Long-term data on hip and knee radio-frequency denervation

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Conflict of Interest:

Scientific Advisory Board: Abbott, Nevro, Saluda, SPR Therapeutics, Neuros, Halyard

Consultant: Gimer Medical, Best Doctors

Research: Stimwave, Nevro, Neuros, Halyard, SPR Therapeutics, Boston Scientific, Medtronic, Saluda

Current treatment Options for Hip/Knee Pain

- Structural repair/regenerative technologies
 - Structural replacement with cells grown on scaffolds
 - Chondrocyte injections, mesenchymal stem cells
- Analgesic augmentive or suppressive injections
 - Hyaluronic acid, steroids Not supported by AAOS.
 - PRP per Nguyen "…evidenced-based research regarding treatment with PRP is scant; the scientific literature on PRP is in its infancy, and PRP cannot be considered a standard of care until further research establishes such standards."

Neuromodification technologies

Nguyen RT, Borg-Stein J, McInnis K. Applications of platelet-rich-plasma in musculoskeletal and sports medicine: an evidence-based approach. *PM R*. 2011;3:226-250.

Vora A, Borg-Stein J, Nguyen RT. Regenerative injection therapy for osteoarthritis: fundamental concepts and evidence-based review. *PM R*. 2012;4(5 Suppl):S104-109.





Therapeutic goals

- Improve function/mobility
- Decrease pain
- Improve quality of life in patients where knee replacement not indicated
- Provide an "opioid sparring effect"





Radiofrequency denervation of the knee



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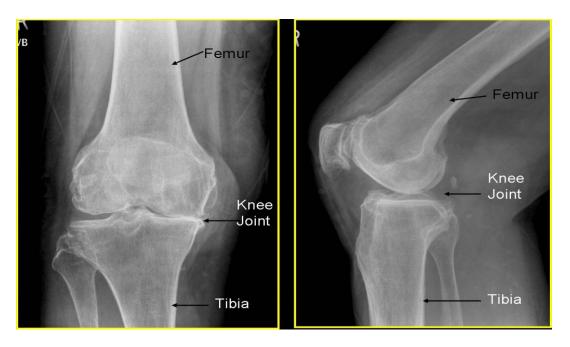
Patient Selection

- -Chronic knee pain, non-responsive to conservative therapy
- -Greater than 50% pain relief from a single block of the geniculate nerves (no more than 0.5-1.0 mL injectate per block)





Peripheral RF for Knee Pain



The knee joint is innervated by the articular branches of various nerves, including the femoral, common peroneal, saphenous, tibial and obturator nerves.

Hirasawa Y, et al. Nerve Distribution to the human knee joint: anatomical and immunohistochemical study. Int Orthop 2000; 24:1-4.

The cutaneous and articular sensory innervation of the knee region is complex and displays considerable variation.

Lund J, et al.. Acta Anaesthesiol Scand 2011; 55: 14-19





The sensory supply to the knee

- Sensory nerves derive largely from nerves supplying the quadriceps muscles. The distal branches related to the overlying muscle and the capsular attachments to femur and tibia.
- Infero-medial sensation- a branch of the saphenous nerve.
- Infero-lateral sensation- peroneal division of the sciatic nerve (fibular nerve). This is excluded from RF lesioning: motor innervation peroneal and recurrent peroneal nerve, inability to safely perform an exclusively sensory nerve interruption given the proximity of motor nerve fibers.
- The nerves do not follow a fixed vascular supply to the anterior knee joint although a very small artery and vein is intimately associated with each nerve.
- Nomenclature Proper names (i.e. nerve from the rectus medialis), geniculate branches (i.e. superomedial geniculate n.) or retinacular nerves used interchangeably.

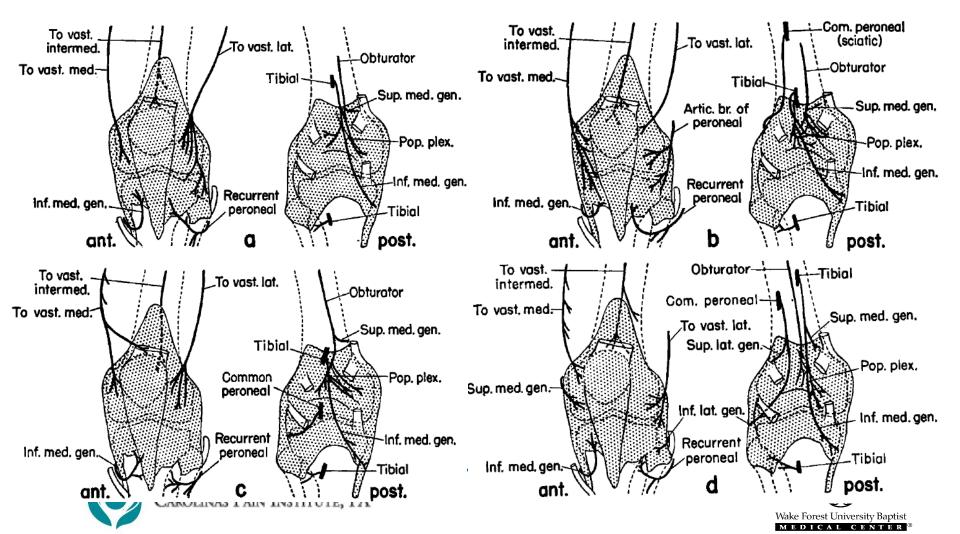




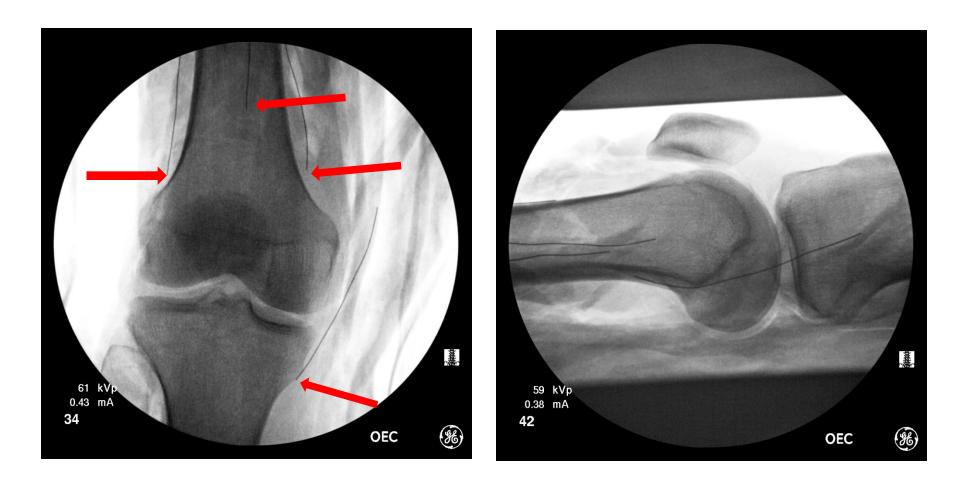
THE INNERVATION OF THE KNEE JOINT¹

ERNEST GARDNER

Department of Anatomy, College of Medicine, Wayne University, Detroit, Michigan



Franco CD, Buvanendran A, Petersohn J, Menzies LP – RAPM 2015;40:363-368.



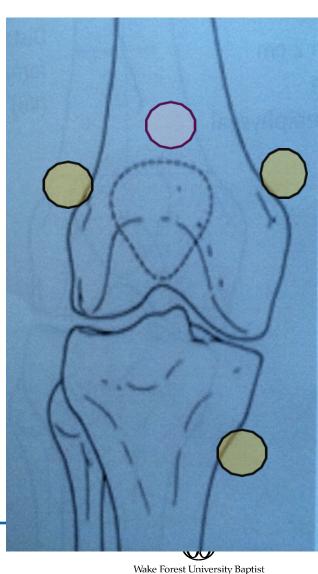




Geniculate Branch Diagnostic Block Technique

Optional lesion for the nerve from the rectus intermedius supplying the subpatellar plexus

- DO NOT block the inferior lateral geniculate nerve! Lesioning this nerve will injure the adjacent common peroneal nerve.
- Adjust c-arm fluoroscopy for lateral image
- Adjust needle tip to be half-way across diaphysis before injecting local anesthetic at each site. Target is Midline femur about 2 cm cephalad of the upper patellar border





Clinical outcome evidence

Woo-Jong Choi, <u>Radiofrequency treatment relieves chronic knee</u> osteoarthritis pain: A double-blind randomized controlled trial. PAIN 152 (2011) 481–487.

Genicular neurotomy vs. sham. N= 38, RF(N=19), sham(N=19);Age 61-75

1, 4, and 12 week follow up. Outcome measures: VAS, Oxford knee scoreIn the RF group 10/17(59%), 11/17(65%), and 10/17(59%) achieved at least 50% knee pain relief at 1, 4, and 12 weeks respectively

No adverse events

Masahiko Ikeuchi, Percutaneous Radiofrequency Treatment for Refractory Anteromedial Pain of Osteoarthritic Knees. Pain Medicine 2011; 12: 546– 551

N=35, RF(N=18), Local anesthetic only (N=17). Age 69-85

4, 8, 12 week follow up. Outcome measures: VAS, WOMAC

Statistically significant pain relief (VAS) for the radiofrequency group at 4, 8, and 12 weeks

No adverse events





- Menzies, Analgesia and Improved Performance in a Patient Treated by Cooled Radiofrequency for Pain and Dysfunction Postbilateral Total Knee Replacement. Pain Practice April 2015
- Following CRF neurotomy, the patient reported marked OKS improvements for both knees (left knee, pain score: 0 to 4 in 3-months; total score: 24 to 42 in 3-months and right knee, pain: 1 to 4 in 1-month; total: 30 to 42 in 1-month). Pain relief and better knee function occurred up to 9- and 6-months, for the left and right knees, respectively. Moreover, the patient reported a significant improvement in quality of life, as illustrated by minimal knee pain, less reliance on analgesics, and ability to walk more freely, including on stairs.
- Bellini, Cooled radiofrequency system relieves chronic knee osteoarthritis pain: the first case-series Anesthesiology Intensive Therapy, 2015:47(1);30-33.
- N=9
- There was improvement in VAS pain scores: 2 ± 0.5 at 1-month, 2.3 ± 0.7 at 3-months, 2.1 ± 0.5 at 6-months, and 2.2 ± 0.2 at 12-months after the procedure. WOMAC score: 20 ± 2 at 1-month, 22 ± 0.5 at 3-months, 21 ± 1.7 at 6-months, and 20 ± 1.0 at 12-months.





Geniculate Branch RF Technique

- Use same positioning and targets as for diagnostic geniculate nerve block following meticulous sterile prep.
- Stimulate each geniculate nerve branch at 50 (0.3-0.5) and 2 Hz up to 1 volt searching for any lower extremity motor activity.
- Inferior lateral geniculate branch is deliberately omitted to avoid lesioning of the common peroneal/fibular nerve
- Radiofrequency lesioning at each site.

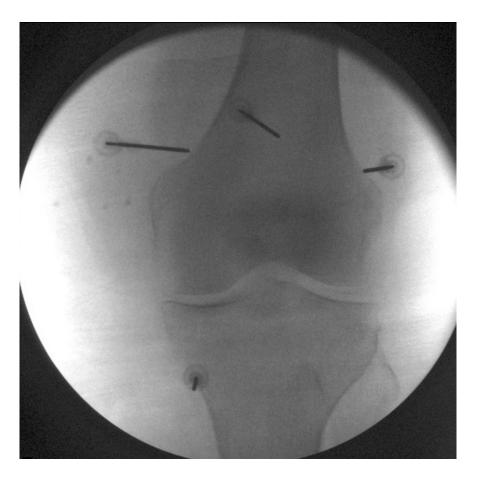




Technique:













Common mistake







True anteroposterior image of distal femur with probes in place



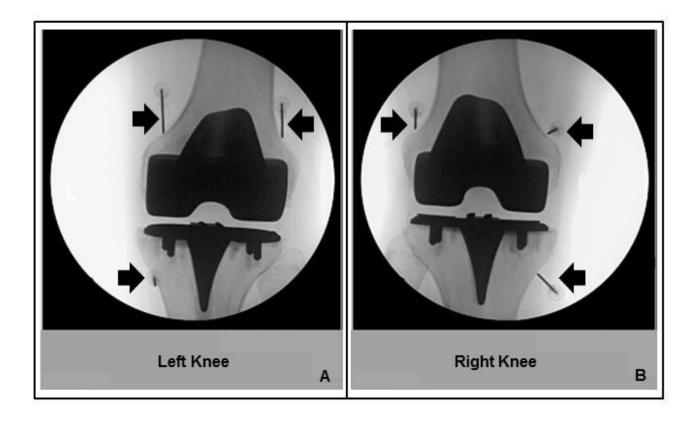
True lateral image of proximal tibia with probes in place







RF treatment for post-prosthetic knee pain







Prospective, Multi-Center, Randomized, Cross-Over Clinical Trial Comparing the Safety and Effectiveness of Cooled Radiofrequency Ablation to Corticosteroid Injection in the Management of Knee Pain from Osteoarthritis

Tim Davis, MD, Eric Loudermilk, MD, Michael DePalma, MD, Corey Hunter, MD, David Lindley, DO, Nilesh Patel, MD, Daniel Choi, MD, Marc Soloman, MD, Anita Gupta, DO, Mehul Desai, MD, Asokumar Buvanendran, MD, Leonardo Kapural, MD, PhD





Subject Disposition and Baseline Characteristics

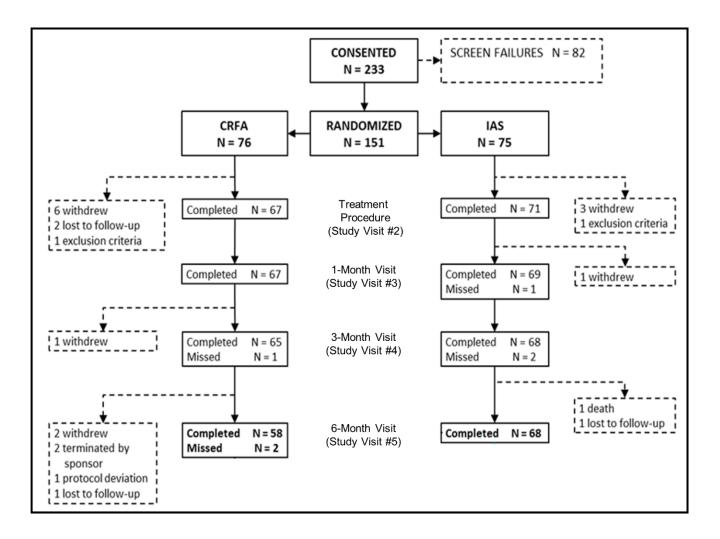
- Study groups were statistically similar at baseline
 - Age (years): CRFA=63, IAS=66
 - Female : Male = 2 : 1
 - Body Mass Index (kg/m²): CRFA=30.6, IAS=30.4
 - Mean duration of knee pain (years): CRFA=11, IAS=9
 - No prior knee injury and were on medications for knee pain
 - Responsive to diagnostic nerve blocks for study entry, with a mean pain decrease of: CRFA= 83.2%, IAS=80.8%

OA Grade	CRFA	IAS	
Grade 2/Mild	34.2%	36.0%	
Grade 3/Moderate	42.1%	46.7%	
Grade 4/Severe	23.7%	17.3%	

- Number of subjects evaluated at 6-months:
 - 87% of CRFA group (58 of 67 treated subjects)
 - 96% of IAS group (68 of 71 treated subjects)



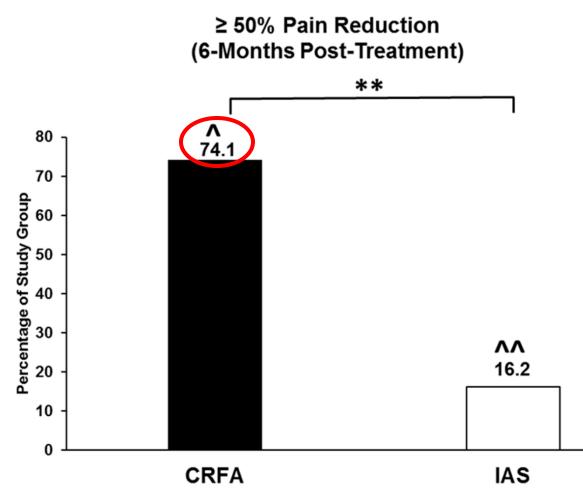




MEDICAL CENTER



Primary Outcome: Numeric Rating Scale



** *p* < 0.0001 difference between groups 95% confidence intervals: ^(62.9, 85.4), ^^ (7.4, 24.9)

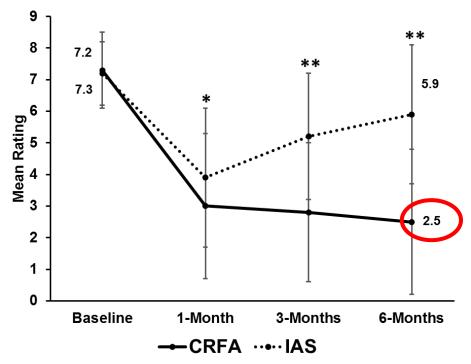
- Primary Study Outcome: the proportion of subjects whose knee pain was reduced by at least 50%, based on the NRS at 6months – treatment "responders"
- A significantly greater percentage of the CRFA cohort reported ≥ 50% pain reduction at 6-months:
 - CRFA: 74.1% were treatment "responders"
 - IAS: 16.2% were treatment "responders"





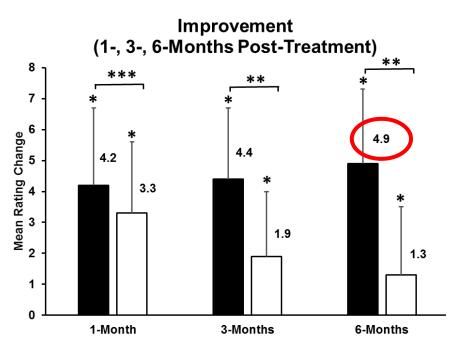
Numeric Rating Scale (Continued)

Mean Usual Level of Pain



* p < 0.05, ** p < 0.0001 difference between groups

Significantly lower mean NRS values reported by the CRFA group at all followup time-points were indicative of greater pain reduction in that cohort compared to that in the IAS group at 6-months



■CRFA □IAS

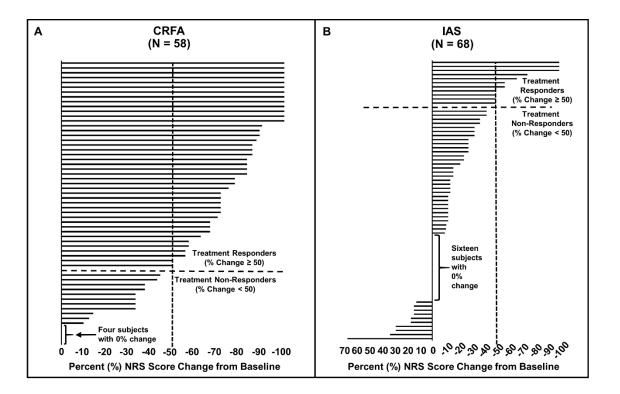
* p < 0.0001 difference from baseline ** p < 0.0001, *** p < 0.05 difference between groups

- The CRFA group experienced significantly greater pain reduction vs. the IAS group at all time-points
- At 6-months, the CRFA cohort reported a mean score drop on the NRS from baseline of 4.9 ± 2.4 vs. 1.3 ± 2.2 in the IAS cohort





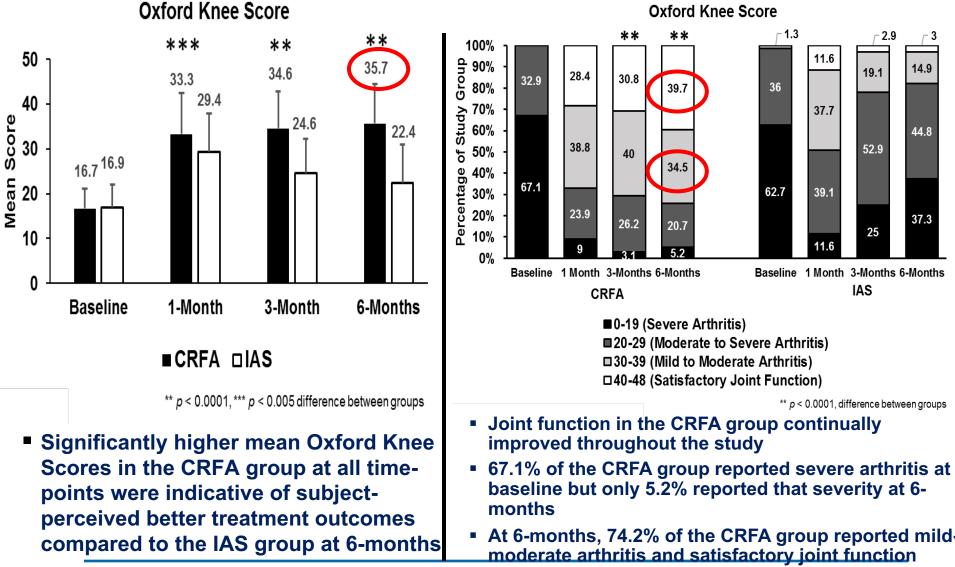
Tornado Charts:







Oxford Knee Score

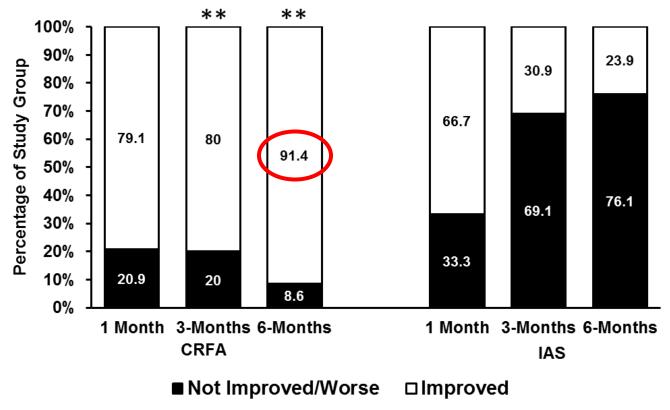




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Patient Global Perceived Effect

Global Perceived Effect



** *p* < 0.0001 difference between groups

A higher fraction of the CRFA cohort reported improvement in overall perceived health status compared to IAS group at all follow-up time-points. This difference between groups was significant at 3- and 6-months.





Safety (Adverse events)

- The number of AEs reported in each study group was similar (CRFA = 61, IAS = 65)
- Most AEs during the study were non-serious, mild-moderate in severity, and were determined as not related to study treatments
- AEs with Possible, Probable, or Definite relationship to procedure:
 - CRFA: post procedure pain (9), ecchymosis (1), pruritic skin lesion (1), swelling and redness - infection (1), mild tenderness to touch (1), increased knee pain severe (1)
 - IAS: white discoloration at injection site (1), fluctuating blood sugar levels (1)
- Post-procedural fall incidence (all non-serious):
 - CRFA: 2 unrelated to procedure
 - IAS: 4 unrelated to procedure





Opioid usage:

- Opioid medication use: no differences between groups at 6-months
 - Mean change from baseline (Total Daily Dose MEQ):
 1.8 mg CRFA and 0.3 mg IAS
- Non-opioid medications (NSAID, Acetaminophen) use: statistically significant differences (p < 0.05) between groups at 6-months
 - Mean change from baseline (Total Daily Dose): -34.5 mg CRFA vs. 135.5 mg IAS





Summary (6 months)

<u>Pain</u>

- ≥ 50% pain relief was experienced by 74.1% of CRFA group vs. 16.2% of IAS group
- CRFA subjects had a 4.9 point mean drop in NRS to 2.5 at 6 months, while IAS had a 1.3 point mean drop to 5.9

Function

- Significant functional improvement was seen in CRFA group; 39.7% of CRFA group reported "Satisfactory Joint Function" vs. 3% in IAS group
- **Perceived Effect**
- Knee condition was reported as "improved" in 91.4% of CRFA group vs. 23.9% in IAS group

Pain Medications

 No differences in opioid usage by either group was seen; however, CRFA group showed significant dose reduction in non-opioid usage compared to IAS group

<u>Safety</u>

 CRFA was as safe as IAS injection – the number of AEs in each group was similar; most AEs were non-serious, mild-moderate in severity, and were determined as not related to study treatments; there were no serious AEs related to either procedure





Summary 12 months (in preparation)

- 52 of the 67 CRFA subjects returned for 12 month visit (22% attrition rate)
- 65.4% (34/52) of the CRFA subjects at 12 month ≥ 50% relief
- Maintained a mean 4.3 point drop 12 months from treatment
- Mean NRS Score at 12 months was 3.1
- Oxford Knee Score 17.3 point change from BL at 12 months
- 46.2% of patients (24/52) 'Satisfactory Joint Function'!
- Another 17.3% (9/52) indicated symptoms of 'Mild/Moderate' arthritis
- As a reminder, at Baseline, 100% of the Cooled Group reported their OA symptoms as '*Mod/Severe*' or '*Severe*'
- GPE- **75%** of 12 month patients continued to report being **'Improved' at 12 months** (vs. 91.4% at 6 months).





Hip denervation



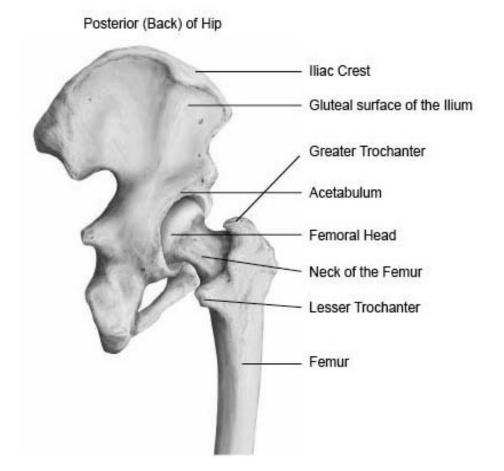
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Application to Hip Pain

Frequent causes of hip pain:

- DJD
- AVN
- Labral tears
- Tumor







Innervation of the hip joint is regionally specific:

- Anteromedial innervation supplied by the articular branches of the obturator nerve or accessory obturator nerve
- Anterior hip joint capsule innervated by sensory articular branches of the femoral nerve
- Posterior innervation supplied by articular branches derived from the sciatic nerve
 - Posteromedial hip joint capsule innervated by articular branches from the nerves to the quadratus femoris muscle
 - Posterolateral hip joint capsule innervated by articular branches from the superior gluteal nerve.

Birnbaum K, Prescher A, Hessler S, Heller KD. The sensory innervation of the hip joint – An anatomical study. Surg Radiol Anat (1997)19; 371-375.

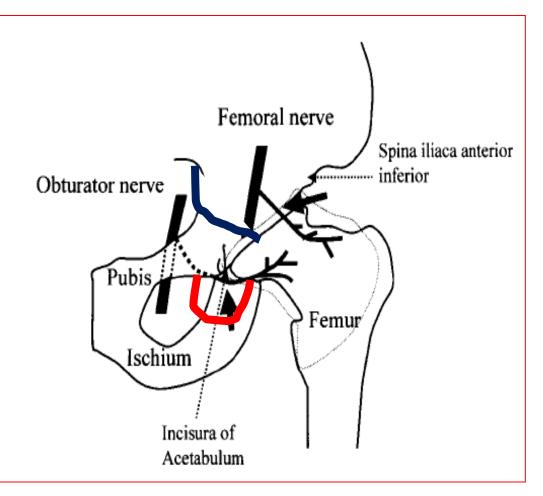




New 2014 data on anatomic variants

Franco CD, RD Menzies, JD Petersohn, A Buvanendran , LP Menzies - manuscript in preparation 2014

- Dissected 7 cadaveric hip joints
- Accessory obturator nerve variant (blue)
- Obturator articular branch variant (red) as seen by Locher.

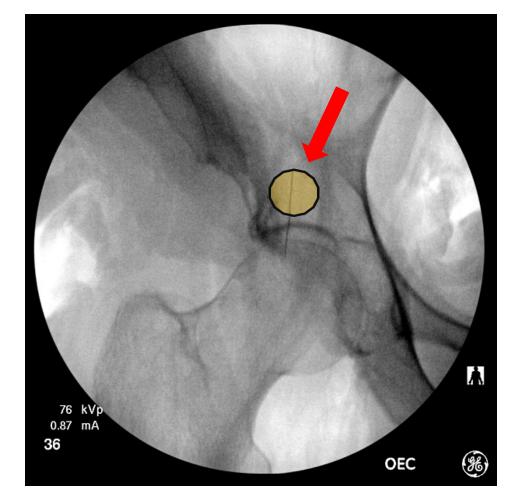






Femoral articular branch innervation

- Innervation to the anterosuperior aspect of the hip is relatively constant across the 11:00 o'clock.
- Two femoral articular branches shown derived from nerve to iliacus mm.
- Hypothetical RF lesions shown in gold







Position of the needles for the block



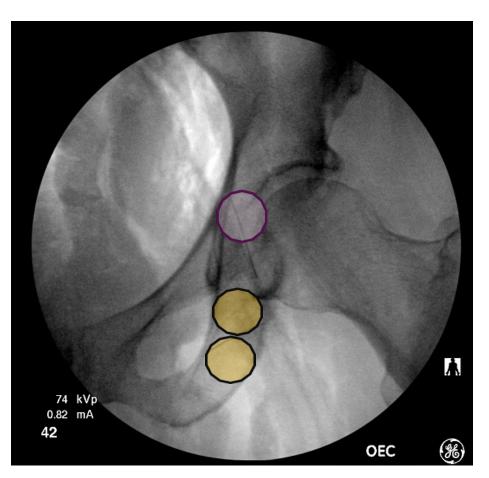


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Variation of obturator nerve innervation pattern

- The paths of the obturator articular branches vary across the ischium – Two vertically adjacent lesions are made with large RF probe over the ischium for reliable denervation
- An additional RF lesion shown may be required to address anatomic variation (accessory obturator nerve).







Rivera F, Mariconda C, Annartone G. *Percutaneous radiofrequency denervation in patients with contraindications for total hip arthroplasty*. Orthopedics (2012)7;35(3)e202-205.

- Prospective pilot study of 17 consecutive patients
- Outcome measures: Harris Hip Score, VAS, WOMAC

	Mean Scores		
	VAS	Harris	WOMAC
pre-procedure	9.52	28.64	75.7
6 month follow up	6.35	43.88	63.7

- 1 Complication- 3 hematomas due to vessel punctureapproach technique altered to prevent reoccurrence
- Conclusion-Percutaneous RF lesioning of the sensory branches of the nerves innervation the hip joint can be an option for patients with intractable hip joint pain and an alternative treatment of hip arthritis with contraindications for THA.



Results:



Percutaneous Radiofrequency Lesioning of Sensory Branches of the Obturator and Femoral Nerves for the Treatment of Non-Operable Hip Pain

Atif Malik, MD, Thomas Simopolous, MD, Mohamed Elkersh, MD, Musa Aner, MD, and Zahid H. Bajwa, MD

Pain Physician. 2003;6:499-502,

- Small case series with n=4
- Outcomes measures- VAS, decrease use of pain meds, improvement in function
- Results- 4 of 4 experienced reduced pain, 2 of 4 decreased pain meds, 3 of 4 improved function
- Complications- 1 report of lateral hip surface numbress
- Conclusion- Percutaneous RF lesioning of the sensory branches of the obturator and femoral nerves appears to be a safe alternative to hip replacement, especially where surgery is not an option





Percutaneous Radiofrequency Lesioning of Sensory Branches of the Obturator and Femoral Nerves for the Treatment of Hip Joint Pain

Masahiko Kawaguchi, M.D., Keiji Hashizume, M.D., Toshio Iwata, M.D., and Hitoshi Furuya, M.D.

Reg Anesth Pain Med 2001;26:576-581.

- Retrospective study of 14 patients with differing techniques
- Outcome Measures- VAS
- Results -mean VAS went from 6.2 to 2.7. 86% of pts saw at least 50% relief of pain for up to 11 months
- No side effects or motor weakness observed





Summary of the literature

- Small sample sizes
- Tedious technique requiring multiple lesions using conventional RF probes to ensure capture of variable nerve courses
- Risk of vascular injury especially involving the femoral artery/vein

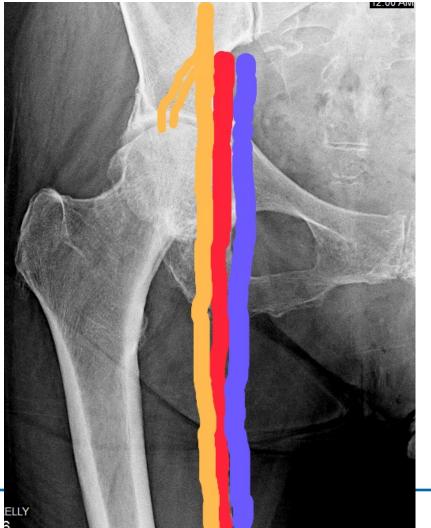




Developing a safe procedural technique

• Major targets for therapeutic partial RF denervation of the hip lie deep to important neurovascular structures!!





Wake Forest University Baptist

Lateral approach to lateral femoral branches

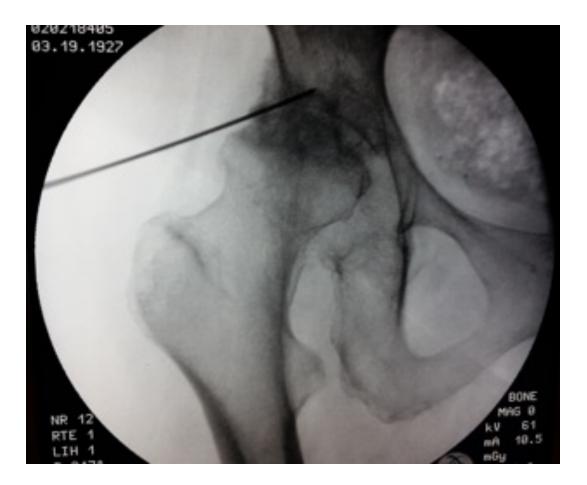




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Advance RF needle introducer under fluoroscopy to the 12 o'clock acetabular target site where osseous acetabulum is contacted





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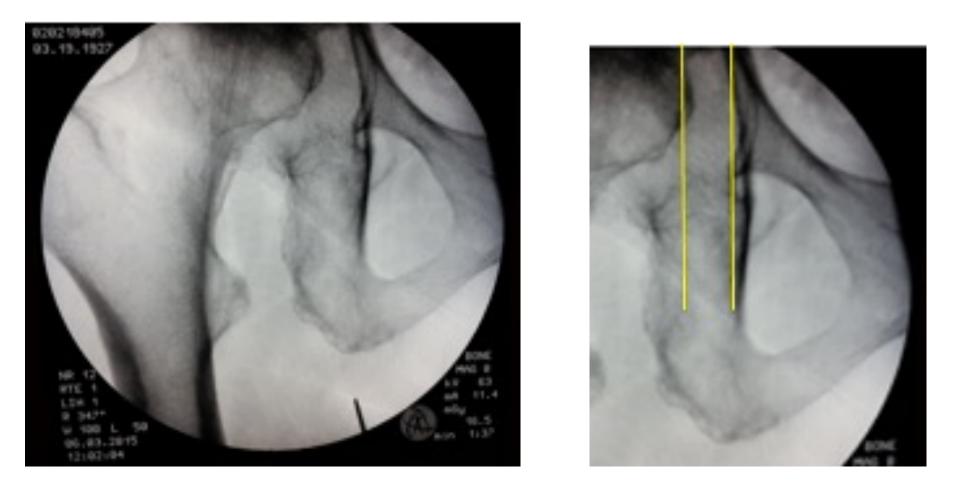
Inferior approach to lateral obturator branches







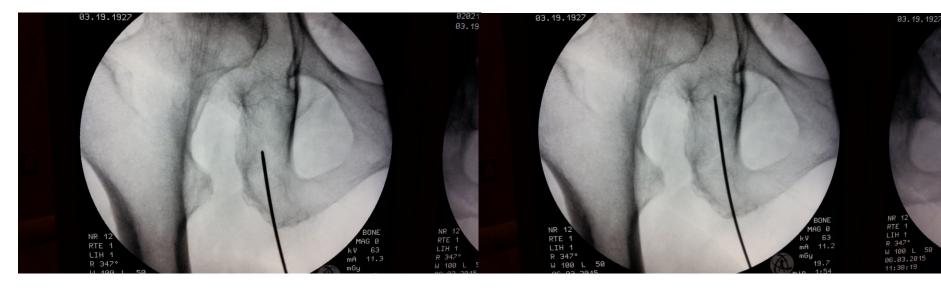
Insert introducer through deep anesthetized track toward lesion site.







Advance introducer towards lesion site



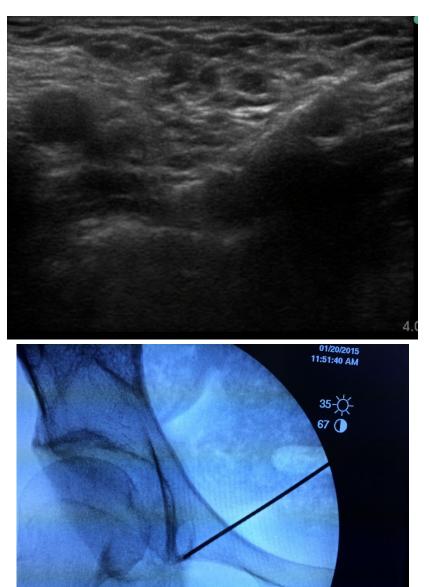






US Guided approach



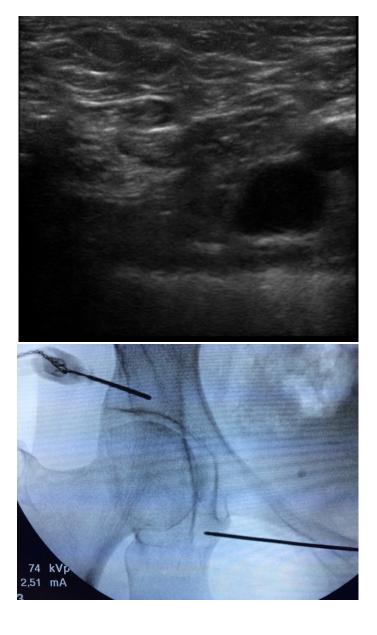






US Guided approach

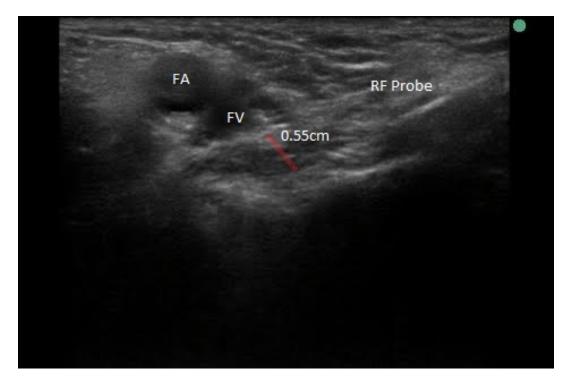








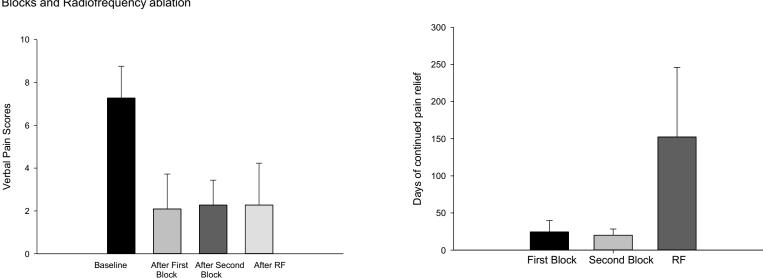
Lateral obturator denervation-pay attention







Jolly S, Ptacek T, Badhey H, Kapural L. Cooled Radiofrequency Neurotomy of the Articular Sensory Branches of the Obturator and Femoral Nerves: Combined approach using fluoroscopy and ultrasound guidance - technical report and safety data



Pain Scores Following Lateral Obturator and Lateral Femoral Branches Blocks and Radiofrequency ablation





Summary: RF for peripheral joint pain

- The anatomic basis for therapeutic partial sensory denervation of the hip and knee joints by RF lesioning techniques has been demonstrated.
- Adjacent neurovascular structures and variations in anatomic innervation must be considered in order to plan safe and effective RF denervation procedures.
- Strong evidence exists for knee RF denervation
- Pilot studies support careful use of these techniques and ongoing study, including clinical trials
- Larger lesion seems to provide an optimal outcome





Thank You lkapuralMD@gmail.com





