follow-up of \ge 80% for each main outcome? No credit, follow-up not reported.
- Adequate sample size? No credit, statistical significance b/w outcomes following primary versus secondary RF ablation not evaluated.
- Controlled for possible confounding variables? Not applicable, as the patients were the same in both treatment groups.

Rambaransingh (2010):

• Independent or blind assessment of primary outcome assessment? No credit: all patients received facet neurotomy and of course were aware of whether they were undergoing the first or second treatment; outcomes reported were patient-reported.

- Co-interventions applied equally? No credit; while both groups appear to have been treated equally regarding ablation, there was no mention as to what additional post-ablation treatments (i.e., meds, physical therapy) patients may have received. No information regarding primary treatment.
- Complete follow-up of ≥ 80% for each main outcome? No credit, 74%(62/84), not reported for third neurotomy.
- Adequate sample size? No credit, statistical significance b/w outcomes following primary versus secondary RF ablation not evaluated.
- Controlled for possible confounding variables? Not applicable, as the patients were the same in both treatment groups.

Schofferman (2004):

- Independent or blind assessment of primary outcome assessment? No credit: all patients received facet neurotomy and of course were aware of whether they were undergoing the first or second treatment; outcomes reported were patient-reported.
- Co-interventions applied equally? No credit; while both groups appear to have been treated equally regarding ablation, there was no mention as to what additional post-ablation treatments (i.e., meds, physical therapy) patients may have received. No information regarding primary treatment.
- Complete follow-up of \ge 80% for each main outcome? No credit, % f/u not reported.
- Adequate sample size? No credit, statistical significance b/w outcomes following first versus second vs third vs fourth RF ablation not evaluated.
- Controlled for possible confounding variables? Not applicable, as the patients were the same in both treatment groups.

Son (2010):

- Independent or blind assessment of primary outcome assessment? No credit: all patients received facet neurotomy and of course were aware of whether they were undergoing the first or second treatment; outcomes reported were patient-reported.
- Co-interventions applied equally? No credit; while both groups appear to have been treated equally regarding ablation, there was no mention as to what additional post-ablation treatments (i.e., meds, physical therapy) patients may have received. No information regarding primary treatment.
- Complete follow-up of \geq 80% for each main outcome? Credit, 100% f/u.
- Adequate sample size? No credit, statistical significance b/w outcomes following first versus second vs third vs fourth RF ablation not evaluated.
- Controlled for possible confounding variables? Not applicable, as the patients were the same in both treatment groups.

Speldewinde (2011):

- Independent or blind assessment of primary outcome assessment? No credit: all patients received facet neurotomy and of course were aware of whether they were undergoing the first or second treatment; outcomes reported were patient-reported.
- Co-interventions applied equally? No credit; while both groups appear to have been treated equally regarding ablation, there was no mention as to what additional post-ablation treatments (i.e., meds, physical therapy) patients may have received.
- Complete follow-up of \ge 80% for each main outcome? Credit, 100% follow-up.

- Adequate sample size? No credit, statistical significance b/w outcomes following first versus second neurotomies not evaluated.
- Controlled for possible confounding variables? Not applicable, as the patients were the same in both treatment groups.

<u>Zotti (2010):</u>

- Independent or blind assessment of primary outcome assessment? No credit: all patients received facet neurotomy and of course were aware of whether they were undergoing the first or second treatment; outcomes reported were patient-reported.
- Co-interventions applied equally? No credit; while both groups appear to have been treated equally regarding ablation, there was no mention as to what additional post-ablation treatments (i.e., meds, physical therapy) patients may have received. No information regarding primary treatment.
- Complete follow-up of \ge 80% for each main outcome? Credit, 95% f/u.
- Adequate sample size? No credit, statistical significance not calculated for primary outcomes.
- Controlled for possible confounding variables? Not applicable, as the patients were the same in both treatment groups.

Cervical Studies:

Husted (2008):

- Independent or blind assessment of primary outcome assessment? No credit: all patients received facet neurotomy and of course were aware of whether they were undergoing the first or second treatment; outcomes reported were patient-reported.
- Co-interventions applied equally? Credit; both groups appear to have been treated equally regarding ablation, and "all patients had been treated with physical therapy. Most were taking medications."
- Complete follow-up of \ge 80% for each main outcome? Credit (95%).
- Adequate sample size? No credit, statistical significance b/w outcomes following primary versus secondary RF ablation not evaluated.
- Controlled for possible confounding variables? Not applicable, as the patients were the same in both treatment groups.

Rambaransingh (2010):

- Independent or blind assessment of primary outcome assessment? No credit: all patients received facet neurotomy and of course were aware of whether they were undergoing the first or second treatment; outcomes reported were patient-reported.
- Co-interventions applied equally? No credit; while both groups appear to have been treated equally regarding ablation, there was no mention as to what additional post-ablation treatments (i.e., meds, physical therapy) patients may have received. No information regarding primary treatment.
- Complete follow-up of ≥ 80% for each main outcome? No credit, 70%(14/20), not reported for third neurotomy.
- Adequate sample size? No credit, statistical significance b/w outcomes following primary versus secondary RF ablation not evaluated.

• Controlled for possible confounding variables? Not applicable, as the patients were the same in both treatment groups.

Speldewinde (2011):

- Independent or blind assessment of primary outcome assessment? No credit: all patients received facet neurotomy and of course were aware of whether they were undergoing the first or second treatment; outcomes reported were patient-reported.
- Co-interventions applied equally? No credit; while both groups appear to have been treated equally regarding ablation, there was no mention as to what additional post-ablation treatments (i.e., meds, physical therapy) patients may have received.
- Complete follow-up of \ge 80% for each main outcome? Credit, 100% follow-up.
- Adequate sample size? No credit, statistical significance b/w outcomes following first versus second neurotomies not evaluated.
- Controlled for possible confounding variables? Not applicable, as the patients were the same in both treatment groups.

Methodological Principle	Tzaan 2000
Study design	
Randomized controlled trial	
Prospective cohort study	
Retrospective cohort study	•
Case-control	
Case-series	
Random sequence generation*	n/a
Statement of concealed allocation*	n/a
Intention to treat*	n/a
Independent or blind assessment	
Co-interventions applied equally	
Complete follow-up of <u>></u> 80%	
Adequate sample size	
Controlling for possible confounding ⁺	
Evidence Level	III

KQ 2c – Unilateral versus bilateral neurotomy

*Applies only to randomized controlled trials

[†]Groups must be comparable on baseline characteristics or evidence of control for confounding presented Blank cells indicate that the criterion was either not met or that it could not be determined

<u> Tzaan (2000):</u>

- Independent or blind assessment of primary outcome assessment? No credit: there was no statement indicating that the patients were unaware of whether they were being treated with unilateral versus bilateral neurotomy. Outcomes were patient-reported.
- Co-interventions applied equally? No credit, it was not clear that the patients in both groups were treated equally (that the unilateral vs bilateral patients received analgesic medication equally).
- Complete follow-up of \ge 80% for each main outcome? No credit, follow-up not reported.
- Adequate sample size? No credit, the difference in success rate between lumbosacral unilateral versus bilateral neurotomy was not statistically significant.
- Controlled for possible confounding variables? No credit; very few baseline characteristics provided; no information on duration of pain and baseline pain levels. while both groups appear to have been treated equally regarding ablation, patients received unilateral neurotomy for unilateral pain and bilateral neurotomy for bilateral pain.

APPENDIX F. Evidence Tables for Included Studies

KQ1 Demographics

Investigator (year) Country,	Study	Patient		Diagnostic Blocks/	Diagnostic	Inclusion/	Follow-up Duration (% followed)
Funding	Design	Demographics	Facet Neurotomy	Interventions	Evaluation	Exclusion Criteria	Outcomes Reported
KQ1a Diagnostic	blocks vs c	other method of dia	gnosis				
Diagnostic block	(s) vs clinic	al exam					
Cohen (2010) United States <u>Funding:</u> Congressional Grant from the John P. Murtha Neuroscience and Pain Institute; the U.S. Army; the Army Regional Anesthesia and Pain Medicine Initiative	RCT	 N = 151 Age (median): 42 years Male: 55.6% Duration of symptoms (median): 3.33 years Levels treated (median): 3.0 Previous decompressio n surgery 6.0% (9/151) Zero Block (Radiofrequency) n = 51 Age (median): 41 years (IQR: 22.0 - 72.0) Male: 60.8% 	 All radiofrequency denervations (all groups) Neurotomy target: medial branch nerve Guidance: fluoroscopy Electrode location confirmation: 50 Hz, with concordant sensation achieved at ≤0.5 V. Before denervation, multifidus stimulation and the absence of leg contractions was verified with electrostimulation at 2 Hz. Neurotomy: Single lesion created using a 10-mm active tip electrode at 80°C for 	 Zero Block (Radiofrequency) (n = 51) Randomized to receive radiofrequenc y denervation without undergoing diagnostic blocks Single Block (MBB) (n = 50) Patients underwent denervation if they obtained ≥50% pain relief that was maintained 	Clinical assessment: • Predominantl y axial low back pain ≥3 months in duration • Paraspinal tenderness <u>Radiologic</u> assessment: • NR <u>Diagnostic</u> blocks: • See "Diagnostic Blocks"	 Inclusion: ≥18 years old Predominantly axial low back pain ≥3 months in duration Failure to respond to more conservative therapy Paraspinal tenderness Absence of focal neurologic signs or symptoms. Exclusion: Patients with a known, specific etiology for low back pain (<i>e.g.</i>, significant spinal stenosis or grade II or III 	 <u>Follow-up:</u> 1, 3 months (51% complete f/u) <u>Outcomes reported:</u> <u>Pain:</u> Numeric Rating Scale (NRS) (0-10 scale; 10 = max pain) <u>Function:</u> Oswestry Disability Index (ODI) <u>Patient satisfaction</u>: NR Adverse Effects Analgesic reduction

Investigator (year) Country, Funding	Study Design	Patient Demographics	Facet Neurotomy	Diagnostic Blocks/ Interventions	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		 Duration of symptoms (median): 3.0 (IQR: 1.0 – 14.0) Levels treated (median): 3.0 (IQR: 3.0 – 4.0) Previous decompressio n surgery 9.8% (5/51) Unilateral: 39.2% (20/51) Bilateral: 60.8% (31/51) Single Block (MBB) n = 50 Age (mena): 44 years (IQR: 23.0 – 66.0) Male: 52.0% Duration of symptoms (mean): 3.0 (IQR: 0.5 – 13.0) Levels treated 	 90 seconds. Post RF denervation injection of steroids or anesthetic: After satisfactory electrode placement, 0.5 ml lidocaine, 2%, mixed with 5 mg depomethylprednisol one was injected through each cannulae *Radiofrequency procedures were done within 4 weeks of the final diagnostic block unless extenuating circumstances dictated otherwise. In subjects who experienced prolonged relief from a diagnostic block, the definitive procedure was done after the pain returned to baseline. If the analgesia lasted more than 3 months, the outcome was 	for at least 3 hours after diagnostic MBB done with 0.5 ml 0.5% bupivacaine Double Block (n = 50) Patients proceeded to denervation only if they experienced $\geq 50\%$ concordant pain relief after comparative local anesthetic done with both 0.5 ml lidocaine, 2% (≥ 1 hour) and 0.5% bupivacaine (≥ 3 h). The 50 patients in		 spondylolisthes- is) A positive response to previous spine interventions such as epidural steroids or sacroiliac joint blocks Previous facet interventions, lumbar spine fusion, untreated coagulopathy, and concomitant medical (<i>e.g.</i>, unstable angina) or psychiatric condition likely to undermine the diagnostic work-up or treatment response. Refused participation High dose opioid therapy Morbid obesity 	

Investigator (year) Country, Funding	Study Design	Patient Demographics	Facet Neurotomy	Diagnostic Blocks/ Interventions	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		(median): 3.0 $(IQR: 3.0 - 4.0)$ $Previous$ $decompressio$ $n surgery:$ $4.0% (2/51)$ $Unilateral:$ $24.0% (12/50)$ $Bilateral:$ $76.0% (38/50)$ $Double Block$ (MBB) $n = 50$ $Age (median):$ $41 years (IQR:$ $26.0 - 73.0)$ $Male: 54.0%$ $Duration of$ $symptoms$ $(median): 4.0$ $(IQR: 0.5 - 20.0)$ $Levels treated$ $(median): 3.0$ $(IQR: 2.0 - 4.0)$ $Previous$ $decompressio$ $n surgery:$	classified as positive.	 this group were suballocated to receive their MBB in random order via the same randomization scheme, with one half receiving the lidocaine blocks first and the other half receiving the bupivacaine injections. Only patients who obtained a positive response to the initial block underwent the second block, and only patients who obtained concordant analgesia from both blocks 			

Investigator (year) Country, Funding	Study Design	Patient Demographics	Facet Neurotomy	Diagnostic Blocks/ Interventions	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		 (2/51 (4.0%) Unilateral: 30.0% (15/50) Bilateral: 70.0% (35/50) Bilateral: 70.0% (35/50) P-values: (zero block vs. single block vs. double block n = 151 Age: 0.754 Male: 0.647 Duration of symptoms: 0.861 Levels treated: 0.049 Previous decompressio n surgery: 0.510 Laterality: 0.250 		proceeded to facet joint denervation. In group 2, the two diagnostic blocks were done within a 2-week interval, and patients were unaware of their suballocation group (<i>i.e.</i> , which local anesthetic they received first).			

Investigator (year) Country, Funding	Study Design	Patient Demographics	Facet Neurotomy	Diagnostic Blocks/ Interventions	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
KQ1b Diagnostic	MBB vs Di	agnostic intraarticu	lar injection				
Birkenmaier (2007) Germany <u>Funding:</u> NR	RCT	 N = 26 Age: NR Male: NR Duration of symptoms (median): NR Levels treated (median): NR Previous decompressio n surgery: NR <u>Medial Branch Block (MBB)</u> n = 13 Age (mean): 55.3 ± 12.4 Male: NR Duration of symptoms (median): NR Levels treated (median): NR Levels treated (median): NR Levels treated (median): NR Previous decompressio n surgery: NR 	 Cryodenervation target: medial branch nerve Guidance: fluoroscopy Electrode location confirmation: 50 Hz, with concordant sensation achieved at ≤ 0.5 V Motor stimulation (multifidus but no leg muscle contractions) (Hz: NR) Neurotomy: tip of the cryoprobe reaches a temperature of -50°C (medical-grade CO₂) Cryodenervation was performed for 2 minutes at each location Pre-surgery analgesics: 1% mepivacaine Post RF denervation injection of steroids or anesthetic: NR 	 <u>All Blocks</u> Before the blocks were performed, patients were examined under fluoroscopy in an attempt to select the painful joints The diagnostic blocks were performed either on the medial branches that supply the painful facet joints at exactly the anatomic location or directly onto the posterior surface of the facet joints without an attempt to achieve an 	Clinical assessment: NR <u>Radiologic</u> assessment: NR <u>Diagnostic</u> <u>blocks:</u> 50% or more improvement in pair for at least 3 hours	 Inclusion: All these patients had exhausted conservative treatments (physical therapy, chiropractic therapy, back braces, NSAIDs analgesics, or acupuncture for a minimum of 3 months) Nonsciatic low back pain Localized paraspinal pain and localized tenderness to pressure, recognized as typical by the patients Positive diagnostic medial branch blocks or pericapsular pericapsular 	 <u>Follow-up:</u> 2 weeks, 6 weeks, 3 months, 6 months (%NR) <u>Outcomes reported:</u> <u>Pain:</u> Visual Analog Scale (VAS) (0-10 scale; 10 = max pain, 24 hours at a time) <u>Function:</u> Perform everyday activities: Macnab rating (3 = excellent, 2 = good, 1 = moderate, 0 = poor). <u>Patient satisfaction</u>: Question: "Given the same level of low back pain as before the procedure, would you choose to have it performed again? Adverse Effects Analgesic reduction,

Investigator (year) Country, Funding	Study Design	Patient Demographics	Facet Neurotomy	Diagnostic Blocks/ Interventions	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		 Pericapsular Blocks (SPB) n = 13 Age (mean): 55.5 ± 11.5 years Male: NR Duration of symptoms (median): NR Levels treated (median): NR Previous decompressio n surgery: NR Unilateral: NR Bilateral: NR 		intra-articular position of the needle tip • Blocks were considered positive when a definite improvement occurred in a patient's specific low back pain of 50% or more for the duration of at least 3 hours. <u>Medial Branch Block (MBB) (n = 13)</u> • A 1-mL dose of bupivacaine 0.5% was used for each medial branch block, 2 of which were performed for each joint		 Exclusion: Presence of radicular (sciatic) pain Previous lumbar- spine surgery with the exception of nucleotomies Relevant spinal- canal stenosis Activated erosive spondylochondr osis Malignant tumors, Chronic inflammatory disease History of depression Pending workman's compensation cases 	

Investigator (year) Country, Funding	Study Design	Patient Demographics	Facet Neurotomy	Diagnostic Blocks/ Interventions	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
				 Blocks (SPB) (n = 13) 2.0 mL of bupivacaine 0.5% were used for each capsular block 			
KQ1c Single vs co	ontrolled di	agnostic blocks					
Cohen (2010)	RCT	N = 151Age (median):	All radiofrequency denervations (all	<u>Single Block</u> (MBB) (n = 50)	<u>Clinical</u> assessment:	Inclusion: • ≥18 years old	<u>Follow-up:</u> 1, 3 months (% follow-up varied
United States <u>Funding:</u> Congressional Grant from the John P. Murtha Neuroscience and Pain Institute; the U.S. Army; the Army Regional Anesthesia and Pain Medicine Initiative		 42.5 years Male: 53% Duration of symptoms (median): 3.5 years Levels treated (median): 3.0 Previous decompressio n surgery: NR Single Block (MBB) n = 50 Age (median): 44 years (IQR: 23.0 - 66.0) Male: 52.0% Duration of symptoms 	 groups) Neurotomy target: medial branch nerve Guidance: fluoroscopy Electrode location confirmation: 50 Hz, with concordant sensation achieved at ≤0.5 V. Before denervation, multifidus stimulation and the absence of leg contractions was verified with electrostimulation at 2 Hz. Neurotomy: Single lesion created using a 10-mm active tip electrode at 80°C for 	 Patients underwent denervation if they obtained ≥50% pain relief that was maintained for at least 3 hours after diagnostic MBB done with 0.5 ml 0.5% bupivacaine Double Block (n = 50) Patients proceeded to denervation only if they 	 Predominantl y axial low back pain ≥3 months in duration Paraspinal tenderness Radiologic assessment: NR Diagnostic blocks: See "Diagnostic Blocks" 	 Predominantly axial low back pain ≥3 months in duration Failure to respond to more conservative therapy Paraspinal tenderness Absence of focal neurologic signs or symptoms. Exclusion: Patients with a known, specific etiology for low back pain (<i>e.g.</i>, significant spinal stenosis or grade II or III 	between outcomes) Outcomes reported: • Pain: Numeric Rating Scale (NRS) (0-10 scale; 10 = max pain) • Function: Oswestry Disability Index (ODI) • Patient satisfaction: NR • Adverse Effects • Analgesic reduction

Investigator (year) Country, Funding	Study Design	Patient Demographics	Facet Neurotomy	Diagnostic Blocks/ Interventions	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		(median): 3.0(IQR: 0.5 -13.0)• Levels treated(median): 3.0(IQR: 3.0 -4.0)• Previousdecompression surgery:4.0% (2/51)• Unilateral:24.0% (12/50)• Bilateral:76.0% (38/50)• Duble Block(MBB)• n = 50• Age (median):41 years (IQR:26.0 - 73.0)• Male: 54.0%• Duration ofsymptoms(median): 4.0(IQR: 0.5 -20.0) years• Levels treated(median): 3.0(IQR: 2.0 -4.0)	 90 seconds. Post RF denervation injection of steroids or anesthetic: After satisfactory electrode placement, 0.5 ml lidocaine, 2%, mixed with 5 mg depomethylprednisol one was injected through each cannulae *Radiofrequency procedures were done within 4 weeks of the final diagnostic block unless extenuating circumstances dictated otherwise. In subjects who experienced prolonged relief from a diagnostic block, the definitive procedure was done after the pain returned to baseline. If the analgesia lasted more than 3 months, the outcome was 	 experienced ≥50% concordant pain relief after comparative local anesthetic done with both 0.5 ml lidocaine, 2% (≥1 hour) and 0.5% bupivacaine (≥3 h). The 50 patients in this group were suballocated to receive their MBB in random order via the same randomization scheme, with one half receiving the lidocaine blocks first and the other half receiving the 		 spondylolisthesis) A positive response to previous spine interventions such as epidural steroids or sacroiliac joint blocks Previous facet interventions, lumbar spine fusion, untreated coagulopathy, and concomitant medical (<i>e.g.</i>, unstable angina) or psychiatric condition likely to undermine the diagnostic work-up or treatment response. Refused participation High dose opioid therapy Morbid obesity 	

Investigator (year) Country, Funding	Study Design	Patient Demographics	Facet Neurotomy	Diagnostic Blocks/ Interventions	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		 Previous decompressio n surgery: (2/51 (4.0%) Unilateral: 30.0% (15/50) Bilateral: 70.0% (35/50) P-values: (zero block vs. single block vs. double block n = 151 Age: 0.754 Male: 0.647 Duration of symptoms: 0.861 Levels treated: 0.049 Previous decompressio n surgery: 0.510 Laterality: 0.250 	classified as positive	 bupivacaine injections. Only patients who obtained a positive response to the initial block underwent the second block, and only patients who obtained concordant analgesia from both blocks proceeded to facet joint denervation. In group 2, the two diagnostic blocks were done within a 2-week interval, and patients were unaware of their suballocation group (<i>i.e.</i>, which local 			

Investigator (year) Country, Funding	Study Design	Patient Demographics	Facet Neurotomy	Diagnostic Blocks/ Interventions	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
				anesthetic they received first).			
KQ1d Differentia	l definition	of successful block	(
Cohen (2008) United States <u>Funding:</u> John P. Murtha Neuroscience and Pain Institute, Johnstown, PA and the Army Regional Anesthesia & Pain Medicine Initiative, Washington, DC.	Retro- spective	 N = 298 Age (mean): 54.2 ± 15.4 (17 - 89) years Male: 47% Duration of symptoms (mean): 5.7 ± 5.9 (0.5 - 40) years Levels treated (mean): 3.1 ± 0.5 (2 - 7) Previous decompressio n surgery: NR Unilateral: NR Bilateral: NR Bilateral: NR Diagnostic MBB, pain relief of 50- <80% (55%; 145/262) Age: 53.1 ± 16 	 <u>Radiofrequency</u> <u>denervations</u> Neurotomy target: medial branch and L5 dorsal rami Guidance: fluoroscopy Electrode location confirmation: at 50 Hz, with concordant sensation achieved at less than 0.5 V; multifidus stimulation and the absence of leg contractions were verified at 2 Hz Neurotomy: Single lesion created with 5- mm active tip; 0.5 mL of 1% lidocaine was injected through each cannula to reduce thermal pain. The RF probe was then reinserted and a 90 second, 80°C lesion 	 Medial Branch Block target: medial branch and L5 dorsal rami Guidance: anterior- posterior and oblique fluoroscopic Medial Branch Block: Before needle placement, the skin at each entry point was anesthetized (1 mL of 1% lidocaine). Patients with unilateral pain underwent unilateral blocks; those with bilateral 	Clinical assessment: • "Presenting symptoms and physical examination" <u>Radiologic</u> assessment: • NR <u>Diagnostic</u> <u>blocks:</u> • MBB	 Inclusion: > 18 years Chronic lower back pain greater than 3 months duration Absence of focal neurological signs or symptoms Reviewed from July 2003 to July 2006 Exclusion: Subjects with ambiguous records or inadequate follow-up (n = 36) Patients with Grade II or higher spondylolisthesis 	Follow-up: 6 months (90%)Outcomes reported:Pain: Visual Analog Scale (VAS) (0 10 scale; 10 = max pain)Function: "Successful Treatment": greater than 50% or equal to average reduction in preprocedure pain score that persisted at least 6 months after the procedurePatient satisfaction: Global Perceived Effect (GPE) (Only for Walter Reed Army Medical Center)Complications: NR"Before the procedure and again in the

Investigator (year) Country, Funding	Study Design	Patient Demographics	Facet Neurotomy	Diagnostic Blocks/ Interventions	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		 Male: 43.4% Duration of symptoms (mean): 5.99 ± 6.6 Levels treated (median): NR Previous decompressio n surgery: NR Unilateral: NR Bilateral: NR Diagnostic MBB, pain relief of >80% (45%; 117/262) Age: 55.5 ± 14.7 Male: 52.1% Duration of symptoms (median): 5.44 ± 5.0 Levels treated (median): NR Previous decompressio n surgery: NR Unilateral: NR Bilateral: NR 	 Post RF denervation injection of steroids or anesthetic: NR 	or central pain received bilateral blocks. The number of levels blocked varied according to the patient's symptoms. At each level, 0.5 mL of bupivacaine or ropivacaine was administered.		 Symptomatic spinal stenosis Vertebral fractures Untreated coagulopathy Concomitant medical or psychiatric illness likely to compromise evaluation or treatment. 	recovery area, patients were instructed to engage in their normal daily activities and to maintain a written 0 to 10 numerical pain diary every 30 minutes for 6 to 8 hours"

Investigator (year) Country, Funding	Study Design	Patient Demographics	Facet Neurotomy	Diagnostic Blocks/ Interventions	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
Cohen (2013) United States <u>Funding:</u> Congressional Grant from the John P. Murtha Neuroscience and Pain Institute, Johnstown, PA; and the US Army; and the Army Regional Anesthesia & Pain Medicine Initiative, Washington, DC	Prospecti ve correlatio n study	 N = 61 Age (mean): 51 years Male: 59% Duration of symptoms (mean): 6.5 years Levels treated (mean): 3.1 ± 0.5 (2 - 7) Previous decompressio n surgery: NR Unilateral: 39% (24/61 Bilateral: NR: 61% (37/62) 	 <u>Radiofrequency</u> <u>denervations</u> Neurotomy target: medial branch and L5 dorsal rami Guidance: fluoroscopy Electrode location confirmation: at 50 Hz, with mean concordant sensation achieved at 0.5V in over 85% of cases. Before heating, multifidus stimulation and the absence of leg contractions was verified at 2 Hz Neurotomy: 0.5mL of lidocaine 2% with 5mg of depomethylprednisol one was injected through each cannulae to prevent neuritis and enhance lesion size. Single lesion created with 10-mm active tip for 90 second, 80°C Post RF denervation injection of steroids or anesthetic: NR 	 Medial Branch Block target: medial branch and L5 dorsal rami Guidance: anterior- posterior and oblique fluoroscopic Medial Branch Block: For L5 dorsal rami, the needle was positioned in the groove between the junction of the sacral ala and articular process. When contrast flow was deemed satisfactory, 0.5mL of 0.5% bupivacaine was injected at each site 	<u>Clinical</u> <u>assessment:</u> • NR <u>Radiologic</u> <u>assessment:</u> • NR <u>Diagnostic</u> <u>blocks:</u> • NR	 Inclusion: > 18 years Predominantly axial lower back pain ≥ 3 months in duration Failure to respond to more conservative therapy Paraspinal tenderness Satisfactory relief after the diagnostic injections Absence of focal neurological signs or symptoms 2007 to July 2010 Exclusion: Presence of documented, specific etiology for lower back pain (eg, significant spinal stenosis or grade II or III 	Follow-up: 3 months (% follow-up not reported) Outcomes reported: • Pain: Numeric Rating Scale (NRS) (0-10 scale; 10 = max pain Function: "successful outcome" (predefined as ≥ 50% reduction in either rest or activity NRS pain score that persisted for >3 months, coupled with a positive global perceived effect that precluded additional interventions • Patient satisfaction: Global Perceived Effect (GPE) Positive Response to: My pain has improved/worsened/sta yed the same since my last visit; 2. I am satisfied/not satisfied with the treatment I received and would recommend it to others. • Complications: NR

Investigator (year) Country, Funding	Study Design	Patient Demographics	Facet Neurotomy	Diagnostic Blocks/ Interventions	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			• All denervation procedures were carried out within 1 month of the diagnostic block	unilateral pain received unilateral blocks, whereas those with bilateral or central pain underwent 2- sided blocks.		 spondylolisthesis) Positive response to previous spine interventions such as epidural steroids or sacroiliac joint blocks Previous facet interventions, lumbar spine fusion, untreated coagulopathy Failure to return the pain diary in a timely fashion Coexisting medical (eg, unstable angina) or psychiatric (posttraumatic stress) morbidity likely to interfere with treatment 	
Derby (2012) United States	Retrospec tive Cohort	N = 211Age (mean):	<u>Medial Branch</u> <u>Neurotomy (MBN)</u> (Patients were offered	Medial Branch Block (MBB) • Neurotomy	<u>Clinical</u> <u>assessment:</u> • Diagnosis of	Inclusion: • Patients with chronic and	<u>Follow-up:</u> 6 months; 61% follow-up (57/94)
<u>Funding:</u> NR		58.2 yearsMale: 45%Duration of	<u>MBN if they reported</u> <u>50% or greater</u> <u>subjective relief of pain</u>	target: medial branch or dorsal ramus	lumbar facet syndrome was typically	debilitating low back pain with or without proximal	Outcomes reported: • <u>Pain:</u> NR • <u>Function:</u> "Positive MBN

Investigator (year) Country, Funding	Study Design	Patient Demographics	Facet Neurotomy	Diagnostic Blocks/ Interventions	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		symptoms (mean): 10.1 years • Levels treated (mean): 5.1 • Previous surgery: 14% (7/51) • Laterality: Unilateral: 55% (28/51) • Bilateral: NR: 45% (23/51)	 for minimum of 2 hours of duration) Neurotomy target: medial branch or dorsal ramus of L5 Guidance: fluoroscopy Electrode location confirmation: NR Neurotomy: Lesions were made using a 1 cm exposed tip needle placed parallel to the medial branch above the intertransverse ligament and slightly above the junction of the transverse process and the superior articular process. RF current was applied for 90 seconds at 85°C. Post RF denervation injection of steroids or anesthetic: NR 	of L5 Guidance: fluoroscopy Electrode location confirmation: NR Neurotomy: 25 gauge 3.5- inch spinal needle was advanced to the junction of the transverse process and superior articular process above L5, and to the junction of the SAP and sacrum to anesthetize the L5 dorsal ramus. At each level, 0.2–0.3 mL of either 0.5% or 0.75% bupivicaine was injected at a minimum of three	made by the senior author when the patient had two or more of the symptoms consistent with posterior element pain: tenderness over one or more facet joints, back pain aggravation by extension and rotation, morning stiffness or pain worse in the morning and improving with movement, and no other obvious cause for chronic back pain <u>Radiologic</u> <u>assessment:</u>	 non-radicular extremity pain of greater than 6- month duration A clinical diagnosis of a lumbar facet syndrome Pain unresponsive to conservative treatment including medical management, physical therapy, and previous interventions Has undergone one or more diagnostic MBB performed on a separate session from medial branch neurotomy Exclusion: Patients undergoing treatment for other sources of pain such as 	 outcome" (Defined: 1. ≥50% of subjective pain relief; 2. duration of pain relief ≥6 months; 3. positive patients' satisfaction; 4. ≥50% of improvement in activity level; 5. no other doctor's visits; and 6. reduction in pain medications use. Patient satisfaction: 1 or 2 Affirmative response to: "The treatment met my expectations"; "I did not improve as much as I had hoped, but I would undergo the same treatment for the same outcome"; "The treatment helped, but I would not undergo the same procedure for the same outcome"; "I am the same or worse than before the treatment" <u>Complications:</u> NR <u>Analgesic Reductions</u>

Investigator (year) Country, Funding	Study Design	Patient Demographics	Facet Neurotomy	Diagnostic Blocks/ Interventions	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
				separate locations along the course of the targeted medial branch or dorsal ramus of L5. Post RF denervation injection of steroids or anesthetic: NR "Patients were tested by an independent observer 45–60 minutes following the block and in more recent cases were also retested 1–2 hours after the procedure, including outside self- testing. The patients would record their responses over	• NR <u>Diagnostic</u> <u>blocks:</u> • NR	concomitant radiculopathy due to a disc herniation or stenosis, or buttock pain due to the sacroiliac (SI) joint pathology.	

Investigator (year) Country, Funding	Study Design	Patient Demographics	Facet Neurotomy	Diagnostic Blocks/ Interventions	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
				the rest of the day and for several days following the block, using a pain diary. Typically, the patients would be seen in follow-up in 2–3 weeks to discuss results of the MBB."			
Derby (2013 (cost) United States <u>Funding:</u> None	Retro- spective Cohort	 N = 48 Age (mean): 59 years Male: 50% Duration of symptoms (mean): 13 years Levels treated (mean): 3.6 Laterality: Unilateral: 54% (26/48) Bilateral: 46%% (22/48) Single Medial Branch Block (MBB1) 	 <u>Radiofrequency</u> <u>denervations</u> Neurotomy target: medial branch dorsal rami Guidance: NR Electrode location confirmation: NR Neurotomy: two 18- gauge 1 cm exposed slightly curved needles were placed parallel to the medial branch (or dorsal ramus) above the inter-transverse ligament and slightly above the junction of the transverse 	 Medial Branch Block target: medial branch dorsal rami Guidance: fluoroscopic Medial Branch Block: 25– gauge needle was advanced to the junction of the transverse process and superior articular process at each lumbar level above 	<u>Clinical</u> <u>assessment:</u> • NR <u>Radiologic</u> <u>assessment:</u> • NR <u>Diagnostic</u> <u>blocks:</u> • NR	 Inclusion: Patients with chronic and debilitating low back pain with or without proximal nonradicular limb pain of greater than 6- month duration Clinical diagnosis of a lumbar facet syndrome Pain unresponsive to conservative treatment including 	 <u>Follow-up:</u> 57% (48/84) 3 months <u>Outcomes reported:</u> <u>Pain:</u> Numeric Rating Scale (NRS) (0-10 scale; 10 = max pain) <u>Function:</u> NR <u>Patient satisfaction</u>: global perceived effect was predefined as an affirmative response (1 or 2) to the following four options. 1. The treatment met my expectations. 2. I did not improve as much as I had hoped,

Investigator (year) Country, Funding	Study Design	Patient Demographics	Facet Neurotomy	Diagnostic Blocks/ Interventions	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		 N = 36 Age (mean): 59.3 ± 12.5 years Male: 50% Duration of symptoms (mean): 8.5 ± 10.2 years Levels treated (mean): 3.6 ± 0.5 Laterality: Unilateral: 50% (18/36) Bilateral: 50% (18/36) Double Medial Branch Block (MMB2) N = 12 Age (mean): 58.6 ± 10.7 years Male: 50% Duration of symptoms (mean): 17.5 ± 11.9 years Levels treated (median): 3.5 	 process current was applied for 90 seconds at 85°C. Most often using only a single lesion at each level, but in most procedures, we used a minimum of two Post RF denervation injection of steroids or anesthetic: NR In the early cases, patients were offered radiofrequency neurotomy if they reported at least 50% subjective relief of pain for at least 2 hours duration. The patients with less than 70% relief, were a minority and except when disallowed by the insurance company were most often scheduled for a confirmatory MBB. 	 L5, to the junction of the SAP and sacrum to anesthetize the L5 dorsal ramus. At each level, .2~.3 mL of either .5% or .75% bupivacaine was injected at a minimum of two depths along the course of the medial branch or dorsal ramus of L5. Patients were again tested by an independent observer in 45–60 minutes following the block, and in more recent cases were 		 medical management, physical therapy, and previous interventions Exclusion: Treated for two sources of pain, including concomitant radiculopathy due to a disc herniation or stenosis Buttock pain due to the sacroiliac joint 	 but I would undergo the same treatment for the same outcome. 3. The treatment helped, but I would not undergo the same procedure for the same outcome. 4. I am the same or worse than before the treatment. "Successful outcome" of Medial branch neurotomy was defined as a ≥ 50% subjective total relief, coupled with a positive global perceived effect that persisted ≥ 3 months. Adverse Effects: NR

Investigator (year) Country, Funding	Study Design	Patient Demographics	Facet Neurotomy	Diagnostic Blocks/ Interventions	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		± 1.2 • Laterality: Unilateral: 67% (8/12) Bilateral: 33% (4/12)		also retested in 1–2 hours after self- testing outside the surgical suite.			
KQ1e Unilatera	al vs. bilatera	l block	1		,		1
No Studies							
KQ1f Single- vs	. Multi-level	block					-
No Studies							

NR: Not reported; MBB; Medial branch Block; RFN; Radiofrequency Neurotomy

February 21, 2014

KQ1 Results

		Interventions				
Investigator (year)	Study Design	Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (include work)
(year) Cohen (2010)	RCT	(% followed) N = 151 Zero Block (SHAM) (n = 51) Single Block (MBB1) (n = 50) Double Block (MBB2) (n = 50) Follow-up: 1, 3 months (% follow-up varied between outcomes)	Pain NRS pain score Baseline score at rest, median (IQR) No block: $4.5 (1.0 - 8.0) (n = 51)$ MBB1: $4.3 (2.0 - 8.0) (n = 50)$ MBB2: $4.8 (2.0 - 8.0) (n = 50)$ MBB2: $4.8 (2.0 - 8.0) (n = 50)$ MBB2: $4.8 (2.0 - 8.0) (n = 50)$ P: >0.999 Baseline score with activity, median (IQR) No block: $8.0 (4.0 - 10.0) (n = 51)$ MBB1: $8.0 (5.0 - 10.0) (n = 50)$ MBB2: $8.0 (4.0 - 10.0) (n = 50)$ MBB1: $8.0 (5.0 - 10.0) (n = 50)$ MBB1 (n = 20): $2.3 (0.0 - 7.0)$ MBB1 (n = 20): $2.3 (0.0 - 4.0)$ MBB2 (n = 16): $1.5 (0.0 - 3.0)$	Baseline ODI score, median (IQR)	Global Perceived Effect 1 month • No block: 35/51 (70%) • MBB1: 16/20 (80%) • MBB2: 75% (12/16) • P: NR 3 month • No block: 74% (23/31) • MBB1: 91.7 (11/12) • MBB2: 100% (11/11) • P: NR	(Include work) Opioid Use Baseline • No block: 25.5% (13/51) • MBB1: 24.0% (12/50) • MBB2: 34.0% (17/50) • P: NR <u>Medication Reduction (≥20% reduction</u> in opioid use or complete cessation of a non-opiod analgesic) 1 month • No block: 44% (19/43) • MBB1: 61% (11/18) • MBB2: 69% (9/13) • P: NR 3 months • No block: 36% (9/25) • MBB1: 82% (9/11) • MBB2: 88% (7/8) • P: NR

		Interventions				
Investigator (year)	Study Design	Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (include work)
			• <i>P:</i> 0.504			
			 month score with activity, median (IQR) No block (n = 51): 4.5 (1.0 - 8.5) MBB1 (n = 20): 4.3 (2.0 - 6.0) MBB2 (n = 16): 2.8 (2.0 - 5.0) <i>P</i>: 0.370 months score at rest, median (IQR) No block (n = 30): 2.0 (0.0 - 6.0) 			
			• MBB1 (n = 12): 2.0 (1.5 - 3.0) • MBB2 (n = 11): 1.0 (0.0 - 1.5) • $P: 0.097$			
			 3 months score with activity, median (IQR) No block (n = 30): 6.3 (1.0 - 9.0) MBB1 (n = 12): 4.5 (2.0 - 7.0) MBB2 (n = 11): 2.0 (1.0 - 3.0) P: 0.015 			

Investigator	Study	Interventions Follow-up				Disability & Medication Use
(year)	Design	(% followed)	Pain	Function	Patient Satisfaction	(include work)
			Successful outcomes			
			(outcome defined as			
			≥50% pain relief			
			either at rest or with activity plus a positive			
			global perceived			
			effect.			
			1 months			
			• No block (n = 51):			
			59% (30/51)			
			• MBB1 (n = 49): 26% (3/49)			
			• MBB2 (n = 49): 23%			
			(11/49)			
			• <i>P:</i> <0.001			
			•			
			3 months			
			• No block (n = 51):			
			33% (17/51)			
			• MBB1 (n = 49): 39%			
			(7/18) • MBB2 (n = 49): 64%			
			(9/14)			
			• P: 0.111			
			1 month (among			
			persons with RF			
			denervations)			
			• No block (n = 51):			
			59% (30/51)			
			• MBB1 (n = 19): 63%			

Investigator (year)	Study Design	Interventions Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (include work)
			(12/19) • MBB2 (n = 49): 64% (9/14) • P: 0.905 3 month (among persons with RF denervations) • No block (n = 51): 33% (17/51) • MBB1 (n = 19):16% (8/49) • MBB2 (n = 49): 22% (11/49) • P: 0.115			
Birkenmaier (2007)	RCT	N = 26 Medial Branch Block (MBB) (n = 13) Simple Pericapsular Blocks (SPB) (n = 13) <u>Follow-up:</u> 2 weeks, 6 weeks, 3 months, 6	pain, 24 hours at a time) Baseline • MBB: 7.4	Function: Perform everyday activities: Macnab rating (3 = excellent, 2 = good, 1 = moderate, 0 = poor) Baseline • MBB: 0.8 • SPB: 0.5 • P: NR 2 weeks • MBB: 1.7 • SPB: 1.3	Patient satisfaction: "Given the same level of low back pain as before the procedure, would you choose to have it performed again?" "Yes" • MBB: 85% (11/13) • SPB: 62% (8/13) • P: NR "No" • MBB: 15% (2/13)	NR

		Interventions				
Investigator (year)	Study Design	Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (include work)
		months (%NR)	6 weeks • MBB: 2.2 • SPB: 4.2 • P: 0.041 3 months • MBB: 2.3 • SPB: 4.2 • P: 0.049 6 months • MBB: 2.7 • SPB: 4.0 • P: 0.148 Percent-change in VAS Pain score Low back Pain (%) Baseline • MBB: 100 • SPB: 100 • P: NR 2 weeks • MBB: 44 • SPB: 51 • P: 0.61 6 weeks • MBB: 32 • SPB: 56 • P: 0.087 3 months • MBB: 29 • SPB: 42	 <i>P:</i> NR 6 weeks MBB: 1.9 SPB: 1.5 <i>P:</i> NR 3 months MBB: 2.0 SPB: 1.5 <i>P:</i> NR 6 months MBB: 2.0 SPB: 1.5 <i>P:</i> NR 	 SPB: 31% (4/13) P: NR *1 patient in SPB = undecided 	

Investigator (year)	Study Design	Interventions Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (include work)
(year)			 <i>P</i>: 0.224 6 months MBB: 33 SPB: 40 <i>P</i>: 0.523 			
Cohen (2008)	Retrospective Cohort	N = 298 Diagnostic MBB, pain relief of 50- <80% (n = 145) Diagnostic MBB, pain relief of >80% n = 117) Follow-up: 6 months (90% for primary outcome)	<pre>Successful Treatment": ≥50% pain relief persisting at least 6 months after RF neurotomy • 50-<80% relief: 52.5% (76/145) • > 80% relief: 56.4% (66/117) P = 0.52</pre>	NR	Global Perceived Effect (GPE) (Only for Walter Reed Army Medical Center) • 50-<80% relief: 66.7% (60/90) • > 80% relief: 65.6% (40/61) • <i>P</i> = 0.89	NR

Investigator (year)	Study Design	Interventions Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (include work)
Cohen 2013	Retrospective Cohort	N = 61 Follow-up: 3 months (%NR)	Percentage of subjects with a positive outcome (≥ 50% reduction in either rest or activity NRS pain score that persisted for >3 months, coupled with a positive global perceived effect that precluded additional interventions) $\frac{1 \text{ month}}{(9/13)}$ 67 - 83%: 65.4% (17/26) > 84%: 68.8% (11/16) P = 0.92 $\frac{3 \text{ months}}{(7/13)}$ 67 - 83%: 61.5%	NR	Global Perceived Effect $\frac{1 \text{ month}}{50 - 66\%: 69.2\%}$ (9/13) 67 - 83%: 76.9% (20/26) > 84%: 75% (12/16) $P = 0.90$ $\frac{3 \text{ months}}{50 - 66\%: 66.7\%}$ (8/12) 67 - 83%: 73.9% (17/23) > 84%: 66.7% (10/15) P = 0.18	Medication reduction $\frac{1 \text{ month}}{50 - 66\%: 53.8\% (7/13)}$ $67 - 83\%: 46.2\% (12/26)$ $> 84\%: 43.8\% (7/16)$ $P = 0.80$ $\frac{3 \text{ months}}{67 - 83\%: 66.7\% (10/15)}$ $> 84\%: 60\% (6/10)$ $P = 0.77$

Investigator (year)	Study Design	Interventions Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (include work)
			• > 84%: 56.3% (9/16) P = 0.28			
Derby 2012	Retrospective Cohort	N = 51 50-79% pain relief following single or double MBB: n = 26 ≥ 80% pain relief following single or double MBB: N =25	Successful Treatment ≥50% pain relief persisting at least 6 months after RF neurotomy ≥ 6 mos. (% patients) • 50 – 79%: 54% (14/26) • ≥80%: 84% (21/25)	 ≥50% improvement in activity level (how measured not defined) at least 6 months after RF neurotomy ≥ 6 mos. (% patients) 50 – 79%: 33% (8/24) ≥80%: 76% (19/25) 	 Patient satisfaction at least 6 months after RF neurotomy (on scale of 1-4, a score of 1 or 2 indicated patient satisfaction, defined as "met expectation" or "would undergo the same treatment") ≥ 6 mos. (% patients) 50 – 79%: 45% (10/22) ≥80%: 88% (21/24) 	Medication reduction (definition NR) ≥ 6 mos. (% patients) • 50 - 79%: 55% (11/20) • ≥80%: 74% (17/23)
Derby (2013) "Cost"	Retrospective Cohort	N = 52 50-79% pain relief following single or double MBB: n = 26 ≥ 80% pain relief following single or	Successful Treatment ≥50% pain relief and positive global perceived effect persisting at least 3 months after RF neurotomy ≥ 6 mos. (% patients) • ≥50%: 56% (27/48) • ≥60%: 71%	NR	NR	NR

Investigator	Study	Interventions Follow-up				Disability & Medication Use
(year)	Design	(% followed) double MBB: N =25	Pain $(26/45)$ $\geq 70\%: 63\%$ $(25/40)$ $\geq 80\%: 76\%$ $(19/25)$ $\geq 90\%: 79\%$ $(15/19)$ The above numbers were converted to the following ranges by subtracting the patients with $\geq 80\%$ pain relief from those who had $\geq 50\%$ pain relief: $\geq 250-79\%$: 35% (8/23) $\geq 80\%$: 76% (19/25)	Function	Patient Satisfaction	(include work)
			Positive global perceived effect- score of 1-2 on the following scale: 1. The treatment met my expectations 2. I did not improve as much as I had hoped			

		Interventions					
Investigator (year)	Study Design	Follow-up (% followed)	Pain		Function	Patient Satisfaction	Disability & Medication Use (include work)
			3.	but I would undergo the same treatment for the same outcome The treatment helped but I would not undergo the same procedure for the same outcome I am the same or worse than before the treatment			

NR: Not reported; MBB; Medial branch Block; RFN; Radiofrequency Neurotomy; MBN: medial branch neurotomy

KQ2 Demographics

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
Gallagher (1994) England <u>Funding:</u> NR	RCT	 N = 41 Age (mean): NR Male: NR Symptom duration: > 3 months FJRF denervation (RFN) n = 24 Age (mean): NR Male: NR Sham Neurotomy (SHAM) n = 17 Age (mean): NR Male: NR 	 N = 41 FJRF denervation (n = 24) Number of levels: NR Treated levels: NR Treated levels: NR Neurotomy target: medial branch of the posterior spinal ramus Guidance: fluoroscopy Electrode location confirmation: first by sensory stimulation at 100Hz and motor stimulation to a maximum of 0.5 V Neurotomy: Single lesion created using an electrode at 80°C for 90 seconds. Anesthetic injected?: Yes, 2 % 0.5 mL lignocaine Post RF denervation injection of steroids or anesthetic performed: NR 	 yes ("diagnosti c block") yes 	 <u>Clinical assessment:</u> low back pain of greater than 3 months duration; (4 or more of the following: Tenderness on palpation, More pain on extension than on flexion, Pain on rotation of the spine, Referred pain (above the knee), Pain exacerbated by exercise and relieved by rest, Pain exacerbated by sitting or standing, Pain not exacerbated by coughing or sneezing, Radiological evidence of facet joint degeneration or predisposing factors, such a~ loss of disc height or spondylolisthesis at the painful level) 	 Inclusion: Back pain > 3 months Age 25-55 years Four or more of the following: Tenderness on palpation More pain on extension than on flexion Pain on rotation of the spine Referred pain (above the knee) Pain exacerbated by exercise and relieved by rest Pain exacerbated by sitting or standing Pain not exacerbated by coughing or sneezing Radiological evidence of facet joint 	Follow-up: 1 & 6 months; 41/41 (100%) Outcomes reported: • Pain: Visual Analogue Pain Scale (VAS) (0-NR scale); McGill Pain Questionnaire • Adverse events

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			 <u>Sham Neurotomy (n = 17)</u> Electrode location confirmation the nerves to the joints were identified with stimulation, local anesthetic injected, in the usual way but no heat lesion was made <u>Post-procedure:</u> NR 		 <u>Radiologic</u> <u>assessment:</u> None Reported <u>Diagnostic blocks:</u> Injection of local anaesthetic (bupivacaine 0.5 per cent 0.5 ml) Assessment of pain relief over the following 12 h. 	 degeneration or predisposing factors, such a~ loss of disc height or spondylolisthesis at the painful level Inclusion range: NR Exclusion: Previous back operations Neurological signs of nerve root compression in the lower limbs Patients with major mental illness or severe personality disorder Pending compensation claims General ill health 	
Leclaire (2001) Canada <u>Funding:</u> grant PE- 92-018 from the	RCT	 N = 70 Age (mean): 46.6 years ± 9.6 Male: 35.7% 	 N = 70 FJRF denervation (n = 36) Number of levels: at 	 Yes (intra- articular) Yes 	• <u>Clinical assessment:</u> medical history and physical examination used for diagnosis; details NR. LBP. Lumbar spine	 Inclusion: 18 - 65 years of age Low back pain >3 months duration Experienced 	<u>Follow-up:</u> 4 weeks: 70/70 (100%); 12 weeks: 66/70 (94.3%)

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
Institut de recherche en sante et securite du travail du Quebec.		 Symptom duration: > 3 months FJRF denervation n = 36 Age (mean): 46.7 years ± 9.3 Male: 33.3% Sham Neurotomy (SHAM) n = 34 Age (mean): 46.4 years ± 9.8 Male: 38.2% 	 least 2 Treated levels: NR ("usually L4–L5 and L5-S1") Neurotomy target: medial branch (articular facet branch) of the distal portion of the spinal posterior rami nerve. Guidance: fluoroscopy Electrode location confirmation: Stimulation at 5 Hz with 0.5 msec pulse duration Neurotomy: For each nerve, two neurotomies were performed (proximal portion and at the distal portion of the articular facet nerve) using a 5-mm active tip electrode at 80°C for 90 seconds. Anesthetic injected?: Yes, 2 mL of 1% lidocaine Post RF denervation 		 mobility assessed: lumbar spine mobility in flexion, extension, side- bending, and rotations; maximum strength against resistance; and angular speed against 25% strength resistance were assessed using triaxial dynamometry (B- 200) <u>Radiologic</u> <u>assessment:</u> none reported <u>Diagnostic blocks:</u> Intraarticular facet injections using Omnipaque (pts experienced significant relief of LBP for ≥24 hrs in week after injection) 	significant relief of their low back pain for at least 24 hours during the week after intraarticular facet injections (Omnipaque, 240 mg, 0.3 mL), as reported by the patient and the physiatrist Inclusion range: (October 1993 to December 1996) <u>Exclusion</u> : Known allergy to a local anesthetic, Blood coagulation disorders Cardiac pace-maker Sciatic pain with a neurologic deficit Low back pain not related to a mechanical disorder (<i>e.g.</i> , bone lesion, spondylitis) Low back surgery, or concomitant medical illness	 <u>Outcomes reported:</u> <u>Pain:</u> Visual Analogue Pain Scale (VAS) (0- 100 scale; 100 = max pain) <u>Function:</u> Roland- Morris (RMQ) (1- 100 scale; 100 = severe disability); Oswestry Disability Index (ODI) (0-100 scale; 100 = max disability); Angular speed against 25% strength resistance were assessed using triaxial dynamometry (B- 200) Adverse events

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			 injection of steroids or anesthetic performed: NR <u>Sham Neurotomy</u> (<u>SHAM</u>) (n = 34) The patients in the control group received the same procedure, except that the temperature of the electrode tip was not raised, but maintained at 37 C. <u>Post-procedure:</u> NR 			likely to compromise ability to participate.	
Nath (2008) Sweden <u>Funding: </u> None	RCT	 N = 40 Age (mean): 54.5 years (36 - 79) Male: 37.5% Symptom duration: at least 2 years 	 N = 40 FJRF denervation (n = 20) Number of levels: NR Treated levels: NR Neurotomy target: medial branch of the dorsal spinal ramus 	• Yes (medial branch block)	 <u>Clinical assessment:</u> At least one symptom consistent with lumbar zygapophysial joint pain; paravertebral tenderness, LBP <u>Radiologic</u> <u>assessment:</u> MRI or 	 Inclusion: Adult patients with continuous low back pain of at least 2 years, who had not responded to previous treatment. Patients had to be able to identify at least one 	Follow-up: 6 months (100%) Outcomes reported: • Pain: Visual Analogue Pain Scale (VAS) (0-11 scale; 11 = max pain) • Function:

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		 n = 20 Age (mean): 56 years (36 – 79) Male: 30.0% <u>Sham Neurotomy</u> (<u>SHAM</u>) n = 20 Age (mean): 53 years (37 – 76) Male: 45.0% 	 Guidance: fluoroscopy Electrode location confirmation: NR Neurotomy: multiple lesions (2-6) created using a 5-mm active tip electrode at 85°C for 60 seconds. Anesthetic injected?: Yes, 1% lidocaine + 2 mL 0.5% bupivacaine Post RF denervation injection of steroids or anesthetic performed: NR Sham Neurotomy (SHAM) (n = 20) No current was used in the placebo group and the electrode tip remained at body temperature (The RF machine was placed behind the operator (S.N.) who was unaware of the current level that was operated by another 		CT • <i>Diagnostic blocks:</i> Medial branch blocks with 0.5% bupivacaine at segmental levels corresponding to sites of paravertebral tenderness (required pain reduction ≥80%)	component of their pain which could be attributed to one or more lumbar zygapophysial joints. • Such patients had to have paravertebral tenderness, and obtain at least 80% relief of pain following controlled, medial branch blocks. (Patients were not required to report relief of all of their pain, but had to be confident that a recognizable component, or region, of their pain was consistently relieved by the blocks) • Inclusion range: NR <u>Exclusion</u> : • Pregnancy, coagulopathies,	 Global perception of improvement (point-reported using 6-pt scale); (back and hip movement, general mobility) Analgesic (6-pt scale) ROM in lumbar spine (measured in degrees using goniometer) Hip movement (measured in degrees using goniometer) QoL (pt-reported using 6-pt scale: analgesic consumption, personal hygiene, walking, sitting, sleep, traveling, social life, standing, leisure, sex, work, and subjective global assessment) Clinical signs (present or

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			 person (C.N.) who was the only one of the workers who was aware of the randomization) <u>Post-procedure:</u> NR 			 malignancy, infections, mental handicap, and psychiatric disorders Patients with a motor deficit or any other indication for surgical treatment Patients who lived too far away to be able to participate in follow- up. 	absent: Laseque test SLR, Crossed laseque test, sacro-iliac test, signs of trochanteritis, para vertebral tenderness (facet joint test), intra- spinal tenderness, dermatomal sensations affected, knee reflex, ankle reflex)
Tekin (2007) Turkey <u>Funding:</u> NR	RCT	 N = 60 Age (mean): 59.3 years ± 8.5 Male: 43.3% Symptom duration: > 6 years Pulsed FJRF 	 N = 60 <u>Conventional FJRF</u> <u>denervation (n = 20)</u> Number of levels: NR Treated levels: L1-L3 or L3-L5 Neurotomy target: medial branch of the dorsal spinal ramus 	 Yes (medial branch block) Yes 	 <u>Clinical assessment:</u> Continuous LBP with/without radiation into upper leg; focal tenderness over the facet joints; pain on hyperextension <u>Radiologic</u> 	back pain with or without radiating into the upper leg, with focal	Follow-up: 6 hours (100%), 6 months (100%), 1 year (100%) Outcomes reported: • Pain: Visual Analogue Pain Scale (VAS) (0-NR scale)
		denervation • n = 20 • Age (mean): 59.6 years ±	 Guidance: fluoroscopy Electrode location confirmation: first by 		• <u>Diagnostic blocks:</u>	tenderness over the facet jointsPain on hyperextension	 <u>Function:</u> Oswestry Disability Index (ODI) (0-NR scale)

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		7.7 • Male: 45.0% <u>Conventional</u> <u>FJRF denervation</u> • n = 20 • Age (mean): 60.5 years ± 8.5 • Male: 40.0% <u>Sham Neurotomy</u> <u>(SHAM)</u> • n = 20 • Age (mean): 57.9 years ± 9.3 • Male: 45.0%	sensory stimulation at 50Hz and motor stimulation up to 1V (Impedance was verified at 300 to 7000 to confirm proper electrode placement) • Neurotomy: Single lesion created using a 10-mm active tip electrode at 80°C for 90 seconds. • Anesthetic injected?: Yes, 1% lidocaine • Post RF denervation injection of steroids or anesthetic performed: NR • Pulse FJRF denervation (n = 20) • Number of levels: NR • Treated levels: L1-L3 or L3-L5 • Neurotomy target: medial branch of the dorsal spinal ramus • Guidance: fluoroscopy • Electrode location		Medial branch blocks with using 0.3mL of lidocaine 2%.at L1-L3 or L3-L5 (required pain reduction ≥50%)	 No finding of obvious neurologic defect No indication for low back surgery No radicular syndrome Unresponsiveness to traditional conservative treatments, such as bed rest, medication, physical therapy, trigger point injection, and epidural block Patients experiencing a positive response to a diagnostic medial branch block (positive if pain score reduction reported by the patient was greater than 50% on VAS and the duration of effect coincided with the expected duration of the local anesthetic 	 Adverse events (4-pt scale; 3: excellent, 0: bad) Reduction in analgesic usage Patients' satisfaction (0-3, 0 = bad, 3 = excellent)

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			 confirmation: first by sensory stimulation at 50Hz and motor stimulation up to 1V (Impedance was verified at 300 to 7000 to confirm proper electrode placement) Neurotomy: 2 Hz PRF waves were applied for 4 minutes (45 V), with the end point being an electrode tip temperature 42°C. Anesthetic injected?: Yes, 1% lidocaine Post RF denervation injection of steroids or anesthetic performed: NR 			used) • Inclusion range: NR <u>Exclusion</u> : • Prior RF treatment • Coagulation disturbances • Allergies to radiopaque contrast media or local anesthetics • Malignancy • Mental handicap or psychiatric condition precluding adequate communication • Language problems Pregnancy	
			 <u>Sham Neurotomy</u> (<u>SHAM</u>) (n = 20) Electrodes and thermocouple probes were positioned same as PRF/CRF without switching on the RF current, only 				

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s) bupivacaine 0.5%, 0.3mL was injected. • Anesthetic injected?: Yes, 1% lidocaine + 2 mL 0.5% bupivacaine	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			Post-procedure: • NR				
van Kleef (1999) Netherlands <u>Funding:</u> Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NOW), Grant MW 940-31- 007.	RCT	 N = 31 Age (mean): 44.0 years ± 7.5 * Male: 35.5%* FJRF denervation n = 15* Age (mean): 46.6 years ± 7.4* Male: 33.3% Symptom duration: 26 months (12 – 120)* Sham Neurotomy (SHAM) n = 16* Age (mean): 41.4 years ± 	 N = 31 FJRF denervation (n = 15) Number of levels: NR Treated levels: L1-L5 Neurotomy target: medial branch of the dorsal spinal ramus Guidance: fluoroscopy Electrode location confirmation: first by sensory stimulation at 50Hz and motor stimulation up to 1.5V Neurotomy: Single lesion created using a 5-mm active tip electrode at 80°C for 60 seconds. Anesthetic injected?: 		 Clinical assessment: LBP, VAS score >4 or VAS high score >7, no neurologic deficit <u>Radiologic</u> <u>assessment:</u> none <u>Diagnostic blocks:</u> Diagnostic nerve block (L3, L4, L5) with 1% lidocaine (required pain reduction ≥50% after blocks administered) 	 Inclusion: 20 – 60 years of age. Chronic low back pain > 12 months Initial mean VAS score of more than 4 or a VAS high score of more than 7 Conservative therapy attempted without success Absence of any neurologic deficit by routine neurologic examination. Stating that they were pain free after a diagnostic block (50% pain relief, 30 minutes after the 	 <u>Follow-up:</u> 8 weeks (NR%); 3, 6, 12 months <u>Outcomes reported:</u> <u>Pain:</u> Visual Analogue Pain Scale (VAS) (0-10 scale; 10 = max pain) <u>Function:</u> Oswestry Disability Index (ODI) (0 - NR); Global perceived effect (4-point Likert scale); Impairment was scored by the patient on a 7- point scale (Waddell) The Dartmouth

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		7.5 * • Male: 37.5% • Symptom duration: 48 months (12 – 192)*	Yes, NR Post RF denervation injection of steroids or anesthetic performed: 1 mL 1% lignocaine <u>Sham Neurotomy</u> <u>(SHAM)</u> <u>(n = 16)</u> Electrodes were introduced as in treatment group, but no radiofrequency lesion was made. Apart from the running radiofrequency current the therapeutic procedures were identical <u>Post-procedure:</u> NR			 blocks were administered, as assessed by a four- point Likert scale) Inclusion range: (June 1994 – April 1996) <u>Exclusion</u>: Clinical lumbar radiculopathies and other neurologic abnormalities Previous back surgery Patients with a known specific cause of low back pain (<i>i.e.</i>, signs of herniation, spondylolisthesis, spondylolisthesis, spinal stenosis, extensive multilevel spondylosis, malignancy, infection, or trauma). Patients with diabetes mellitus 	COOP Functional Health Assessment Charts/World Organization of Primary Care Physicians chart, quality of life questionnaire • Adverse events • Reduction in analgesic usage (0 – 7; 7: max impairment), patients' satisfaction

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
						• Patients with more than one pain syndrome	
van Wijk (2005) Netherlands <u>Funding:</u> Grant (OG 95-027) from the Dutch Health Insurance Council and by a contribution from the Pain Expertise Center Nijmegen.	RCT	 N = 81 Age (mean): 47.5 years ± 12.1 Male: 28.4% Symptom duration: > 6 months FJRF denervation n = 40 Age (mean): 46.9 years ± 11.5 Male: 25.0% Sham Neurotomy (SHAM) n = 41 Age (mean): 48.1 years ± 12.6 Male: 31.7% 	 N = 81 FJRF denervation (n = 40) Number of levels: NR Treated levels: Th12– L2, L2–L4, or L4–S1 Neurotomy target: medial branch of the dorsal spinal ramus Guidance: fluoroscopy Electrode location confirmation: first by sensory stimulation at 50Hz and motor stimulation up to 2Hz Neurotomy: 2 lesions per level created using a 5-mm active tip electrode at 80°C for 60 seconds. Anesthetic injected?: Yes (0.5mL 2% mepivacaine) Post RF denervation injection of steroids or anesthetic 	• Yes (intra- articular)	 <u>Clinical assessment:</u> continuous LBP with or without radiating pain into upper leg; focal tenderness over facet joints <u>Radiologic</u> <u>assessment:</u> none <u>Diagnostic blocks:</u> Diagnostic nerve block with 2% lidocaine (required pain reduction ≥50% 30 minutes after blocks administered) 	 Inclusion: > 17 years Continuous low back pain with or without radiating pain into the upper leg for more than 6 months with focal tenderness over the facet joints, > 6 months ≥ 50% VAS reduction, 30 minutes after diagnostic blocks Inclusion range: (May 1996 – Jan 1999) Exclusion: Prior radiofrequency treatment Radicular syndrome (no sensory or motor deficits and no positive straight leg raising test) 	 <u>Follow-up</u>: Follow-up: 3 months (100%), 6 months (% f/u NR), 9 months (% f/u NR), 12 months (% f/u NR) "Blinding was ended at 3 months follow-up in more than 70% of patients, and some patients in both groups were lost to follow-up" <u>Outcomes reported</u>: <u>Pain</u>: Visual Numeric Pain Scale (maximum low back pain level, for pain radiating into the leg) (0-10 scale; 10 = max pain); <u>Function</u>: Global perceived effect(4-point

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			performed: 0.5 mL of mepivacaine 2% <u>Sham Neurotomy</u> (<u>SHAM</u>) (n = 41) • Electrodes and thermocouple probes were positioned same as treatment group, but without switching on the RF current <u>Post-procedure:</u> • NR			 Low back surgery Coagulopathies Specific allergies (local anesthetics, radiopaque contrast) Cancer Mental handicap or psychiatric condition precluding adequate communication, language problems Pregnancy 	Likert scale); Impairment was scored by the patient on a 7- point scale (Waddell) Quality of life (SF- 36 questionnaire) • Adverse events • Reduction in analgesic usage, patients' satisfaction • Primary outcome of treatment was determined using a predefined multidimensional combined outcome measure (COM) comprising a balance between changes in VAS- back and changes in daily physical activities and use of analgesics.
Civelek (2012) Turkey	RCT	 N = 100 Age (mean): 54.2 years ± 	• N = 100	• NR	<u>Clinical assessment</u> : Symptoms of lumbar facet syndrome (2 of	Inclusion: • Chronic and debilitating LBP	<u>Follow-up:</u> 1 year (%NR)

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
<u>Funding:</u> NR		17.4 • Male: 29.6% FJRF denervation • n = 50 • Age (mean): 51.8 years ± 17.4 • Male: 30% • Symptom duration: 18.9 ± 12.9 mos. (mean) FJ injections (MBB) • n = 50 • Age (mean): 56.5 years ± 17.7 • Male: 29.2% • Symptom duration: 18.7 ± 12.3 mos. (mean) •	 FJRF denervation (n = 50) Number of levels: 1.7 per pt (mean) I-level: n = 21 I-level: n = 14 I-levels: n = 9 I-levels: n = 2 Treated levels: NR Neurotomy target: medial branch of the dorsal spinal ramus Guidance: fluoroscopy Electrode location confirmation: first by sensory stimulation at 50Hz (1 millisecond pulse) and motor stimulation at 2Hz (1 millisecond pulse), to a maximum of 1V each. Neurotomy: Single lesion created using a 5-mm active tip electrode at 80°C for 120 seconds. Anesthetic injected?: No 		 4 of the following required: local tenderness over one or more FJs, back pain aggravated by hyperextension and rotation, morning stiffness or pain increasing in the morning, hip and buttock pain of a non-radicular distribution) <u>Radiologic</u> <u>assessment</u>: Radiographic and CT assessments were made, not clear what was required for inclusion. (<i>Radiographs:</i> Static and dynamic radiographs of lumbosacral spine examined for narrowing of FJs, osteoarthritis with narrowing, eburnation, and osteophyte 	 leading to a diagnosis of a lumbar facet syndrome Only those patients having at least 2 of the 4 symptoms of facet syndrome (symptoms of facet syndrome are local tenderness over one or more FJs, back pain aggravation by hyperextension and rotation, morning stiffness or pain increasing in the morning and hip and buttock pain of a non-radicular distribution) Not responding to conservative treatment for up to 6 weeks including various analgesics and physical therapy and additionally pain relief after FJI for FJRF neurotomy 	Outcomes reported: • <u>Pain:</u> Visual Numeric Pain Scale (VNS) (0-10 scale; 10 = max pain) • <u>Function:</u> EQ-5D • <u>Patient</u> <u>satisfaction</u> : North American SpineSociety (NASS) patient satisfaction questionnaire • Adverse Effects

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			 injection of steroids or anesthetic was not performed Medial Branch Block (MBB): (n = 50) Number of levels: 1.6 per pt (mean) 1-level: n = 22 2-levels: n = 13 3-levels: n = 8 4-levels: n = 2 Injection target: medial branch of the dorsal spinal ramus Guidance: fluoroscopy (nonionic contrast injected) Injection: steroid, anesthetic mixture: 40 mg methyl- prednisolone acetate (1 mL volume) & 1.5-2 mL bupivacaine (0.25%-0.5%). Post-procedure: Discharged after ~24 hrs Rest treated region for several days, avoid activities that would 		formation.) (<i>CT scans:</i> Computed tomography scans assessed for facet arthrosis, related central spinal canal, lateral recess, neural foramen stenosis, and posterior element alterations associated with various forms of spondylolisthesis) • <u>Diagnostic blocks</u> : none reported •	patients. Inclusion range: NR Exclusion: Radicular pain, neurogenic claudication, and neurological deficits. Patients having an acute or uncontrolled medical illness, known history of adverse reactions to local anesthetics and pregnant or lactating women	

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s) typically cause pain Pain medication provided for 1 week	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
Lakemeier (2013) Germany <u>Funding:</u> None	RCT	 N = 56 Age (mean): 57.0 years ± 11.8 * Male: 63.5%* Symptom duration: at least 24 months* FJRF denervation n = 29 Age (mean): 57.6 years ± 12.8 * Male: 65.4%* FJ steroid injections + sham n = 27 Age (mean): 56.3 years ± 10.8 * Male: 61.5%* 	 N = 56 FJRF denervation (n = 29) Number of levels: NR Treated levels: "relevant" L3/L4- L5/S1 Neurotomy target: dorsal ramus medial branch of the relevant segments Guidance: fluoroscopy Electrode location confirmation: first by sensory electrostimulation at 50Hz and motor stimulation at 2Hz. Anesthetic injected?: Yes, 1 mL 0.5% bupivacaine injected immediately prior to neurotomy Neurotomy: Single lesion created using a 20-G curved RF 	Yes (intra- articular) Yes	 Clinical assessment: physical examination used for diagnosis; details NR. Lumbar facet joint related LBP <u>Radiologic</u> <u>assessment:</u> MRI confirmation of lumbar FJ osteoarthritis and hypertrophy <u>Diagnostic blocks:</u> Intraarticular diagnostic block of L3/L4 – L5/S1 facet joints with 5 ml, 0.5% bupivacaine (required pain reduction ≥50%) 	 Inclusion: LFJ-related low back pain for ≥ 24 months, involving L3/L4 – L5/S1 segments. ≥18 years of age; Ability to understand the study protocol and to provide voluntary written informed consent and participate in outcome measurements A positive response/ benefit in pain reduction of at least 50% after a test injection of local anesthetics into the L3/L4– L5/S1 LFJs MRI-proven LFJ osteoarthritis and hypertrophy in the L3/L4–L5/S1 	 Follow-up: 6 months: 52/56 (93.0%) <u>Outcomes reported:</u> <u>Pain:</u> Visual Analogue Pain Scale (VAS) (0-10 scale; 10 = max pain) <u>Function:</u> Roland- Morris (RMQ) (1- 24 scale; 24 = severe disability); Oswestry Disability Index (ODI) (0-5 scale ; 5 = max disability) Analgesic Intake Adverse events

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			 needles with 100-mm active tips electrode at 80°C for 90 seconds. Post RF denervation injection of steroids or anesthetic performed: NR <u>Intra-articular FJ</u> injections + sham (n = 27) Number of levels: NR Treated levels: "relevant" L3/L4– L5/S1 Injection target: dorsal ramus medial branch of the relevant facet joints Guidance: fluoroscopy Injection: mixture of 0.5 mL of 0.5% bupivacaine and 1 mL of betamethasone (3 mg) into the target joint Sham denervation performed following injection (as in 			 segments. Inclusion range: (May 2009 – September 2011) Exclusion: Lack of positive response to a L3/L4–L5/S1 test infiltration History of osteoporosis or malignancies; allergies to local anesthetics Pregnancy or lactating Lumbar spinal stenosis or spinal instabilities; vertebral fractures; symptomatic radiculopathies Uncontrolled psychiatric disorders, uncontrolled medical illnesses, and any conditions that could interfere with the 	

Investigator (year)	Study	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
Country, Funding	Design	Demographics	 Intervention(s) neurotomy group but the electrodes were not connected to pain generator device) <u>Post-procedure:</u> Discharge time: NR Most of the patients were administered analgesics (an opioid and NSAID) Continuation of previously directed exercise programs and work No specific physical exercise program, 	to Block?	Diagnostic Evaluation	 Exclusion Criteria interpretation of the outcome assessments History of adverse reactions to corticosteroids 	Reported
			manual therapy, physiotherapy, or other interventions were offered to the patients.				
Chakraverty (2004)	Audit	 N = 72 Age (mean): 61.0 years (30 - 90) 	 N = 72 <u>FJRF denervation (n =</u> 38) 	• NR • NR	<u>Clinical assessment:</u> continuous LBP with or without radiating pain into upper leg;	Inclusion: NR Inclusion range: (October 2000 and February 2003) 	Follow-up: NR Outcomes reported: • Pain: Subjective
England		• Male: 37.5%	 Number of levels: NR Treated levels: NR Neurotomy target: 		focal tenderness over facet joints • VAS score >4 or VAS	Exclusion: NR	global improvement
<u>Funding:</u> NR		• $n = 38$	 Neurotomy target: medial branch of the 		high score >7, no		

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		 Age (mean): 57 years (30 – 85) Male: 31.6% Symptom duration: 5.0 years (1-10) (mean) <u>Intra-articular</u> <u>facet joint</u> <u>injections with</u> <u>local</u> Anesthetic n = 34 Age (mean): 65 years (32 – 90) Male: 44.1% Symptom duration: 5.6 years (0.5-20) (mean) 	 posterior primary ramus Guidance: fluoroscopy Electrode location confirmation: first by sensory stimulation at 50Hz and motor stimulation up to 2Hz Neurotomy: 2 lesions to each medial branch at 80°C for 60 seconds. Anesthetic injected?: NR Post RF denervation injection of steroids or anesthetic performed: NR <u>Intra-articular facet</u> joint injections (n = 34) Number of levels: NR Injection target: medial branch of the dorsal spinal ramus Guidance: fluoroscopy (nonionic contrast injected) Injection: steroid, 		neurologic deficit		

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			anesthetic mixture: 40 mg methyl- prednisolone acetate (1 mL volume) & 1.5- 2 mL bupivacaine (0.25%-0.5%). <u>Post-procedure:</u> • NR				
Lord (1996)	RCT	 N = 24 Age (mean): 	• N = 24	 Yes (medial 	• <u>Clinical assessment:</u> zygapophyseal joint	Inclusion: • Patients with C3–4	<u>Follow-up:</u> 3 months (100%)
Australia		43.5 years ± 12 • Male: 37.5%	FJRF denervation (n = 12) • Number of levels: NR	branch block)	pain, no other details reported	to C6–7 zygapophyseal joint pain	Informally at 3-2 days and 2-3 weeks postop
<u>Funding:</u> Motor Accidents Authority of New		FJRF denervation • n = 12	 Treated levels: C3 – C7 		 <u>Radiologic</u> <u>assessment</u>: none 	 Nonresponsive to conservative therapy (analgesics, 	
South Wales		 Age (mean): 44 years ± 12 Male: 41.7% Symptom duration: at least 23 months Symptom duration: 44 months 	 Neurotomy target: medial branch of the posterior primary ramus Guidance: fluoroscopy Electrode location confirmation: NR Neurotomy: 2-3 lesions per level using 		 <u>Diagnostic blocks:</u> medial branch block of dorsal rami with either 2% lidocaine or 0.5% bupivacaine (required pain reduction ≥50% 30 minutes after blocks administered) 	nonsteroidal anti- inflammatory drugs, opioids, physiotherapy, traction, acupuncture, chiropractice, TENS, locally applied heat, and/or exercise) • Patient had	 <u>Pain:</u> Visual Analogue Pain Scale (VAS) (0- 100 scale; 100 = max pain); McGill Pain Questionnaire <u>Function:</u> SCL-90-
		(median) <u>Sham Neurotomy</u>	a 4-mm active tip electrode at 80°C for 90 seconds.Anesthetic injected?:		(required complete pain relief); test also performed with saline (required no	complete relief of pain each time a local anesthetic was used, but no relief	R, psychological evaluation (90- item checklist): Somatization,

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		(SHAM) • n = 12 • Age (mean): 43 years ± 12 • Male: 33.3% • Symptom duration: 34 months (median)	 yes, 2 mL of 0.5% bupivacaine Post RF denervation injection of steroids or anesthetic performed: NR <u>Sham Neurotomy</u> (<u>SHAM</u>) (n = 12) The temperature was maintained at 37°C. In every other respect the procedures used in the two groups were identical. <u>Post-procedure:</u> NR 		pain relief)	 when normal saline was used Inclusion range: NR Exclusion: Patients with C2–3 zygapophyseal joint pain Patients that had relief of pain when the confirmatory diagnostic blocks were used or because they had responses when the blocks involving saline were used 	Obsessive– compulsive disorder, Interpersonal hypersensitivity, Depression, Anxiety, Hostility, Phobic anxiety, Paranoid ideation, Psychotic symptoms • Adverse events
Haspeslagh (2006) Netherlands <u>Funding:</u> NR	RCT	 N = 30 Age (mean): 48.3 years ± 12.0 Male: 26.7% FJRF denervation n = 15 Age (mean): 47.5 years ± 11.0 Male: 26.7% 	 N = 30 FJRF denervation (n = 15) Number of levels: NR Treated levels: C3-C6 Neurotomy target: medial branches of the posterior primary rami from C3 to C6 Guidance: fluoroscopy 	• No	• <u>Clinical assessment:</u> physical examination: tenderness at certain areas. At least two adjacent levels were tested at weekly intervals; An initial visual analogue scale (VAS) score of more than 50 mm during a pain period	than 2 years' duration	 <u>Follow-up:</u> 8 weeks (93.3%) <u>Outcomes reported:</u> <u>Pain:</u> Visual Numeric Pain Scale (VNS) (0- 100 scale; 100 = max pain); number of headaches

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		 Symptom duration: 9.7 years (mean) FJ injections (MBB) n = 15 Age (mean): 49.1 years ± 12.8 Male: 26.7% Symptom duration: 6.6 years (mean) 	 Electrode location confirmation: first by sensory stimulation at 50Hz and motor stimulation at 0.5V and 2Hz Neurotomy: Single lesion created using a 4-mm active tip electrode for 60 seconds at 67°C Anesthetic injected?: yes, 1 mL of 2% lidocaine Post RF denervation injection of steroids or anesthetic performed: 1 mL 2% Lidocaine <u>Injection of the greater</u> <u>occipital nerve (n = 15)</u> Number of levels: NR Injection target: greater occipital nerve Guidance: X-ray Injection: 2 ml. of Bupivacaine 0.5 % <u>Post-procedure:</u> 		 <u>Radiologic</u> <u>assessment:</u> none <u>Diagnostic blocks:</u> none 	 than 50 mm during a pain period Significant pain during at least two days per week. Inclusion range: September 1997 until June 2002 <u>Exclusion</u>: Patients who had had previous surgical procedures of the cervical spine Patients who had coagulation disturbances Pregnancy Patients who had multilevel severe degenerative changes at their cervical X-ray Patients who were diagnosed with post-whiplash syndrome. 	 <u>Function:</u> Global perceived effect (7-point Likert scale; ranging from -3 - + 3); The RAND-36, measuring Physical and Social Function, the Role Physical and Role Emotional Limitations, the Mental Health, the Vitality, the Bodily Pain and the General Health

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block? Good Response to Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			• NR				

LBP: lower back pain; LFJ: lumbar facet joint; FJI: facet joint injection; FJRF: facet join radiofrequency; (NASS): North American Spine Society patient satisfaction questionnaire; (Euro-Qol in 5 dimensions) EQ-5D; VAS: visual analog scale; VNS: Visual Numeric Pain Scale; RMQ: Roland-Morris Questionnaire; ODI: Oswestry Disability Index; CI: Confidence Interval; ROM: range of motion: ROM: range of motion; NSAID: nonsteroidal anti-inflammatory drug

*Data reported for patients after loss to follow-up.

VAS visual analogue scale (pain))

KQ2 Results

Investigator (year)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events						
Lumbar: Facet	Imbar: Facet neurotomy versus Sham neurotomy												
Gallagher (1994)	RCT	 N = 30 FJRF denervation (RFN) (n = 18, group A only) Sham Neurotomy (SHAM) (n = 12, group C only) Follow-up:1 and 6 mos. (100%) 	VAS (0-100) (mean ± standard error) <u>Pre-denervation</u> • RFN: 51 ± 6.0 • SHAM: 73 ± 4.1 • $P = NR$ <u>Baseline.</u> • RFN: 58 ± 4.2 • SHAM: 72 ± 5.6 • $P = NR$ <u>Postprocedure</u> <u>1 months</u> • RFN: 34 ± 6.9 • SHAM: 60 ± 9.8 • $P = NR$ <u>6 months</u> • RFN: 44 ± 7.2 • SHAM: 70 ± 8.5 • $P = NR$	• NR	NR	NR	<u>"Adverse events" (not defined)</u> RFN: 0% (0/18) SHAM: 0% (0/12) <i>P</i> = NR 						
			Shortened McGill Pain Score (0-NR) (mean ±										

Investigator (year)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
			standard error) <u>Pre-denervation</u> • RFN: 12 ± 1.6 • SHAM: 18 ± 2.6 • <i>P</i> = NR				
			Baseline. • RFN: 15 ± 2.3 • SHAM: 19 ± 2.4 • <i>P</i> = NR Postprocedure				
			Postprocedure <u>1 mos.</u> • RFN: 9 ± 2.3 • SHAM: 16 ± 2.8 • $P = NR$				
			6 mos. • RFN: 12 ± 7.2 • SHAM: 17 ± 3.2 • P = NR				
Leclaire (2001)	RCT	 N = 70 FJRF denervation (RFN) (n = 36) Sham Neurotomy (SHAM) (n = 34) 	 VAS (0-100) <u>Baseline.</u> RFN: 51.9 ± 26.7 SHAM: 51.5 ± 20.8 P = NR <u>4 weeks</u> RFN: 48.2 	Roland-Morris (converted to scale of 0-100) <u>Baseline.</u> • RFN: 52.9 ± 18.2 • SHAM: 51.6 ± 22.8 • <i>P</i> = NR	NR	 Analgesic use Acetaminophen or NSAIDs P = NR (between treatment groups) Data: NR "No statistical difference found" 	RFN: NRSHAM: NR

 Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
	• Follow-up: 4 weeks (100%); 12 weeks (94.3%)	 RFN change from baseline to 4 weeks: 3.6 ± 24.0 SHAM change from baseline to 4 weeks: - 0.6 ± 23.6 P > 0.05 (RFN vs SHAM between 4- weeks and baseline) <u>12 weeks</u> RFN: 52.3 SHAM: 44.4 P = NR RFN Change from baseline to 12 weeks: 0.5 ± 2.0 SHAM Change from baseline to 12 weeks: 	4 weeks• RFN: 44.5• SHAM: 49.5• $P = NR$ • RFN change from baseline to 4 weeks: 8.4 \pm 17.4• SHAM Change from baseline to 4 weeks: 2.2 \pm 14.7• $P = 0.05$ (RFN vs SHAM between 4- weeks and baseline)12 weeks• RFN: 9.8 \pm 19.5• SHAM: 7.2 \pm 17.0• $P = NR$ • RFN Change from baseline to 12 weeks: 9.8 \pm 19.5• SHAM Change from baseline to 12 weeks: 9.8 \pm 19.5• SHAM Change from baseline to 12 weeks: 7.2 \pm 17.0• $P > 0.05$ (RFN vs SHAM between 12-		 Non-pharmacologic treatment (physiotherapy or chiropractic treatment) <i>P</i> = NR (between treatment groups) Data: NR Return to work after 12 weeks (RFN): 44% (8/18) (SHAM): 38% (8/21) <i>P</i> = NR 	

Investigator (year)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
				weeks and baseline)			
				ODI (0-100) <u>Baseline.</u> • RFN: 38.3 ± 14.7 • SHAM: 36.4 ± 14.6 • $P = NR$ <u>4 weeks</u> • RFN: 35.6 • SHAM: 34.4 • $P = NR$ • RFN change from baseline to 4 weeks: 2.7 ± 12.4 • SHAM change from baseline to 4 weeks: 2.1 ± 9.4 • $P > 0.05$ (RFN vs SHAM between 4-weeks and baseline) • (95% CI: 0.6 (- 4.5 - 5.7))			
				<u>12 weeks</u> • RFN: 33.6 • SHAM: 33.7			

Investigator (year)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
				 P = NR RFN change from baseline to 12 weeks: 4.7 ± 12.0 SHAM change from baseline to 12 weeks: 2.7 ± 9.1 P > 0.05 (RFN vs SHAM between 12- weeks and baseline) (95% Cl: 1.9 (- 3.2 - 7.0)) 			
Nath (2008)	RCT	 N = 40 FJRF denervation (RFN) (n = 20) Sham neurotomy (SHAM) (n = 20) Follow-up: 6 months (100%) 	VAS (back pain) (0 – 10) Baseline • RFN: 5.98 • SHAM: 4.38 • $P = NR$ <u>6 Months</u> • RFN: 3.88 • SHAM: 3.68 • $P = NR$ Pain Reduction (from baseline to <u>6 months</u>) • RFN: 2.1 • SHAM: 0.7 RFN v. SHAM:	NR	NR	Analgesic use (6-pt scale, range NR) Baseline • RFN: 3.95 • SHAM: 3.80 • $P = NR$ <u>6 Months</u> • RFN: 2.55 • SHAM: 3.20 • $P = NR$ Difference (from baseline to 6 months) • RFN: -1.40 • $P < 0.001$ (6 months vs.	• NR

Investigator (year)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction		Complications & Adverse Events
			(95% CI: 3.0,			baseline)	
			0.17) <i>, P</i> = 0.08			• SHAM: -0.60	
						 <i>P</i> = 0.024 (6 months vs. 	
			VAS (leg pain) (0			baseline)	
			– 10) <u>Baseline</u>				
			• RFN: 4.33			Total Difference : • RFN vs. SHAM: -	
			• SHAM: 2.68			0.8 (95% CI: 1.50,	
			• <i>P</i> = NR			-0.04), $P = 0.04$	
			<u>6 Months</u>				
			• RFN: 2.73				
			• SHAM: 2.55			Work (6-pt scale,	
			• <i>P</i> = NR			range NR)	
			Pain Reduction			<u>Baseline</u>	
			(from baseline to			• RFN: 4.75	
			<u>6 months)</u>			• SHAM: 3.70	
			• RFN: 1.6			• <i>P</i> = NR	
			• SHAM: 0.13			<u>6 Months</u>	
			• RFN v. SHAM:			• RFN: 3.15	
			(95% CI: -0.03,			• SHAM: 3.55	
			0.46), <i>P</i> =			• <i>P</i> = NR	
			0.046			Difference (from	
						baseline to 6	
			VAS (generalized			<u>months)</u>	
			pain) (0 – 10)			• RFN: -1.60	
			Baseline			• SHAM: -0.15	
			• RFN: 6.03			• <i>P</i> = NR	
			 SHAM: 4.35 <i>P</i> = NR 				
						Total Difference :	
			<u>6 Months</u>			RFN vs. SHAM:	
			• RFN: 4.10			-1.45 (95% CI: -	

Investigator (vear)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
Investigator (year)	Study Design		 Pain SHAM: 9.38 P = NR Pain Reduction (from baseline to 6 months) RFN: 1.9 SHAM: 0.4 RFN v. SHAM: 0.8 (95% CI, - 0.8, 3.0), P = 0.02 Subjective global assessment of improvement (6- pt scale, range NR) Baseline RFN: 3.85 	Function	Patient Satisfaction		Complications & Adverse Events
			• RFN: 3.85 • SHAM: 3.35 • $P = NR$ • RFN: 2.75 • SHAM: 3.05 • $P = NR$ <u>Difference (from</u> <u>baseline to 6</u> <u>months)</u> • RFN: -1.1 • SHAM: -0.30 <u>Total Difference :</u>				

Investigator (year)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
			 RFN vs. SHAM: -0.8 (95% Cl, - 1.3, -0.3), P = 0.004 				
Tekin (2007)	RCT	 N = 60 Pulsed RF denervation (PRF) (n = 20) conventional radiofrequenc y denervation (CRF) (n = 20) Sham Neurotomy (SHAM) (n = 20) Follow-up: 6 hours (100%), 6 months (100%), 1 year (100%) 	VAS (Back Pain) (0 - 10) Baseline. • PRF: 6.6 ± 1.6 • CRF: 6.5 ± 1.5 • SHAM: 6.8 ± 1.6 • P = See Below Postprocedure • PRF: 2.8 ± 1.5 • CRF: 2.3 ± 1.4 • SHAM: 4.3 ± 1.0 • P = See Below <u>6 months</u> • PRF: 2.9 ± 1.6 • CRF: 2.3 ± 1.3 • SHAM: 3.1 ± 0.8 • P = See Below <u>1 year</u> • PRF: 2.5 ± 1.3 • CRF: 2.4 ± 1.1 • SHAM: 3.9 ± 1.2 • P = See Below	ODI (0 - 100) <u>Baseline.</u> • PRF: 39.4 ± 5.0 • CRF: 39.2 ± 3.5 • SHAM: 40.1 ± 2.8 • P = See Below <u>Postprocedure</u> • PRF: 24.4 ± 5.7 • CRF: 25.6 ± 6.5 • SHAM: 30.5 ± 5.7 • P = See Below <u>6 months</u> • PRF: 25.3 ± 6.9 • CRF: 25.1 ± 6.4 • SHAM: 28.9 ± 5.7 • P = See Below <u>1 year</u> • PRF: 28.5 ± 6.1 • CRF: 28.0 ± 7.1 • SHAM: 33.6 ± 5.7 • P = See Below	PRF • Excellent: (35 (7/20) • Good: 50% (10/20) • Moderate: 15% (3/20) • Bad: 0% (0/20) CRF • Excellent: 65% (13/20) • Good: 30% (6/20) • Moderate: 5% (1/20) • Bad: 0% (0/20) SHAM • Excellent: 20%	Analgesic use (% pts using analgesics at 1 year) • PRF: 75% (15/20) • CRF: 40% (8/20) • SHAM: 95% (19/20) • <i>P</i> = NR	Adverse events (Not defined) • PRF: 0% (0/20) • CRF: 0% (0/20) • SHAM: 0% (0/20) • P = NR

Investigator (year)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
			"(SHAM =PRF; PRF=CRF; CRF < SHAM, P<0.001, repeated measures analysis, post hoc test Tukey honest significant difference.) <u>Pre-procedure:</u> SHAM =PRF=CRF <u>Postprocedure:</u> SHAM >PRF=CRF, P<0.001; 6mo, SHAM =PRF>CRF P<0.05; 1 y, SHAM =PRF>CRF, P<0.05."	SHAM =PRF, PRF=CRF, CRF< SHAM, P<0.05. 1	"CRF, PRF > SHAM (<i>P</i> = 0.03) CRF > SHAM, PRF (<i>P</i> = 0.004)"		
van Kleef (1999)	RCT	 N = 31 LRF denervation (RFN) (n = 15) Sham neurotomy (SHAM) (n = 16) 	VAS (Pain) (0 – 10) (Average of three daily measurements over 4 days) Baseline VAS mean • RFN: 5.2 ± 1.7 (2.9, 7.7) • SHAM: 5.2 ±	 ODI (0 - 100) <u>Baseline</u> RFN: 31.0 ± 14.2 SHAM: 38.0 ± 13.1 P = NR <u>8 weeks (mean</u> <u>change)</u> RFN: -11.07 SHAM: 1.69 	The Dartmouth COOP Functional Health Assessment Charts/World Organization of Primary Care Physicians chart, quality of life questionnaire (COOP/WONCA) (5 point scale)	Analgesic use (Median number of analgesic tablets per 4 days) (Patients primarily were taking NSAIDs) Baseline (median) • RFN: 0 (0 – 12) • SHAM: 0 (0 – 12) • P = NR	Adverse events (Not defined) RFN: 0% (0/15) SHAM: 0% (0/16) <i>P</i> = NR

Investigator Study (year) Desig		Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
	• Follow-up: 8 weeks (NR%); 3, 6, 12 months	1.6 (3.0, 7.6) • <i>P</i> = NR 8 Weeks (Difference) VAS mean • RFN: -2.37 (range: -1.85, - 3.64) • SHAM:-0.43 (range: 0.48, - 1.02) SHAM vs RFN Difference Adjusted (90% CI) • VAS mean: 2.46 (0.72 - 4.20) (<i>P</i> < .05) SHAM vs RFN Difference Unadjusted • VAS mean: 1.94 (0.24 - 3.64) (<i>P</i> < .05) "Success" (8 weeks) • RFN: 66.7% • SHAM: 37.5% • OR	• $P = NR$ Difference Adjusted • 10.90 • $P < 0.05$ • Cl: 1.76 - 20.0 Difference Unadjusted • 15.75 • $P < 0.01$ • Cl: 4.16 - 21.35 Impairment according to Waddell (7-point scale) Baseline (mean score) • RFN: 1.8 ± 1.5 • SHAM: 2.8 ± 1.1 • $P = NR$ 8 weeks (mean change) • RFN: -0.33 • SHAM: -0.07 • $P = NR$ Difference Adjusted • 0.31	Baseline • RFN: 20.2 \pm 3.8 • SHAM: 21.6 \pm 3.6 • P = NR 8 weeks (mean change) • RFN: -3.13 • SHAM: -1.62 • P = NR Difference Adjusted • 2.27 • P > 0.05 • Cl: -1.77 - 6.30 Difference Unadjusted • 1.51 • P > 0.05 • Cl: -1.85 - 4.97	8 weeks (change from baseline) • RFN: -2.13 • SHAM: 1.75 • $P = NR$ Difference Adjusted • 3.24 • $P > 0.05$ • CI: -0.13 - 6.60 Difference Unadjusted • 3.88 • $P < 0.05$ • CI: 1.19 - 6.57	

Investigator Study (year) Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
		(unadjusted): 3.33 (90% Cl, 0.97, 11.5) • OR (adjusted): 9.53 (90% Cl, 1.50, 60.5) "Success" required both a 2-point reduction on the VAS scale (0-10) and \geq 50% pain reduction on global perceived effect. Global Perceived effect (-3, 3) 8 weeks (mean) • RFN: 1.33 • SHAM: 0.37 • $P = NR$ Difference Adjusted • -1.10 • $P < 0.05$ • Cl: -1.89 - 0.30 Difference Unadjusted • -0.96 • $P < 0.05$	• $P \ge 0.05$ • Cl: -0.74 - 1.35 <u>Difference</u> <u>Unadjusted</u> • 0.27 • $P \ge 0.05$ • Cl: -0.69 - 1.22			

		Intervention(s) Follow-up (% followed)	Pain • Cl: -1.70 – 0.22	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
van Wijk (2005)	RCT	 N = 81 LRF denervation (RFN) (n = 40) Sham Neurotomy (SHAM) (n = 41) Follow-up: 3 months (100%), 6 months (% f/u NR), 9 months (% f/u NR), 12 months (% f/u NR) "Blinding was ended at 3 months follow- up in more than 70% of patients, and some patients in both groups were lost to 	VAS (Pain) (0 – 10) (median of 4 measurements over 2 weeks) Baseline VAS back (median, SD) • RFN: 5.8 ± 1.8 • SHAM: 6.5 ± 1.8 • P = NR VAS leg (median, SD) • RFN: 4.2 ± 2.6 • SHAM: 4.1 ± 2.8 • P = NR 3 months (mean change from baseline) VAS back • RFN: -2.1 • SHAM: -1.6 VAS leg • RFN: -1.1	Physical Activity <u>Baseline</u> (median, SD) • RFN: 20.6 ± 4.2 • SHAM: 18.4 ± 4.5 <u>3 months</u> <u>Mean change in</u> <u>Physical activity</u> • RFN: 1.5 • SHAM: 0.9	SF-36 (Quality of Life Questionnaire)BaselinePhysical Functioning \circ RFN: 42.9 ± 19.3 \circ SHAM: 33.8 ± 17.0 \circ P = NRSocial Functioning \circ RFN: 59.7 ± 23.1 \circ SHAM: 53.0 ± 24.7 \circ P = NRPhysical Role Restriction \circ RFN: 20.0 ± 37.6 \circ SHAM: 18.4 ± 21.8 \circ P = NREmotional Role Restriction \circ RFN: 55.8 ± 45.5 \circ SHAM: 70.3 ± 41.4 \circ P = NR	Analgesic Intake (scale, 0-8) (8: highest) (median of 4 measurements over 2 weeks) Baseline (median) • RFN: 1.0 ± 1.0 • SHAM: 1.5 ± 1.7 • $P = NR$ 8 weeks (mean change) • RFN: -0.1 • SHAM: -0.2 • $P = NR$	Adverse Events (Time of f/u: NR)Treatment Related Pain NoneNoneRFN: 30.8% (12/39)SHAM: 53.8% (21/39) $P = NR$ LittleRFN: 4/39 (10.3%)SHAM: 4/39 (10.3%) $P = NR$ ModerateRFN: 23.0% (9/39)SHAM: 10.3% (4/39) $P = NR$ Severe (necessitating analgesics)RFN: 35.9% (14/39)SHAM: 25.6% (10/39) $P = NR$ Change of sensibility (Not defined) UnalteredUnalteredRFN: 94.8% (37/39)

follow	 w-up" SHAM: -0.7 VAS-back pain reduction by ≥2 points (n (%)) ● RFN: 47.5% 	Mental Health • RFN: 62.9 ± 21.8 • SHAM: 70.2 ±	 SHAM: 97.5% (39/40) <i>P</i> = NR
	(19/40) • SHAM: 48.8% (20/41) • $P = NR$ VAS-back pain reduction by \geq 25% (n (%)) • RFN: 62.5% (25/40) • SHAM: 48.8% (20/41) • $P = NR$ VAS-back pain reduction by \geq 50% (n (%)) • RFN: 32.5% (13/40) • SHAM: 34.1% (14/41) • $P = NR$ Global Perceived Effect (back pain) \geq 50% pain relief	16.8 • $P = NR$ Vitality • RFN: 43.5 ± 21.6 • SHAM: 49.2 ± 19.6 • $P = NR$ Pain • RFN: 37.3 ± 15.6 • SHAM: 31.2 ± 15.3 • $P = NR$ General Health • RFN: 56.8 ± 21.9 • SHAM: 57.3 ± 19.8 • $P = NR$ Health Change (vs. 1 year prior) • RFN: 36.3 ± 22.6 • SHAM: 28.4 ± 20.5 • $P = NR$ 3 months (Mean difference from baseline) Physical Functioning	Discrete • RFN: 0% (0/39) • SHAM: 2.5% (1/40) • $P = NR$ Irritating • RFN: 2.6% (1/39) • SHAM: 0% (0/40) • $P = NR$ Evident dysaesthesia or allodynia • RFN: 2.6% (1/39) • SHAM: 0% (0/40) • $P = NR$ Loss of Motor Function Unaltered • RFN: 94.7% (36/38) • SHAM: 95.2% (39/41) • $P = NR$ Discrete • RFN: 5.3% (2/38) • SHAM: 2.4% (1/41) • $P = NR$ Irritating • RFN: 0% (0/38) • SHAM: 2.4% (1/41) • $P = NR$

Investigator (year)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
			 RFN: 61.5% (24/39) SHAM: 39.0% (16/41) <i>P</i> = NR 50% pain relief or pain increase RFN: 38.5% (15/39) SHAM: 61.0% (25/41) <i>P</i> = 0.044 OR: 2.5 (95% Cl: 1.0 - 6.1) Global Perceived Effect (leg pain) ≥ 50% pain relief 		 RFN: 4.7 ± 16.9 SHAM: 7.8 ± 19.7 <i>P</i> = NR Social Functioning RFN: 5.3 ± 36.1 SHAM: 2.6 ± 29.6 <i>P</i> = NR Physical Role Restriction RFN improvement: 25% (10/40); no improvement: 78% (3/40) SHAM: improvement: 27% (11/41); no improvement: 		 RFN: 0% (0/38) SHAM: 0% (0/41) P = NR
			 RFN: 50.0% (19/38) SHAM: 36.6% (15/41) P = NR < 50% pain relief or pain increase RFN: 50% (19/38) SHAM: 63.4% (26/41) P = NR 		20% (8/41) • <i>P</i> = NR <u>Emotional Role</u> <u>Restriction</u> • RFN: improvement: 3% (1/40); no improvement: 0% (0/40) • SHAM: improvement: 5% (2/41); no improvement: 7% (3/41)		

Investigator (year)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
					• $P = NR$ • $P = NR$ • $RFN: 2.7 \pm 26.8$ • $SHAM: 0.7 \pm 23.9$ • $P = NR$ • $Vitality$ • $RFN: 5.3 \pm 14.6, P$ = 0.03 (3 months vs. baseline) • $SHAM: -2.4 \pm 17.7$ • $P = NR$ Pain • $RFN: 11.8 \pm 22.9$ • $SHAM: 11.6 \pm 20.6$ • $P = NR$ General Health		
					 RFN: 1.8 ± 13.6 SHAM: -1.3 ± 17.5 P = NR <u>Health Change (vs. 1</u> <u>year prior)</u> RFN: improvement: 55% (22/40); no improvement: 1% (4/40) SHAM: improvement: 44% (18/41); no improvement: 		

Investigator (year)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
					5% (2/41) ● <i>P</i> = NR		
Lumbar: Facet	neurotom	y versus Spinal inje	ctions	1		I	
Civelek (2012)	RCT	 N = 100 FJRF Neurotomy (RFN) (n = 50) FJ Injections (medial branch block) (n = 50) Follow-up: 1 yr. (100%) 	VNS (0-10) <u>Baseline</u> • RFN: 8.2 • MBB: 8.5 • $P = 0.06$ <u>Postprocedure</u> • RFN: 2.4 • MBB: 1.2 • $P = 0.02$ <u>1 month</u> • RFN: 2.2 • MBB: 3.4 • $P = 0.04$ <u>6 months</u> • RFN: 2.5 • MBB: 4.4 • $P = 0.03$ <u>12 months</u> • RFN: 2.6 • MBB: 4.9 • $P = 0.03$ <u>VNS "Success"</u> (>50% decrease	NR	EQ-5D Baseline • RFN: 13.8 • MBB: 14.7 • $P = 0.09$ Post-procedure 1 month • RFN: 5.6 • MBB: 6.0 • $P = 0.17$ 6 months • RFN: 6.5 • MBB: 7.2 • $P = 0.22$ 12 months • RFN: 6.7 • MBB: 8.0 • $P = 0.11$ EQ-5D "Success" (EQ-5D score < 9)	NR	Infection:• RFN: 0% (0/50)• MBB: 0% (0/50)• MBB: 0% (0/50)• RFN: 0% (0/50)• MBB: 0% (0/50)• MBB: 0% (0/50)• MBB: 0% (0/50)Superficial burns:• RFN: 4% (2/50) ("burning-like sensation in the lesion-performed region and increase in severity of LBP in early follow-up period; resolved after 6-8 weeks with medication for neuropathy."• MBB: n/aIncrease in LBP:• RFN: 4% (2/50) (see superficial burns)• MBB: NR

Investigator Stu (year) Des	udy	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
			in pain score) (% pts) <u>1 mos.</u> • RFN: 100% (50/50) • MBB: 80% (40/50) • <i>P</i> = NR <u>6 mos.</u> • RFN: 90% (45/50) • MBB: 68% (34/50) • <i>P</i> = NR <u>12 mos.</u> • RFN: 88% (44/50) • MBB: 62% (31/50) <i>P</i> = NR		(45/50) • $P = NR$ <u>6 mos.</u> • RFN: 92% (46/50) • MBB: 76% (38/50) • $P = NR$ <u>12 mos.</u> • RFN: 90% (45/50) • MBB: 69% (35/50) P = NR NASS Patient Satisfaction (1-4): <u>Postprocedure</u> • RFN: NR • MBB: NR <u>1 mos.</u> • RFN: NR • MBB: NR <u>1 mos.</u> • RFN: 1.3 • MBB: 1.3 • $P = 1.00$ <u>6 mos.</u> • RFN: 1.4 • MBB: 1.7 • $P = 0.13$ <u>12 mos.</u> • RFN: 1.5 • MBB: 2.0 • $P = 0.04$		

Investigator (year)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
					NASS Patient Satisfaction "Success" (NASS score of 1 or 2) (% pts) <u>1 mos.</u> • RFN: 100% (50/50) • MBB: 88% (44/50) • <i>P</i> = NR <u>6 mos.</u> • RFN: 90% (45/50) • MBB: 76% (38/50) • <i>P</i> = NR <u>12 mos.</u> • RFN: 88% (44/50) • MBB: 68% (34/50) • <i>P</i> = NR		
Lakemeier (2013)	RCT	 N = 56 FJRF denervation (RFN) (n = 29) Intra-articular FJ steroid injections (IAI) 	<pre>VNS (0-10) Baseline</pre>	Roland-Morris (0-24) Baseline • RFN: 12.8 ± 5.4 • IAI + sham: 13.2 ± 5.9 • <i>P</i> = NR <u>6 months</u>	NR	 Analgesic use No difference between treatment groups at 6 mos. (data NR) "The majority of patients at baseline and 6 mos. received 	 Adverse events "No major adverse events reported during the observation period of 6 mos." Complications were <u>not</u> specified as outcomes of interest in the methods section.

Investigator (year)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
		+ sham denervation (n = 27) Follow-up: 6 mos. months (93.0% (52/56)	 IAI + sham: 5.4 ± 2.1 <i>P</i> = NR 	• RFN: 9.1 ± 6.0 • IAI + sham: 9.0 ± 6.4 • $P = NR$ ODI (0-100) (higher score = greater disability) Baseline. • RFN: 40.8 ± 16.4 • IAI + sham: 38.7 ± 18.4 • $P = NR$ <u>6 months</u> • RFN: 28.0 ± 20.0 • IAI + sham: 33.0 ± 17.4 • $P = NR$ Improvement • RFN: 12.5 • IAI + sham: 5.7 • $P = 0.069$		moderate doses of analgesics."	
Chakraverty (2004) England	Retro. cohort study	 N = 72 FJRF denervation (n = 38) Intra-articular 	50% subjective improvement in pain (%, (n)) <u>3 months</u> • RFN Mean: 78% (27/38)	NR	NR	NR	NR

Investigator (year)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
<u>Funding:</u> NR		facet joint injections (n = 34)	 RFN Mean improvement: 5.6 (2 – 10) 				
		 Follow-up: 3 (62.5%), 6 (36.1%), 12 (16.7%) months 	 IAI Mean: NR IAI Mean improvement: NR <u>6 months</u> RFN Mean: (50%) 16/32 RFN Mean improvement: 5.3 (2 - 9) IAI Mean: (29%) 10/34 IAI Mean improvement: NR 				
Cervical: Facet	Neuroton	ny versus Sham Nei	urotomy			l	
Lord (1996)	RCT	 N = 24 FJRF denervation (RFN) (n = 12) Sham Neurotomy (SHAM) (n = 12) 	Return of accustomed pain in the period immediately after the operation (): • RFN: 25% (3/12) • SHAM: 50% (6/12)	NR	NR	NR	Psoriatic rash (other adverse effects: NR) • RFN: 8% (1/12) • SHAM: 0% (0/12) • <i>P</i> = NR Pain Associated with procedure (Not defined) • RFN: 13.5 days (IQR: 6 - 15) • SHAM: 3.5 (IQR: 1 - 15) • <i>P</i> = 0.26
		• Follow-up: 3	Pain free at 27				Numbness in the territory of

Investigator (year)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
		months (100%) Informally at 3-2 days and 2-3 weeks postop	weeks: • RFN: 54% (7/12) • SHAM: 8% (1/12) The median time that before pain returned to at least 50 percent of the preoperative level of pain: • RFN: 263 days • SHAM: 8 days (P = 0.04)				the treated nerves (not considered troubling): • RFN: 38% (5/12) • SHAM: 0% (0/12)
Cervical: Facet	neurotom	y versus spinal inje		<u> </u>			
Haspeslagh (2006) Netherlands <u>Funding:</u> NR	RCT	 N = 30 FJRF denervation (n = 15) Anesthetic injection at greater occipital nerve (n = 15) Follow-up: 8 weeks (93.3%), 16 weeks (93.3%), 6 	VAS (0-100) Baseline) (Mean VAS/weeks) • RFN: 68.1 ± 12.7 • Inj: 76.51 ± 16.6 Days headache/ <u>4 weeks</u> • RFN: 25.9 ± 5.0 • Inj: 19.0 ± 9.3 <u>Headache</u> intensity/week • RFN: 2.1 ± 0.4	"Success" (reduction in mean VAS by ≥20 pts and/or global perceived effect of +2 or +3) <u>8 weeks</u> • RFN: 80% (12/15) • Inj: 71% (10/14)	The RAND-36, score Baseline Physical Function • RFN: 70.0 ± 21.4 • Inj: 57.0 ± 24.6 Social Function • RFN: 71.7 ± 18.0 • Inj: 59.2 ± 23.4 Role Physical Limitations • RFN: 31.7 ± 34.7 • Inj: 36.7 ± 35.2 Role Emotional	NR	NR

Investigator Study (year) Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
	(80.0%), 8 (66.7%), 10 (66.7%), (12 66.7%) months	• Inj: 1.9 ± 0.4 Mean Difference in VAS <u>8 weeks –</u> <u>baseline</u> • RFN 30.5 ± 17.3 • Inj: 32.4 ± 24.7 • <i>P</i> = 0.81 • Cl: -14.4 – 18.3 Mean VAS Improvement (Compared with Baseline %) <u>8 weeks</u> • RFN 43.9 ± 22.0 • Inj: 42.4 ± 28.6 • <i>P</i> = 0.87 • Cl: -21.2 – 18.1 Mean Headache Difference <u>8 weeks –</u> <u>baseline</u> • RFN 4.2 ± 5.1 • Inj: 5.5 ± 8.7 • <i>P</i> = 0.62 • Cl: -4.3 – 7.1 Mean Headache Intensity Difference <u>8 weeks –</u> <u>baseline</u>		Limitations • RFN: 64.4 ± 38.8 • Inj: 66.7 ± 35.6 <u>Mental Health</u> • RFN: 65.3 ± 16.2 • Inj: 69.6 ± 16.8 <u>Vitality</u> • RFN: 53.7 ± 24.3 • Inj: 45.3 ± 15.2 <u>Bodily Pain</u> • RFN: 41.8 ± 19.4 • Inj: 38.1 ± 18.5 <u>General Health</u> • RFN: 58.7 ± 21.0 • Inj: 54.7 ± 18.5 8 weeks: "No significant difference between the mean health scores of both groups."		

Investigator (year)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Return to work)	Complications & Adverse Events
			<u>baseline</u>				
			• RFN 1.5 ± 4.0				
			• Inj: -0.5 ± 8.7				
			• <i>P</i> = 0.43				
			• CI: -3.1 – 7.1				

CI: Confidence Interval; EQ-5D: (Euro-Qol in 5 dimensions); FJI: facet joint injection; FJRF: facet join radiofrequency; LBP: lower back pain; LFJ: lumbar facet joint; MBB: Medial Branch Block; MPI-DLV Multidimensional Pain Inventory in the Dutch Language); MPQ: McGill Pain Questionnaire; (NASS): North American Spine Society patient satisfaction questionnaire; RMQ: Roland-Morris Questionnaire; ODI: Oswestry Disability Index; ROM: range of motion; RFN: Radiofrequency nervation; VAS: visual analog scale; VNS: Visual Numeric Pain Scale;

KQ2a Demographics

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
Lumbar Kroll (2007) United States Funding: Anesthesia Research Fund, Henry Ford Hospital, Detroit, MI.	RCT	 N = 50 Age (mean): 58.3 years Male: 29.6% Symptom duration: > 1 month PRF denervation n = 13 Age (mean): 57.0 years ± 8.4 Male: 38% CRF denervation n = 13 Age (mean): 59.5 years ± 11.6 Male: 54% 	 N = 50 <u>PRF denervation</u> (n = 13) Treated levels: L3 - S1: n = 11 L4 - L5: n = 1 L4 - L5: n = 1 Neurotomy target: medial branch of the posterior ramus Guidance: fluoroscopy Electrode location confirmation: provocative sensory testing at a frequency of 50 Hz at less than one volt, and absence of motor stimulation in the lower extremity at a frequency of two Hz and 	• yes (medial branch block)	 Clinical assessment: Symptoms were reproduced by extension- rotation of the lumbar spine and palpation of the paraspinal region. <u>Radiologic</u> assessment: Disc herniation and spinal stenosis were ruled out radiographically. <u>Diagnostic blocks</u>: Medial branch block (bupivacaine 0.5 per cent 1.0 mL) per level, minimum two levels; Subjects obtaining >50% pain reduction 	Inclusion: Physical status I, II, and III Patients who were at least 18 years old Unilateral or bilateral lumbar back pain greater than one month in duration, with no radiating symptoms below the knee. Exclusion: History of previous back surgery, presence of neurological deficits, claudication, active psychiatric disorder, bleeding disorder, or active infection Pregnant Involved in current litigation, or ongoing Workers'	Follow-up: 3 months: 52% (26/50) Outcomes reported: • Pain: Visual Analogue Pain Scale (VAS) (0-NR scale) • Function: Oswestry (ODI) Low Back Pain and Disability Questionnaire • Patient satisfaction: NR • Adverse Effects

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			 voltage up to 2.5 volts Neurotomy: Lesions created using a either 21-gauge, 100- mm length, 5 mm active tip or 20-guage, 145- mm length, 5 mm active tip at 42°C for 20 ms (pulse rate: 22 Hz for 120 seconds) Anesthetic injected?: yes, after VAS scores taken, before operation: Intravenous sedation was provided with 2 mg midazolam and up to 100 µg of fentanyl for procedural comfort only; Skin and subcutaneous tissue were anesthetized with 2.0 mL of 		based on their mean (VAS) pain assessment for at least 3 hours after each diagnostic block, were considered candidates for the study	Compensation claims. • Disc herniation and spinal stenosis were ruled out radiographically.	

Investigator (year) Country,	Study	Patient		Diagnostic	Diagnostic	Inclusion/	Follow-up Duration (% followed)
Funding	Design	Demographics	Intervention(s)	Block?	Evaluation	Exclusion Criteria	Outcomes Reported
			1% lidocaine at				
			each puncture				
			site.				
			Post RF				
			denervation				
			injection of				
			steroids or				
			anesthetic: NR				
			CRF denervation				
			<u>(n = 13)</u>				
			Treated levels:				
			• L3 – S1: n = 11				
			• L4 – S1: n = 1				
			• L4 – L5: n = 1				
			 Neurotomy 				
			target: medial				
			branch of the				
			dorsal ramus				
			 Guidance: 				
			fluoroscopy				
			Electrode				
			location				
			confirmation:				
			provocative				
			sensory testing				
			at a frequency				
			of 50 Hz at less				
			than one volt,				
			and absence of				
			motor				
			stimulation in				

Investigator (year) Country,	Study	Patient		Diagnostic	Diagnostic	Inclusion/	Follow-up Duration (% followed)
Funding	Design	Demographics	Intervention(s)	Block?	Evaluation	Exclusion Criteria	Outcomes Reported
			the lower extremity at a frequency of two Hz and voltage up to 2.5 volts • Neurotomy: Lesions created using a either 21-gauge, 100- mm length, 5 mm active tip or 20-guage, 145- mm length, 5 mm active tip at 80°C for 75 seconds • Anesthetic injected?: yes, after VAS scores				
			after VAS scorestaken, beforeoperation:Intravenoussedation wasprovided with 2mg midazolamand up to 100µg of fentanylfor proceduralcomfort only;Skin andsubcutaneoustissue were				

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			 anesthetized with 2.0 mL of 1% lidocaine at each puncture site. Post RF denervation injection of steroids or anesthetic: NR Post-procedure: 				
			• NR				
Tekin (2007) Turkey <u>Funding:</u> NR	Prospective Case series LoE:	 N = 60 Age (mean): 60.1 years Male: 42.5% Symptom duration: > 6 years Pulsed FJRF denervation n = 20 Age (mean): 59.6 years ± 7.7 Male: 40.0% Conventional FJRF	 N = 60 <u>Conventional FJRF</u> <u>denervation (n =</u> <u>20)</u> Number of levels: NR Treated levels: L1-L3 or L3-L5 Neurotomy target: medial branch of the dorsal spinal ramus Guidance: fluoroscopy Electrode location confirmation: 	• Yes (medial branch block)	 <u>Clinical</u> <u>assessment:</u> Continuous LBP with/without radiation into upper leg; focal tenderness over the facet joints; pain on hyperextension <u>Radiologic</u> <u>assessment:</u> none <u>Diagnostic blocks:</u> Medial branch blocks with using 0.3mL of 	 Inclusion: > 17 years The following symptoms for > 6 months: Continuous low back pain with or without radiating into the upper leg, with focal tenderness over the facet joints Pain on hyperextension No finding of obvious neurologic defect No indication for low back surgery 	 Follow-up: 6 hours 100% (60/60), 6 months 100% (60/60), 1 year 100% (60/60) <u>Outcomes reported:</u> <u>Pain:</u> Visual Analogue Pain Scale (VAS) (0-NR scale) <u>Function:</u> Oswestry Disability Index (ODI) (0- NR scale) Adverse events (4-pt scale; 3: excellent, 0: bad) Reduction in analgesic usage Patients' satisfaction (0-

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		<u>denervation</u> • n = 20 • Age (mean): 60.5 years ± 8.5 • Male: 45.0%	first by sensory stimulation at 50Hz and motor stimulation up to 1V (Impedance was verified at 300 to 7000 to confirm proper electrode placement) • Neurotomy: Single lesion created using a 10-mm active tip electrode at 80°C for 90 seconds. • Anesthetic injected?: Yes, 1% lidocaine • Post RF denervation injection of steroids or anesthetic performed: NR <u>Pulse FJRF</u> denervation (n = <u>20)</u> • Number of		lidocaine 2%.at L1-L3 or L3-L5 (required pain reduction ≥50%)	 No radicular syndrome Unresponsiveness to traditional conservative treatments, such as bed rest, medication, physical therapy, trigger point injection, and epidural block Patients experiencing a positive response to a diagnostic medial branch block (positive if pain score reduction reported by the patient was greater than 50% on VAS and the duration of effect coincided with the expected duration of the local anesthetic used) Inclusion range: NR 	3, 0 = bad, 3 = excellent)

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			 levels: NR Treated levels: L1-L3 or L3-L5 Neurotomy target: medial branch of the dorsal spinal ramus Guidance: fluoroscopy Electrode location confirmation: first by sensory stimulation at 50Hz and motor stimulation up to 1V (Impedance was verified at 300 to 7000 to confirm proper electrode placement) Neurotomy: 2 Hz PRF waves were applied for 4 minutes (45 V), with the end point being an electrode tip temperature 42°C. 			 Exclusion: Prior RF treatment Coagulation disturbances Allergies to radiopaque contrast media or local anesthetics Malignancy Mental handicap or psychiatric condition precluding adequate communication Language problems Pregnancy 	

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			 Anesthetic injected?:_Yes, 1% lidocaine Post RF denervation injection of steroids or anesthetic performed: NR <u>Post-procedure:</u> NR 				
Thoracolumb	ar		1		1		-1
Joo (2013) Korea		 N = 40 Age (mean): 68.3 years Male: 42.5% 	• N = 40 <u>Radiofrequency</u>	Yes (radiofrequen cy medial branch block)	<u>Clinical</u> <u>assessment:</u> patients were considered to	 Inclusion: Recurrent thoracolumbar facet joint pain 	Follow-up: 1 week, 1, 6, 9, 12, 18, 21, 24 months: % f/u NR
<u>Funding: NR</u>		 Male: 42.3% <u>Radiofrequency</u> <u>ablation (RFA)</u> <u>denervation</u> n = 20 Age (mean): 67.8 years ± 18.2 Male: 45% Initial Duration of Pain: 10.4 months (6.3 – 13.3) 	 <u>ablation (RFA)</u> <u>denervation (n =</u> <u>20)</u> Number of levels: NR Treated levels: NR Neurotomy target: medial branch of the posterior ramus Guidance: fluoroscopy Electrode location 		 have recurrent thoracolumbar facet joint pain after successful thermal RFA when the NRS score was ≥7 and the revised ODI was ≥22 %. <u>Radiologic</u> <u>assessment:</u> none 	Exclusion: • NR	 <u>Outcomes reported:</u> <u>Pain: Recurrence-free</u> <u>ration (%) (</u>Based off of NRS < 7, and ODI < 22%) Numeric Rating Scale (NRS) (0-10 scale; 10 = max pain) <u>Function:</u> Oswestry (ODI) Low Back Pain and Disability Questionnaire <u>Patient satisfaction</u>: NR Adverse Effects

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
		Alcohol Ablation (AA) denervation • n = 20 • Age (mean): 68.7 years ± 15.5 • Male: 40% • Initial Duration of Pain: 10.7 months (6.3 – 12.7)	 confirmation: 0.2 mL of iopamidol was injected to verify proper placement of the nonvascular needle Impedance was verified at 300– 700 v; sensory stimulation (50 Hz) and motor stimulation up to 1 V was applied to observe contractions of the leg Neurotomy: Single lesion created using a 10-mm active tip electrode at 80°C for 90 seconds. Anesthetic injected?:_Yes, intravenous: 30 mg ketorolac; skin injections, 0.5mL 1% 		 Diaqnostic blocks: Recurrent thoracolumbar facet joint syndrome was diagnosed by controlled comparative local anesthetic blocks using lidocaine and bupivacaine after initial successful RF medial branch neurotomy. Initial successful RFA was defined as ≥50 % relief of the targeted pain lasting for more than 6 months after RFA and sufficient patient satisfaction with the result of the prior RFA to have it performed again when the benefits dissipated 		

Investigator (year)							Follow-up Duration (% followed)
Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Outcomes Reported
			lidocaine				
			Post RF				
			denervation				
			injection of				
			steroids or				
			anesthetic				
			performed: NR				
			Alcohol Ablation				
			(AA) denervation				
			<u>(n = 20)</u>				
			Number of				
			levels: NR				
			• Treated levels:				
			NR				
			 Neurotomy 				
			target: medial				
			branch of the				
			posterior ramus				
			Guidance:				
			fluoroscopy Needle location 				
			 Needle location confirmation: 				
			0.2 mL of				
			iopamidol was				
			injected to verify				
			proper				
			placement of				
			the nonvascular				
			needle				
			Impedance was				
			verified at 300-				

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			700 ʊ; sensory stimulation (50 Hz) and motor stimulation up to 1 V was applied to observe contractions of the leg Needle placement was ensured from				
			the anteroposterior viewpoint before the injection of contrast				
			medium was monitored from the lateral viewpoint.				
			 Neurotomy: Contrast medium with a 1-ml Syringe was injected (volume of contrast medium was carefully measured and 				

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			recorded to prevent leakage into the posterior epidural surface) the volume of the dehydrated alcohol injection should be no more than the volume of contrast medium injected. Next, the same volume of 1 % lidocaine was injected as used for the alcohol injection. Determined alcohol volume was slowly injected over 15 seconds • Anesthetic injected?:_Yes, intravenous: 30 mg ketorolac; skin injections, 0.5 mL 1% lidocaine				

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			 Post RF denervation injection of steroids or anesthetic performed: NR 				
			<u>Post-procedure:</u> NR				

AA: alcohol ablation; CRF: continuous radiofrequency thermocoagulation; LoE: level of evidence; NR: not reported; NRS: numeric rating system ODI: Oswestry disability index; PRF: pulsed radiofrequency denervation; RCT: randomized control trial; RFA: radiofrequency ablation; RFN: radiofrequency nervation;; VAS: visual analog scale;

KQ2a Results

Investigator (year)	Study Design LoE	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Include work)	Complications & Adverse Events
Conventional	versus P	ulsed RF Neurotomy	,				
Kroll (2007)	RCT	• N = 50	<u>VAS (0-NR)</u>	<u>ODI (0-NR)</u>	NR	NR	Adverse events (Not defined)
	LOE:	 Pulsed RF denervation (PRF) (n = 13) 	Baseline • PRF: 63.5 ± 18.3 • CRF: 76.2 ± 16.0 • P = NR	Baseline • PRF: 44.9 ± 10.4 • CRF: 52.0 ± 17.3 • <i>P</i> = NR			 PRF: 0% (0/13) CRF: 0% (0/13) P = NR
		 conventional radiofrequency denervation (CRF) (n = 13) 	3 months post procedure • PRF: 51.2 ± 21.5 • P = 0.21 (baseline vs. 3 months)	$\frac{3 \text{ months post}}{\text{procedure}}$ • PRF: 42.2 ± 19.0 • P = 0.61 (baseline vs. 3 months)			
		 Follow-up: 3 months: 26/50 (52%) 	 CRF: 51.9 ± 27.4 <i>P</i> = 0.02 (baseline vs. 3 months) 	 CRF: 41.7 ± 16.9 P = 0.03 (baseline vs. 3 months) 			
		 Procedure Site Unilateral: NR Bilateral: NR 	 Improvement: PRF: 10.6% (NR/NR) (SD: 45.0) CRF: 24.7% (NR/NR) (SD: 50.1) P = 0.46 (PRF vs. CRF) 	Improvement: • PRF: 4.1% (NR/NR) (SD: 44.3) • CRF: 18.3% (NR/NR) (SD: 30.7) • P = 0.35 (PRF vs. CRF)			
Tekin (2007)	RCT	 N = 60 Pulsed RF denervation 	VAS (Back Pain) (0 – NR) Baseline.	ODI (0 – NR) <u>Baseline.</u> • PRF: 39.4 ± 5.0 • CRF: 39.2 ± 3.5	Patient Satisfaction (0-3, 0 = bad, 3 = excellent) (4-pt scale:	Analgesic use (% pts using analgesics at 1 year) • PRF: 75%	Adverse events (Not defined) • PRF: 0% (0/20) • CRF: 0% (0/20)
		(PRF) (n = 20) • Conventional	 PRF: 6.6 ± 1.6 CRF: 6.5 ± 1.5 	• SHAM: 40.1 ± 2.8	PRF • Excellent:	(15/20) • CRF: 40%	• SHAM: 0% (0/20)

Investigator D	Study Design LOE	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Include work)	Complications & Adverse Events
		radiofrequency denervation (CRF) (n = 20) • Sham Neurotomy (SHAM) (n = 20) • Follow-up: 6 hours (100%), 6 months (100%), 1 year (100%) • Procedure Site Unilateral: NR Bilateral: NR	• SHAM: 6.8 ± 1.6 • $P = \text{See Below}$ Postprocedure • PRF: 2.8 ± 1.5 • CRF: 2.3 ± 1.4 • SHAM: 4.3 ± 1.0 • $P = \text{See Below}$ 6 months • PRF: 2.9 ± 1.6 • CRF: 2.3 ± 1.3 • SHAM: 3.1 ± 0.8 • $P = \text{See Below}$ 1 year • PRF: 3.5 ± 1.3 • CRF: 2.4 ± 1.1 • SHAM: 3.9 ± 1.2 • $P = \text{See Below}$ "(SHAM =PRF; PRF=CRF; CRF < SHAM, P<0.001, repeated measures analysis, post hoc test Tukey honest significant difference.) <u>Pre-procedure:</u> SHAM =PRF=CRF <u>Postprocedure:</u> SHAM =PRF=CRF, P<0.001; 6mo, SHAM =PRF>CRF, P<0.05; 1 y, SHAM =PRF>CRF,	• $P = \text{See Below}$ Postprocedure • PRF: 24.4 ± 5.7 • CRF: 25.6 ± 6.5 • SHAM: 30.5 ± 5.7 • $P = \text{See Below}$ 6 months • PRF: 25.3 ± 6.9 • CRF: 25.1 ± 6.4 • SHAM: 28.9 ± 5.7 • $P = \text{See Below}$ 1 year • PRF: 28.5 ± 6.1 • CRF: 28.0 ± 7.1 • SHAM: 33.6 ± 5.7 • $P = \text{See Below}$ "ODI postprocedure, 6mo and 1 y compared < preprocedure in all groups (P<0.001, paired t test). SHAM >PRF>CRF, P<0.001, Preprocedure, SHAM =PRF=CRF. Postprocedure, SHAM >PRF=CRF, P<0.001. 6mo, SHAM =PRF, PRF=CRF, CRF< SHAM, P<0.05. 1 y,	(35 (7/20) • Good: 50% (10/20) • Moderate: 15% (3/20) • Bad: 0% (0/20) CRF • Excellent: 65% (13/20) • Good: 30% (6/20) • Moderate: 5% (1/20) • Bad: 0% (0/20) SHAM • Excellent: 20% (4/20) • Good: 50% (10/20) • Moderate: 25% (5/20) • Bad: 5% (1/20) • Moderate: 25% (5/20) • Bad: 5% (1/20) • CRF, PRF > SHAM (P = 0.03) CRF > SHAM,	(8/20) • SHAM: 95% (19/20) • <i>P</i> = NR	• <i>P</i> = NR

Investigator (year)	Study Design LoE	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Include work)	Complications & Adverse Events
			P<0.05."	SHAM >PRF>CRF, P<0.05."	PRF (<i>P</i> = 0.004)"		
RF Neurotom	y versus A	Alcohol Ablation					
Joo (2013)	RCT LOE:	 N = 40 Radiofrequency ablation denervation (RFA) (n = 20) Alcohol Ablation (AA) denervation (n = 20) Follow-up: 1 week, 1, 6, 9, 12, 18, 21, 24 months: 18/40 (45%) 1st Procedure Site: Unilateral: RFA: n = 3 AA: n = 4 Bilateral: RFA: n = 17 AA: n = 16 	Recurrence-free ratio (%) (Based off of NRS <	NR	NR	NR	 Pain in deep soft tissue of the injection site (subsided in 24 hours): RFA: (25%) 5/20 (aching and shooting pain) AA: (35%) 7/20 (burning and dysesthesia pain)

Investigator (year)	Study Design LoE	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Include work)	Complications & Adverse Events
			• $P = NR$ 12 months • RFA: 25% (5/20) • AA: 100% (20/20) • $P < 0.001$ 15 months • RFA: 10% (2/20) • AA: 100% (20/20) • $P < 0.001$ 18 months • RFA: 5% (1/20) • AA: 90% (18/20) • $P < 0.001$ 21 months • RFA: 5% (1/20) • AA: 85% (17/20) • $P < 0.001$ 24 months • RFA: 5 (1/20) • AA: 85 (17/20) • AA: 85 (17/20) • $P < 0.001$				

AA: alcohol ablation; CRF: continuous radiofrequency thermocoagulation; LoE: level of evidence; NR: not reported; ODI: Oswestry disability index; PRF: pulsed radiofrequency denervation; RFA: radiofrequency ablation; RFN: radiofrequency nervation; NRS: numeric rating system; VAS: visual analog scale

*Follow-up rate after outcome measurement

KQ2b Demographics

Investigator (year) Country, Funding Lumbar	Study Design	Patient Demographics	Intervention(s)	Used Diagnostic Block?	Required Primary Procedure Success?	Inclusion/Exclusion Criteria	Follow-up Duration (% followed)
Joo (2013) Japan <u>Funding:</u> None	Case series (for the purposes of evaluative repeat neurotomy)	 N = 40 Age (mean): 68.3 years Male: 42.5% Initial duration of pain relief: 10.6 years Previous fusion surgery (mean): 5.5 <u>Repeated</u> <u>Radiofrequency</u> <u>ablation (RFA)</u> n = 20 Age (mean): 67.8 ± 18.2 years Male: 45% Initial duration of pain relief: 10.4 (6.3 – 13.3) Previous fusion surgery: 25% 	 Procedure Site Unilateral: 7/40 Bilateral: 33/40 Both Procedures Skin at the treatment site was sterilized, 30 mg of ketorolac was injected intravenously before the ablative procedures were performed. At least two medial branches of each joint were ablated. If the T3–T4 facet joint was suspected to be involved, medial branch ablations were carried out at T2 and T3 levels Neurotomy target: medial branch of the posterior ramus Guidance: 	• Yes	Yes	Inclusion: • Recurrent thoracolumbar facet joint syndrome were diagnosed by controlled comparative local anesthetic blocks using lidocaine and bupivacaine after initial successful* Radiofrequency medial branch neurotomy Exclusion: • NR *"Successful neurotomy was defined as ≥50% relief of the targeted pain lasting for more than 6 months after neurotomy and sufficient patient satisfaction with the result of the prior neurotomy to have it performed again when the benefits dissipated"	 Follow-up: 1 week and 1, 6, 9, 12, 15, 18, 21, and 24 months; % f/u NR <u>RFN1:</u> N = 20 <u>RFN2:</u> N = 20

Investigator (year)				Used	Required Primary		
Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Procedure Success?	Inclusion/Exclusion Criteria	Follow-up Duration (% followed)
		(5/20)	 fluoroscopy Electrode location confirmation: Sensory stimulation (50 Hz) reproduced the patients' pain at less than 0.5 V. Motor stimulation up to 1 V was applied to observe contractions of the leg Neurotomy: 10-mm exposed tip was placed parallel to the targeted nerves along the expected course of the nerve at the base of the transverse process. Anesthetic injected?: yes Time between procedures: NR Repeated Radiofrequency ablation (RFA) (n = 20) Procedure Site Unilateral: 3/20 Bilateral: 17/20 				

Investigator (year)				Used	Required Primary		
Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Procedure Success?	Inclusion/Exclusion Criteria	Follow-up Duration (% followed)
			 medial branch of the posterior ramus Electrode location confirmation: See above Neurotomy: Lesioning was performed at 90 °C for 90 s (after the injection of 0.5 ml of 1 % lidocaine) Anesthetic injected?: 0.2 ml of iopamidol Time between procedures: NR Alcohol ablation (AA) (n = 20) Procedure Site Unilateral: 16/20 Neurotomy target: medial branch of the posterior ramus Electrode location confirmation: See above Neurotomy: The injected volume of contrast medium was carefully 				

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Used Diagnostic Block?	Required Primary Procedure Success?	Inclusion/Exclusion Criteria	Follow-up Duration (% followed)
Rambaransingh (2010)	Case series	• N = 84 • Age (mean): NR	 measured and recorded. The same volume of 1 % lidocaine was injected as used for the alcohol injection. The determined alcohol volume was injected over 15 s to avoid unwanted spread Anesthetic injected?: NR Time between procedures: NR Procedure Site (total) Unilateral: NR Bilateral: NR 	• NR	Yes	Inclusion: • Received repeat RFN (patient reported >3	Follow-up: • % followed NR
Canada <u>Funding:</u> None		 Male: NR Previous surgery cervical: NR During of prior back pain (mean): NR 	 Neurotomy target: medial branch of the posterior ramus Guidance: NR Electrode location confirmation: NR Neurotomy: NR Anesthetic injected?: NR Time between procedures: NR 			 points on visual analog scale), the index pain recurred and the patient was sufficiently satisfied with the previous RFN <u>Exclusion</u>: NR 	<u>RFN1:</u> n = 64 (8.9 ± 6.1 weeks) <u>RFN2:</u> n = 64 (7.8 ± 3.0 weeks) <u>RFN3:</u> n = 32 (8.0 ± 3.1 weeks)

(2004) • Age (mean): 48 (26 - 63) • Unilateral: 50% (10/20) • ≥50% reduction in the target pain after the initial RFN after after exercised United States • Bilateral: 50% • Bilateral: 50% f/u Years • Bilateral: 50% • Eventual dissipation of the relief • RFI Funding: None • Previous surgery • Neurotomy target: • Sufficient patient • RFI	Follow-up Duration (% followed)
 Indexeduce 2. Indexedu	e $f/u NR$) n of $\frac{RFN1:}{RFN2:} N = 20$ $\frac{RFN2:}{N} = 20$ $\frac{RFN3:}{N} = 16$ $\frac{RFN4:}{N} = 8$ ed tan ve hat ns

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Used Diagnostic Block?	Required Primary Procedure Success?	Inclusion/Exclusion Criteria	Follow-up Duration (% followed)
Son (2010) Korea <u>Funding:</u> NR	Case Series	 N = 60 Age (mean): 52.4 (26 - 83) years Male: 20.0% Previous surgery lumbar: 20% (12/60) March 2006 - February 2009 Total Patient Neurotomy: Procedure 2: 55 Procedure 3: 5 	 N = 60 Treated levels: NR Unilateral: 63% (38/60) Bilateral: 37% (22/60) Neurotomy target: medial branch of the posterior primary ramus Guidance: fluoroscopy Electrode location confirmation: first by sensory stimulation at 50Hz (threshold 0.3 V – 0.9 V) and motor stimulation at 2Hz (Threshold 1.5 x sensory) Neurotomy: Multiple lesion created using a 5- mm active tip electrode at 80°C for 60 - 90 seconds. Anesthetic injected?: NR "Several patients required a small dose of local 	• Yes (two, medial branch block)	Yes	 Inclusion: Consecutive patients with successful primary neurotomy (≥ 50% pain relief) who underwent repeated procedures due to pain recurrence Low back and buttock pain over 6 months of duration Absence of neurological deficits, Pseudoradicular pain down to posterior thigh above the knee Tenderness on paravertebral area corresponding to zygapophyseal joins More than 50% of pain relief from at least two diagnostic nerve blocks on medial branches of posterior primary ramus. Exclusion: Coagulopathy, infection and compensation related to industrial or traffic accident. Patients who had below 50% relief of pain after 	 Follow-up: NR <u>RFN1:</u> N = 60 <u>RFN2:</u> N = 55 <u>RFN3:</u> N = 5

Investigator (year) Country,	Study	Patient		Used Diagnostic	Required Primary Procedure	Inclusion/Exclusion	Follow-up Duration
Funding	Design	Demographics	Intervention(s)	Block?	Success?	Criteria	(% followed)
			 anesthetic before final lesioning due to intolerability of pain" Time between procedures: NR "Previously, all patients had tried medication, physical therapy and other forms of treatments without satisfactory pain relief" 			initial RF medial branch neurotomy	
Speldewinde (2011)	Case Series	 N = 180 Age (range): NR 	<u>Procedure Site</u>Unilateral: NRBilateral: NR	• Yes, 3	Yes	 Inclusion: Positive response to diagnostic block 	 <u>Follow-up</u>: 3 – 36 mos., % f/u NR <u>RFN1</u>: N = 180
Australia		Male: NRDuration of				(undefined)	<u>Repeat procedures</u> following successful first
<u>Funding:</u> None		 Duration of pain: NR • 	If and when pain recurred patients were eligible for repeat treatment.			Exclusion: • NR	neurotomy: total N NR, but there were 39 procedures done
			 Neurotomy target: third occipital nerve, medial branch nerve, lateral branch nerves Guidance: fluoroscopy 				
			Electrode location				

Investigator (year) Country,	Study	Patient		Used Diagnostic	Required Primary Procedure	Inclusion/Exclusion	Follow-up Duration
Funding	Design	Demographics	Intervention(s)	Block?	Success?	Criteria	(% followed)
			confirmation: NR				
			Neurotomy: a 10				
			mm tip were used				
			for the cervical, thoracic and				
			sacroiliac regions,				
			and 10 mm tips				
			were used for the				
			lumbar region. In				
			each region, a				
			minimum of three				
			contiguous "burns"				
			to each target nerve				
			(third occipital				
			nerve, medial				
			branch nerve,				
			lateral branch				
			nerves) were applied at 80°C for				
			90 seconds each.				
			(For the second				
			cohort, during the				
			final two years (185				
			patients), the				
			technique was				
			modified to use 18				
			gauge needle with				
			shorter durations of				
			thermal coagulation				
			(60 seconds) but still				
			at 80°C)				
			Anesthetic				

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Used Diagnostic Block?	Required Primary Procedure Success?	Inclusion/Exclusion Criteria	Follow-up Duration (% followed)
			injected?: NRTime between procedures: NR				
Zotti 2010 Australia <u>Funding:</u> None	Prospective Cohort CoE: III	 N = 65 Age (median): 47 years Male: 42% Symptom duration: NR <u>Total Patient</u> <u>Neurotomy:</u> Procedure 2: 47% (29/62) Procedure 3: 32% (20/62) Procedure 4: 21% (13/62) 	 N = 65 <u>Radiofrequency facet</u> joint denervation (n = 24) Neurotomy target: medial branch nerve Guidance: fluoroscopy Electrode location confirmation: NR Neurotomy: 20-gauge silicone- coated probe was inserted for 90 seconds per joint at a temperature of 90°C Anesthetic injected?: "neuroleptic intravenous sedation" Post RF denervation injection of steroids or anesthetic performed: NR 	yes	yes	 Inclusion: Patients who had undergone a successful primary procedure Previously undergone a successful diagnostic medial branch blockade (success being defined as >50 percent subjective pain relief post-intervention with the former defined by the patient as being satisfied that the procedure was useful for them) Exclusion: Patients who had other invasive or manipulative spinal procedures performed during the period of the study Patients, who following the repeat RFJD procedure, would have had more than four procedures. 	<u>Follow-up:</u> 12 months; (95% f/u) • <u>RFN1</u> : N = 62 • <u>RFN2, 3, or 4</u> : N = 62

Investigator (year) Country, Funding Cervical	Study Design	Patient Demographics	Intervention(s)	Used Diagnostic Block?	Required Primary Procedure Success?	Inclusion/Exclusion Criteria	Follow-up Duration (% followed)
Husted (2009) United States <u>Funding</u> : NR	Cohort study CoE: III	 N = 22 Age (mean): 47 (34 – 66) years Male: 36.0% Previous surgery cervical: 0% (0/20) Total Patient Neurotomy: Procedure 1: 100% (22/22) Procedure 2: 95% (21/22) Procedure 3: 50% (11/22) Procedure 4: 18% (4/22) Procedure 5: 9% (2/22) Procedure 5: 9% (2/22) Procedure 5: 9% (2/22) Procedure 5: 9% (2/22) Procedure 5: 5% (1/22) Procedure 7: 5% (1/22) 1998–2006 	 N = 22 Treated levels: C3-C8 Procedure Site Unilateral: NR ("not predictive of outcome") Bilateral: NR ("not predictive of outcome") Neurotomy target: medial branch of the posterior ramus Guidance: fluoroscopy Electrode location confirmation: NR Neurotomy: a single lesion was created using a 10-mm exposed tip electrode at 80°C for 70 seconds. Anesthetic injected?: yes, NR Time between procedures: NR 	• Yes	• Yes	 Inclusion: Greater than 50% reduction in the target pain after the initial RFN Return of pain, and sufficient patient satisfaction with the initial RFN to have it repeated when pain recurred. At least 1 repeat RFN was performed Exclusion: Patients who had other types of cervical injections were. Patient who had cervical spine surgery during the study 	 Follow-up: 3 – 30 months Procedure 1: 100% (22/22) Procedure 2: 86% (18/21) Procedure 3: 73% (8/11) Procedure 4: 100% (4/4) Procedure 5: 100% (2/2) Procedure 6: 50% (1/2) Procedure 7: 0% (0/7) Pain: "Successful subjective pain relief" ≥ 50%) Function/Disability: NR Patient satisfaction: patient had to be sufficiently satisfied with the results of the prior RFN to have it performed again

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Used Diagnostic Block?	Required Primary Procedure Success?	Inclusion/Exclusion Criteria	Follow-up Duration (% followed)
Rambaransingh (2010) Canada <u>Funding:</u> None	Cohort Study	 N = 20 Age (mean):NR Male: NR Previous surgery cervical: NR During of prior back pain (mean):NR 	 Procedure Site (total) Unilateral: NR Bilateral: NR Neurotomy target: medial branch of the posterior ramus Guidance: NR Electrode location confirmation: NR Neurotomy: NR Anesthetic injected?: NR Time between procedures: NR 	NR	Yes	 Inclusion: Received repeat RFN (patient reported >3 points on visual analog scale), the index pain recurred and the patient was sufficiently satisfied with the previous RFN Exclusion: NR 	 Follow-up: % followed NR Procedure 2: 8.9 ± 6.1 weeks Procedure 3: 7.8 ± 3.0 weeks Procedure 4: 8.0 ± 3.1 weeks Pain: % pain relief achieved Function/Disability: NR Patient satisfaction: NR
Speldewinde (2011) Australia <u>Funding:</u> None	Case Series	 N = 151 Age (range): NR Male: NR Duration of pain: NR 	 <u>Procedure Site</u> Unilateral: NR Bilateral: NR If and when pain recurred patients were eligible for repeat treatment. Neurotomy target: third occipital nerve, medial branch nerve, lateral branch nerves 	Yes, 3	Yes	 <u>Inclusion</u>: Positive response to diagnostic block (undefined) <u>Exclusion</u>: NR 	 <u>Follow-up</u>: 3 – 36 mos., % f/u NR <u>RFN1</u>: N = 180 <u>Repeat procedures</u> following successful first neurotomy: total N NR, but there were 40 procedures done

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Used Diagnostic Block?	Required Primary Procedure Success?	Inclusion/Exclusion Criteria	Follow-up Duration (% followed)
			 Guidance: fluoroscopy Electrode location confirmation: NR Neurotomy: a 10 mm tip were used for the cervical, thoracic and sacroiliac regions, and 10 mm tips were used for the lumbar region. In each region, a minimum of three contiguous "burns" to each target nerve (third occipital nerve, medial branch nerve, lateral branch nerves) were applied at 80°C for 90 seconds each. (For the second cohort, during the final two years (185 patients), the technique was modified to use 18 gauge needle with shorter durations of thermal coagulation 				

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Used Diagnostic Block?	Required Primary Procedure Success?	Inclusion/Exclusion Criteria	Follow-up Duration (% followed)
			 (60 seconds) but still at 80°C) Anesthetic injected?: NR Time between procedures: NR 				

LBP: lower back pain; LFJ: lumbar facet joint; FJI: facet joint injection; FJRF: facet join radiofrequency; (NASS): North American Spine Society patient satisfaction questionnaire; (Euro-Qol in 5 dimensions) EQ-5D; VAS: visual analog scale; VNS: Visual Numeric Pain Scale; RMQ: Roland-Morris Questionnaire; ODI: Oswestry Disability Index; CI: Confidence Interval; ROM: range of motion: ROM: range of motion; NSAID: nonsteroidal anti-inflammatory drug

KQ2b Results

Investigator (year)	Study Design	N	Pain	Function	Patient Satisfaction	Disability & medication use (Include work)	Complications & Adverse Events
Lumbar Joo (2013)	Case series	 N = 40 <u>Repeated</u> <u>Radiofrequency</u> <u>ablation (RFA) (n</u> <u>= 20)</u> <u>Alcohol ablation</u> (AA) (n = 20) 	Recurrence Ratio (NRS score ≥7 and ODI of ≥22 %: Median effective period: • RFA: 10.7 months (5.4–24) • AA: 24 months (16.8–24 • $P < 0.001$ Baseline • RFA: 100% (20/20) • AA: 20% (20/20) • AA: 100% (20/20) • AA: 100% (20/20) • AA: 100% (20/20) • P = NR 3 months • RFA: 100% (20/20) • AA: 100% (20/20) • P = NR 6 months • RFA: 95% (19/20) • AA: 100% (20/20) • P = NR 9 months • RFA: 85% (17/20) • AA: 100% (20/20)	NR	NR	NR	 Pain in deep soft tissue of the injection site (subsided in 24 hours): RFA: (25%) 5/20 (aching and shooting pain) AA: (35%) 7/20 (burning and dysesthesia pain)

Investigator (year)	Study Design	N	Pain	Function	Patient Satisfaction	Disability & medication use (Include work)	Complications & Adverse Events
			12 months • RFA: 25% (5/20) • AA: 100% (20/20) • $P < 0.001$ 15 months • RFA: 10% (2/20) • AA: 100% (20/20) • AA: 100% (20/20) • $P < 0.001$ 18 months • RFA: 5% (1/20) • AA: 90% (18/20) • $P < 0.001$ 21 months • RFA: 5% (1/20) • AA: 85% (17/20) • $P < 0.001$ 24 months • RFA: 5% (1/20) • AA: 85% (17/20) • $P < 0.001$				
Rambaransingh (Lumbar) (2010)	Case series	• N = 84	Lumbar RFN % pain intensity improvement Procedure 1 • 0-24%: 14% (9/62) • 25-49%: 31% (19/62) • 50-74%: 37% (23/62) • 75-100%: 18%	NR	NR	NR	 Permanent complications" (not defined): NR "Major complications" (not defined): NR Motor weakness: NR Sensory changes: NR

Investigator (year)	Study Design	N	Pain	Function	Patient Satisfaction	Disability & medication use (Include work)	Complications & Adverse Events
			$(11/62)$ • $P = NR$ $\frac{Procedure 2}{• 0-24\%: 27\% (17/62)}$ • 25-49%: 18% (11/62) • 50-74\%: 39% (24/62) • 75-100%: 16% (10/62) • $P = NR$ $\frac{Procedure 3}{• 0-24\%: 14\% (4/29)}$ • 25-49%: 35% (10/29) • 50-74\%: 41% (12/29) • 75-100%: 10% (3/29) • $P = NR$				
Schofferman (2004)	Case series	• N = 20	<pre> <u>"Success": pain relief</u> <u>> 50% Primary Procedure Follow up: NR Success: 100% (20/20) Failure: 0% (0/20) Mean duration of pain relief: NR</u></pre>	NR	NR	NR	 Permanent complications" (not defined): NR "Major complications" (not defined): NR Motor weakness: NR Sensory changes: NR

Investigator (year)	Study Design	N	Pain	Function	Patient Satisfaction	Disability & medication use (Include work)	Complications & Adverse Events
			Procedure 2 <u>Immediately after</u> procedure • Success: 85% (17/20) • Failure: 15% (0/20) • Mean duration of pain relief: 11.6 (6 – 19) months; 85% (17/20) • <u>Continued relief</u> <u>(time: NR)</u> : 5% (1/20)				
			Procedure 3 <u>Immediately after</u> procedure • Success: 94 (15/16) • Failure: 6% (1/16) • Mean duration of pain relief: 11.2 (5 – 23) months; 26% (9/16) • <u>Continued relief</u> <u>(time: NR)</u> : 30% (6/16)				
			Repeat Procedure 4 Immediately after procedure • Success: 7/8 (88%)				

Investigator (year)	Study Design	N	Pain	Function	Patient Satisfaction	Disability & medication use (Include work)	Complications & Adverse Events
			 Failure: 1/8 (12%) Mean duration of pain relief: 11.2 (5 – 23) months (3/8; 38%) <u>Continued relief (time: NR)</u>: 4/8 (50%) 				
Son (2010)	Case series	• N = 60	<pre>"Success": pain relief ≥ 50% Primary Procedure Immediately after procedure • Success: 85% (51/60) • Failure: 15% (9/60) • Mean duration of pain relief: 10.9 (3 – 28) months • P = NR "Success" as compared with first neurotomy (details NR)</pre>		NR	NR	 Permanent complications" (not defined): 0% (0/60) "Major complications" (not defined): 0% (0/60) Transient worsening of pain on back/buttock areas, as well as paresthesia for several days: 10% (6/60) (3 from repeat procedure #1, 3 from additional repeat procedures) Motor weakness: 0% (0/60) Sensory changes: 0% (0/60)
			Procedure 2 Immediately after procedure • Success: 91% (50/55)				

Investigator (year)	Study Design	N	Pain	Function	Patient Satisfaction	Disability & medication use (Include work)	Complications & Adverse Events
			 Failure: 9% (5/55) Mean duration of pain relief: 10.2 (3 – 24) months <i>P</i> = NR 				
			 Procedure 3 Immediately after procedure Success: 80% (4/5) Failure: 20% (1/5) Mean duration of pain relief: 9.8 (5 – 16) months P = NR 				
Speldewinde (2011)	Case Series	• N = 282	Success and Failure in Repeat Treatments; (Successful = at least 50% reduction of pain, for at least 2 months, in the region relevant to the joint or joints treated; Failure = less than 50%)	NR	NR	NR	• NR
			Repeats Cervical: 47 (n = 26) Lumbar: 44 (n = 33) Initial neurotomy was a success, repeat neurotomy was a				

Investigator (year)	Study Design	N	Pain	Function	Patient Satisfaction	Disability & medication use (Include work)	Complications & Adverse Events
			 success Cervical: 72% (34/47) Lumbar: 77% (34/44) 				
			Initial neurotomy was a success, repeat neurotomy failed • Cervical: 13% 6/47 • Lumbar: 11% 5/44				
			Initial neurotomy failed, repeat neurotomy was Success • Cervical: 9% 4/47 • Lumbar: 7% 3/44				
			Initial neurotomy failed, repeat neurotomy failed • Cervical: 6% 3/47 • Lumbar: 5% 2/44				
			Duration of subsequent successes (months) • Cervical: 9.7				
Zotti 2010	Case series	• N = 65	Lumbar: 12.2 Repeat procedures (range, 2-4)	Repeat procedures	Repeat procedures (range, 2-4)	LBOS: reduced	<u>Adverse events" (not</u> defined)
			Visual Analog Pain Scale (VAS) (0-11 scale; 11 = max pain)	(range, 2-4)	(LBOS) (effects of the pain experienced upon	for pain medications (improvement)	• RFN: 0% (0/65)

Investigator (year)	Study Design	N	Pain	Function	Patient Satisfaction	Disability & medication use (Include work)	Complications & Adverse Events
			 (improvement) Repeat procedures, mean improvement: 1.21 (<i>P</i> = NR) Overall change in LBOS following repeat procedures: Pre-procedure: 2.37 Post-procedure: 3.58 <i>P</i> < 0.03 	categories: • Poor: LBOS 0-29 • Fair: LBOS 30-49 • Good: LBOS $50-64$ • Excellent: LBOS ≥ 65 Pre-Repeat radiofrequency facet joint denervation • Poor: 69% (43/62) • Fair:26% (16/62) • Good: 5% (3/62) • Excellent: 0% (0/62) • P < 0.01 <u>Post-Repeat</u> radiofrequency facet joint denervation • Poor: 42% (26/62) • Fair: 45% (28/42)	activities of daily living, function, need for treatment, and pain levels in the way of a visual analog scale [VAS]) Baseline • Pre-procedure: 28.45 • Post-procedure: 33.75 • <i>P</i> < 0.01 • "Patients with the impression that the repeat procedure was as helpful as the previous successful procedures": 69.3% General LBOS Improvements: • Sleeping: 0.31 (<i>P</i> < 0.02) • Sitting: 0.4 (<i>P</i> < 0.02) • Traveling: 0.39 (<i>P</i> < 0.02) • Getting Dressed: 0.3 (<i>P</i> < 0.03)	 0.2 (P < 0.03) Decreased need to seek treatment for pain 1.06 (P < 0.01) 	

Investigator (year)	Study Design	N	Pain	Function	Patient Satisfaction	Disability & medication use (Include work)	Complications & Adverse Events
				 Good: 11% (7/62) Excellent: 1% (2/62) <i>P</i> = NR 	 Sex life: 0.1 (<i>P</i> < 0.07) Household Chores: 0.17 (<i>P</i> < 0.05) Physical Activities: 0.38 (<i>P</i> < 0.04) Subjective Assessment of 		
					Duration of Pain Relief from Most Repeat Radiofrequency Facet Joint Denervation Procedure		
					Months • < 6: 24% (15/62) • 6 - 7: 16% (10/62) • 8 - 9: 40% (25/62) • 9 - 10:17% (11/62) • 11 - 12: 3% (2/62)		
					 Pain still present at 12 months: 2 (1/62) <i>P</i> = NR 		
					"Subjective Assessment of How Helpful Repeat Radiofrequency		

Investigator (year)	Study Design	N	Pain	Function	Patient Satisfaction	Disability & medication use (Include work)	Complications & Adverse Events
					Facet Joint Denervation Procedure Was Compared with Previous Successful Procedures" <u>Months</u> • Satisfied: 15% (9/62) • Neutral: 16% (10/62) • Unsatisfied: 69% (43/62)		
Cervical			I		<u> </u>	I	<u> </u>
Husted (2009)	Case series	• N = 22	<u>"Success":</u> subjective pain relief ≥ 50% and patient satisfied with prior RFN to have treatment repeated, each repeat RFN was successful if ≥ pain relief was achieved Primary Procedure <u>Immediately after</u> <u>procedure</u> • Success: 100% (22/22) • Failure: 0% (0/22)	NR	See Pain	NR	 Permanent complications" (not defined): NR "Major complications" (not defined): NR Motor weakness: NR Sensory changes: NR

Investigator (year)	Study Design	N	Pain	Function	Patient Satisfaction	Disability & medication use (Include work)	Complications & Adverse Events
			 Mean duration of pain relief: 12.5 (3 – 25) months (100% (22/22)) <u>Continued relief</u> (<u>time: 0)</u>: 0% (0/22) 				
			RFN2 Immediately after procedure • Success: 95% (20/21)* • Failure: 5% (1/21) • Mean duration of pain relief: 12.7 (3 – 30) months (86% (18/21)) • <u>Continued relief</u> (time: > 7 months): 9.5% (2/21)				
			RFN3 <u>Immediately after</u> <u>procedure</u> • Success: 91% (10/11) • Failure: 9% (1/11) • Mean duration of pain relief: 9.5 (3 – 16) months (73% (8/11) • <u>Continued relief</u> (time: > 7 months):				

Investigator (year)	Study Design	N	Pain	Function	Patient Satisfaction	Disability & medication use (Include work)	Complications & Adverse Events
	Ŭ		2/11 (18%)				
			•				
			RFN4:				
			Immediately after				
			<u>procedure</u>				
			• Success: 4/4 (100%)				
			• Failure: 0/4 (0%)				
			Mean duration of				
			pain relief: 8.8 $(4 - 12)$ months (4/4)				
			12) months (4/4; 100%)				
			<u>Continued relief</u>				
			(time: 0): 0/4 (0%)				
			<u> </u>				
			RFN5:				
			Immediately after				
			<u>procedure</u>				
			• Success: 2/2 (100%)				
			• Failure: 0/2 (0%)				
			Mean duration of				
			pain relief: 9 (7 – 11) months (2/2;				
			100%)				
			<u>Continued relief</u>				
			(time: 0): 0/2 (0%)				
			*Patient lost to				
			follow-up after 1 st				
			procedure				
Rambaransingh	Case	• N = 20	Lumbar RFN % pain	NR	NR	NR	Permanent
(Cervical) (2010)	series		intensity				complications" (not
			<u>improvement</u>				defined): NR

Investigator (year)	Study Design	N	Pain	Function	Patient Satisfaction	Disability & medication use (Include work)	Complications & Adverse Events
			Procedure 1 • 0-24%: 36% (5/14) • 25-49%: 21% (3/14) • 50-74%:14% (2/14) • 75-100%: 29% (4/14) • 0-24%: 21% (3/14) • 25-49%: 14% (2/14) • 50-74%: 36% (5/14) • 50-74%: 36% (5/14) • 75-100%: 29% (4/14) • 0-24%: 14% (1/7) • 0-24%: 14% (1/7) • 0-24%: 14% (1/7) • 0-24%: 14% (3/7) • 0-24%: 14% (3/7)				 "Major complications" (not defined): NR Motor weakness: NR Sensory changes: NR

LBP: lower back pain; LFJ: lumbar facet joint; FJI: facet joint injection; FJRF: facet join radiofrequency; (NASS): North American Spine Society patient satisfaction questionnaire; (Euro-Qol in 5 dimensions) EQ-5D; VAS: visual analog scale; VNS: Visual Numeric Pain Scale; RMQ: Roland-Morris Questionnaire; ODI: Oswestry Disability Index; CI: Confidence Interval; ROM: range of motion: ROM: range of motion; MPQ: McGill Pain Questionnaire; MBB: Medial Branch Block; RFN: Radiofrequency neurotomy; VAS visual analogue scale (pain))

KQ2c demographics

Investigator (year) Country,	Study	Patient		Diagnostic		Inclusion/	Follow-up Duration (% followed)
Funding	Design	Demographics	Intervention(s)	Block?	Diagnostic Evaluation	Exclusion Criteria	Outcomes Reported
Cervical & Lui		T	1	1			
Cervical & Lui Tzaan (2000) Canada <u>Funding:</u> NR	Prospective cohort	 N = 90 Age (mean): 43 years Male: 63.3% Total number of procedures: 118 Number of procedure repeated at same level: 23 <u>FJRF bilateral</u> denervation n = NR Total number of procedures: 33 <u>FJRF unilateral</u> denervation n = NR 	 N = 90, procedure (including repeats) n = 118 Treated levels: Cervical: n = 13 Thoracic: n = 17 lumbosacral: n = 88 Number of procedure repeated at same level: Cervical: n = 2 Thoracic: n = 2 Lumbosacral: n = 19 FJRF bilateral denervation (n = NR, procedure n = 33) (Bilateral denervation was done in patients suffering from midline pain or pain on both sides of the trunk) Treated levels: All levels: n = 33 lumbosacral: n = 18 	• Yes, (local anestheti c)	 <u>Clinical assessment</u>: Appropriate facet syndrome pain of at least six months <u>Radiologic</u> <u>assessment</u>: Plain radiography, myelography, computed tomography or magnetic resonance imaging studies were performed to exclude the possibility of pathology that was amenable to primary therapy <u>Diagnostic blocks</u>: All patients reported at least 50% reduction of their pain after 	 Inclusion: Appropriate facet syndrome pain of at least six months duration that was refractory to conservative treatment including bed rest, physical therapy, analgesics and muscle relaxants for at least six weeks. All patients reported at least 50% reduction of their pain after local anesthetic blockade of the facet joints to be denervated was performed and assessed by a radiologist, who was independent 	 <u>Follow-up:</u> 1 – 33 months (mean 5.6) (%NR) <u>Outcomes reported:</u> <u>Pain:</u> 50% reduction of their pain (successful procedures) <u>Function:</u> <u>Patient satisfaction</u>: Adverse Effects
		 Total number of procedures: 62 	 Neurotomy target: articular nerve of the medial branch of the 		local anesthetic blockade of the facet joints to be denervated was	of the surgical team • Inclusion range: October 1983 –	

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			 posterior primary ramus Guidance: fluoroscopy Electrode location confirmation: electrical stimulation was then done at 2 Hz and 100 Hz in those patients operated on under local anesthesia and at 2 Hz in those receiving general anesthesia, 100 Hz stimulation in the awake patient induced paresthesia below 2 volts, without extension beyond the proximal part of the appropriate ipsilateral limb, even with suprathreshold Stimulation at 2 Hz evoked contraction of ipsilateral paraspinal muscles below 1-2 volts, without contractions in the appropriate limb musculature, below 7 volts (signifying a safe distance between electrode tip and anterior ramus). If 		performed and assessed by a radiologist, who was independent of the surgical team	December 1994 <u>Exclusion:</u> • NR	

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			 there were unsuitable responses to stimulation, electrode position was changed and repeated until suitable responses occurred. If no response occurred, or one at an undesirably high voltage despite repeated attempts, localization was then based on radiological criteria alone, (most common at the L5-S1 segments) Neurotomy: Single lesion created using a 5-mm active tip electrode at 80°C for 90 seconds. Anesthetic injected?: yes, Before 1991, the procedures were done under local anesthesia; after that, under general anesthesia. When the procedure was performed under local anesthesia, additional sedation or anesthetic was given at the time of lesion 				

Investigator (year) Country,	Study	Patient		Diagnostic		Inclusion/	Follow-up Duration (% followed)
Funding	Design	Demographics	Intervention(s)	Block?	Diagnostic Evaluation	Exclusion Criteria	Outcomes Reported
Funding	Design	Demographics	 making Patients were usually discharged home on the day of surgery and required analgesic medication for the first five days <u>FJRF unilateral</u> denervation (n = NR, procedure n = 62) (Unilateral denervation was done in those with strictly unilateral pain.) 	Block?	Diagnostic Evaluation	Exclusion Criteria	Outcomes Reported
			 Treated levels: All levels: n = 62 lumbosacral: n = 51 Neurotomy target: 				
			articular nerve of the medial branch of the posterior primary ramus				
			 Guidance: fluoroscopy Electrode location confirmation: electrical stimulation was then done at 2 Hz and 100 				
			Hz in those patients operated on under local anesthesia and at 2 Hz in those receiving				

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Diagnostic Evaluation	Inclusion/	Follow-up Duration (% followed) Outcomes Reported
			general anesthesia, 100 Hz stimulation in the awake patient induced paresthesia below 2 volts, without extension beyond the proximal part of the appropriate ipsilateral limb, even with suprathreshold Stimulation at 2 Hz evoked contraction of ipsilateral paraspinal muscles below 1-2 volts, without contractions in the appropriate limb musculature, below 7 volts (signifying a safe distance between electrode tip and anterior ramus). If				
			there were unsuitable responses to stimulation, electrode position was changed and repeated until suitable responses occurred. If no response occurred, or one at an undesirably high voltage despite repeated attempts,				

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			 localization was then based on radiological criteria alone, (most common at the L5-S1 segments) Neurotomy: Single lesion created using a 5-mm active tip electrode at 80°C for 90 seconds. Anesthetic injected?: yes, Before 1991, the procedures were done under local anesthesia; after that, under general anesthesia. When the procedure was performed under local anesthesia, additional sedation or anesthetic was given at the time of lesion making Patients were usually discharged home on the day of surgery and required analgesic medication for the first five days *FJs were denervated from one vertebral 				

Investigator (year) Country, Funding	Study Design	Patient Demographics	Intervention(s)	Diagnostic Block?	Diagnostic Evaluation	Inclusion/ Exclusion Criteria	Follow-up Duration (% followed) Outcomes Reported
			level above to one below the patient's level of significant pain or to the level of the S1 vertebra				

FJRF: facet join radiofrequency; NR: not reported

KQ2c Results

Investigator (year)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Include work)	Complications & Adverse Events
Cervical & Lu Tzaan (2000)	Retrospective cohort	 N = 90 FJRF bilateral denervation (n = NR); (Total number of procedures: 33) FJ unilateral denervation (n = NR); (Total number of procedures: 62) Follow-up: 1 – 33 months (mean 5.6) (%NR) 	Proportion of successful procedures with complete elimination or a greater than 50% subjective reduction of pain (first or only procedure)Level• Cervical: 41% (5/11) • Thoracic: 40% (6/15) • Lumbosacral: 41% (28/69) • Total: 41% (39/95) • $p = 0.9506$ Unilateral • All Levels: 36% (12/33) • Lumbosacral: 33% (6/18)• 2-3 joints denervated: 42% (5/12) • > 3: 17% (1/6) • $p = 0.600 (2-3 \text{ vs. > 3})joints)Bilateral• All Levels: 45% (28/62)• p = 0.5427 (bilateral vs.unilateral all levels)• Lumbosacral: 45% (23/51)$	NR	NR	Comparison of results for procedures done under local and general anesthesia (first or only procedure) <u>Anesthetic method</u> • Local: 37% (14/38) • General: 46% (26/57) • <i>p</i> = 0.5246	<pre>Adverse events • Pain worse: 3% (4/118) • Transient neuropathic pain: 10% (12/118) • Transient leg pain: 1% (1/118) • Subjective leg weakness: 2% (2/118) (1 persistent: 1% (1/118) • p = NR</pre>

Investigator (year)	Study Design	Intervention(s) Follow-up (% followed)	Pain	Function	Patient Satisfaction	Disability & Medication Use (Include work)	Complications & Adverse Events
			 <i>p</i> = 0.5541 (bilateral vs. unilateral lumbosacral) 2-3 joints denervated: 35% (7/20) > 3: 52% (16/31) <i>p</i> = 0.3811 (2-3 vs. > 3 joints) Success rate of facet denervation in relieving pain in the presence and absence of aggravation by spinal extension Proportion of successful procedures Pain aggravated by extension: 39% (18/46) Pain not aggravated by extension: 47% (8/17) <i>p</i> = 0.7802 				

FJRF: facet join radiofrequency; NR: not reported

APPENDIX G. FDA-Approved Neurotomy Devices

FDA-Approved Devices (FDA 510(k) PMA*)

Manufacturer	Device Name	510(k) Number	Year of Approval	Indications for Use	Recalls?	
Radiofrequency Lesion Probe Devices (FDA 510(k) PMA)						
Baylis Medical Co. Ontario, Canada	Baylis Pain Management Probe	K002389	2000	Used to create RF lesions in nervous tissue (in conjunction with the Baylis Pain Management Connector Cable and RF Generator)	Yes – Class: NR <u>Device:</u> BMC RF Cannula Curved Sharp RadiOpaque, Non- Pyrogenic, Active Tip <u>Reason:</u> unsealed packaging	
Baylis Medical Co. Ontario, Canada	Baylis Pain Management Cooled Probe	K053082	2005	Used to create RF lesions in nervous tissue (in conjunction with a RF Generator)	Yes – Class 2 6/03/2010 <u>Device</u> : Baylis LumbarCool Pain Management Kit <u>Reason</u> : Name on packing sleeve is incorrect	
Baylis Medical Co. Ontario, Canada	Baylis Pain Management Single-Use Probe	K071745	2007	Used to create RF lesions in nervous tissue (in conjunction with a Baylis Pain Management Connector Cable and the Baylis Pain Management Generator)		
Pajunk GmbH Medizintechnologie Geisingen, Germany	Pajunk RFTL Radiofrequency Needle	K060397	2006	Used either for percutaneous nerve blocks with local anesthetic solution or for RF lesioning		
Smith & Nephew, Inc. Andover, MA, USA	Smith & Nephew RF Denervation Probes & RF Cannulae	K034012, K071300	2004	Used in RF heat lesion procedures for the relief of pain	Yes – Class 1 <u>Device:</u> Denervation Probes, 15cm, 10cm, 5cm <u>Reason:</u> Incorrectly labeled as sterile	
Stryker Instruments Kalamazoo, MI, USA	Stryker RF Electrodes and Cannulae	K032406, K043442, K123178	2004	Used for coagulation of soft tissues and selective denervation and tissue destruction procedures on spinal cord, peripheral	Yes – Class 2 <u>Device:</u> RF Cannula <u>Reason:</u> Incorrect labeling (5mm and 10mm needle and packaging switched)	

Manufacturer	Device Name	510(k) Number	Year of Approval	Indications for Use	Recalls?		
				nerves, and nerve roots for the relief of pain			
Technomed Europe The Netherlands	Radionics disposable RF Cannulae (SC-C, RFK-DB, RFK-DS)	K042375	2004	Used for percutaneous nerve blocks with local anesthetic solution or for RF lesioning	Adverse event 08/01/2002 <u>Device</u> : Radionics radio frequency generator <u>Reason</u> : loss of temperature control		
Cryo Lesion Probe Dev	Cryo Lesion Probe Devices (FDA 510(k) PMA)						
Cryomedical Instruments Itd	Spembly Lloyd Neurostat®	K050272	2005	Intended for use in blocking pain by temporarily ablating the peripheral nerves.			
Alcohol/Chemical Lesion Probe Devices (FDA 510(k) PMA)							
None identified							
Laser Lesion Probe Devices (FDA 510(k) PMA)							
None identified							

*http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?ID=3303&min_report_year=2007&manufac turer=EPIMED&pmndecision=SUBSTANTIALLY%20EQUIVALENT#EPIMED

PMA: pre-market approval; RF: radiofrequency

APPENDIX H. Clinical Peer Reviewers

Reviewer	Areas of Expertise	Reviews Received
Jason Attaman, M.D Practicing at: Swedish Hospital, Seattle, WA Overlake Hospital, Bellevue, WA Multicare Auburn Hospital, Auburn, WA Overlake Surgery Center, Bellevue, WA Seattle Surgery Center, Seattle, WA	Interventional pain management	Dr. Attaman withdrew as a peer-reviewer on December 23, 2013.
Paul Dreyfuss, M.D Practicing at: Evergreen Health, Kirkland, WA Academic positions: Clinical Professor, Department of Physical Medicine and Rehabilitation, University of Washington, Seattle, WA	 Fluoroscopically guided spine injection and radiofrequency procedures Professional Affiliations: North American Spine Society (NASS) International Spine Intervention Society (ISIS) American Academy of Physical Medicine and Rehabilitation (AAPMR) American Medical Society (AMA) Washington State Medical Society (WSMA) King County Medical Society (KCMS) Puget Sound Spine Interest Group (PSSIG) 	Peer review received.
Michael Gofeld, M.D Practicing at: St. Michael's Hospital, University of Toronto, Canada (Staff Anesthesiologist)		No review was received.

The following have agreed to provide clinical peer review:

- 1. Ofman JJ, Sullivan SD, Neumann PJ, et al. Examining the value and quality of health economic analyses: implications of utilizing the QHES. J Manag Care Pharm 2003;9:53-61.
- 2. Chiou CF, Hay JW, Wallace JF, et al. Development and validation of a grading system for the quality of cost-effectiveness studies. Med Care 2003;41:32-44.